GLOBAL BIOTECHNOLOGY VALIDATION MASTER LIST

Cell Banks & Upstream • Chromatography / UF-DF • Viral Clearance • DQ/IQ/OQ/PQ • Sterile Aseptic Filling & Lyophilization • Potency & Analytical Methods

3,477 micro-level checkpoints | **38** controlled sections | **India + Ireland** contact details

Prepared for global biotechnology and biologics manufacturing, API / intermediates / drug substance / sterile and nonsterile drug product validation planning.

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01 APPLICATION INSTRUCTIONS

Master screening register

Apply the 3,477 candidate checks only to processes and products that exist on site. Screen mammalian/microbial platforms, vaccines, recombinant proteins, antibodies, ADC, plasma fractionation, mRNA/LNP, viral vectors and cell therapies separately. Mark non-applicable cases with rationale and add site-specific assets.

Activities are not interchangeable

Differentiate qualification (URS/DQ, FAT, SAT, IQ, OQ, PQ), process validation and ongoing monitoring from instrument calibration, analytical-method validation, method suitability, sterility assurance, microbiological qualification and staff training.

Global GMP regulatory landscape

FDA 21 CFR 210/211 and biologics requirements, EU GMP Annex 2 and Annex 15, EU Annex 1 for sterile steps, ICH Q5A(R2)/Q5D/Q5E/Q6B, WHO biologics guidance, Indian revised Schedule M, PIC/S PE 009-18 and PI 006-4, and MHRA/TGA rules as adopted locally. EU ATMPs are under Part IV rather than Annex 2. Confirm local applicability and edition.

Biological platform-specific risks

Cell banks require identity, adventitious agents and stability controls; cell culture requires organism/culture control; purification requires clearance of process-related impurities; viral safety programs require justified multi-barrier controls. Intentional viral-vector/viable cell products are not automatically suited to virus inactivation/removal.

Sterile versus nonsterile

Apply contamination control strategy, cleanroom qualification, filtration validation, aseptic process simulations, glove qualification and operator monitoring only as relevant to sterile/aseptic activities. A media fill is not a universal requirement for all upstream fermentation and purified nonsterile intermediates.

Study design and statistics

Qualify CPPs, CQAs, material variability, culture passages, resin ages, membrane load, product concentration, mixing, operator and worst-case batch loads. PPQ batch number, sample size and revalidation frequency require a documented science/risk basis; avoid automatic three-batch and annual rules.

Evidence trail

For each entry, attach actual asset/system ID, protocol number, executed raw data, deviations, report, QA disposition, owner, approval date and next-review trigger. Ensure the editable spreadsheet is populated and formally approved in the site QMS before use.

No fabricated limits or approvals

The register is a planning template, not executed validation. Numeric biological acceptance criteria, virus log reductions, Grade classification, endotoxin limits, PPQ acceptance and cleaning HBELs must be determined product-by-product under relevant official requirements.

Local exceptions

Australia TGA adoption of a PIC/S edition may lag the latest international PE 009 release; UK, EU, US, and India approval paths differ. Indian Schedule Y historically addresses clinical requirements; it should not be used as a substitute for manufacturing validation under revised Schedule M / product-specific rules.

02 COVERAGE INDEX

NO.	CONTROLLED SECTION	CHECKPOINTS	PRIMARY OWNER GROUP
01	01 | VMP, Quality Assurance & validation governance	78	QA / Validation
02	02 | R&D, cell lines, genetic constructs & cell banks	105	R&D / QA / Microbiology
03	03 | Microbial fermentation & inoculum expansion	96	Production / R&D
04	04 | Mammalian cell culture & seed train	102	Production / R&D
05	05 | Single-use technologies & closed processing	96	Engineering / Production
06	06 | Media, buffers, reagents & formulation preparations	96	Production / QC
07	07 | Harvest, clarification and cell disruption	78	Production / Engineering
08	08 | Chromatography, capture and polishing	114	Production / QC
09	09 | UF/DF, concentration, nanofiltration and membrane operations	90	Production / Engineering
10	10 | Viral safety, clearance and adventitious agents	99	Viral Safety / QA / QC
11	11 | Bulk drug substance, intermediate & hold times	72	Production / QA
12	12 | ADCs, high-potency conjugates & chemical-biologic interfaces	63	Production / R&D / EHS
13	13 | mRNA, plasmid DNA and lipid nanoparticles	72	Production / R&D / QC
14	14 | Vaccine antigens, adjuvants & formulation	72	Production / QC
15	15 | Plasma-derived products and blood fractionation	72	Production / QA / QC
16	16 | Cell therapy, gene therapy, viral vectors & ATMPs	93	R&D / Production / QA
17	17 | Biosimilars, comparability & technology transfers	66	R&D / Analytical / RA
18	18 | Cleanrooms, facility layout, HVAC & AHUs	102	Engineering / Microbiology
19	19 | Pharmaceutical water, WFI & process utilities	96	Engineering / QC / Microbiology
20	20 | Clean steam, compressed gases, vacuum & HVAC utilities	93	Engineering / QC
21	21 | CIP, COP, cleaning validation and cross-contamination	90	QA / Production / Microbiology
22	22 | Sterilization, SIP, autoclaves and depyrogenation	87	Engineering / Microbiology / QA
23	23 | Aseptic manufacture, APS/media fill & CCS	120	QA / Microbiology / Production
24	24 | Fill finish, vial/ampoule, syringes and lyophilization	129	Production / Engineering / QA
25	25 | Analytical method validation & ADL	156	ADL / QC / QA
26	26 | Potency bioassays, immunoassays & cell-based QC	117	QC / ADL / R&D
27	27 | QC microbiology, sterility, endotoxin and EM	102	Microbiology / QA
28	28 | Physical chemistry, stability and structural characterization	108	QC / ADL / Stability
29	29 | Instruments, metrology and calibration	84	QC / Engineering / QA
30	30 | CSV, SCADA, PLC, LIMS and data integrity	105	IT / Automation / QA
31	31 | Warehouse, supplier management & cold chain	99	Warehouse / Purchase / QA
32	32 | Packaging, CCIT, extractables/leachables & distribution	84	Production / QA / R&D
33	33 | Engineering maintenance, utilities and change control	84	Engineering / QA
34	34 | HR, training, gowning, admin & EHS/biosafety	99	HR / Admin / EHS / QA
35	35 | PPQ, continued process verification and annual reviews	72	QA / Production / MSAT
36	36 | Contamination prevention, biosafety & pest/environment	72	QA / Microbiology / EHS
37	37 | Regulatory, site licensing, validation records & inspection	45	QA / RA / Legal

NO.	CONTROLLED SECTION	CHECKPOINTS	PRIMARY OWNER GROUP
38	38 | Specialized biotech modality & novel processing	69	MSAT / R&D / QA
	TOTAL	3477	Cross-functional QA / Engineering / QC / Production / RA

03 REGULATORY REFERENCE CROSSWALK

B01 | US FDA - 21 CFR Parts 210, 211 and 600-680: drug and biological product cGMP and biologics

https://www.ecfr.gov/current/title-21/chapter-I/subchapter-F/part-600

B02 | US FDA - Process Validation: General Principles and Practices; lifecycle framework

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/process-validation-general-principles-and-practices

B03 | EU / EMA - EU GMP Volume 4 Annex 2: biological active substances and medicinal products

https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en

B04 | EU / EMA - EU GMP Annex 1: manufacture of sterile medicinal products; CCS and APS

https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en

B05 | EU / EMA - EU GMP Annex 15: qualification and validation

https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en

B06 | PIC/S - PE 009-18 GMP Guide (24 September 2026); PI 006-4 qualification and validation (1 October 2026)

https://picscheme.org/en/publications

B07 | ICH - ICH Q5A(R2): viral safety evaluation for products derived from human/animal cell lines

https://www.ich.org/page/quality-guidelines

B08 | ICH - ICH Q5B / Q5D: expression construct and characterization of cell substrates

https://www.ema.europa.eu/en/human-regulatory-overview/research-development/scientific-guidelines/ich-guidelines/ich-guidelines-quality

B09 | ICH - ICH Q5C: stability testing of biotechnological/biological products

https://www.ema.europa.eu/en/human-regulatory-overview/research-development/scientific-guidelines/ich-guidelines/ich-guidelines-quality

B10 | ICH - ICH Q5E: comparability after biotechnological manufacturing changes

https://www.ema.europa.eu/en/human-regulatory-overview/research-development/scientific-guidelines/ich-guidelines/ich-guidelines-quality

B11 | ICH - ICH Q6B: specifications for biotechnology/biological products

https://www.ema.europa.eu/en/human-regulatory-overview/research-development/scientific-guidelines/ich-guidelines/ich-guidelines-quality

B12 | ICH - ICH Q7, Q8, Q9(R1), Q10, Q11, Q12: API GMP, development, risk, PQS, drug substance, lifecycle

https://www.ich.org/page/quality-guidelines

B13 | WHO - WHO TRS 1043 Annex 4: monoclonal antibodies and related products

https://www.who.int/publications/m/item/trs1043-annex4

B14 | WHO - WHO Expert Committee on Biological Standardization TRS and biological guidelines

https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/biologicals

B15 | India / CDSCO - Revised Schedule M, Drugs and Cosmetics Rules; current Indian GMP framework

https://www.pib.gov.in/PressReleasePage.aspx?PRID=2102291

B16 | India / CDSCO - New Drugs and Clinical Trials Rules 2019; applicable biologics and similar biologics approvals

https://cdsco.gov.in/opencms/opencms/en/Acts-and-rules/New-Drugs-and-Clinical-Trials-Rules-2019/

B17 | Australia / TGA - Current legally adopted manufacturing principles and PIC/S edition; verify current determination

https://www.tga.gov.au/products/medicines/manufacturing/manufacture-medicine/good-manufacturing-practice-gmp/complying-pics-guide-good-manufacturing-practice-medicinal-products

B18 | UK / MHRA - MHRA GMP inspections, GMP/GDP and data-integrity expectations

https://www.gov.uk/government/collections/good-manufacturing-practice-and-good-distribution-practice

B19 | EU / EMA - EU GMP Annex 11 Computerised Systems; Annex 17 Real-Time Release Testing where applicable

https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en

B20 | USP / EP - USP and Ph. Eur. compendial tests, biologics potency, microbial, endotoxin and sterile tests

https://www.usp.org/

B21 | ISO - ISO 14644 cleanroom classification and ISO 14698 biocontamination control as applicable

https://www.iso.org/search.html?q=ISO%2014644

B22 | EU / EMA - EU GMP Part IV: GMP for Advanced Therapy Medicinal Products (distinct from Annex 2)

https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en

B23 | ICH - ICH Q2(R2) analytical procedure validation and Q14 analytical procedure development

https://www.ich.org/page/quality-guidelines

B24 | PDA / ASTM / ISPE - Technical standards and industry guidance as applicable; non-binding unless adopted

https://www.ispe.org/

B25 | US FDA - FDA CBER biologics product guidance and biological product licensing

https://www.fda.gov/vaccines-blood-biologics

04 LIFECYCLE STAGES & EVIDENCE CONTROL

STAGE	EXPECTED EVIDENCE PRINCIPLE
Process design / characterization	Link development knowledge, biological cell substrate, CQAs, CPPs, process risks and control strategy to commercial manufacturing.
URS / Design Qualification	Trace process and user requirements to facility, cleanroom, equipment, utility, single-use and computerized design.
FAT / SAT	Factory / site challenges of critical functions with scientifically justified use of supplier documentation.
Installation Qualification (IQ)	As-built drawings, contact materials, utilities, sensors, hardware/software versions and traceable instrument calibration.
Operational Qualification (OQ)	Approved ranges, limits, faults, interlocks, start/stop scenarios, alarm escalation and critical parameters.
Performance Qualification (PQ)	Representative reproducible performance on justified loads, equipment configurations and biological variability.
PPQ & Continued Process Verification	Validated commercial manufacturing performance and ongoing statistical monitoring of CPP/CQA and impurity profiles.
Cell bank qualification	Master/working cell bank identity, genetic/phenotypic stability, adventitious agents, storage and thaw viability.
Upstream process validation	Culture conditions, media/feeds, inoculum, expression, scale-up, viability, harvest endpoint and containment.
Downstream process validation	Chromatography, membrane operations, column/resin lifetime, cleaning and process-related impurity clearance.
Viral safety validation	Product-appropriate testing, inactivation/removal, orthogonal strategies, scale-down model and robust clearance, as applicable.
Cleaning & microbial controls	Product-specific residues, toxicology/HBEL where appropriate, swab/rinse recovery, CIP/SIP, bioburden/endotoxin, holds.
Sterile aseptic processing	CCS, cleanroom qualification, sterile filter retention, APS/media fill, isolator/RABS and glove controls when applicable.
Analytical and potency method validation	Identity, purity, potency, specificity, accuracy, precision, linearity/range, sensitivity, robustness and matrix suitability.
Hold, stability & cold chain	Validated time/temperature, freeze-thaw, biological stability, container closure, product handling, transport and excursions.
CSV and data integrity	PLC/SCADA, electronic batch records, LIMS/CDS, data transfer, audit trails, security, backup and recovery.
Comparability & lifecycle	ICH Q5E comparability after process change and risk-triggered requalification based on quality trends.

01 VMP, QUALITY ASSURANCE & VALIDATION GOVERNANCE

78 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-01-0001	Validation Master Plan	Protocol / design: Define product family, process boundaries and lifecycle strategy	Preapproved risk-based study design; endpoint: Master VMP across DS, DP, pilot, process development and commercial operations.	Planning	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0002	Validation Master Plan	Execution / boundary verification: Define product family, process boundaries and lifecycle strategy	Documented raw observations, calibration, relevant worst cases and defined acceptance for Master VMP across DS, DP, pilot, process development and commercial operations.	Execution	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0003	Validation Master Plan	Review / lifecycle: Define product family, process boundaries and lifecycle strategy	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Master VMP across DS, DP, pilot, process development and commercial operations.	Review	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	Medium
BTV-01-0004	Biological CQAs	Protocol / design: Link identity, purity, potency, safety and process-related impurities to validation scope	Preapproved risk-based study design; endpoint: CQA/CPP control strategy with approved justifications.	Planning	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0005	Biological CQAs	Execution / boundary verification: Link identity, purity, potency, safety and process-related impurities to validation scope	Documented raw observations, calibration, relevant worst cases and defined acceptance for CQA/CPP control strategy with approved justifications.	Execution	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0006	Biological CQAs	Review / lifecycle: Link identity, purity, potency, safety and process-related impurities to validation scope	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on CQA/CPP control strategy with approved justifications.	Review	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	Medium
BTV-01-0007	Qualification inventory	Protocol / design: Reconcile site assets, automated control systems, software and critical service assets	Preapproved risk-based study design; endpoint: Tagged asset inventory with system owner, impact and validated state.	Planning	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0008	Qualification inventory	Execution / boundary verification: Reconcile site assets, automated control systems, software and critical service assets	Documented raw observations, calibration, relevant worst cases and defined acceptance for Tagged asset inventory with system owner, impact and validated state.	Execution	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0009	Qualification inventory	Review / lifecycle: Reconcile site assets, automated control systems, software and critical service assets	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Tagged asset inventory with system owner, impact and validated state.	Review	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	Medium
BTV-01-0010	Qualification strategy	Protocol / design: Justify URS/DQ/FAT/SAT/IQ/OQ/PQ leveraging supplier documentation	Preapproved risk-based study design; endpoint: Design-risk trace matrix and validation stage selection.	Planning	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0011	Qualification strategy	Execution / boundary verification: Justify URS/DQ/FAT/SAT/IQ/OQ/PQ leveraging supplier documentation	Documented raw observations, calibration, relevant worst cases and defined acceptance for Design-risk trace matrix and validation stage selection.	Execution	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0012	Qualification strategy	Review / lifecycle: Justify URS/DQ/FAT/SAT/IQ/OQ/PQ leveraging supplier documentation	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Design-risk trace matrix and validation stage selection.	Review	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	Medium
BTV-01-0013	Protocol approval	Protocol / design: Ensure pre-approved endpoints and acceptance criteria before test execution	Preapproved risk-based study design; endpoint: Controlled protocols and qualified reviewers.	Planning	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0014	Protocol approval	Execution / boundary verification: Ensure pre-approved endpoints and acceptance criteria before test execution	Documented raw observations, calibration, relevant worst cases and defined acceptance for Controlled protocols and qualified reviewers.	Execution	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0015	Protocol approval	Review / lifecycle: Ensure pre-approved endpoints and acceptance criteria before test execution	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Controlled protocols and qualified reviewers.	Review	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	Medium
BTV-01-0016	Risk assessments	Protocol / design: Evaluate contamination, adventitious agents, mix-up, data integrity and supply continuity	Preapproved risk-based study design; endpoint: Risk register and links to CAPA/change controls.	Planning	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0017	Risk assessments	Execution / boundary verification: Evaluate contamination, adventitious agents, mix-up, data integrity and supply continuity	Documented raw observations, calibration, relevant worst cases and defined acceptance for Risk register and links to CAPA/change controls.	Execution	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0018	Risk assessments	Review / lifecycle: Evaluate contamination, adventitious agents, mix-up, data integrity and supply continuity	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Risk register and links to CAPA/change controls.	Review	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	Medium
BTV-01-0019	Process validation strategy	Protocol / design: Document process design, PPQ and CPV approach for biologics	Preapproved risk-based study design; endpoint: Scientific batch-count rationale and CPP/CQA sampling plan.	Planning	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0020	Process validation strategy	Execution / boundary verification: Document process design, PPQ and CPV approach for biologics	Documented raw observations, calibration, relevant worst cases and defined acceptance for Scientific batch-count rationale and CPP/CQA sampling plan.	Execution	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0021	Process validation strategy	Review / lifecycle: Document process design, PPQ and CPV approach for biologics	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Scientific batch-count rationale and CPP/CQA sampling plan.	Review	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-01-0022	Reprocessing and rework	Protocol / design: Determine permitted biological reprocessing by product and filing	Preapproved risk-based study design; endpoint: Product impact assessment and authorized protocol.	Planning	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0023	Reprocessing and rework	Execution / boundary verification: Determine permitted biological reprocessing by product and filing	Documented raw observations, calibration, relevant worst cases and defined acceptance for Product impact assessment and authorized protocol.	Execution	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0024	Reprocessing and rework	Review / lifecycle: Determine permitted biological reprocessing by product and filing	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Product impact assessment and authorized protocol.	Review	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	Medium
BTV-01-0025	Regulatory filing linkage	Protocol / design: Link commercial process and control strategy to registered commitments	Preapproved risk-based study design; endpoint: Comparability assessments and filings for significant changes.	Planning	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0026	Regulatory filing linkage	Execution / boundary verification: Link commercial process and control strategy to registered commitments	Documented raw observations, calibration, relevant worst cases and defined acceptance for Comparability assessments and filings for significant changes.	Execution	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0027	Regulatory filing linkage	Review / lifecycle: Link commercial process and control strategy to registered commitments	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Comparability assessments and filings for significant changes.	Review	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	Medium
BTV-01-0028	Sampling science	Protocol / design: Justify worst-case products, culture ages, media and virus models	Preapproved risk-based study design; endpoint: Sampling rationale and power/confidence where applicable.	Planning	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0029	Sampling science	Execution / boundary verification: Justify worst-case products, culture ages, media and virus models	Documented raw observations, calibration, relevant worst cases and defined acceptance for Sampling rationale and power/confidence where applicable.	Execution	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0030	Sampling science	Review / lifecycle: Justify worst-case products, culture ages, media and virus models	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Sampling rationale and power/confidence where applicable.	Review	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	Medium
BTV-01-0031	Lifecycle validation changes	Protocol / design: Define scale, site, equipment, raw material and software changes	Preapproved risk-based study design; endpoint: Revalidation decision and comparability governance.	Planning	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0032	Lifecycle validation changes	Execution / boundary verification: Define scale, site, equipment, raw material and software changes	Documented raw observations, calibration, relevant worst cases and defined acceptance for Revalidation decision and comparability governance.	Execution	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0033	Lifecycle validation changes	Review / lifecycle: Define scale, site, equipment, raw material and software changes	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Revalidation decision and comparability governance.	Review	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	Medium
BTV-01-0034	Vendor evidence leverage	Protocol / design: Evaluate qualification documents and outsourced validation	Preapproved risk-based study design; endpoint: Documented acceptance of vendor reports and gap closure.	Planning	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0035	Vendor evidence leverage	Execution / boundary verification: Evaluate qualification documents and outsourced validation	Documented raw observations, calibration, relevant worst cases and defined acceptance for Documented acceptance of vendor reports and gap closure.	Execution	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0036	Vendor evidence leverage	Review / lifecycle: Evaluate qualification documents and outsourced validation	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Documented acceptance of vendor reports and gap closure.	Review	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	Medium
BTV-01-0037	Validation deviations	Protocol / design: Predefine invalid-run, repeat study and OOS/OOT handling	Preapproved risk-based study design; endpoint: Deviation investigation, integrity and statistical treatment.	Planning	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0038	Validation deviations	Execution / boundary verification: Predefine invalid-run, repeat study and OOS/OOT handling	Documented raw observations, calibration, relevant worst cases and defined acceptance for Deviation investigation, integrity and statistical treatment.	Execution	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0039	Validation deviations	Review / lifecycle: Predefine invalid-run, repeat study and OOS/OOT handling	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Deviation investigation, integrity and statistical treatment.	Review	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	Medium
BTV-01-0040	Validation review frequency	Protocol / design: Determine risk-based periodic review instead of universal annual schedule	Preapproved risk-based study design; endpoint: Scheduled state-of-control review and change-triggered assessment.	Planning	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0041	Validation review frequency	Execution / boundary verification: Determine risk-based periodic review instead of universal annual schedule	Documented raw observations, calibration, relevant worst cases and defined acceptance for Scheduled state-of-control review and change-triggered assessment.	Execution	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0042	Validation review frequency	Review / lifecycle: Determine risk-based periodic review instead of universal annual schedule	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Scheduled state-of-control review and change-triggered assessment.	Review	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	Medium
BTV-01-0043	Data integrity	Protocol / design: Protect original chromatograms, sequence data and automated logs	Preapproved risk-based study design; endpoint: ALCOA+ controls, access, backup, audit trails, reconstruction.	Planning	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0044	Data integrity	Execution / boundary verification: Protect original chromatograms, sequence data and automated logs	Documented raw observations, calibration, relevant worst cases and defined acceptance for ALCOA+ controls, access, backup, audit trails, reconstruction.	Execution	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0045	Data integrity	Review / lifecycle: Protect original chromatograms, sequence data and automated logs	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on ALCOA+ controls, access, backup, audit trails, reconstruction.	Review	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-01-0046	QA release gates	Protocol / design: Prevent use of unqualified systems and unvalidated manufacturing steps	Preapproved risk-based study design; endpoint: Approved qualification release/milestone authorization.	Planning	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0047	QA release gates	Execution / boundary verification: Prevent use of unqualified systems and unvalidated manufacturing steps	Documented raw observations, calibration, relevant worst cases and defined acceptance for Approved qualification release/milestone authorization.	Execution	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0048	QA release gates	Review / lifecycle: Prevent use of unqualified systems and unvalidated manufacturing steps	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Approved qualification release/milestone authorization.	Review	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	Medium
BTV-01-0049	Validation training	Protocol / design: Qualify protocol authors, reviewers, samplers and executors	Preapproved risk-based study design; endpoint: Competency records and practical assessments.	Planning	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0050	Validation training	Execution / boundary verification: Qualify protocol authors, reviewers, samplers and executors	Documented raw observations, calibration, relevant worst cases and defined acceptance for Competency records and practical assessments.	Execution	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0051	Validation training	Review / lifecycle: Qualify protocol authors, reviewers, samplers and executors	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Competency records and practical assessments.	Review	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	Medium
BTV-01-0052	Facility transfer	Protocol / design: Evaluate continuity of validated state during site or CMOs transfer	Preapproved risk-based study design; endpoint: Facility qualification, tech transfer and validation gap matrix.	Planning	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0053	Facility transfer	Execution / boundary verification: Evaluate continuity of validated state during site or CMOs transfer	Documented raw observations, calibration, relevant worst cases and defined acceptance for Facility qualification, tech transfer and validation gap matrix.	Execution	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0054	Facility transfer	Review / lifecycle: Evaluate continuity of validated state during site or CMOs transfer	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Facility qualification, tech transfer and validation gap matrix.	Review	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	Medium
BTV-01-0055	Deviation linkage	Protocol / design: Assess critical departures from validated operating ranges	Preapproved risk-based study design; endpoint: Predefined escalation, batch impact and potential product rejection.	Planning	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0056	Deviation linkage	Execution / boundary verification: Assess critical departures from validated operating ranges	Documented raw observations, calibration, relevant worst cases and defined acceptance for Predefined escalation, batch impact and potential product rejection.	Execution	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0057	Deviation linkage	Review / lifecycle: Assess critical departures from validated operating ranges	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Predefined escalation, batch impact and potential product rejection.	Review	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	Medium
BTV-01-0058	Critical subcontractors	Protocol / design: Define owner responsibility for vendor sterilization / testing / filling	Preapproved risk-based study design; endpoint: Quality agreement, oversight and access to raw evidence.	Planning	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0059	Critical subcontractors	Execution / boundary verification: Define owner responsibility for vendor sterilization / testing / filling	Documented raw observations, calibration, relevant worst cases and defined acceptance for Quality agreement, oversight and access to raw evidence.	Execution	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	High
BTV-01-0060	Critical subcontractors	Review / lifecycle: Define owner responsibility for vendor sterilization / testing / filling	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Quality agreement, oversight and access to raw evidence.	Review	All biotechnology operations	B01 B02 B03 B05 B06 B12 B15	Medium
BTV-01-0061	Protocol lifecycle approval	Protocol / design: Confirm amendment handling, superseded revision and scientific repeat-test rules	Preapproved risk-based study design; endpoint: Full controlled protocol lineage.	Planning	All biotech	B02 B03 B05 B12	High
BTV-01-0062	Protocol lifecycle approval	Execution / boundary verification: Confirm amendment handling, superseded revision and scientific repeat-test rules	Documented raw observations, calibration, relevant worst cases and defined acceptance for Full controlled protocol lineage.	Execution	All biotech	B02 B03 B05 B12	High
BTV-01-0063	Protocol lifecycle approval	Review / lifecycle: Confirm amendment handling, superseded revision and scientific repeat-test rules	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Full controlled protocol lineage.	Review	All biotech	B02 B03 B05 B12	Medium
BTV-01-0064	Qualification report annexes	Protocol / design: Reconcile calibration and deviations attachments	Preapproved risk-based study design; endpoint: Complete report attachments.	Planning	All biotech	B02 B03 B05 B12	High
BTV-01-0065	Qualification report annexes	Execution / boundary verification: Reconcile calibration and deviations attachments	Documented raw observations, calibration, relevant worst cases and defined acceptance for Complete report attachments.	Execution	All biotech	B02 B03 B05 B12	High
BTV-01-0066	Qualification report annexes	Review / lifecycle: Reconcile calibration and deviations attachments	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Complete report attachments.	Review	All biotech	B02 B03 B05 B12	Medium
BTV-01-0067	Validation due-date review	Protocol / design: Test remediation priority and critical asset aging	Preapproved risk-based study design; endpoint: Timely execution and release gate.	Planning	All biotech	B02 B03 B05 B12	High
BTV-01-0068	Validation due-date review	Execution / boundary verification: Test remediation priority and critical asset aging	Documented raw observations, calibration, relevant worst cases and defined acceptance for Timely execution and release gate.	Execution	All biotech	B02 B03 B05 B12	High
BTV-01-0069	Validation due-date review	Review / lifecycle: Test remediation priority and critical asset aging	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Timely execution and release gate.	Review	All biotech	B02 B03 B05 B12	Medium
BTV-01-0070	Quality metrics escalation	Protocol / design: Validate rules for quality-trend thresholds	Preapproved risk-based study design; endpoint: No uninvestigated deterioration.	Planning	All biotech	B02 B03 B05 B12	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-01-0071	Quality metrics escalation	Execution / boundary verification: Validate rules for quality-trend thresholds	Documented raw observations, calibration, relevant worst cases and defined acceptance for No uninvestigated deterioration.	Execution	All biotech	B02 B03 B05 B12	High
BTV-01-0072	Quality metrics escalation	Review / lifecycle: Validate rules for quality-trend thresholds	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No uninvestigated deterioration.	Review	All biotech	B02 B03 B05 B12	Medium
BTV-01-0073	Validation campaign strategy	Protocol / design: Justify shared assets and process family coverage	Preapproved risk-based study design; endpoint: Scientifically sound bracketing.	Planning	All biotech	B02 B03 B05 B12	High
BTV-01-0074	Validation campaign strategy	Execution / boundary verification: Justify shared assets and process family coverage	Documented raw observations, calibration, relevant worst cases and defined acceptance for Scientifically sound bracketing.	Execution	All biotech	B02 B03 B05 B12	High
BTV-01-0075	Validation campaign strategy	Review / lifecycle: Justify shared assets and process family coverage	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Scientifically sound bracketing.	Review	All biotech	B02 B03 B05 B12	Medium
BTV-01-0076	Qualification matrix	Protocol / design: Ensure each asset maps to installation, operating, performance and monitoring	Preapproved risk-based study design; endpoint: No critical asset omitted.	Planning	All biotech	B02 B03 B05 B12	High
BTV-01-0077	Qualification matrix	Execution / boundary verification: Ensure each asset maps to installation, operating, performance and monitoring	Documented raw observations, calibration, relevant worst cases and defined acceptance for No critical asset omitted.	Execution	All biotech	B02 B03 B05 B12	High
BTV-01-0078	Qualification matrix	Review / lifecycle: Ensure each asset maps to installation, operating, performance and monitoring	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No critical asset omitted.	Review	All biotech	B02 B03 B05 B12	Medium

02 R&D, CELL LINES, GENETIC CONSTRUCTS & CELL BANKS

105 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-02-0001	Cell line provenance	Protocol / design: Trace origin, species, clone genealogy and history	Preapproved risk-based study design; endpoint: Complete chain from parental line to production MCB.	Planning	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0002	Cell line provenance	Execution / boundary verification: Trace origin, species, clone genealogy and history	Documented raw observations, calibration, relevant worst cases and defined acceptance for Complete chain from parental line to production MCB.	Execution	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0003	Cell line provenance	Review / lifecycle: Trace origin, species, clone genealogy and history	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Complete chain from parental line to production MCB.	Review	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	Medium
BTV-02-0004	Expression construct	Protocol / design: Characterize vector identity, insert structure, copy number and stability	Preapproved risk-based study design; endpoint: Sequencing, junction maps and expression stability.	Planning	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0005	Expression construct	Execution / boundary verification: Characterize vector identity, insert structure, copy number and stability	Documented raw observations, calibration, relevant worst cases and defined acceptance for Sequencing, junction maps and expression stability.	Execution	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0006	Expression construct	Review / lifecycle: Characterize vector identity, insert structure, copy number and stability	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Sequencing, junction maps and expression stability.	Review	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	Medium
BTV-02-0007	Master cell bank qualification	Protocol / design: Establish identity, purity, adventitious agent and genetic stability tests	Preapproved risk-based study design; endpoint: MCB certificate, panel rationale and reference characterization.	Planning	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0008	Master cell bank qualification	Execution / boundary verification: Establish identity, purity, adventitious agent and genetic stability tests	Documented raw observations, calibration, relevant worst cases and defined acceptance for MCB certificate, panel rationale and reference characterization.	Execution	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0009	Master cell bank qualification	Review / lifecycle: Establish identity, purity, adventitious agent and genetic stability tests	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on MCB certificate, panel rationale and reference characterization.	Review	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	Medium
BTV-02-0010	Working cell bank qualification	Protocol / design: Demonstrate WCB consistency from MCB	Preapproved risk-based study design; endpoint: WCB ID, microbiological purity and performance linkage.	Planning	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0011	Working cell bank qualification	Execution / boundary verification: Demonstrate WCB consistency from MCB	Documented raw observations, calibration, relevant worst cases and defined acceptance for WCB ID, microbiological purity and performance linkage.	Execution	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0012	Working cell bank qualification	Review / lifecycle: Demonstrate WCB consistency from MCB	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on WCB ID, microbiological purity and performance linkage.	Review	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	Medium
BTV-02-0013	Cell bank storage	Protocol / design: Map liquid nitrogen/vapor phase locations and excursion recovery	Preapproved risk-based study design; endpoint: Temperature profiles, redundant alarms and inventory control.	Planning	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0014	Cell bank storage	Execution / boundary verification: Map liquid nitrogen/vapor phase locations and excursion recovery	Documented raw observations, calibration, relevant worst cases and defined acceptance for Temperature profiles, redundant alarms and inventory control.	Execution	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0015	Cell bank storage	Review / lifecycle: Map liquid nitrogen/vapor phase locations and excursion recovery	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Temperature profiles, redundant alarms and inventory control.	Review	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	Medium
BTV-02-0016	Post-production cell bank	Protocol / design: Document viability, productivity and genetic stability after maximum passage	Preapproved risk-based study design; endpoint: End-of-production cell bank comparability and testing.	Planning	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0017	Post-production cell bank	Execution / boundary verification: Document viability, productivity and genetic stability after maximum passage	Documented raw observations, calibration, relevant worst cases and defined acceptance for End-of-production cell bank comparability and testing.	Execution	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0018	Post-production cell bank	Review / lifecycle: Document viability, productivity and genetic stability after maximum passage	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on End-of-production cell bank comparability and testing.	Review	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	Medium
BTV-02-0019	Cell line stability	Protocol / design: Define maximum generations/PDL/culture duration	Preapproved risk-based study design; endpoint: Identity, titer and quality profile within validated windows.	Planning	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0020	Cell line stability	Execution / boundary verification: Define maximum generations/PDL/culture duration	Documented raw observations, calibration, relevant worst cases and defined acceptance for Identity, titer and quality profile within validated windows.	Execution	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0021	Cell line stability	Review / lifecycle: Define maximum generations/PDL/culture duration	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Identity, titer and quality profile within validated windows.	Review	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	Medium
BTV-02-0022	Adventitious agent detection	Protocol / design: Qualify mycoplasma and species-specific virus testing	Preapproved risk-based study design; endpoint: Validated sensitive assays and controls.	Planning	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-02-0023	Adventitious agent detection	Execution / boundary verification: Qualify mycoplasma and species-specific virus testing	Documented raw observations, calibration, relevant worst cases and defined acceptance for Validated sensitive assays and controls.	Execution	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0024	Adventitious agent detection	Review / lifecycle: Qualify mycoplasma and species-specific virus testing	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Validated sensitive assays and controls.	Review	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	Medium
BTV-02-0025	Cell bank reconciliation	Protocol / design: Confirm vial identity, closure, thaw records and chain of custody	Preapproved risk-based study design; endpoint: Contamination and misidentification controls.	Planning	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0026	Cell bank reconciliation	Execution / boundary verification: Confirm vial identity, closure, thaw records and chain of custody	Documented raw observations, calibration, relevant worst cases and defined acceptance for Contamination and misidentification controls.	Execution	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0027	Cell bank reconciliation	Review / lifecycle: Confirm vial identity, closure, thaw records and chain of custody	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Contamination and misidentification controls.	Review	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	Medium
BTV-02-0028	Thaw recovery	Protocol / design: Qualify thaw temperature, time, inoculum and viability window	Preapproved risk-based study design; endpoint: Reproducible viable inoculum and growth.	Planning	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0029	Thaw recovery	Execution / boundary verification: Qualify thaw temperature, time, inoculum and viability window	Documented raw observations, calibration, relevant worst cases and defined acceptance for Reproducible viable inoculum and growth.	Execution	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0030	Thaw recovery	Review / lifecycle: Qualify thaw temperature, time, inoculum and viability window	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Reproducible viable inoculum and growth.	Review	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	Medium
BTV-02-0031	Clone selection transfer	Protocol / design: Demonstrate comparability across research and manufacturing banks	Preapproved risk-based study design; endpoint: Titer, heterogeneity, glycosylation and bioactivity trends.	Planning	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0032	Clone selection transfer	Execution / boundary verification: Demonstrate comparability across research and manufacturing banks	Documented raw observations, calibration, relevant worst cases and defined acceptance for Titer, heterogeneity, glycosylation and bioactivity trends.	Execution	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0033	Clone selection transfer	Review / lifecycle: Demonstrate comparability across research and manufacturing banks	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Titer, heterogeneity, glycosylation and bioactivity trends.	Review	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	Medium
BTV-02-0034	Cryopreservation formulation	Protocol / design: Validate DMSO/cryoprotectant concentration, fill and cool profile	Preapproved risk-based study design; endpoint: Viability post-thaw and recoverability.	Planning	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0035	Cryopreservation formulation	Execution / boundary verification: Validate DMSO/cryoprotectant concentration, fill and cool profile	Documented raw observations, calibration, relevant worst cases and defined acceptance for Viability post-thaw and recoverability.	Execution	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0036	Cryopreservation formulation	Review / lifecycle: Validate DMSO/cryoprotectant concentration, fill and cool profile	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Viability post-thaw and recoverability.	Review	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	Medium
BTV-02-0037	Cell bank labeling	Protocol / design: Validate cryo-compatible labels and freezer barcode traceability	Preapproved risk-based study design; endpoint: Legible identity, lifecycle, storage assignment.	Planning	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0038	Cell bank labeling	Execution / boundary verification: Validate cryo-compatible labels and freezer barcode traceability	Documented raw observations, calibration, relevant worst cases and defined acceptance for Legible identity, lifecycle, storage assignment.	Execution	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0039	Cell bank labeling	Review / lifecycle: Validate cryo-compatible labels and freezer barcode traceability	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Legible identity, lifecycle, storage assignment.	Review	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	Medium
BTV-02-0040	Reference biological standard	Protocol / design: Qualify reference stock identity and potency assignment	Preapproved risk-based study design; endpoint: Traceable controls and stability evidence.	Planning	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0041	Reference biological standard	Execution / boundary verification: Qualify reference stock identity and potency assignment	Documented raw observations, calibration, relevant worst cases and defined acceptance for Traceable controls and stability evidence.	Execution	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0042	Reference biological standard	Review / lifecycle: Qualify reference stock identity and potency assignment	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Traceable controls and stability evidence.	Review	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	Medium
BTV-02-0043	Cell bank controlled-rate freezer	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Cooling profile, vial load, thermocouple placement to product impact on Post-thaw viability, identity and recovery.	URS / DQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0044	Cell bank controlled-rate freezer	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Cell bank controlled-rate freezer.	IQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	Medium
BTV-02-0045	Cell bank controlled-rate freezer	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Cooling profile, vial load, thermocouple placement; compare challenge outputs to predefined Post-thaw viability, identity and recovery acceptance.	OQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-02-0046	Cell bank controlled-rate freezer	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Post-thaw viability, identity and recovery.	OQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0047	Cell bank controlled-rate freezer	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Post-thaw viability, identity and recovery at relevant Cooling profile, vial load, thermocouple placement; sampling scientifically justified.	PQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0048	Cell bank controlled-rate freezer	Continued verification / risk-based requalification trigger evaluation	Trend Cooling profile, vial load, thermocouple placement and impact on Post-thaw viability, identity and recovery; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	Medium
BTV-02-0049	Vapor-phase LN2 tank	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Temperature gradient, liquid level, alarm test to product impact on Long-term sample stability and traceability.	URS / DQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0050	Vapor-phase LN2 tank	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Vapor-phase LN2 tank.	IQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	Medium
BTV-02-0051	Vapor-phase LN2 tank	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Temperature gradient, liquid level, alarm test; compare challenge outputs to predefined Long-term sample stability and traceability acceptance.	OQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0052	Vapor-phase LN2 tank	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Long-term sample stability and traceability.	OQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0053	Vapor-phase LN2 tank	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Long-term sample stability and traceability at relevant Temperature gradient, liquid level, alarm test; sampling scientifically justified.	PQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0054	Vapor-phase LN2 tank	Continued verification / risk-based requalification trigger evaluation	Trend Temperature gradient, liquid level, alarm test and impact on Long-term sample stability and traceability; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	Medium
BTV-02-0055	LN2 distribution manifold	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Supply pressure, valve alarm, venting to product impact on Uninterrupted controlled cryogenic storage.	URS / DQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0056	LN2 distribution manifold	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for LN2 distribution manifold.	IQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	Medium
BTV-02-0057	LN2 distribution manifold	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Supply pressure, valve alarm, venting; compare challenge outputs to predefined Uninterrupted controlled cryogenic storage acceptance.	OQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0058	LN2 distribution manifold	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Uninterrupted controlled cryogenic storage.	OQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0059	LN2 distribution manifold	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Uninterrupted controlled cryogenic storage at relevant Supply pressure, valve alarm, venting; sampling scientifically justified.	PQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0060	LN2 distribution manifold	Continued verification / risk-based requalification trigger evaluation	Trend Supply pressure, valve alarm, venting and impact on Uninterrupted controlled cryogenic storage; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	Medium
BTV-02-0061	-80C freezer	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Mapping, alarms, power loss recovery to product impact on Stable cell bank and reagent storage.	URS / DQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0062	-80C freezer	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for -80C freezer.	IQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	Medium
BTV-02-0063	-80C freezer	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Mapping, alarms, power loss recovery; compare challenge outputs to predefined Stable cell bank and reagent storage acceptance.	OQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0064	-80C freezer	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Stable cell bank and reagent storage.	OQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0065	-80C freezer	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Stable cell bank and reagent storage at relevant Mapping, alarms, power loss recovery; sampling scientifically justified.	PQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-02-0066	-80C freezer	Continued verification / risk-based requalification trigger evaluation	Trend Mapping, alarms, power loss recovery and impact on Stable cell bank and reagent storage; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	Medium
BTV-02-0067	Cell thawing station	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Thaw temperature and time profile to product impact on Viable contamination-free inoculum.	URS / DQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0068	Cell thawing station	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Cell thawing station.	IQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	Medium
BTV-02-0069	Cell thawing station	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Thaw temperature and time profile; compare challenge outputs to predefined Viable contamination-free inoculum acceptance.	OQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0070	Cell thawing station	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Viable contamination-free inoculum.	OQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0071	Cell thawing station	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Viable contamination-free inoculum at relevant Thaw temperature and time profile; sampling scientifically justified.	PQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0072	Cell thawing station	Continued verification / risk-based requalification trigger evaluation	Trend Thaw temperature and time profile and impact on Viable contamination-free inoculum; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	Medium
BTV-02-0073	Cell counter / viability analyzer	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Dynamic range, counting repeatability, dye response to product impact on Accurate viable cell counts.	URS / DQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0074	Cell counter / viability analyzer	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Cell counter / viability analyzer.	IQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	Medium
BTV-02-0075	Cell counter / viability analyzer	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Dynamic range, counting repeatability, dye response; compare challenge outputs to predefined Accurate viable cell counts acceptance.	OQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0076	Cell counter / viability analyzer	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Accurate viable cell counts.	OQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0077	Cell counter / viability analyzer	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Accurate viable cell counts at relevant Dynamic range, counting repeatability, dye response; sampling scientifically justified.	PQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0078	Cell counter / viability analyzer	Continued verification / risk-based requalification trigger evaluation	Trend Dynamic range, counting repeatability, dye response and impact on Accurate viable cell counts; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	Medium
BTV-02-0079	Automated colony picker	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Picking accuracy, line identity, well tracking to product impact on Correct clonal selection traceability.	URS / DQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0080	Automated colony picker	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Automated colony picker.	IQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	Medium
BTV-02-0081	Automated colony picker	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Picking accuracy, line identity, well tracking; compare challenge outputs to predefined Correct clonal selection traceability acceptance.	OQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0082	Automated colony picker	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Correct clonal selection traceability.	OQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0083	Automated colony picker	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Correct clonal selection traceability at relevant Picking accuracy, line identity, well tracking; sampling scientifically justified.	PQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0084	Automated colony picker	Continued verification / risk-based requalification trigger evaluation	Trend Picking accuracy, line identity, well tracking and impact on Correct clonal selection traceability; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	Medium
BTV-02-0085	Biosafety cabinet for cell banks	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Airflow, HEPA integrity, aseptic technique to product impact on Contamination-free controlled handling.	URS / DQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0086	Biosafety cabinet for cell banks	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Biosafety cabinet for cell banks.	IQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-02-0087	Biosafety cabinet for cell banks	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Airflow, HEPA integrity, aseptic technique; compare challenge outputs to predefined Contamination-free controlled handling acceptance.	OQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0088	Biosafety cabinet for cell banks	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Contamination-free controlled handling.	OQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0089	Biosafety cabinet for cell banks	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Contamination-free controlled handling at relevant Airflow, HEPA integrity, aseptic technique; sampling scientifically justified.	PQ	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	High
BTV-02-0090	Biosafety cabinet for cell banks	Continued verification / risk-based requalification trigger evaluation	Trend Airflow, HEPA integrity, aseptic technique and impact on Contamination-free controlled handling; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Mammalian, microbial, recombinant biologics	B03 B08 B11 B13 B25	Medium
BTV-02-0091	MCB identity STR	Protocol / design: Assess species/line authentication and drift	Preapproved risk-based study design; endpoint: No cell line misidentification.	Planning	Cell bank and molecular biology	B08 B11	High
BTV-02-0092	MCB identity STR	Execution / boundary verification: Assess species/line authentication and drift	Documented raw observations, calibration, relevant worst cases and defined acceptance for No cell line misidentification.	Execution	Cell bank and molecular biology	B08 B11	High
BTV-02-0093	MCB identity STR	Review / lifecycle: Assess species/line authentication and drift	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No cell line misidentification.	Review	Cell bank and molecular biology	B08 B11	Medium
BTV-02-0094	Cell substrate tumorigenicity	Protocol / design: Evaluate relevance to selected cell line and product	Preapproved risk-based study design; endpoint: Risk-addressed cell substrate.	Planning	Cell bank and molecular biology	B08 B11	High
BTV-02-0095	Cell substrate tumorigenicity	Execution / boundary verification: Evaluate relevance to selected cell line and product	Documented raw observations, calibration, relevant worst cases and defined acceptance for Risk-addressed cell substrate.	Execution	Cell bank and molecular biology	B08 B11	High
BTV-02-0096	Cell substrate tumorigenicity	Review / lifecycle: Evaluate relevance to selected cell line and product	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Risk-addressed cell substrate.	Review	Cell bank and molecular biology	B08 B11	Medium
BTV-02-0097	Cell line clonality	Protocol / design: Justify evidence for clonally derived production line	Preapproved risk-based study design; endpoint: Defined clonal origin.	Planning	Cell bank and molecular biology	B08 B11	High
BTV-02-0098	Cell line clonality	Execution / boundary verification: Justify evidence for clonally derived production line	Documented raw observations, calibration, relevant worst cases and defined acceptance for Defined clonal origin.	Execution	Cell bank and molecular biology	B08 B11	High
BTV-02-0099	Cell line clonality	Review / lifecycle: Justify evidence for clonally derived production line	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Defined clonal origin.	Review	Cell bank and molecular biology	B08 B11	Medium
BTV-02-0100	Recombinant copy stability	Protocol / design: Check insert rearrangement at terminal culture	Preapproved risk-based study design; endpoint: Expression consistency.	Planning	Cell bank and molecular biology	B08 B11	High
BTV-02-0101	Recombinant copy stability	Execution / boundary verification: Check insert rearrangement at terminal culture	Documented raw observations, calibration, relevant worst cases and defined acceptance for Expression consistency.	Execution	Cell bank and molecular biology	B08 B11	High
BTV-02-0102	Recombinant copy stability	Review / lifecycle: Check insert rearrangement at terminal culture	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Expression consistency.	Review	Cell bank and molecular biology	B08 B11	Medium
BTV-02-0103	Cell bank freeze-thaw tracking	Protocol / design: Limit freeze-thaw history and vial labels	Preapproved risk-based study design; endpoint: Stable recovered growth.	Planning	Cell bank and molecular biology	B08 B11	High
BTV-02-0104	Cell bank freeze-thaw tracking	Execution / boundary verification: Limit freeze-thaw history and vial labels	Documented raw observations, calibration, relevant worst cases and defined acceptance for Stable recovered growth.	Execution	Cell bank and molecular biology	B08 B11	High
BTV-02-0105	Cell bank freeze-thaw tracking	Review / lifecycle: Limit freeze-thaw history and vial labels	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Stable recovered growth.	Review	Cell bank and molecular biology	B08 B11	Medium

03 MICROBIAL FERMENTATION & INOCULUM EXPANSION

96 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-03-0001	Inoculum train	Protocol / design: Prove flask/seed train reproducible growth and transfer timing	Preapproved risk-based study design; endpoint: CFU, OD, viability, plasmid retention and identity.	Planning	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0002	Inoculum train	Execution / boundary verification: Prove flask/seed train reproducible growth and transfer timing	Documented raw observations, calibration, relevant worst cases and defined acceptance for CFU, OD, viability, plasmid retention and identity.	Execution	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0003	Inoculum train	Review / lifecycle: Prove flask/seed train reproducible growth and transfer timing	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on CFU, OD, viability, plasmid retention and identity.	Review	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	Medium
BTV-03-0004	Fermentation scale-up	Protocol / design: Establish oxygen transfer, heat removal and mixing equivalence	Preapproved risk-based study design; endpoint: Critical growth, titer and impurity profiles across scales.	Planning	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0005	Fermentation scale-up	Execution / boundary verification: Establish oxygen transfer, heat removal and mixing equivalence	Documented raw observations, calibration, relevant worst cases and defined acceptance for Critical growth, titer and impurity profiles across scales.	Execution	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0006	Fermentation scale-up	Review / lifecycle: Establish oxygen transfer, heat removal and mixing equivalence	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Critical growth, titer and impurity profiles across scales.	Review	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	Medium
BTV-03-0007	Feed strategy	Protocol / design: Qualify carbon/nitrogen feed composition, rate and ramp	Preapproved risk-based study design; endpoint: Yield, acetate/by-product and titer consistency.	Planning	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0008	Feed strategy	Execution / boundary verification: Qualify carbon/nitrogen feed composition, rate and ramp	Documented raw observations, calibration, relevant worst cases and defined acceptance for Yield, acetate/by-product and titer consistency.	Execution	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0009	Feed strategy	Review / lifecycle: Qualify carbon/nitrogen feed composition, rate and ramp	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Yield, acetate/by-product and titer consistency.	Review	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	Medium
BTV-03-0010	Induction strategy	Protocol / design: Demonstrate inducible promoter timing and induction strength	Preapproved risk-based study design; endpoint: Protein expression and aggregation balance.	Planning	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0011	Induction strategy	Execution / boundary verification: Demonstrate inducible promoter timing and induction strength	Documented raw observations, calibration, relevant worst cases and defined acceptance for Protein expression and aggregation balance.	Execution	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0012	Induction strategy	Review / lifecycle: Demonstrate inducible promoter timing and induction strength	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Protein expression and aggregation balance.	Review	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	Medium
BTV-03-0013	Foam control	Protocol / design: Qualify anti-foam dose, control logic and filter/vent protection	Preapproved risk-based study design; endpoint: No wet vent filter or contamination excursion.	Planning	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0014	Foam control	Execution / boundary verification: Qualify anti-foam dose, control logic and filter/vent protection	Documented raw observations, calibration, relevant worst cases and defined acceptance for No wet vent filter or contamination excursion.	Execution	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0015	Foam control	Review / lifecycle: Qualify anti-foam dose, control logic and filter/vent protection	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No wet vent filter or contamination excursion.	Review	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	Medium
BTV-03-0016	pH control	Protocol / design: Study base/acid overshoot and control loops	Preapproved risk-based study design; endpoint: Metabolic health, yield and product quality.	Planning	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0017	pH control	Execution / boundary verification: Study base/acid overshoot and control loops	Documented raw observations, calibration, relevant worst cases and defined acceptance for Metabolic health, yield and product quality.	Execution	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0018	pH control	Review / lifecycle: Study base/acid overshoot and control loops	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Metabolic health, yield and product quality.	Review	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	Medium
BTV-03-0019	Oxygen control	Protocol / design: Qualify cascade DO, agitation, airflow and oxygen enrichment	Preapproved risk-based study design; endpoint: Reproducible oxygen exposure and product profile.	Planning	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0020	Oxygen control	Execution / boundary verification: Qualify cascade DO, agitation, airflow and oxygen enrichment	Documented raw observations, calibration, relevant worst cases and defined acceptance for Reproducible oxygen exposure and product profile.	Execution	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0021	Oxygen control	Review / lifecycle: Qualify cascade DO, agitation, airflow and oxygen enrichment	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Reproducible oxygen exposure and product profile.	Review	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	Medium
BTV-03-0022	Off-gas analytics	Protocol / design: Verify CO2/O2 mass balance analyzer response	Preapproved risk-based study design; endpoint: Productivity process monitoring and alarm accuracy.	Planning	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-03-0023	Off-gas analytics	Execution / boundary verification: Verify CO2/O2 mass balance analyzer response	Documented raw observations, calibration, relevant worst cases and defined acceptance for Productivity process monitoring and alarm accuracy.	Execution	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0024	Off-gas analytics	Review / lifecycle: Verify CO2/O2 mass balance analyzer response	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Productivity process monitoring and alarm accuracy.	Review	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	Medium
BTV-03-0025	Heat removal	Protocol / design: Challenge highest heat generation load	Preapproved risk-based study design; endpoint: Temperature control and no culture excursion.	Planning	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0026	Heat removal	Execution / boundary verification: Challenge highest heat generation load	Documented raw observations, calibration, relevant worst cases and defined acceptance for Temperature control and no culture excursion.	Execution	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0027	Heat removal	Review / lifecycle: Challenge highest heat generation load	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Temperature control and no culture excursion.	Review	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	Medium
BTV-03-0028	Harvest endpoint	Protocol / design: Define growth/viability and metabolite thresholds	Preapproved risk-based study design; endpoint: In-process release criteria and product quality.	Planning	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0029	Harvest endpoint	Execution / boundary verification: Define growth/viability and metabolite thresholds	Documented raw observations, calibration, relevant worst cases and defined acceptance for In-process release criteria and product quality.	Execution	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0030	Harvest endpoint	Review / lifecycle: Define growth/viability and metabolite thresholds	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on In-process release criteria and product quality.	Review	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	Medium
BTV-03-0031	Biological containment	Protocol / design: Validate negative pressure/exhaust and inactivation where required	Preapproved risk-based study design; endpoint: No viable release in applicable containment boundary.	Planning	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0032	Biological containment	Execution / boundary verification: Validate negative pressure/exhaust and inactivation where required	Documented raw observations, calibration, relevant worst cases and defined acceptance for No viable release in applicable containment boundary.	Execution	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0033	Biological containment	Review / lifecycle: Validate negative pressure/exhaust and inactivation where required	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No viable release in applicable containment boundary.	Review	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	Medium
BTV-03-0034	Batch genealogy	Protocol / design: Trace organism lot, media lot and culture passage	Preapproved risk-based study design; endpoint: Complete batch record and segregation.	Planning	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0035	Batch genealogy	Execution / boundary verification: Trace organism lot, media lot and culture passage	Documented raw observations, calibration, relevant worst cases and defined acceptance for Complete batch record and segregation.	Execution	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0036	Batch genealogy	Review / lifecycle: Trace organism lot, media lot and culture passage	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Complete batch record and segregation.	Review	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	Medium
BTV-03-0037	Microbial seed fermenter 5-50 L	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Temperature, DO, pH, agitation and sterility to product impact on Viable seed culture identity and growth.	URS / DQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0038	Microbial seed fermenter 5-50 L	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Microbial seed fermenter 5-50 L.	IQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	Medium
BTV-03-0039	Microbial seed fermenter 5-50 L	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Temperature, DO, pH, agitation and sterility; compare challenge outputs to predefined Viable seed culture identity and growth acceptance.	OQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0040	Microbial seed fermenter 5-50 L	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Viable seed culture identity and growth.	OQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0041	Microbial seed fermenter 5-50 L	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Viable seed culture identity and growth at relevant Temperature, DO, pH, agitation and sterility; sampling scientifically justified.	PQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0042	Microbial seed fermenter 5-50 L	Continued verification / risk-based requalification trigger evaluation	Trend Temperature, DO, pH, agitation and sterility and impact on Viable seed culture identity and growth; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	Medium
BTV-03-0043	Production fermenter stainless steel	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Heat transfer, mixing, DO cascade, pH and foam to product impact on Titer, viable growth and aggregate/impurity profile.	URS / DQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0044	Production fermenter stainless steel	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Production fermenter stainless steel.	IQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-03-0045	Production fermenter stainless steel	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Heat transfer, mixing, DO cascade, pH and foam; compare challenge outputs to predefined Titer, viable growth and aggregate/impurity profile acceptance.	OQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0046	Production fermenter stainless steel	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Titer, viable growth and aggregate/impurity profile.	OQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0047	Production fermenter stainless steel	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Titer, viable growth and aggregate/impurity profile at relevant Heat transfer, mixing, DO cascade, pH and foam; sampling scientifically justified.	PQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0048	Production fermenter stainless steel	Continued verification / risk-based requalification trigger evaluation	Trend Heat transfer, mixing, DO cascade, pH and foam and impact on Titer, viable growth and aggregate/impurity profile; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	Medium
BTV-03-0049	Single-use seed fermenter	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Probe calibration, mixing, bag integrity and oxygen transfer to product impact on Reproducible sterile inoculum.	URS / DQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0050	Single-use seed fermenter	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Single-use seed fermenter.	IQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	Medium
BTV-03-0051	Single-use seed fermenter	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Probe calibration, mixing, bag integrity and oxygen transfer; compare challenge outputs to predefined Reproducible sterile inoculum acceptance.	OQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0052	Single-use seed fermenter	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Reproducible sterile inoculum.	OQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0053	Single-use seed fermenter	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Reproducible sterile inoculum at relevant Probe calibration, mixing, bag integrity and oxygen transfer; sampling scientifically justified.	PQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0054	Single-use seed fermenter	Continued verification / risk-based requalification trigger evaluation	Trend Probe calibration, mixing, bag integrity and oxygen transfer and impact on Reproducible sterile inoculum; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	Medium
BTV-03-0055	Media feed skid	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Flow accuracy, sterile connection, hold time to product impact on Controlled media addition without contamination.	URS / DQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0056	Media feed skid	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Media feed skid.	IQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	Medium
BTV-03-0057	Media feed skid	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Flow accuracy, sterile connection, hold time; compare challenge outputs to predefined Controlled media addition without contamination acceptance.	OQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0058	Media feed skid	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Controlled media addition without contamination.	OQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0059	Media feed skid	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Controlled media addition without contamination at relevant Flow accuracy, sterile connection, hold time; sampling scientifically justified.	PQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0060	Media feed skid	Continued verification / risk-based requalification trigger evaluation	Trend Flow accuracy, sterile connection, hold time and impact on Controlled media addition without contamination; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	Medium
BTV-03-0061	Antifoam dosing pump	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Pump accuracy and dose alarm to product impact on Foam suppression and vent filter protection.	URS / DQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0062	Antifoam dosing pump	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Antifoam dosing pump.	IQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	Medium
BTV-03-0063	Antifoam dosing pump	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Pump accuracy and dose alarm; compare challenge outputs to predefined Foam suppression and vent filter protection acceptance.	OQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0064	Antifoam dosing pump	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Foam suppression and vent filter protection.	OQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-03-0065	Antifoam dosing pump	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Foam suppression and vent filter protection at relevant Pump accuracy and dose alarm; sampling scientifically justified.	PQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0066	Antifoam dosing pump	Continued verification / risk-based requalification trigger evaluation	Trend Pump accuracy and dose alarm and impact on Foam suppression and vent filter protection; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	Medium
BTV-03-0067	Fermenter exhaust HEPA train	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Integrity, condensation prevention, differential pressure to product impact on Biological containment and sterile boundary.	URS / DQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0068	Fermenter exhaust HEPA train	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Fermenter exhaust HEPA train.	IQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	Medium
BTV-03-0069	Fermenter exhaust HEPA train	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Integrity, condensation prevention, differential pressure; compare challenge outputs to predefined Biological containment and sterile boundary acceptance.	OQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0070	Fermenter exhaust HEPA train	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Biological containment and sterile boundary.	OQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0071	Fermenter exhaust HEPA train	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Biological containment and sterile boundary at relevant Integrity, condensation prevention, differential pressure; sampling scientifically justified.	PQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0072	Fermenter exhaust HEPA train	Continued verification / risk-based requalification trigger evaluation	Trend Integrity, condensation prevention, differential pressure and impact on Biological containment and sterile boundary; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	Medium
BTV-03-0073	Off-gas mass spectrometer	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace O2, CO2, flow and calibration gases to product impact on Accurate mass balance and metabolic trending.	URS / DQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0074	Off-gas mass spectrometer	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Off-gas mass spectrometer.	IQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	Medium
BTV-03-0075	Off-gas mass spectrometer	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of O2, CO2, flow and calibration gases; compare challenge outputs to predefined Accurate mass balance and metabolic trending acceptance.	OQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0076	Off-gas mass spectrometer	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Accurate mass balance and metabolic trending.	OQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0077	Off-gas mass spectrometer	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Accurate mass balance and metabolic trending at relevant O2, CO2, flow and calibration gases; sampling scientifically justified.	PQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0078	Off-gas mass spectrometer	Continued verification / risk-based requalification trigger evaluation	Trend O2, CO2, flow and calibration gases and impact on Accurate mass balance and metabolic trending; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	Medium
BTV-03-0079	Agitation motor/drive	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Speed, torque, vibration and seal to product impact on Consistent mixing and no contamination.	URS / DQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0080	Agitation motor/drive	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Agitation motor/drive.	IQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	Medium
BTV-03-0081	Agitation motor/drive	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Speed, torque, vibration and seal; compare challenge outputs to predefined Consistent mixing and no contamination acceptance.	OQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0082	Agitation motor/drive	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Consistent mixing and no contamination.	OQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0083	Agitation motor/drive	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Consistent mixing and no contamination at relevant Speed, torque, vibration and seal; sampling scientifically justified.	PQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0084	Agitation motor/drive	Continued verification / risk-based requalification trigger evaluation	Trend Speed, torque, vibration and seal and impact on Consistent mixing and no contamination; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-03-0085	Sterile harvest transfer pump	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Flow, pressure, seal containment to product impact on Harvest transfer recovery and product integrity.	URS / DQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0086	Sterile harvest transfer pump	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Sterile harvest transfer pump.	IQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	Medium
BTV-03-0087	Sterile harvest transfer pump	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Flow, pressure, seal containment; compare challenge outputs to predefined Harvest transfer recovery and product integrity acceptance.	OQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0088	Sterile harvest transfer pump	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Harvest transfer recovery and product integrity.	OQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0089	Sterile harvest transfer pump	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Harvest transfer recovery and product integrity at relevant Flow, pressure, seal containment; sampling scientifically justified.	PQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0090	Sterile harvest transfer pump	Continued verification / risk-based requalification trigger evaluation	Trend Flow, pressure, seal containment and impact on Harvest transfer recovery and product integrity; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	Medium
BTV-03-0091	Fermenter SIP skid	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Temperature mapping, steam quality, exposure to product impact on Reproducible equipment bioburden inactivation.	URS / DQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0092	Fermenter SIP skid	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Fermenter SIP skid.	IQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	Medium
BTV-03-0093	Fermenter SIP skid	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Temperature mapping, steam quality, exposure; compare challenge outputs to predefined Reproducible equipment bioburden inactivation acceptance.	OQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0094	Fermenter SIP skid	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Reproducible equipment bioburden inactivation.	OQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0095	Fermenter SIP skid	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Reproducible equipment bioburden inactivation at relevant Temperature mapping, steam quality, exposure; sampling scientifically justified.	PQ	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	High
BTV-03-0096	Fermenter SIP skid	Continued verification / risk-based requalification trigger evaluation	Trend Temperature mapping, steam quality, exposure and impact on Reproducible equipment bioburden inactivation; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	E. coli, yeast, microbial fermentation	B02 B03 B05 B12 B15	Medium

04 MAMMALIAN CELL CULTURE & SEED TRAIN

102 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-04-0001	Seed expansion strategy	Protocol / design: Define shake flask/rocking bag/stirred tank transition	Preapproved risk-based study design; endpoint: Cell density, viability, growth rate and product attributes.	Planning	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0002	Seed expansion strategy	Execution / boundary verification: Define shake flask/rocking bag/stirred tank transition	Documented raw observations, calibration, relevant worst cases and defined acceptance for Cell density, viability, growth rate and product attributes.	Execution	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0003	Seed expansion strategy	Review / lifecycle: Define shake flask/rocking bag/stirred tank transition	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Cell density, viability, growth rate and product attributes.	Review	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	Medium
BTV-04-0004	Cell expansion media	Protocol / design: Verify feed composition and osmolality limits	Preapproved risk-based study design; endpoint: Cell growth and glycan/charge variant consistency.	Planning	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0005	Cell expansion media	Execution / boundary verification: Verify feed composition and osmolality limits	Documented raw observations, calibration, relevant worst cases and defined acceptance for Cell growth and glycan/charge variant consistency.	Execution	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0006	Cell expansion media	Review / lifecycle: Verify feed composition and osmolality limits	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Cell growth and glycan/charge variant consistency.	Review	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	Medium
BTV-04-0007	Temperature shift	Protocol / design: Characterize shift time/rate across batch trajectory	Preapproved risk-based study design; endpoint: Titer and glycosylation within control ranges.	Planning	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0008	Temperature shift	Execution / boundary verification: Characterize shift time/rate across batch trajectory	Documented raw observations, calibration, relevant worst cases and defined acceptance for Titer and glycosylation within control ranges.	Execution	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0009	Temperature shift	Review / lifecycle: Characterize shift time/rate across batch trajectory	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Titer and glycosylation within control ranges.	Review	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	Medium
BTV-04-0010	Dissolved gases	Protocol / design: Qualify CO2/O2 balance and gas transfer	Preapproved risk-based study design; endpoint: pCO2, DO and pH stability with no excess shear.	Planning	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0011	Dissolved gases	Execution / boundary verification: Qualify CO2/O2 balance and gas transfer	Documented raw observations, calibration, relevant worst cases and defined acceptance for pCO2, DO and pH stability with no excess shear.	Execution	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0012	Dissolved gases	Review / lifecycle: Qualify CO2/O2 balance and gas transfer	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on pCO2, DO and pH stability with no excess shear.	Review	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	Medium
BTV-04-0013	Foam/shear stress	Protocol / design: Establish impeller and sparger safe operating windows	Preapproved risk-based study design; endpoint: Viability, aggregates and fragmentation.	Planning	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0014	Foam/shear stress	Execution / boundary verification: Establish impeller and sparger safe operating windows	Documented raw observations, calibration, relevant worst cases and defined acceptance for Viability, aggregates and fragmentation.	Execution	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0015	Foam/shear stress	Review / lifecycle: Establish impeller and sparger safe operating windows	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Viability, aggregates and fragmentation.	Review	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	Medium
BTV-04-0016	Perfusion control	Protocol / design: Validate CSPR, bleed, cell retention and waste lines	Preapproved risk-based study design; endpoint: Stable VCD and product residence time.	Planning	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-04-0017	Perfusion control	Execution / boundary verification: Validate CSPR, bleed, cell retention and waste lines	Documented raw observations, calibration, relevant worst cases and defined acceptance for Stable VCD and product residence time.	Execution	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0018	Perfusion control	Review / lifecycle: Validate CSPR, bleed, cell retention and waste lines	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Stable VCD and product residence time.	Review	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	Medium
BTV-04-0019	Fed-batch feed	Protocol / design: Prove feeding recipe accuracy and timing	Preapproved risk-based study design; endpoint: Reproducible cell viability/productivity and quality.	Planning	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0020	Fed-batch feed	Execution / boundary verification: Prove feeding recipe accuracy and timing	Documented raw observations, calibration, relevant worst cases and defined acceptance for Reproducible cell viability/productivity and quality.	Execution	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0021	Fed-batch feed	Review / lifecycle: Prove feeding recipe accuracy and timing	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Reproducible cell viability/productivity and quality.	Review	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	Medium
BTV-04-0022	Harvest decision	Protocol / design: Demonstrate endpoints for viable cell death and protease burden	Preapproved risk-based study design; endpoint: Purity, HCP and aggregate acceptance.	Planning	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0023	Harvest decision	Execution / boundary verification: Demonstrate endpoints for viable cell death and protease burden	Documented raw observations, calibration, relevant worst cases and defined acceptance for Purity, HCP and aggregate acceptance.	Execution	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0024	Harvest decision	Review / lifecycle: Demonstrate endpoints for viable cell death and protease burden	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Purity, HCP and aggregate acceptance.	Review	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	Medium
BTV-04-0025	Culture sampling	Protocol / design: Qualify aseptic sampling intervals and representative composition	Preapproved risk-based study design; endpoint: No loss of sterility and accurate process trend.	Planning	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0026	Culture sampling	Execution / boundary verification: Qualify aseptic sampling intervals and representative composition	Documented raw observations, calibration, relevant worst cases and defined acceptance for No loss of sterility and accurate process trend.	Execution	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0027	Culture sampling	Review / lifecycle: Qualify aseptic sampling intervals and representative composition	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No loss of sterility and accurate process trend.	Review	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	Medium
BTV-04-0028	Bioreactor contamination	Protocol / design: Challenge microbial/mycoplasma testing response and action	Preapproved risk-based study design; endpoint: Rapid detect/isolate/contain response.	Planning	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0029	Bioreactor contamination	Execution / boundary verification: Challenge microbial/mycoplasma testing response and action	Documented raw observations, calibration, relevant worst cases and defined acceptance for Rapid detect/isolate/contain response.	Execution	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0030	Bioreactor contamination	Review / lifecycle: Challenge microbial/mycoplasma testing response and action	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Rapid detect/isolate/contain response.	Review	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	Medium
BTV-04-0031	Inoculation boundary	Protocol / design: Validate aseptic connector weld/seal and transfer	Preapproved risk-based study design; endpoint: Sterility and chain-of-identity during expansion.	Planning	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0032	Inoculation boundary	Execution / boundary verification: Validate aseptic connector weld/seal and transfer	Documented raw observations, calibration, relevant worst cases and defined acceptance for Sterility and chain-of-identity during expansion.	Execution	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0033	Inoculation boundary	Review / lifecycle: Validate aseptic connector weld/seal and transfer	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Sterility and chain-of-identity during expansion.	Review	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	Medium
BTV-04-0034	Bioreactor mass balance	Protocol / design: Validate accurate mass and working volume determination	Preapproved risk-based study design; endpoint: Reliable feed, sampling and harvest yields.	Planning	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-04-0035	Bioreactor mass balance	Execution / boundary verification: Validate accurate mass and working volume determination	Documented raw observations, calibration, relevant worst cases and defined acceptance for Reliable feed, sampling and harvest yields.	Execution	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0036	Bioreactor mass balance	Review / lifecycle: Validate accurate mass and working volume determination	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Reliable feed, sampling and harvest yields.	Review	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	Medium
BTV-04-0037	Shake flask incubator orbital	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Orbital speed, CO2, humidity, temperature mapping to product impact on Culture growth/viability and homogeneous performance.	URS / DQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0038	Shake flask incubator orbital	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Shake flask incubator orbital.	IQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	Medium
BTV-04-0039	Shake flask incubator orbital	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Orbital speed, CO2, humidity, temperature mapping; compare challenge outputs to predefined Culture growth/viability and homogeneous performance acceptance.	OQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0040	Shake flask incubator orbital	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Culture growth/viability and homogeneous performance.	OQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0041	Shake flask incubator orbital	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Culture growth/viability and homogeneous performance at relevant Orbital speed, CO2, humidity, temperature mapping; sampling scientifically justified.	PQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0042	Shake flask incubator orbital	Continued verification / risk-based requalification trigger evaluation	Trend Orbital speed, CO2, humidity, temperature mapping and impact on Culture growth/viability and homogeneous performance; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	Medium
BTV-04-0043	Wave/rocking bioreactor	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Rock angle, speed, aeration, load cells to product impact on Mixing, gas transfer and viability.	URS / DQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0044	Wave/rocking bioreactor	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Wave/rocking bioreactor.	IQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	Medium
BTV-04-0045	Wave/rocking bioreactor	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Rock angle, speed, aeration, load cells; compare challenge outputs to predefined Mixing, gas transfer and viability acceptance.	OQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0046	Wave/rocking bioreactor	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Mixing, gas transfer and viability.	OQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0047	Wave/rocking bioreactor	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Mixing, gas transfer and viability at relevant Rock angle, speed, aeration, load cells; sampling scientifically justified.	PQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0048	Wave/rocking bioreactor	Continued verification / risk-based requalification trigger evaluation	Trend Rock angle, speed, aeration, load cells and impact on Mixing, gas transfer and viability; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	Medium
BTV-04-0049	Stainless mammalian bioreactor	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace DO, pH, agitation, CO2 stripping, temperature to product impact on Titer, critical glycan and aggregate profile.	URS / DQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0050	Stainless mammalian bioreactor	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Stainless mammalian bioreactor.	IQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	Medium
BTV-04-0051	Stainless mammalian bioreactor	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of DO, pH, agitation, CO2 stripping, temperature; compare challenge outputs to predefined Titer, critical glycan and aggregate profile acceptance.	OQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0052	Stainless mammalian bioreactor	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Titer, critical glycan and aggregate profile.	OQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-04-0053	Stainless mammalian bioreactor	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Titer, critical glycan and aggregate profile at relevant DO, pH, agitation, CO2 stripping, temperature; sampling scientifically justified.	PQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0054	Stainless mammalian bioreactor	Continued verification / risk-based requalification trigger evaluation	Trend DO, pH, agitation, CO2 stripping, temperature and impact on Titer, critical glycan and aggregate profile; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	Medium
BTV-04-0055	Single-use stirred tank bioreactor	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Bag assembly, pressure, DO, temperature, leak test to product impact on Reproducible cell growth and product quality.	URS / DQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0056	Single-use stirred tank bioreactor	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Single-use stirred tank bioreactor.	IQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	Medium
BTV-04-0057	Single-use stirred tank bioreactor	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Bag assembly, pressure, DO, temperature, leak test; compare challenge outputs to predefined Reproducible cell growth and product quality acceptance.	OQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0058	Single-use stirred tank bioreactor	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Reproducible cell growth and product quality.	OQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0059	Single-use stirred tank bioreactor	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Reproducible cell growth and product quality at relevant Bag assembly, pressure, DO, temperature, leak test; sampling scientifically justified.	PQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0060	Single-use stirred tank bioreactor	Continued verification / risk-based requalification trigger evaluation	Trend Bag assembly, pressure, DO, temperature, leak test and impact on Reproducible cell growth and product quality; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	Medium
BTV-04-0061	Perfusion cell retention unit ATF	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Alternating-flow pump speed, membrane pressure to product impact on Cell retention and product harvest recovery.	URS / DQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0062	Perfusion cell retention unit ATF	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Perfusion cell retention unit ATF.	IQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	Medium
BTV-04-0063	Perfusion cell retention unit ATF	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Alternating-flow pump speed, membrane pressure; compare challenge outputs to predefined Cell retention and product harvest recovery acceptance.	OQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0064	Perfusion cell retention unit ATF	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Cell retention and product harvest recovery.	OQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0065	Perfusion cell retention unit ATF	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Cell retention and product harvest recovery at relevant Alternating-flow pump speed, membrane pressure; sampling scientifically justified.	PQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0066	Perfusion cell retention unit ATF	Continued verification / risk-based requalification trigger evaluation	Trend Alternating-flow pump speed, membrane pressure and impact on Cell retention and product harvest recovery; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	Medium
BTV-04-0067	Perfusion cell retention unit TFF	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Membrane flux, recirculation and bleed to product impact on Viability and retention performance.	URS / DQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0068	Perfusion cell retention unit TFF	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Perfusion cell retention unit TFF.	IQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	Medium
BTV-04-0069	Perfusion cell retention unit TFF	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Membrane flux, recirculation and bleed; compare challenge outputs to predefined Viability and retention performance acceptance.	OQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0070	Perfusion cell retention unit TFF	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Viability and retention performance.	OQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-04-0071	Perfusion cell retention unit TFF	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Viability and retention performance at relevant Membrane flux, recirculation and bleed; sampling scientifically justified.	PQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0072	Perfusion cell retention unit TFF	Continued verification / risk-based requalification trigger evaluation	Trend Membrane flux, recirculation and bleed and impact on Viability and retention performance; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	Medium
BTV-04-0073	Cell culture inline Raman/NIR	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Wavelength, calibration, spectral drift to product impact on Predictive glucose/lactate and control strategy.	URS / DQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0074	Cell culture inline Raman/NIR	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Cell culture inline Raman/NIR.	IQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	Medium
BTV-04-0075	Cell culture inline Raman/NIR	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Wavelength, calibration, spectral drift; compare challenge outputs to predefined Predictive glucose/lactate and control strategy acceptance.	OQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0076	Cell culture inline Raman/NIR	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Predictive glucose/lactate and control strategy.	OQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0077	Cell culture inline Raman/NIR	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Predictive glucose/lactate and control strategy at relevant Wavelength, calibration, spectral drift; sampling scientifically justified.	PQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0078	Cell culture inline Raman/NIR	Continued verification / risk-based requalification trigger evaluation	Trend Wavelength, calibration, spectral drift and impact on Predictive glucose/lactate and control strategy; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	Medium
BTV-04-0079	Cell counting analyzer	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Dilution linearity, viable gating and counting to product impact on Accurate VCD growth trends.	URS / DQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0080	Cell counting analyzer	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Cell counting analyzer.	IQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	Medium
BTV-04-0081	Cell counting analyzer	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Dilution linearity, viable gating and counting; compare challenge outputs to predefined Accurate VCD growth trends acceptance.	OQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0082	Cell counting analyzer	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Accurate VCD growth trends.	OQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0083	Cell counting analyzer	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Accurate VCD growth trends at relevant Dilution linearity, viable gating and counting; sampling scientifically justified.	PQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0084	Cell counting analyzer	Continued verification / risk-based requalification trigger evaluation	Trend Dilution linearity, viable gating and counting and impact on Accurate VCD growth trends; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	Medium
BTV-04-0085	Mass-flow controller gas panel	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace O2/air/CO2 calibration and blending to product impact on Stable DO and pH control.	URS / DQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0086	Mass-flow controller gas panel	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Mass-flow controller gas panel.	IQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	Medium
BTV-04-0087	Mass-flow controller gas panel	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of O2/air/CO2 calibration and blending; compare challenge outputs to predefined Stable DO and pH control acceptance.	OQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0088	Mass-flow controller gas panel	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Stable DO and pH control.	OQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-04-0089	Mass-flow controller gas panel	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Stable DO and pH control at relevant O2/air/CO2 calibration and blending; sampling scientifically justified.	PQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0090	Mass-flow controller gas panel	Continued verification / risk-based requalification trigger evaluation	Trend O2/air/CO2 calibration and blending and impact on Stable DO and pH control; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	Medium
BTV-04-0091	Bioreactor load cell/scale	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Load range, drift, tare and weighing to product impact on Accurate culture volume and feed quantity.	URS / DQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0092	Bioreactor load cell/scale	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Bioreactor load cell/scale.	IQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	Medium
BTV-04-0093	Bioreactor load cell/scale	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Load range, drift, tare and weighing; compare challenge outputs to predefined Accurate culture volume and feed quantity acceptance.	OQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0094	Bioreactor load cell/scale	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Accurate culture volume and feed quantity.	OQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0095	Bioreactor load cell/scale	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Accurate culture volume and feed quantity at relevant Load range, drift, tare and weighing; sampling scientifically justified.	PQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0096	Bioreactor load cell/scale	Continued verification / risk-based requalification trigger evaluation	Trend Load range, drift, tare and weighing and impact on Accurate culture volume and feed quantity; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	Medium
BTV-04-0097	Sampling aseptic manifold	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Connections, hold-up volume and aseptic boundary to product impact on Representative and contamination-free samples.	URS / DQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0098	Sampling aseptic manifold	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Sampling aseptic manifold.	IQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	Medium
BTV-04-0099	Sampling aseptic manifold	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Connections, hold-up volume and aseptic boundary; compare challenge outputs to predefined Representative and contamination-free samples acceptance.	OQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0100	Sampling aseptic manifold	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Representative and contamination-free samples.	OQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0101	Sampling aseptic manifold	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Representative and contamination-free samples at relevant Connections, hold-up volume and aseptic boundary; sampling scientifically justified.	PQ	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	High
BTV-04-0102	Sampling aseptic manifold	Continued verification / risk-based requalification trigger evaluation	Trend Connections, hold-up volume and aseptic boundary and impact on Representative and contamination-free samples; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	CHO, HEK293 and mammalian expression systems	B02 B03 B07 B08 B13	Medium

05 SINGLE-USE TECHNOLOGIES & CLOSED PROCESSING

96 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-05-0001	Bag extractables and leachables	Protocol / design: Assess material, process media, time, temperature and gamma exposure	Preapproved risk-based study design; endpoint: Toxicological and product-quality risk assessment.	Planning	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0002	Bag extractables and leachables	Execution / boundary verification: Assess material, process media, time, temperature and gamma exposure	Documented raw observations, calibration, relevant worst cases and defined acceptance for Toxicological and product-quality risk assessment.	Execution	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0003	Bag extractables and leachables	Review / lifecycle: Assess material, process media, time, temperature and gamma exposure	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Toxicological and product-quality risk assessment.	Review	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	Medium
BTV-05-0004	Supplier gamma irradiation	Protocol / design: Verify irradiation qualification and certificate traceability	Preapproved risk-based study design; endpoint: Sterility claim and material compatibility.	Planning	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0005	Supplier gamma irradiation	Execution / boundary verification: Verify irradiation qualification and certificate traceability	Documented raw observations, calibration, relevant worst cases and defined acceptance for Sterility claim and material compatibility.	Execution	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0006	Supplier gamma irradiation	Review / lifecycle: Verify irradiation qualification and certificate traceability	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Sterility claim and material compatibility.	Review	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	Medium
BTV-05-0007	Single-use assembly integrity	Protocol / design: Challenge leak tests at boundary of operating pressure	Preapproved risk-based study design; endpoint: No compromise in process or aseptic transfer.	Planning	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0008	Single-use assembly integrity	Execution / boundary verification: Challenge leak tests at boundary of operating pressure	Documented raw observations, calibration, relevant worst cases and defined acceptance for No compromise in process or aseptic transfer.	Execution	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0009	Single-use assembly integrity	Review / lifecycle: Challenge leak tests at boundary of operating pressure	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No compromise in process or aseptic transfer.	Review	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	Medium
BTV-05-0010	Tubing weld	Protocol / design: Qualify weld strength, occlusion and post-weld integrity	Preapproved risk-based study design; endpoint: Leak-free bioprocess transfer.	Planning	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0011	Tubing weld	Execution / boundary verification: Qualify weld strength, occlusion and post-weld integrity	Documented raw observations, calibration, relevant worst cases and defined acceptance for Leak-free bioprocess transfer.	Execution	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0012	Tubing weld	Review / lifecycle: Qualify weld strength, occlusion and post-weld integrity	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Leak-free bioprocess transfer.	Review	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	Medium
BTV-05-0013	Sterile connector	Protocol / design: Qualify mating orientation and aseptic connection process	Preapproved risk-based study design; endpoint: Sterile process fluid pathway.	Planning	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0014	Sterile connector	Execution / boundary verification: Qualify mating orientation and aseptic connection process	Documented raw observations, calibration, relevant worst cases and defined acceptance for Sterile process fluid pathway.	Execution	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0015	Sterile connector	Review / lifecycle: Qualify mating orientation and aseptic connection process	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Sterile process fluid pathway.	Review	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	Medium
BTV-05-0016	Assembly design change	Protocol / design: Validate alternative film/port/tubing and supplier changes	Preapproved risk-based study design; endpoint: Comparability and E&L impact.	Planning	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-05-0017	Assembly design change	Execution / boundary verification: Validate alternative film/port/tubing and supplier changes	Documented raw observations, calibration, relevant worst cases and defined acceptance for Comparability and E&L impact.	Execution	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0018	Assembly design change	Review / lifecycle: Validate alternative film/port/tubing and supplier changes	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Comparability and E&L impact.	Review	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	Medium
BTV-05-0019	Pinch-valve behavior	Protocol / design: Prove flow control and tube wear at extremes	Preapproved risk-based study design; endpoint: Stable CPP and no particulate generation.	Planning	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0020	Pinch-valve behavior	Execution / boundary verification: Prove flow control and tube wear at extremes	Documented raw observations, calibration, relevant worst cases and defined acceptance for Stable CPP and no particulate generation.	Execution	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0021	Pinch-valve behavior	Review / lifecycle: Prove flow control and tube wear at extremes	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Stable CPP and no particulate generation.	Review	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	Medium
BTV-05-0022	SUS mixing	Protocol / design: Validate mixing time, foam, stratification and addition order	Preapproved risk-based study design; endpoint: Homogeneity for salts, protein and excipients.	Planning	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0023	SUS mixing	Execution / boundary verification: Validate mixing time, foam, stratification and addition order	Documented raw observations, calibration, relevant worst cases and defined acceptance for Homogeneity for salts, protein and excipients.	Execution	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0024	SUS mixing	Review / lifecycle: Validate mixing time, foam, stratification and addition order	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Homogeneity for salts, protein and excipients.	Review	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	Medium
BTV-05-0025	Closed processing	Protocol / design: Validate interfaces within defined classified/background environment	Preapproved risk-based study design; endpoint: Contamination control and microbial integrity.	Planning	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0026	Closed processing	Execution / boundary verification: Validate interfaces within defined classified/background environment	Documented raw observations, calibration, relevant worst cases and defined acceptance for Contamination control and microbial integrity.	Execution	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0027	Closed processing	Review / lifecycle: Validate interfaces within defined classified/background environment	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Contamination control and microbial integrity.	Review	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	Medium
BTV-05-0028	SUS shipping	Protocol / design: Verify bag transit damage and packaging protection	Preapproved risk-based study design; endpoint: Fit-for-use assemblies on receipt.	Planning	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0029	SUS shipping	Execution / boundary verification: Verify bag transit damage and packaging protection	Documented raw observations, calibration, relevant worst cases and defined acceptance for Fit-for-use assemblies on receipt.	Execution	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0030	SUS shipping	Review / lifecycle: Verify bag transit damage and packaging protection	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Fit-for-use assemblies on receipt.	Review	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	Medium
BTV-05-0031	Sterile filtration path	Protocol / design: Confirm presterilized assembly compatibility and batch genealogy	Preapproved risk-based study design; endpoint: Sterile boundary traceability.	Planning	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0032	Sterile filtration path	Execution / boundary verification: Confirm presterilized assembly compatibility and batch genealogy	Documented raw observations, calibration, relevant worst cases and defined acceptance for Sterile boundary traceability.	Execution	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0033	Sterile filtration path	Review / lifecycle: Confirm presterilized assembly compatibility and batch genealogy	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Sterile boundary traceability.	Review	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	Medium
BTV-05-0034	Contact material compatibility	Protocol / design: Study product adsorption and shear/extractable behavior	Preapproved risk-based study design; endpoint: Product recovery and CQA protection.	Planning	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-05-0035	Contact material compatibility	Execution / boundary verification: Study product adsorption and shear/extractable behavior	Documented raw observations, calibration, relevant worst cases and defined acceptance for Product recovery and CQA protection.	Execution	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0036	Contact material compatibility	Review / lifecycle: Study product adsorption and shear/extractable behavior	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Product recovery and CQA protection.	Review	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	Medium
BTV-05-0037	2D bioprocess bag	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Film integrity, port weld, fill weight to product impact on Leak-free product hold and recovery.	URS / DQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0038	2D bioprocess bag	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for 2D bioprocess bag.	IQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	Medium
BTV-05-0039	2D bioprocess bag	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Film integrity, port weld, fill weight; compare challenge outputs to predefined Leak-free product hold and recovery acceptance.	OQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0040	2D bioprocess bag	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Leak-free product hold and recovery.	OQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0041	2D bioprocess bag	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Leak-free product hold and recovery at relevant Film integrity, port weld, fill weight; sampling scientifically justified.	PQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0042	2D bioprocess bag	Continued verification / risk-based requalification trigger evaluation	Trend Film integrity, port weld, fill weight and impact on Leak-free product hold and recovery; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	Medium
BTV-05-0043	3D bioprocess storage bag	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Max fill, handling load, seam integrity to product impact on Storage integrity, hold time and E&L control.	URS / DQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0044	3D bioprocess storage bag	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for 3D bioprocess storage bag.	IQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	Medium
BTV-05-0045	3D bioprocess storage bag	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Max fill, handling load, seam integrity; compare challenge outputs to predefined Storage integrity, hold time and E&L control acceptance.	OQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0046	3D bioprocess storage bag	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Storage integrity, hold time and E&L control.	OQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0047	3D bioprocess storage bag	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Storage integrity, hold time and E&L control at relevant Max fill, handling load, seam integrity; sampling scientifically justified.	PQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0048	3D bioprocess storage bag	Continued verification / risk-based requalification trigger evaluation	Trend Max fill, handling load, seam integrity and impact on Storage integrity, hold time and E&L control; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	Medium
BTV-05-0049	Single-use mixer	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Impeller speed, mixing time, bag geometry to product impact on Buffer concentration homogeneity.	URS / DQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0050	Single-use mixer	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Single-use mixer.	IQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	Medium
BTV-05-0051	Single-use mixer	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Impeller speed, mixing time, bag geometry; compare challenge outputs to predefined Buffer concentration homogeneity acceptance.	OQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0052	Single-use mixer	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Buffer concentration homogeneity.	OQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-05-0053	Single-use mixer	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Buffer concentration homogeneity at relevant Impeller speed, mixing time, bag geometry; sampling scientifically justified.	PQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0054	Single-use mixer	Continued verification / risk-based requalification trigger evaluation	Trend Impeller speed, mixing time, bag geometry and impact on Buffer concentration homogeneity; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	Medium
BTV-05-0055	Single-use tubing welder	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Weld temperature, tube size and strength to product impact on Secure aseptic fluid transfers.	URS / DQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0056	Single-use tubing welder	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Single-use tubing welder.	IQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	Medium
BTV-05-0057	Single-use tubing welder	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Weld temperature, tube size and strength; compare challenge outputs to predefined Secure aseptic fluid transfers acceptance.	OQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0058	Single-use tubing welder	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Secure aseptic fluid transfers.	OQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0059	Single-use tubing welder	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Secure aseptic fluid transfers at relevant Weld temperature, tube size and strength; sampling scientifically justified.	PQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0060	Single-use tubing welder	Continued verification / risk-based requalification trigger evaluation	Trend Weld temperature, tube size and strength and impact on Secure aseptic fluid transfers; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	Medium
BTV-05-0061	Tube sealer	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Seal time, temperature and strength to product impact on Leak-free segmented tubing.	URS / DQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0062	Tube sealer	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Tube sealer.	IQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	Medium
BTV-05-0063	Tube sealer	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Seal time, temperature and strength; compare challenge outputs to predefined Leak-free segmented tubing acceptance.	OQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0064	Tube sealer	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Leak-free segmented tubing.	OQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0065	Tube sealer	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Leak-free segmented tubing at relevant Seal time, temperature and strength; sampling scientifically justified.	PQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0066	Tube sealer	Continued verification / risk-based requalification trigger evaluation	Trend Seal time, temperature and strength and impact on Leak-free segmented tubing; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	Medium
BTV-05-0067	Aseptic connector	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Connection insertion, pressure leak and technique to product impact on Maintained sterile boundary.	URS / DQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0068	Aseptic connector	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Aseptic connector.	IQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	Medium
BTV-05-0069	Aseptic connector	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Connection insertion, pressure leak and technique; compare challenge outputs to predefined Maintained sterile boundary acceptance.	OQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0070	Aseptic connector	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Maintained sterile boundary.	OQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-05-0071	Aseptic connector	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Maintained sterile boundary at relevant Connection insertion, pressure leak and technique; sampling scientifically justified.	PQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0072	Aseptic connector	Continued verification / risk-based requalification trigger evaluation	Trend Connection insertion, pressure leak and technique and impact on Maintained sterile boundary; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	Medium
BTV-05-0073	Pinch valve array	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Valve position accuracy and cycle count to product impact on Correct path routing and no cross connection.	URS / DQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0074	Pinch valve array	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Pinch valve array.	IQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	Medium
BTV-05-0075	Pinch valve array	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Valve position accuracy and cycle count; compare challenge outputs to predefined Correct path routing and no cross connection acceptance.	OQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0076	Pinch valve array	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Correct path routing and no cross connection.	OQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0077	Pinch valve array	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Correct path routing and no cross connection at relevant Valve position accuracy and cycle count; sampling scientifically justified.	PQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0078	Pinch valve array	Continued verification / risk-based requalification trigger evaluation	Trend Valve position accuracy and cycle count and impact on Correct path routing and no cross connection; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	Medium
BTV-05-0079	Single-use sensor pH/DO	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Pre-calibration, drift, range and reference check to product impact on Reliable process control.	URS / DQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0080	Single-use sensor pH/DO	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Single-use sensor pH/DO.	IQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	Medium
BTV-05-0081	Single-use sensor pH/DO	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Pre-calibration, drift, range and reference check; compare challenge outputs to predefined Reliable process control acceptance.	OQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0082	Single-use sensor pH/DO	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Reliable process control.	OQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0083	Single-use sensor pH/DO	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Reliable process control at relevant Pre-calibration, drift, range and reference check; sampling scientifically justified.	PQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0084	Single-use sensor pH/DO	Continued verification / risk-based requalification trigger evaluation	Trend Pre-calibration, drift, range and reference check and impact on Reliable process control; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	Medium
BTV-05-0085	Single-use sampling kit	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Sample isolation, volume and aseptic boundary to product impact on Representative uncontaminated samples.	URS / DQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0086	Single-use sampling kit	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Single-use sampling kit.	IQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	Medium
BTV-05-0087	Single-use sampling kit	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Sample isolation, volume and aseptic boundary; compare challenge outputs to predefined Representative uncontaminated samples acceptance.	OQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0088	Single-use sampling kit	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Representative uncontaminated samples.	OQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-05-0089	Single-use sampling kit	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Representative uncontaminated samples at relevant Sample isolation, volume and aseptic boundary; sampling scientifically justified.	PQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0090	Single-use sampling kit	Continued verification / risk-based requalification trigger evaluation	Trend Sample isolation, volume and aseptic boundary and impact on Representative uncontaminated samples; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	Medium
BTV-05-0091	Disposable depth filter kit	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Connection integrity and differential pressure to product impact on Clarified product with controlled bioburden.	URS / DQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0092	Disposable depth filter kit	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Disposable depth filter kit.	IQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	Medium
BTV-05-0093	Disposable depth filter kit	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Connection integrity and differential pressure; compare challenge outputs to predefined Clarified product with controlled bioburden acceptance.	OQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0094	Disposable depth filter kit	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Clarified product with controlled bioburden.	OQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0095	Disposable depth filter kit	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Clarified product with controlled bioburden at relevant Connection integrity and differential pressure; sampling scientifically justified.	PQ	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	High
BTV-05-0096	Disposable depth filter kit	Continued verification / risk-based requalification trigger evaluation	Trend Connection integrity and differential pressure and impact on Clarified product with controlled bioburden; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Bioreactors, mixers, assemblies, sterile transfers	B03 B04 B05 B12 B24	Medium

06 MEDIA, BUFFERS, REAGENTS & FORMULATION PREPARATIONS

96 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-06-0001	Media preparation	Protocol / design: Confirm dissolution, mixing time, dissolution endpoint and bioburden	Preapproved risk-based study design; endpoint: Homogeneous nutrients without contamination.	Planning	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0002	Media preparation	Execution / boundary verification: Confirm dissolution, mixing time, dissolution endpoint and bioburden	Documented raw observations, calibration, relevant worst cases and defined acceptance for Homogeneous nutrients without contamination.	Execution	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0003	Media preparation	Review / lifecycle: Confirm dissolution, mixing time, dissolution endpoint and bioburden	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Homogeneous nutrients without contamination.	Review	All biologics and sterile buffers	B02 B03 B04 B05 B12	Medium
BTV-06-0004	Buffer preparation	Protocol / design: Validate pH, conductivity, ionic strength and temperature dependence	Preapproved risk-based study design; endpoint: Consistent chromatography loading / elution.	Planning	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0005	Buffer preparation	Execution / boundary verification: Validate pH, conductivity, ionic strength and temperature dependence	Documented raw observations, calibration, relevant worst cases and defined acceptance for Consistent chromatography loading / elution.	Execution	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0006	Buffer preparation	Review / lifecycle: Validate pH, conductivity, ionic strength and temperature dependence	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Consistent chromatography loading / elution.	Review	All biologics and sterile buffers	B02 B03 B04 B05 B12	Medium
BTV-06-0007	Raw water impact	Protocol / design: Demonstrate selected PW/WFI grade suitability for intended use	Preapproved risk-based study design; endpoint: Controlled endotoxin, TOC and conductivity.	Planning	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0008	Raw water impact	Execution / boundary verification: Demonstrate selected PW/WFI grade suitability for intended use	Documented raw observations, calibration, relevant worst cases and defined acceptance for Controlled endotoxin, TOC and conductivity.	Execution	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0009	Raw water impact	Review / lifecycle: Demonstrate selected PW/WFI grade suitability for intended use	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Controlled endotoxin, TOC and conductivity.	Review	All biologics and sterile buffers	B02 B03 B04 B05 B12	Medium
BTV-06-0010	Filter compatibility	Protocol / design: Assess adsorption and protein loss in sterile media/buffer filtration	Preapproved risk-based study design; endpoint: Recovery and formulation composition.	Planning	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0011	Filter compatibility	Execution / boundary verification: Assess adsorption and protein loss in sterile media/buffer filtration	Documented raw observations, calibration, relevant worst cases and defined acceptance for Recovery and formulation composition.	Execution	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0012	Filter compatibility	Review / lifecycle: Assess adsorption and protein loss in sterile media/buffer filtration	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Recovery and formulation composition.	Review	All biologics and sterile buffers	B02 B03 B04 B05 B12	Medium
BTV-06-0013	Media hold-time	Protocol / design: Qualify growth promotion/contamination control over max hold	Preapproved risk-based study design; endpoint: Expiry and hold labels for media.	Planning	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0014	Media hold-time	Execution / boundary verification: Qualify growth promotion/contamination control over max hold	Documented raw observations, calibration, relevant worst cases and defined acceptance for Expiry and hold labels for media.	Execution	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0015	Media hold-time	Review / lifecycle: Qualify growth promotion/contamination control over max hold	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Expiry and hold labels for media.	Review	All biologics and sterile buffers	B02 B03 B04 B05 B12	Medium
BTV-06-0016	Amino acids/feed mix	Protocol / design: Validate concentration and precipitation at temperature extremes	Preapproved risk-based study design; endpoint: Stable composition without insoluble particles.	Planning	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0017	Amino acids/feed mix	Execution / boundary verification: Validate concentration and precipitation at temperature extremes	Documented raw observations, calibration, relevant worst cases and defined acceptance for Stable composition without insoluble particles.	Execution	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0018	Amino acids/feed mix	Review / lifecycle: Validate concentration and precipitation at temperature extremes	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Stable composition without insoluble particles.	Review	All biologics and sterile buffers	B02 B03 B04 B05 B12	Medium
BTV-06-0019	Concentration scale	Protocol / design: Prove gravimetric and volumetric preparation agreement	Preapproved risk-based study design; endpoint: Correct buffer formulation strength.	Planning	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0020	Concentration scale	Execution / boundary verification: Prove gravimetric and volumetric preparation agreement	Documented raw observations, calibration, relevant worst cases and defined acceptance for Correct buffer formulation strength.	Execution	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0021	Concentration scale	Review / lifecycle: Prove gravimetric and volumetric preparation agreement	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Correct buffer formulation strength.	Review	All biologics and sterile buffers	B02 B03 B04 B05 B12	Medium
BTV-06-0022	Mixing order	Protocol / design: Demonstrate sensitive salt/polymer addition sequence	Preapproved risk-based study design; endpoint: No local precipitation or pH excursion.	Planning	All biologics and sterile buffers	B02 B03 B04 B05 B12	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-06-0023	Mixing order	Execution / boundary verification: Demonstrate sensitive salt/polymer addition sequence	Documented raw observations, calibration, relevant worst cases and defined acceptance for No local precipitation or pH excursion.	Execution	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0024	Mixing order	Review / lifecycle: Demonstrate sensitive salt/polymer addition sequence	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No local precipitation or pH excursion.	Review	All biologics and sterile buffers	B02 B03 B04 B05 B12	Medium
BTV-06-0025	Ready-to-use media	Protocol / design: Qualify vendor transportation, storage, release and use life	Preapproved risk-based study design; endpoint: Acceptable microbiological and functional performance.	Planning	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0026	Ready-to-use media	Execution / boundary verification: Qualify vendor transportation, storage, release and use life	Documented raw observations, calibration, relevant worst cases and defined acceptance for Acceptable microbiological and functional performance.	Execution	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0027	Ready-to-use media	Review / lifecycle: Qualify vendor transportation, storage, release and use life	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Acceptable microbiological and functional performance.	Review	All biologics and sterile buffers	B02 B03 B04 B05 B12	Medium
BTV-06-0028	SUS mixing qualification	Protocol / design: Challenge max/min working volume and viscosity	Preapproved risk-based study design; endpoint: Uniform concentration and temperature.	Planning	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0029	SUS mixing qualification	Execution / boundary verification: Challenge max/min working volume and viscosity	Documented raw observations, calibration, relevant worst cases and defined acceptance for Uniform concentration and temperature.	Execution	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0030	SUS mixing qualification	Review / lifecycle: Challenge max/min working volume and viscosity	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Uniform concentration and temperature.	Review	All biologics and sterile buffers	B02 B03 B04 B05 B12	Medium
BTV-06-0031	Media simulation in aseptic prep	Protocol / design: Evaluate contamination control of manual intervention steps	Preapproved risk-based study design; endpoint: Aseptic assurance as justified.	Planning	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0032	Media simulation in aseptic prep	Execution / boundary verification: Evaluate contamination control of manual intervention steps	Documented raw observations, calibration, relevant worst cases and defined acceptance for Aseptic assurance as justified.	Execution	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0033	Media simulation in aseptic prep	Review / lifecycle: Evaluate contamination control of manual intervention steps	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Aseptic assurance as justified.	Review	All biologics and sterile buffers	B02 B03 B04 B05 B12	Medium
BTV-06-0034	Buffer supply tracking	Protocol / design: Validate barcode, recipe, lot genealogy and expiry	Preapproved risk-based study design; endpoint: No wrong buffer connection or mixture.	Planning	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0035	Buffer supply tracking	Execution / boundary verification: Validate barcode, recipe, lot genealogy and expiry	Documented raw observations, calibration, relevant worst cases and defined acceptance for No wrong buffer connection or mixture.	Execution	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0036	Buffer supply tracking	Review / lifecycle: Validate barcode, recipe, lot genealogy and expiry	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No wrong buffer connection or mixture.	Review	All biologics and sterile buffers	B02 B03 B04 B05 B12	Medium
BTV-06-0037	Media preparation vessel	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Agitation, heating, load cell, CIP/SIP to product impact on Composition, bioburden and reproducible mixing.	URS / DQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0038	Media preparation vessel	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Media preparation vessel.	IQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	Medium
BTV-06-0039	Media preparation vessel	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Agitation, heating, load cell, CIP/SIP; compare challenge outputs to predefined Composition, bioburden and reproducible mixing acceptance.	OQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0040	Media preparation vessel	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Composition, bioburden and reproducible mixing.	OQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0041	Media preparation vessel	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Composition, bioburden and reproducible mixing at relevant Agitation, heating, load cell, CIP/SIP; sampling scientifically justified.	PQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0042	Media preparation vessel	Continued verification / risk-based requalification trigger evaluation	Trend Agitation, heating, load cell, CIP/SIP and impact on Composition, bioburden and reproducible mixing; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	All biologics and sterile buffers	B02 B03 B04 B05 B12	Medium
BTV-06-0043	Buffer mixing vessel	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace pH conductivity, agitation, temperature to product impact on Defined pH and conductivity distribution.	URS / DQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0044	Buffer mixing vessel	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Buffer mixing vessel.	IQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-06-0045	Buffer mixing vessel	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of pH conductivity, agitation, temperature; compare challenge outputs to predefined Defined pH and conductivity distribution acceptance.	OQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0046	Buffer mixing vessel	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Defined pH and conductivity distribution.	OQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0047	Buffer mixing vessel	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Defined pH and conductivity distribution at relevant pH conductivity, agitation, temperature; sampling scientifically justified.	PQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0048	Buffer mixing vessel	Continued verification / risk-based requalification trigger evaluation	Trend pH conductivity, agitation, temperature and impact on Defined pH and conductivity distribution; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	All biologics and sterile buffers	B02 B03 B04 B05 B12	Medium
BTV-06-0049	Inline pH correction skid	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Dosing accuracy, setpoint response to product impact on Correct buffer pH without overshoot.	URS / DQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0050	Inline pH correction skid	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Inline pH correction skid.	IQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	Medium
BTV-06-0051	Inline pH correction skid	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Dosing accuracy, setpoint response; compare challenge outputs to predefined Correct buffer pH without overshoot acceptance.	OQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0052	Inline pH correction skid	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Correct buffer pH without overshoot.	OQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0053	Inline pH correction skid	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Correct buffer pH without overshoot at relevant Dosing accuracy, setpoint response; sampling scientifically justified.	PQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0054	Inline pH correction skid	Continued verification / risk-based requalification trigger evaluation	Trend Dosing accuracy, setpoint response and impact on Correct buffer pH without overshoot; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	All biologics and sterile buffers	B02 B03 B04 B05 B12	Medium
BTV-06-0055	In-line dilution system	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Flow ratio, conductivity feedback to product impact on Accurate salt and buffer concentration.	URS / DQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0056	In-line dilution system	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for In-line dilution system.	IQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	Medium
BTV-06-0057	In-line dilution system	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Flow ratio, conductivity feedback; compare challenge outputs to predefined Accurate salt and buffer concentration acceptance.	OQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0058	In-line dilution system	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Accurate salt and buffer concentration.	OQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0059	In-line dilution system	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Accurate salt and buffer concentration at relevant Flow ratio, conductivity feedback; sampling scientifically justified.	PQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0060	In-line dilution system	Continued verification / risk-based requalification trigger evaluation	Trend Flow ratio, conductivity feedback and impact on Accurate salt and buffer concentration; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	All biologics and sterile buffers	B02 B03 B04 B05 B12	Medium
BTV-06-0061	Powder transfer isolator	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Pressure, dust capture, weigh loss to product impact on No mix-up, no personnel exposure.	URS / DQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0062	Powder transfer isolator	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Powder transfer isolator.	IQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	Medium
BTV-06-0063	Powder transfer isolator	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Pressure, dust capture, weigh loss; compare challenge outputs to predefined No mix-up, no personnel exposure acceptance.	OQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0064	Powder transfer isolator	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect No mix-up, no personnel exposure.	OQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0065	Powder transfer isolator	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable No mix-up, no personnel exposure at relevant Pressure, dust capture, weigh loss; sampling scientifically justified.	PQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-06-0066	Powder transfer isolator	Continued verification / risk-based requalification trigger evaluation	Trend Pressure, dust capture, weigh loss and impact on No mix-up, no personnel exposure; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	All biologics and sterile buffers	B02 B03 B04 B05 B12	Medium
BTV-06-0067	Bag mixing platform	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Mass, impeller speed and hold periods to product impact on Homogeneous product-compatible media.	URS / DQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0068	Bag mixing platform	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Bag mixing platform.	IQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	Medium
BTV-06-0069	Bag mixing platform	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Mass, impeller speed and hold periods; compare challenge outputs to predefined Homogeneous product-compatible media acceptance.	OQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0070	Bag mixing platform	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Homogeneous product-compatible media.	OQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0071	Bag mixing platform	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Homogeneous product-compatible media at relevant Mass, impeller speed and hold periods; sampling scientifically justified.	PQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0072	Bag mixing platform	Continued verification / risk-based requalification trigger evaluation	Trend Mass, impeller speed and hold periods and impact on Homogeneous product-compatible media; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	All biologics and sterile buffers	B02 B03 B04 B05 B12	Medium
BTV-06-0073	Media sterile filtration skid	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Flux, differential pressure, filter integrity to product impact on Sterile filtered medium with recovery.	URS / DQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0074	Media sterile filtration skid	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Media sterile filtration skid.	IQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	Medium
BTV-06-0075	Media sterile filtration skid	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Flux, differential pressure, filter integrity; compare challenge outputs to predefined Sterile filtered medium with recovery acceptance.	OQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0076	Media sterile filtration skid	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Sterile filtered medium with recovery.	OQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0077	Media sterile filtration skid	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Sterile filtered medium with recovery at relevant Flux, differential pressure, filter integrity; sampling scientifically justified.	PQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0078	Media sterile filtration skid	Continued verification / risk-based requalification trigger evaluation	Trend Flux, differential pressure, filter integrity and impact on Sterile filtered medium with recovery; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	All biologics and sterile buffers	B02 B03 B04 B05 B12	Medium
BTV-06-0079	Buffer transfer skid	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Route selection, flow and hold-up to product impact on Correct identity and low microbial load.	URS / DQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0080	Buffer transfer skid	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Buffer transfer skid.	IQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	Medium
BTV-06-0081	Buffer transfer skid	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Route selection, flow and hold-up; compare challenge outputs to predefined Correct identity and low microbial load acceptance.	OQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0082	Buffer transfer skid	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Correct identity and low microbial load.	OQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0083	Buffer transfer skid	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Correct identity and low microbial load at relevant Route selection, flow and hold-up; sampling scientifically justified.	PQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0084	Buffer transfer skid	Continued verification / risk-based requalification trigger evaluation	Trend Route selection, flow and hold-up and impact on Correct identity and low microbial load; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	All biologics and sterile buffers	B02 B03 B04 B05 B12	Medium
BTV-06-0085	Balances and floor scales	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Linearity, repeatability, eccentricity to product impact on Correct component weights.	URS / DQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0086	Balances and floor scales	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Balances and floor scales.	IQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-06-0087	Balances and floor scales	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Linearity, repeatability, eccentricity; compare challenge outputs to predefined Correct component weights acceptance.	OQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0088	Balances and floor scales	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Correct component weights.	OQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0089	Balances and floor scales	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Correct component weights at relevant Linearity, repeatability, eccentricity; sampling scientifically justified.	PQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0090	Balances and floor scales	Continued verification / risk-based requalification trigger evaluation	Trend Linearity, repeatability, eccentricity and impact on Correct component weights; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	All biologics and sterile buffers	B02 B03 B04 B05 B12	Medium
BTV-06-0091	Conductivity/pH meter	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Slope, temperature compensation, reference check to product impact on Reliable buffer release tests.	URS / DQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0092	Conductivity/pH meter	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Conductivity/pH meter.	IQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	Medium
BTV-06-0093	Conductivity/pH meter	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Slope, temperature compensation, reference check; compare challenge outputs to predefined Reliable buffer release tests acceptance.	OQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0094	Conductivity/pH meter	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Reliable buffer release tests.	OQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0095	Conductivity/pH meter	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Reliable buffer release tests at relevant Slope, temperature compensation, reference check; sampling scientifically justified.	PQ	All biologics and sterile buffers	B02 B03 B04 B05 B12	High
BTV-06-0096	Conductivity/pH meter	Continued verification / risk-based requalification trigger evaluation	Trend Slope, temperature compensation, reference check and impact on Reliable buffer release tests; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	All biologics and sterile buffers	B02 B03 B04 B05 B12	Medium

07 HARVEST, CLARIFICATION AND CELL DISRUPTION

78 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-07-0001	Harvest timing	Protocol / design: Define delay after end of culture and viable cell death limits	Preapproved risk-based study design; endpoint: HCP, proteolysis and product integrity.	Planning	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0002	Harvest timing	Execution / boundary verification: Define delay after end of culture and viable cell death limits	Documented raw observations, calibration, relevant worst cases and defined acceptance for HCP, proteolysis and product integrity.	Execution	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0003	Harvest timing	Review / lifecycle: Define delay after end of culture and viable cell death limits	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on HCP, proteolysis and product integrity.	Review	Fermentation and cell culture harvest	B02 B03 B05 B12	Medium
BTV-07-0004	Centrifugation	Protocol / design: Establish g-force, flow, separation and temperature windows	Preapproved risk-based study design; endpoint: Solids separation, yield and purity.	Planning	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0005	Centrifugation	Execution / boundary verification: Establish g-force, flow, separation and temperature windows	Documented raw observations, calibration, relevant worst cases and defined acceptance for Solids separation, yield and purity.	Execution	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0006	Centrifugation	Review / lifecycle: Establish g-force, flow, separation and temperature windows	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Solids separation, yield and purity.	Review	Fermentation and cell culture harvest	B02 B03 B05 B12	Medium
BTV-07-0007	Depth filtration	Protocol / design: Qualify load and pressure to breakthrough and pool quality	Preapproved risk-based study design; endpoint: Turbidity and product yield.	Planning	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0008	Depth filtration	Execution / boundary verification: Qualify load and pressure to breakthrough and pool quality	Documented raw observations, calibration, relevant worst cases and defined acceptance for Turbidity and product yield.	Execution	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0009	Depth filtration	Review / lifecycle: Qualify load and pressure to breakthrough and pool quality	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Turbidity and product yield.	Review	Fermentation and cell culture harvest	B02 B03 B05 B12	Medium
BTV-07-0010	Cell disruption	Protocol / design: Characterize passes, energy and cooling limits	Preapproved risk-based study design; endpoint: Recovery, soluble fraction and fragmentation.	Planning	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0011	Cell disruption	Execution / boundary verification: Characterize passes, energy and cooling limits	Documented raw observations, calibration, relevant worst cases and defined acceptance for Recovery, soluble fraction and fragmentation.	Execution	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0012	Cell disruption	Review / lifecycle: Characterize passes, energy and cooling limits	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Recovery, soluble fraction and fragmentation.	Review	Fermentation and cell culture harvest	B02 B03 B05 B12	Medium
BTV-07-0013	Precipitation	Protocol / design: Validate pH, temperature and salt concentration	Preapproved risk-based study design; endpoint: Target purity and no irreversible aggregation.	Planning	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0014	Precipitation	Execution / boundary verification: Validate pH, temperature and salt concentration	Documented raw observations, calibration, relevant worst cases and defined acceptance for Target purity and no irreversible aggregation.	Execution	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0015	Precipitation	Review / lifecycle: Validate pH, temperature and salt concentration	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Target purity and no irreversible aggregation.	Review	Fermentation and cell culture harvest	B02 B03 B05 B12	Medium
BTV-07-0016	Clarified harvest hold	Protocol / design: Set hold time, storage temperature and bioburden limits	Preapproved risk-based study design; endpoint: Controlled HCP and degradation.	Planning	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0017	Clarified harvest hold	Execution / boundary verification: Set hold time, storage temperature and bioburden limits	Documented raw observations, calibration, relevant worst cases and defined acceptance for Controlled HCP and degradation.	Execution	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0018	Clarified harvest hold	Review / lifecycle: Set hold time, storage temperature and bioburden limits	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Controlled HCP and degradation.	Review	Fermentation and cell culture harvest	B02 B03 B05 B12	Medium
BTV-07-0019	Filter sizing	Protocol / design: Determine area versus turbidity / solids load	Preapproved risk-based study design; endpoint: Pressure and throughput at batch scale.	Planning	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0020	Filter sizing	Execution / boundary verification: Determine area versus turbidity / solids load	Documented raw observations, calibration, relevant worst cases and defined acceptance for Pressure and throughput at batch scale.	Execution	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0021	Filter sizing	Review / lifecycle: Determine area versus turbidity / solids load	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Pressure and throughput at batch scale.	Review	Fermentation and cell culture harvest	B02 B03 B05 B12	Medium
BTV-07-0022	Harvest transfer	Protocol / design: Qualify transfer line shear and bubble entrainment	Preapproved risk-based study design; endpoint: No induced product aggregation.	Planning	Fermentation and cell culture harvest	B02 B03 B05 B12	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-07-0023	Harvest transfer	Execution / boundary verification: Qualify transfer line shear and bubble entrainment	Documented raw observations, calibration, relevant worst cases and defined acceptance for No induced product aggregation.	Execution	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0024	Harvest transfer	Review / lifecycle: Qualify transfer line shear and bubble entrainment	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No induced product aggregation.	Review	Fermentation and cell culture harvest	B02 B03 B05 B12	Medium
BTV-07-0025	Endotoxin control	Protocol / design: Validate control of endotoxin at process interface	Preapproved risk-based study design; endpoint: Acceptance for product-specific endotoxin limits.	Planning	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0026	Endotoxin control	Execution / boundary verification: Validate control of endotoxin at process interface	Documented raw observations, calibration, relevant worst cases and defined acceptance for Acceptance for product-specific endotoxin limits.	Execution	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0027	Endotoxin control	Review / lifecycle: Validate control of endotoxin at process interface	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Acceptance for product-specific endotoxin limits.	Review	Fermentation and cell culture harvest	B02 B03 B05 B12	Medium
BTV-07-0028	Microbial boundary	Protocol / design: Validate sanitization of harvest equipment interfaces	Preapproved risk-based study design; endpoint: Controlled pre-purification bioburden.	Planning	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0029	Microbial boundary	Execution / boundary verification: Validate sanitization of harvest equipment interfaces	Documented raw observations, calibration, relevant worst cases and defined acceptance for Controlled pre-purification bioburden.	Execution	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0030	Microbial boundary	Review / lifecycle: Validate sanitization of harvest equipment interfaces	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Controlled pre-purification bioburden.	Review	Fermentation and cell culture harvest	B02 B03 B05 B12	Medium
BTV-07-0031	Disc-stack centrifuge	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Bowl speed, flow, solids purge rate to product impact on Clarified harvest purity and yield.	URS / DQ	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0032	Disc-stack centrifuge	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Disc-stack centrifuge.	IQ	Fermentation and cell culture harvest	B02 B03 B05 B12	Medium
BTV-07-0033	Disc-stack centrifuge	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Bowl speed, flow, solids purge rate; compare challenge outputs to predefined Clarified harvest purity and yield acceptance.	OQ	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0034	Disc-stack centrifuge	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Clarified harvest purity and yield.	OQ	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0035	Disc-stack centrifuge	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Clarified harvest purity and yield at relevant Bowl speed, flow, solids purge rate; sampling scientifically justified.	PQ	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0036	Disc-stack centrifuge	Continued verification / risk-based requalification trigger evaluation	Trend Bowl speed, flow, solids purge rate and impact on Clarified harvest purity and yield; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Fermentation and cell culture harvest	B02 B03 B05 B12	Medium
BTV-07-0037	Continuous-flow centrifuge	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Residence time, g-force, cooling to product impact on Cell recovery and product integrity.	URS / DQ	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0038	Continuous-flow centrifuge	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Continuous-flow centrifuge.	IQ	Fermentation and cell culture harvest	B02 B03 B05 B12	Medium
BTV-07-0039	Continuous-flow centrifuge	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Residence time, g-force, cooling; compare challenge outputs to predefined Cell recovery and product integrity acceptance.	OQ	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0040	Continuous-flow centrifuge	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Cell recovery and product integrity.	OQ	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0041	Continuous-flow centrifuge	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Cell recovery and product integrity at relevant Residence time, g-force, cooling; sampling scientifically justified.	PQ	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0042	Continuous-flow centrifuge	Continued verification / risk-based requalification trigger evaluation	Trend Residence time, g-force, cooling and impact on Cell recovery and product integrity; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Fermentation and cell culture harvest	B02 B03 B05 B12	Medium
BTV-07-0043	Depth filtration skid	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace DP limit, staged grades, preflush to product impact on Turbidity removal and product yield.	URS / DQ	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0044	Depth filtration skid	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Depth filtration skid.	IQ	Fermentation and cell culture harvest	B02 B03 B05 B12	Medium
BTV-07-0045	Depth filtration skid	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of DP limit, staged grades, preflush; compare challenge outputs to predefined Turbidity removal and product yield acceptance.	OQ	Fermentation and cell culture harvest	B02 B03 B05 B12	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-07-0046	Depth filtration skid	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Turbidity removal and product yield.	OQ	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0047	Depth filtration skid	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Turbidity removal and product yield at relevant DP limit, staged grades, preflush; sampling scientifically justified.	PQ	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0048	Depth filtration skid	Continued verification / risk-based requalification trigger evaluation	Trend DP limit, staged grades, preflush and impact on Turbidity removal and product yield; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Fermentation and cell culture harvest	B02 B03 B05 B12	Medium
BTV-07-0049	Cell homogenizer high pressure	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Pressure, passes, outlet temperature to product impact on Cell lysis and protein integrity.	URS / DQ	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0050	Cell homogenizer high pressure	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Cell homogenizer high pressure.	IQ	Fermentation and cell culture harvest	B02 B03 B05 B12	Medium
BTV-07-0051	Cell homogenizer high pressure	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Pressure, passes, outlet temperature; compare challenge outputs to predefined Cell lysis and protein integrity acceptance.	OQ	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0052	Cell homogenizer high pressure	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Cell lysis and protein integrity.	OQ	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0053	Cell homogenizer high pressure	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Cell lysis and protein integrity at relevant Pressure, passes, outlet temperature; sampling scientifically justified.	PQ	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0054	Cell homogenizer high pressure	Continued verification / risk-based requalification trigger evaluation	Trend Pressure, passes, outlet temperature and impact on Cell lysis and protein integrity; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Fermentation and cell culture harvest	B02 B03 B05 B12	Medium
BTV-07-0055	Microfluidizer	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Energy input, recirculation, cooling to product impact on Lysis and particle distribution.	URS / DQ	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0056	Microfluidizer	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Microfluidizer.	IQ	Fermentation and cell culture harvest	B02 B03 B05 B12	Medium
BTV-07-0057	Microfluidizer	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Energy input, recirculation, cooling; compare challenge outputs to predefined Lysis and particle distribution acceptance.	OQ	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0058	Microfluidizer	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Lysis and particle distribution.	OQ	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0059	Microfluidizer	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Lysis and particle distribution at relevant Energy input, recirculation, cooling; sampling scientifically justified.	PQ	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0060	Microfluidizer	Continued verification / risk-based requalification trigger evaluation	Trend Energy input, recirculation, cooling and impact on Lysis and particle distribution; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Fermentation and cell culture harvest	B02 B03 B05 B12	Medium
BTV-07-0061	Harvest transfer manifold	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Valve path, pressure and hose length to product impact on Correct lot segregation and low shear.	URS / DQ	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0062	Harvest transfer manifold	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Harvest transfer manifold.	IQ	Fermentation and cell culture harvest	B02 B03 B05 B12	Medium
BTV-07-0063	Harvest transfer manifold	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Valve path, pressure and hose length; compare challenge outputs to predefined Correct lot segregation and low shear acceptance.	OQ	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0064	Harvest transfer manifold	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Correct lot segregation and low shear.	OQ	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0065	Harvest transfer manifold	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Correct lot segregation and low shear at relevant Valve path, pressure and hose length; sampling scientifically justified.	PQ	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0066	Harvest transfer manifold	Continued verification / risk-based requalification trigger evaluation	Trend Valve path, pressure and hose length and impact on Correct lot segregation and low shear; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Fermentation and cell culture harvest	B02 B03 B05 B12	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-07-0067	Solids collection system	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Containment, bagging and cleaning to product impact on Prevent product and environmental cross-contamination.	URS / DQ	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0068	Solids collection system	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Solids collection system.	IQ	Fermentation and cell culture harvest	B02 B03 B05 B12	Medium
BTV-07-0069	Solids collection system	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Containment, bagging and cleaning; compare challenge outputs to predefined Prevent product and environmental cross-contamination acceptance.	OQ	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0070	Solids collection system	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Prevent product and environmental cross-contamination.	OQ	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0071	Solids collection system	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Prevent product and environmental cross-contamination at relevant Containment, bagging and cleaning; sampling scientifically justified.	PQ	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0072	Solids collection system	Continued verification / risk-based requalification trigger evaluation	Trend Containment, bagging and cleaning and impact on Prevent product and environmental cross-contamination; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Fermentation and cell culture harvest	B02 B03 B05 B12	Medium
BTV-07-0073	Harvest collection tank	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Mixing, temperature and hold time to product impact on No product degradation prior to purification.	URS / DQ	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0074	Harvest collection tank	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Harvest collection tank.	IQ	Fermentation and cell culture harvest	B02 B03 B05 B12	Medium
BTV-07-0075	Harvest collection tank	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Mixing, temperature and hold time; compare challenge outputs to predefined No product degradation prior to purification acceptance.	OQ	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0076	Harvest collection tank	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect No product degradation prior to purification.	OQ	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0077	Harvest collection tank	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable No product degradation prior to purification at relevant Mixing, temperature and hold time; sampling scientifically justified.	PQ	Fermentation and cell culture harvest	B02 B03 B05 B12	High
BTV-07-0078	Harvest collection tank	Continued verification / risk-based requalification trigger evaluation	Trend Mixing, temperature and hold time and impact on No product degradation prior to purification; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Fermentation and cell culture harvest	B02 B03 B05 B12	Medium

08 CHROMATOGRAPHY, CAPTURE AND POLISHING

114 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-08-0001	Protein A capture	Protocol / design: Establish resin load, pH, elution and wash controls	Preapproved risk-based study design; endpoint: Yield, HCP, DNA and aggregate clearance.	Planning	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0002	Protein A capture	Execution / boundary verification: Establish resin load, pH, elution and wash controls	Documented raw observations, calibration, relevant worst cases and defined acceptance for Yield, HCP, DNA and aggregate clearance.	Execution	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0003	Protein A capture	Review / lifecycle: Establish resin load, pH, elution and wash controls	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Yield, HCP, DNA and aggregate clearance.	Review	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium
BTV-08-0004	Ion exchange	Protocol / design: Define conductivity/pH gradients and load variability	Preapproved risk-based study design; endpoint: Host-cell impurity removal and purity.	Planning	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0005	Ion exchange	Execution / boundary verification: Define conductivity/pH gradients and load variability	Documented raw observations, calibration, relevant worst cases and defined acceptance for Host-cell impurity removal and purity.	Execution	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0006	Ion exchange	Review / lifecycle: Define conductivity/pH gradients and load variability	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Host-cell impurity removal and purity.	Review	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium
BTV-08-0007	Hydrophobic interaction	Protocol / design: Validate salt gradient and pooling logic	Preapproved risk-based study design; endpoint: Target purity and recovery.	Planning	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0008	Hydrophobic interaction	Execution / boundary verification: Validate salt gradient and pooling logic	Documented raw observations, calibration, relevant worst cases and defined acceptance for Target purity and recovery.	Execution	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0009	Hydrophobic interaction	Review / lifecycle: Validate salt gradient and pooling logic	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Target purity and recovery.	Review	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium
BTV-08-0010	Mixed-mode separation	Protocol / design: Qualify selectivity and cycle robustness	Preapproved risk-based study design; endpoint: Critical impurity clearance.	Planning	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0011	Mixed-mode separation	Execution / boundary verification: Qualify selectivity and cycle robustness	Documented raw observations, calibration, relevant worst cases and defined acceptance for Critical impurity clearance.	Execution	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0012	Mixed-mode separation	Review / lifecycle: Qualify selectivity and cycle robustness	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Critical impurity clearance.	Review	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium
BTV-08-0013	Column packing	Protocol / design: Define height, compression and asymmetry acceptance	Preapproved risk-based study design; endpoint: Reproducible HETP, peak asymmetry and performance.	Planning	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0014	Column packing	Execution / boundary verification: Define height, compression and asymmetry acceptance	Documented raw observations, calibration, relevant worst cases and defined acceptance for Reproducible HETP, peak asymmetry and performance.	Execution	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0015	Column packing	Review / lifecycle: Define height, compression and asymmetry acceptance	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Reproducible HETP, peak asymmetry and performance.	Review	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium
BTV-08-0016	Column cleaning	Protocol / design: Qualify CIP agent concentration/contact and resin carryover	Preapproved risk-based study design; endpoint: Resin reuse without contamination.	Planning	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0017	Column cleaning	Execution / boundary verification: Qualify CIP agent concentration/contact and resin carryover	Documented raw observations, calibration, relevant worst cases and defined acceptance for Resin reuse without contamination.	Execution	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0018	Column cleaning	Review / lifecycle: Qualify CIP agent concentration/contact and resin carryover	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Resin reuse without contamination.	Review	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium
BTV-08-0019	Resin reuse and lifetime	Protocol / design: Trend yield, pressure, ligand leaching and impurity profiles	Preapproved risk-based study design; endpoint: Maximum reuse cycles supported by data.	Planning	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0020	Resin reuse and lifetime	Execution / boundary verification: Trend yield, pressure, ligand leaching and impurity profiles	Documented raw observations, calibration, relevant worst cases and defined acceptance for Maximum reuse cycles supported by data.	Execution	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0021	Resin reuse and lifetime	Review / lifecycle: Trend yield, pressure, ligand leaching and impurity profiles	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Maximum reuse cycles supported by data.	Review	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium
BTV-08-0022	Resin storage	Protocol / design: Validate storage solution, hold, microbial and expiry limits	Preapproved risk-based study design; endpoint: Functional resin and clean state.	Planning	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-08-0023	Resin storage	Execution / boundary verification: Validate storage solution, hold, microbial and expiry limits	Documented raw observations, calibration, relevant worst cases and defined acceptance for Functional resin and clean state.	Execution	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0024	Resin storage	Review / lifecycle: Validate storage solution, hold, microbial and expiry limits	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Functional resin and clean state.	Review	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium
BTV-08-0025	Pool cut	Protocol / design: Validate UV/conductivity-controlled fractions and manual overrides	Preapproved risk-based study design; endpoint: Consistent identity, purity and yield.	Planning	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0026	Pool cut	Execution / boundary verification: Validate UV/conductivity-controlled fractions and manual overrides	Documented raw observations, calibration, relevant worst cases and defined acceptance for Consistent identity, purity and yield.	Execution	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0027	Pool cut	Review / lifecycle: Validate UV/conductivity-controlled fractions and manual overrides	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Consistent identity, purity and yield.	Review	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium
BTV-08-0028	Chromatography skid routing	Protocol / design: Challenge valve assignment, line volumes and CIP paths	Preapproved risk-based study design; endpoint: No wrong pool, cross connection or carryover.	Planning	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0029	Chromatography skid routing	Execution / boundary verification: Challenge valve assignment, line volumes and CIP paths	Documented raw observations, calibration, relevant worst cases and defined acceptance for No wrong pool, cross connection or carryover.	Execution	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0030	Chromatography skid routing	Review / lifecycle: Challenge valve assignment, line volumes and CIP paths	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No wrong pool, cross connection or carryover.	Review	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium
BTV-08-0031	Buffer exchange between steps	Protocol / design: Qualify diafiltration/conductivity suitability	Preapproved risk-based study design; endpoint: Correct next-step loading conditions.	Planning	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0032	Buffer exchange between steps	Execution / boundary verification: Qualify diafiltration/conductivity suitability	Documented raw observations, calibration, relevant worst cases and defined acceptance for Correct next-step loading conditions.	Execution	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0033	Buffer exchange between steps	Review / lifecycle: Qualify diafiltration/conductivity suitability	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Correct next-step loading conditions.	Review	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium
BTV-08-0034	Column scale change	Protocol / design: Evaluate diameter, bed height, linear flow and distribution	Preapproved risk-based study design; endpoint: Process scale equivalency and impurity profiles.	Planning	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0035	Column scale change	Execution / boundary verification: Evaluate diameter, bed height, linear flow and distribution	Documented raw observations, calibration, relevant worst cases and defined acceptance for Process scale equivalency and impurity profiles.	Execution	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0036	Column scale change	Review / lifecycle: Evaluate diameter, bed height, linear flow and distribution	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Process scale equivalency and impurity profiles.	Review	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium
BTV-08-0037	Chromatography viral contribution	Protocol / design: Characterize step virus-removal contribution when claimed	Preapproved risk-based study design; endpoint: Mechanism, robustness and scale-down fit.	Planning	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0038	Chromatography viral contribution	Execution / boundary verification: Characterize step virus-removal contribution when claimed	Documented raw observations, calibration, relevant worst cases and defined acceptance for Mechanism, robustness and scale-down fit.	Execution	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0039	Chromatography viral contribution	Review / lifecycle: Characterize step virus-removal contribution when claimed	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Mechanism, robustness and scale-down fit.	Review	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium
BTV-08-0040	Protein A leachate	Protocol / design: Validate assay and action on ligand leaching	Preapproved risk-based study design; endpoint: Residual Protein A within product-specific limits.	Planning	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0041	Protein A leachate	Execution / boundary verification: Validate assay and action on ligand leaching	Documented raw observations, calibration, relevant worst cases and defined acceptance for Residual Protein A within product-specific limits.	Execution	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0042	Protein A leachate	Review / lifecycle: Validate assay and action on ligand leaching	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Residual Protein A within product-specific limits.	Review	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium
BTV-08-0043	Protein A column	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Packing HETP, flow, residence time, CIP to product impact on mAb capture yield and impurity removal.	URS / DQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0044	Protein A column	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Protein A column.	IQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium
BTV-08-0045	Protein A column	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Packing HETP, flow, residence time, CIP; compare challenge outputs to predefined mAb capture yield and impurity removal acceptance.	OQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-08-0046	Protein A column	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect mAb capture yield and impurity removal.	OQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0047	Protein A column	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable mAb capture yield and impurity removal at relevant Packing HETP, flow, residence time, CIP; sampling scientifically justified.	PQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0048	Protein A column	Continued verification / risk-based requalification trigger evaluation	Trend Packing HETP, flow, residence time, CIP and impact on mAb capture yield and impurity removal; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium
BTV-08-0049	Anion exchange column	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Load, conductivity, flow distribution to product impact on DNA and HCP removal.	URS / DQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0050	Anion exchange column	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Anion exchange column.	IQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium
BTV-08-0051	Anion exchange column	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Load, conductivity, flow distribution; compare challenge outputs to predefined DNA and HCP removal acceptance.	OQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0052	Anion exchange column	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect DNA and HCP removal.	OQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0053	Anion exchange column	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable DNA and HCP removal at relevant Load, conductivity, flow distribution; sampling scientifically justified.	PQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0054	Anion exchange column	Continued verification / risk-based requalification trigger evaluation	Trend Load, conductivity, flow distribution and impact on DNA and HCP removal; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium
BTV-08-0055	Cation exchange column	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Binding capacity, gradient, pool cut to product impact on Charge variant and impurity profile.	URS / DQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0056	Cation exchange column	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Cation exchange column.	IQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium
BTV-08-0057	Cation exchange column	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Binding capacity, gradient, pool cut; compare challenge outputs to predefined Charge variant and impurity profile acceptance.	OQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0058	Cation exchange column	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Charge variant and impurity profile.	OQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0059	Cation exchange column	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Charge variant and impurity profile at relevant Binding capacity, gradient, pool cut; sampling scientifically justified.	PQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0060	Cation exchange column	Continued verification / risk-based requalification trigger evaluation	Trend Binding capacity, gradient, pool cut and impact on Charge variant and impurity profile; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium
BTV-08-0061	Hydrophobic interaction column	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Salt gradient, protein load, temperature to product impact on Aggregate and impurity reduction.	URS / DQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0062	Hydrophobic interaction column	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Hydrophobic interaction column.	IQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium
BTV-08-0063	Hydrophobic interaction column	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Salt gradient, protein load, temperature; compare challenge outputs to predefined Aggregate and impurity reduction acceptance.	OQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0064	Hydrophobic interaction column	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Aggregate and impurity reduction.	OQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0065	Hydrophobic interaction column	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Aggregate and impurity reduction at relevant Salt gradient, protein load, temperature; sampling scientifically justified.	PQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0066	Hydrophobic interaction column	Continued verification / risk-based requalification trigger evaluation	Trend Salt gradient, protein load, temperature and impact on Aggregate and impurity reduction; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-08-0067	Mixed-mode column	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Selectivity, pH, load and cycle number to product impact on Critical impurity clearance.	URS / DQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0068	Mixed-mode column	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Mixed-mode column.	IQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium
BTV-08-0069	Mixed-mode column	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Selectivity, pH, load and cycle number; compare challenge outputs to predefined Critical impurity clearance acceptance.	OQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0070	Mixed-mode column	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Critical impurity clearance.	OQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0071	Mixed-mode column	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Critical impurity clearance at relevant Selectivity, pH, load and cycle number; sampling scientifically justified.	PQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0072	Mixed-mode column	Continued verification / risk-based requalification trigger evaluation	Trend Selectivity, pH, load and cycle number and impact on Critical impurity clearance; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium
BTV-08-0073	Chromatography skid	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Valve position, pumps, UV and conductivity to product impact on Correct fractions and pool purity.	URS / DQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0074	Chromatography skid	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Chromatography skid.	IQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium
BTV-08-0075	Chromatography skid	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Valve position, pumps, UV and conductivity; compare challenge outputs to predefined Correct fractions and pool purity acceptance.	OQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0076	Chromatography skid	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Correct fractions and pool purity.	OQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0077	Chromatography skid	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Correct fractions and pool purity at relevant Valve position, pumps, UV and conductivity; sampling scientifically justified.	PQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0078	Chromatography skid	Continued verification / risk-based requalification trigger evaluation	Trend Valve position, pumps, UV and conductivity and impact on Correct fractions and pool purity; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium
BTV-08-0079	Process UV detector	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Linearity, wavelength, peak response to product impact on Accurate process pool cut.	URS / DQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0080	Process UV detector	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Process UV detector.	IQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium
BTV-08-0081	Process UV detector	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Linearity, wavelength, peak response; compare challenge outputs to predefined Accurate process pool cut acceptance.	OQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0082	Process UV detector	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Accurate process pool cut.	OQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0083	Process UV detector	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Accurate process pool cut at relevant Linearity, wavelength, peak response; sampling scientifically justified.	PQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0084	Process UV detector	Continued verification / risk-based requalification trigger evaluation	Trend Linearity, wavelength, peak response and impact on Accurate process pool cut; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium
BTV-08-0085	Conductivity inline probe	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Compensation, drift and check standards to product impact on Correct gradient and binding conditions.	URS / DQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0086	Conductivity inline probe	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Conductivity inline probe.	IQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium
BTV-08-0087	Conductivity inline probe	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Compensation, drift and check standards; compare challenge outputs to predefined Correct gradient and binding conditions acceptance.	OQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0088	Conductivity inline probe	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Correct gradient and binding conditions.	OQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-08-0089	Conductivity inline probe	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Correct gradient and binding conditions at relevant Compensation, drift and check standards; sampling scientifically justified.	PQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0090	Conductivity inline probe	Continued verification / risk-based requalification trigger evaluation	Trend Compensation, drift and check standards and impact on Correct gradient and binding conditions; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium
BTV-08-0091	Column packing station	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Bed compression and resin slurry distribution to product impact on Reproducible plate height and symmetry.	URS / DQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0092	Column packing station	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Column packing station.	IQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium
BTV-08-0093	Column packing station	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Bed compression and resin slurry distribution; compare challenge outputs to predefined Reproducible plate height and symmetry acceptance.	OQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0094	Column packing station	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Reproducible plate height and symmetry.	OQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0095	Column packing station	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Reproducible plate height and symmetry at relevant Bed compression and resin slurry distribution; sampling scientifically justified.	PQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0096	Column packing station	Continued verification / risk-based requalification trigger evaluation	Trend Bed compression and resin slurry distribution and impact on Reproducible plate height and symmetry; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium
BTV-08-0097	Fraction collector	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Fraction switching, timing and traceability to product impact on Correct harvest/pool identity.	URS / DQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0098	Fraction collector	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Fraction collector.	IQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium
BTV-08-0099	Fraction collector	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Fraction switching, timing and traceability; compare challenge outputs to predefined Correct harvest/pool identity acceptance.	OQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0100	Fraction collector	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Correct harvest/pool identity.	OQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0101	Fraction collector	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Correct harvest/pool identity at relevant Fraction switching, timing and traceability; sampling scientifically justified.	PQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0102	Fraction collector	Continued verification / risk-based requalification trigger evaluation	Trend Fraction switching, timing and traceability and impact on Correct harvest/pool identity; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium
BTV-08-0103	Resin storage tank	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Temperature, preservative concentration to product impact on Viable resin reuse without bioburden.	URS / DQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0104	Resin storage tank	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Resin storage tank.	IQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium
BTV-08-0105	Resin storage tank	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Temperature, preservative concentration; compare challenge outputs to predefined Viable resin reuse without bioburden acceptance.	OQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0106	Resin storage tank	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Viable resin reuse without bioburden.	OQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0107	Resin storage tank	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Viable resin reuse without bioburden at relevant Temperature, preservative concentration; sampling scientifically justified.	PQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0108	Resin storage tank	Continued verification / risk-based requalification trigger evaluation	Trend Temperature, preservative concentration and impact on Viable resin reuse without bioburden; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-08-0109	Chromatography CIP system	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Chemical concentration, flow and contact to product impact on Clean/bioburden controlled reuse.	URS / DQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0110	Chromatography CIP system	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Chromatography CIP system.	IQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium
BTV-08-0111	Chromatography CIP system	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Chemical concentration, flow and contact; compare challenge outputs to predefined Clean/bioburden controlled reuse acceptance.	OQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0112	Chromatography CIP system	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Clean/bioburden controlled reuse.	OQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0113	Chromatography CIP system	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Clean/bioburden controlled reuse at relevant Chemical concentration, flow and contact; sampling scientifically justified.	PQ	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	High
BTV-08-0114	Chromatography CIP system	Continued verification / risk-based requalification trigger evaluation	Trend Chemical concentration, flow and contact and impact on Clean/bioburden controlled reuse; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Protein, mAbs, recombinant enzyme DS	B02 B03 B05 B11 B12 B13	Medium

09 UF/DF, CONCENTRATION, NANOFILTRATION AND MEMBRANE OPERATIONS

90 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-09-0001	UF membrane compatibility	Protocol / design: Assess binding, integrity and product adsorption	Preapproved risk-based study design; endpoint: Recovery and impurity carryover.	Planning	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0002	UF membrane compatibility	Execution / boundary verification: Assess binding, integrity and product adsorption	Documented raw observations, calibration, relevant worst cases and defined acceptance for Recovery and impurity carryover.	Execution	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0003	UF membrane compatibility	Review / lifecycle: Assess binding, integrity and product adsorption	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Recovery and impurity carryover.	Review	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	Medium
BTV-09-0004	UF concentration	Protocol / design: Define TMP, flux, shear and temperature limits	Preapproved risk-based study design; endpoint: Stable potency and aggregate levels.	Planning	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0005	UF concentration	Execution / boundary verification: Define TMP, flux, shear and temperature limits	Documented raw observations, calibration, relevant worst cases and defined acceptance for Stable potency and aggregate levels.	Execution	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0006	UF concentration	Review / lifecycle: Define TMP, flux, shear and temperature limits	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Stable potency and aggregate levels.	Review	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	Medium
BTV-09-0007	DF endpoint	Protocol / design: Qualify diavolume, conductivity and pH acceptance	Preapproved risk-based study design; endpoint: Specified buffer exchange and salts.	Planning	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0008	DF endpoint	Execution / boundary verification: Qualify diavolume, conductivity and pH acceptance	Documented raw observations, calibration, relevant worst cases and defined acceptance for Specified buffer exchange and salts.	Execution	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0009	DF endpoint	Review / lifecycle: Qualify diavolume, conductivity and pH acceptance	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Specified buffer exchange and salts.	Review	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	Medium
BTV-09-0010	Membrane reuse	Protocol / design: Validate cleaning, storage, integrity and lifetime	Preapproved risk-based study design; endpoint: Stable permeability and low bioburden.	Planning	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0011	Membrane reuse	Execution / boundary verification: Validate cleaning, storage, integrity and lifetime	Documented raw observations, calibration, relevant worst cases and defined acceptance for Stable permeability and low bioburden.	Execution	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0012	Membrane reuse	Review / lifecycle: Validate cleaning, storage, integrity and lifetime	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Stable permeability and low bioburden.	Review	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	Medium
BTV-09-0013	Nanofiltration scale-down	Protocol / design: Confirm virus retention capacity and load/fouling challenge	Preapproved risk-based study design; endpoint: Viral clearance study where applicable.	Planning	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0014	Nanofiltration scale-down	Execution / boundary verification: Confirm virus retention capacity and load/fouling challenge	Documented raw observations, calibration, relevant worst cases and defined acceptance for Viral clearance study where applicable.	Execution	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0015	Nanofiltration scale-down	Review / lifecycle: Confirm virus retention capacity and load/fouling challenge	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Viral clearance study where applicable.	Review	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	Medium
BTV-09-0016	Membrane integrity testing	Protocol / design: Validate test pressure and relevant leak/retention correlation	Preapproved risk-based study design; endpoint: No hidden membrane failures.	Planning	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-09-0017	Membrane integrity testing	Execution / boundary verification: Validate test pressure and relevant leak/retention correlation	Documented raw observations, calibration, relevant worst cases and defined acceptance for No hidden membrane failures.	Execution	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0018	Membrane integrity testing	Review / lifecycle: Validate test pressure and relevant leak/retention correlation	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No hidden membrane failures.	Review	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	Medium
BTV-09-0019	UF/DF pool hold	Protocol / design: Assess worst-case concentration and hold conditions	Preapproved risk-based study design; endpoint: Aggregation and product recovery.	Planning	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0020	UF/DF pool hold	Execution / boundary verification: Assess worst-case concentration and hold conditions	Documented raw observations, calibration, relevant worst cases and defined acceptance for Aggregation and product recovery.	Execution	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0021	UF/DF pool hold	Review / lifecycle: Assess worst-case concentration and hold conditions	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Aggregation and product recovery.	Review	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	Medium
BTV-09-0022	Mixing/shear	Protocol / design: Validate pump shear sensitivity and recirculation time	Preapproved risk-based study design; endpoint: CQA stability.	Planning	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0023	Mixing/shear	Execution / boundary verification: Validate pump shear sensitivity and recirculation time	Documented raw observations, calibration, relevant worst cases and defined acceptance for CQA stability.	Execution	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0024	Mixing/shear	Review / lifecycle: Validate pump shear sensitivity and recirculation time	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on CQA stability.	Review	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	Medium
BTV-09-0025	TMP control	Protocol / design: Challenge alarm, sensor failure and blocked membrane condition	Preapproved risk-based study design; endpoint: No membrane rupture or product loss.	Planning	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0026	TMP control	Execution / boundary verification: Challenge alarm, sensor failure and blocked membrane condition	Documented raw observations, calibration, relevant worst cases and defined acceptance for No membrane rupture or product loss.	Execution	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0027	TMP control	Review / lifecycle: Challenge alarm, sensor failure and blocked membrane condition	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No membrane rupture or product loss.	Review	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	Medium
BTV-09-0028	Concentration calculation	Protocol / design: Verify mass balance with assay and tank weight	Preapproved risk-based study design; endpoint: Accurate final concentration and yield.	Planning	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0029	Concentration calculation	Execution / boundary verification: Verify mass balance with assay and tank weight	Documented raw observations, calibration, relevant worst cases and defined acceptance for Accurate final concentration and yield.	Execution	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0030	Concentration calculation	Review / lifecycle: Verify mass balance with assay and tank weight	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Accurate final concentration and yield.	Review	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	Medium
BTV-09-0031	Membrane extractables	Protocol / design: Assess disposable material compatibility at maximum contact	Preapproved risk-based study design; endpoint: Product safety and quality.	Planning	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0032	Membrane extractables	Execution / boundary verification: Assess disposable material compatibility at maximum contact	Documented raw observations, calibration, relevant worst cases and defined acceptance for Product safety and quality.	Execution	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0033	Membrane extractables	Review / lifecycle: Assess disposable material compatibility at maximum contact	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Product safety and quality.	Review	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	Medium
BTV-09-0034	Membrane post-use analysis	Protocol / design: Verify membrane integrity or performance after run	Preapproved risk-based study design; endpoint: Evidence process remained controlled.	Planning	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-09-0035	Membrane post-use analysis	Execution / boundary verification: Verify membrane integrity or performance after run	Documented raw observations, calibration, relevant worst cases and defined acceptance for Evidence process remained controlled.	Execution	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0036	Membrane post-use analysis	Review / lifecycle: Verify membrane integrity or performance after run	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Evidence process remained controlled.	Review	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	Medium
BTV-09-0037	Tangential-flow filtration skid	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace TMP, pressure, recirc flow and load cells to product impact on Protein concentration and membrane integrity.	URS / DQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0038	Tangential-flow filtration skid	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Tangential-flow filtration skid.	IQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	Medium
BTV-09-0039	Tangential-flow filtration skid	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of TMP, pressure, recirc flow and load cells; compare challenge outputs to predefined Protein concentration and membrane integrity acceptance.	OQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0040	Tangential-flow filtration skid	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Protein concentration and membrane integrity.	OQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0041	Tangential-flow filtration skid	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Protein concentration and membrane integrity at relevant TMP, pressure, recirc flow and load cells; sampling scientifically justified.	PQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0042	Tangential-flow filtration skid	Continued verification / risk-based requalification trigger evaluation	Trend TMP, pressure, recirc flow and load cells and impact on Protein concentration and membrane integrity; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	Medium
BTV-09-0043	Hollow-fiber UF module	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Fiber shear, flow and pore distribution to product impact on Recovery and aggregate profile.	URS / DQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0044	Hollow-fiber UF module	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Hollow-fiber UF module.	IQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	Medium
BTV-09-0045	Hollow-fiber UF module	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Fiber shear, flow and pore distribution; compare challenge outputs to predefined Recovery and aggregate profile acceptance.	OQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0046	Hollow-fiber UF module	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Recovery and aggregate profile.	OQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0047	Hollow-fiber UF module	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Recovery and aggregate profile at relevant Fiber shear, flow and pore distribution; sampling scientifically justified.	PQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0048	Hollow-fiber UF module	Continued verification / risk-based requalification trigger evaluation	Trend Fiber shear, flow and pore distribution and impact on Recovery and aggregate profile; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	Medium
BTV-09-0049	Cassette UF module	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Membrane area, pressure distribution to product impact on Consistent recovery and purity.	URS / DQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0050	Cassette UF module	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Cassette UF module.	IQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	Medium
BTV-09-0051	Cassette UF module	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Membrane area, pressure distribution; compare challenge outputs to predefined Consistent recovery and purity acceptance.	OQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0052	Cassette UF module	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Consistent recovery and purity.	OQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-09-0053	Cassette UF module	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Consistent recovery and purity at relevant Membrane area, pressure distribution; sampling scientifically justified.	PQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0054	Cassette UF module	Continued verification / risk-based requalification trigger evaluation	Trend Membrane area, pressure distribution and impact on Consistent recovery and purity; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	Medium
BTV-09-0055	Virus removal nanofilter skid	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Flux, filter loading, integrity, pressure to product impact on Demonstrated virus-retention capability when applicable.	URS / DQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0056	Virus removal nanofilter skid	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Virus removal nanofilter skid.	IQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	Medium
BTV-09-0057	Virus removal nanofilter skid	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Flux, filter loading, integrity, pressure; compare challenge outputs to predefined Demonstrated virus-retention capability when applicable acceptance.	OQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0058	Virus removal nanofilter skid	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Demonstrated virus-retention capability when applicable.	OQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0059	Virus removal nanofilter skid	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Demonstrated virus-retention capability when applicable at relevant Flux, filter loading, integrity, pressure; sampling scientifically justified.	PQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0060	Virus removal nanofilter skid	Continued verification / risk-based requalification trigger evaluation	Trend Flux, filter loading, integrity, pressure and impact on Demonstrated virus-retention capability when applicable; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	Medium
BTV-09-0061	Ultrafiltration feed vessel	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Mixing, temperature, load cell to product impact on Uniform product without aggregation.	URS / DQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0062	Ultrafiltration feed vessel	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Ultrafiltration feed vessel.	IQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	Medium
BTV-09-0063	Ultrafiltration feed vessel	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Mixing, temperature, load cell; compare challenge outputs to predefined Uniform product without aggregation acceptance.	OQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0064	Ultrafiltration feed vessel	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Uniform product without aggregation.	OQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0065	Ultrafiltration feed vessel	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Uniform product without aggregation at relevant Mixing, temperature, load cell; sampling scientifically justified.	PQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0066	Ultrafiltration feed vessel	Continued verification / risk-based requalification trigger evaluation	Trend Mixing, temperature, load cell and impact on Uniform product without aggregation; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	Medium
BTV-09-0067	Membrane integrity tester	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Pressure decay, flow calibration, leak sensitivity to product impact on Validated integrity test decisions.	URS / DQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0068	Membrane integrity tester	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Membrane integrity tester.	IQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	Medium
BTV-09-0069	Membrane integrity tester	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Pressure decay, flow calibration, leak sensitivity; compare challenge outputs to predefined Validated integrity test decisions acceptance.	OQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0070	Membrane integrity tester	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Validated integrity test decisions.	OQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-09-0071	Membrane integrity tester	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Validated integrity test decisions at relevant Pressure decay, flow calibration, leak sensitivity; sampling scientifically justified.	PQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0072	Membrane integrity tester	Continued verification / risk-based requalification trigger evaluation	Trend Pressure decay, flow calibration, leak sensitivity and impact on Validated integrity test decisions; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	Medium
BTV-09-0073	Single-pass TFF system	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Pressure, concentration factor, residence to product impact on Continuous concentration with quality control.	URS / DQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0074	Single-pass TFF system	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Single-pass TFF system.	IQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	Medium
BTV-09-0075	Single-pass TFF system	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Pressure, concentration factor, residence; compare challenge outputs to predefined Continuous concentration with quality control acceptance.	OQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0076	Single-pass TFF system	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Continuous concentration with quality control.	OQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0077	Single-pass TFF system	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Continuous concentration with quality control at relevant Pressure, concentration factor, residence; sampling scientifically justified.	PQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0078	Single-pass TFF system	Continued verification / risk-based requalification trigger evaluation	Trend Pressure, concentration factor, residence and impact on Continuous concentration with quality control; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	Medium
BTV-09-0079	Diafiltration buffer addition skid	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Flow accuracy, mass balance to product impact on Target buffer exchange endpoint.	URS / DQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0080	Diafiltration buffer addition skid	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Diafiltration buffer addition skid.	IQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	Medium
BTV-09-0081	Diafiltration buffer addition skid	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Flow accuracy, mass balance; compare challenge outputs to predefined Target buffer exchange endpoint acceptance.	OQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0082	Diafiltration buffer addition skid	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Target buffer exchange endpoint.	OQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0083	Diafiltration buffer addition skid	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Target buffer exchange endpoint at relevant Flow accuracy, mass balance; sampling scientifically justified.	PQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0084	Diafiltration buffer addition skid	Continued verification / risk-based requalification trigger evaluation	Trend Flow accuracy, mass balance and impact on Target buffer exchange endpoint; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	Medium
BTV-09-0085	TFF heat exchanger	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Temperature control and pressure differential to product impact on Stable product temperature under operation.	URS / DQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0086	TFF heat exchanger	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for TFF heat exchanger.	IQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	Medium
BTV-09-0087	TFF heat exchanger	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Temperature control and pressure differential; compare challenge outputs to predefined Stable product temperature under operation acceptance.	OQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0088	TFF heat exchanger	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Stable product temperature under operation.	OQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-09-0089	TFF heat exchanger	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Stable product temperature under operation at relevant Temperature control and pressure differential; sampling scientifically justified.	PQ	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	High
BTV-09-0090	TFF heat exchanger	Continued verification / risk-based requalification trigger evaluation	Trend Temperature control and pressure differential and impact on Stable product temperature under operation; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biologics DS / DP concentration and purification	B02 B03 B05 B07 B12	Medium

10 VIRAL SAFETY, CLEARANCE AND ADVENTITIOUS AGENTS

99 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-10-0001	Virus-risk assessment	Protocol / design: Identify cell substrate, media, animal-derived raw material and process risks	Preapproved risk-based study design; endpoint: Risk-based viral testing and clearance controls.	Planning	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0002	Virus-risk assessment	Execution / boundary verification: Identify cell substrate, media, animal-derived raw material and process risks	Documented raw observations, calibration, relevant worst cases and defined acceptance for Risk-based viral testing and clearance controls.	Execution	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0003	Virus-risk assessment	Review / lifecycle: Identify cell substrate, media, animal-derived raw material and process risks	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Risk-based viral testing and clearance controls.	Review	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	Medium
BTV-10-0004	Viral clearance strategy	Protocol / design: Choose orthogonal inactivation/removal steps appropriate to product	Preapproved risk-based study design; endpoint: Justified integrated viral safety program.	Planning	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0005	Viral clearance strategy	Execution / boundary verification: Choose orthogonal inactivation/removal steps appropriate to product	Documented raw observations, calibration, relevant worst cases and defined acceptance for Justified integrated viral safety program.	Execution	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0006	Viral clearance strategy	Review / lifecycle: Choose orthogonal inactivation/removal steps appropriate to product	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Justified integrated viral safety program.	Review	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	Medium
BTV-10-0007	Virus-model selection	Protocol / design: Justify enveloped/non-enveloped and relevant physicochemical properties	Preapproved risk-based study design; endpoint: Scientifically sound model viruses.	Planning	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0008	Virus-model selection	Execution / boundary verification: Justify enveloped/non-enveloped and relevant physicochemical properties	Documented raw observations, calibration, relevant worst cases and defined acceptance for Scientifically sound model viruses.	Execution	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0009	Virus-model selection	Review / lifecycle: Justify enveloped/non-enveloped and relevant physicochemical properties	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Scientifically sound model viruses.	Review	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	Medium
BTV-10-0010	Scale-down qualification	Protocol / design: Demonstrate small-scale process represents commercial flow path	Preapproved risk-based study design; endpoint: Comparable CPPs, step capacity and clearance behavior.	Planning	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0011	Scale-down qualification	Execution / boundary verification: Demonstrate small-scale process represents commercial flow path	Documented raw observations, calibration, relevant worst cases and defined acceptance for Comparable CPPs, step capacity and clearance behavior.	Execution	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0012	Scale-down qualification	Review / lifecycle: Demonstrate small-scale process represents commercial flow path	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Comparable CPPs, step capacity and clearance behavior.	Review	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	Medium
BTV-10-0013	Low-pH viral inactivation	Protocol / design: Qualify minimum pH, contact time, temperature and mixing	Preapproved risk-based study design; endpoint: Validated kill envelope without protein damage.	Planning	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0014	Low-pH viral inactivation	Execution / boundary verification: Qualify minimum pH, contact time, temperature and mixing	Documented raw observations, calibration, relevant worst cases and defined acceptance for Validated kill envelope without protein damage.	Execution	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0015	Low-pH viral inactivation	Review / lifecycle: Qualify minimum pH, contact time, temperature and mixing	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Validated kill envelope without protein damage.	Review	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	Medium
BTV-10-0016	Detergent viral inactivation	Protocol / design: Qualify concentration, temperature and contact time if used	Preapproved risk-based study design; endpoint: Validated inactivation and downstream clearance.	Planning	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0017	Detergent viral inactivation	Execution / boundary verification: Qualify concentration, temperature and contact time if used	Documented raw observations, calibration, relevant worst cases and defined acceptance for Validated inactivation and downstream clearance.	Execution	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0018	Detergent viral inactivation	Review / lifecycle: Qualify concentration, temperature and contact time if used	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Validated inactivation and downstream clearance.	Review	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	Medium
BTV-10-0019	Virus-retentive membrane	Protocol / design: Challenge critical process conditions and max load	Preapproved risk-based study design; endpoint: Virus log reduction robust to fouling.	Planning	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0020	Virus-retentive membrane	Execution / boundary verification: Challenge critical process conditions and max load	Documented raw observations, calibration, relevant worst cases and defined acceptance for Virus log reduction robust to fouling.	Execution	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0021	Virus-retentive membrane	Review / lifecycle: Challenge critical process conditions and max load	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Virus log reduction robust to fouling.	Review	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	Medium
BTV-10-0022	Chromatography virus removal	Protocol / design: Establish validated clearance contribution where claimed	Preapproved risk-based study design; endpoint: LRV robustness across resin life and process limits.	Planning	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-10-0023	Chromatography virus removal	Execution / boundary verification: Establish validated clearance contribution where claimed	Documented raw observations, calibration, relevant worst cases and defined acceptance for LRV robustness across resin life and process limits.	Execution	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0024	Chromatography virus removal	Review / lifecycle: Establish validated clearance contribution where claimed	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on LRV robustness across resin life and process limits.	Review	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	Medium
BTV-10-0025	Orthogonality	Protocol / design: Evaluate independence and complementarity of control steps	Preapproved risk-based study design; endpoint: No overstatement from correlated mechanisms.	Planning	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0026	Orthogonality	Execution / boundary verification: Evaluate independence and complementarity of control steps	Documented raw observations, calibration, relevant worst cases and defined acceptance for No overstatement from correlated mechanisms.	Execution	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0027	Orthogonality	Review / lifecycle: Evaluate independence and complementarity of control steps	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No overstatement from correlated mechanisms.	Review	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	Medium
BTV-10-0028	Adventitious agent assays	Protocol / design: Qualify sensitivity, specificity and interference controls	Preapproved risk-based study design; endpoint: Detection limits for relevant contaminants.	Planning	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0029	Adventitious agent assays	Execution / boundary verification: Qualify sensitivity, specificity and interference controls	Documented raw observations, calibration, relevant worst cases and defined acceptance for Detection limits for relevant contaminants.	Execution	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0030	Adventitious agent assays	Review / lifecycle: Qualify sensitivity, specificity and interference controls	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Detection limits for relevant contaminants.	Review	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	Medium
BTV-10-0031	Mycoplasma testing	Protocol / design: Validate NAT/culture method for product matrix	Preapproved risk-based study design; endpoint: Reliable negative/positive controls and limits.	Planning	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0032	Mycoplasma testing	Execution / boundary verification: Validate NAT/culture method for product matrix	Documented raw observations, calibration, relevant worst cases and defined acceptance for Reliable negative/positive controls and limits.	Execution	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0033	Mycoplasma testing	Review / lifecycle: Validate NAT/culture method for product matrix	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Reliable negative/positive controls and limits.	Review	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	Medium
BTV-10-0034	Bioburden controls	Protocol / design: Qualify pre/post viral steps sampling and test hold	Preapproved risk-based study design; endpoint: Evidence of control within validated clearance assumptions.	Planning	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0035	Bioburden controls	Execution / boundary verification: Qualify pre/post viral steps sampling and test hold	Documented raw observations, calibration, relevant worst cases and defined acceptance for Evidence of control within validated clearance assumptions.	Execution	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0036	Bioburden controls	Review / lifecycle: Qualify pre/post viral steps sampling and test hold	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Evidence of control within validated clearance assumptions.	Review	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	Medium
BTV-10-0037	Max hold before inactivation	Protocol / design: Prove product and contamination acceptance	Preapproved risk-based study design; endpoint: Controlled viral safety step inputs.	Planning	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0038	Max hold before inactivation	Execution / boundary verification: Prove product and contamination acceptance	Documented raw observations, calibration, relevant worst cases and defined acceptance for Controlled viral safety step inputs.	Execution	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0039	Max hold before inactivation	Review / lifecycle: Prove product and contamination acceptance	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Controlled viral safety step inputs.	Review	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	Medium
BTV-10-0040	Spiking study biosafety	Protocol / design: Verify containment, segregation and waste inactivation	Preapproved risk-based study design; endpoint: No cross contamination to commercial GMP.	Planning	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0041	Spiking study biosafety	Execution / boundary verification: Verify containment, segregation and waste inactivation	Documented raw observations, calibration, relevant worst cases and defined acceptance for No cross contamination to commercial GMP.	Execution	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0042	Spiking study biosafety	Review / lifecycle: Verify containment, segregation and waste inactivation	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No cross contamination to commercial GMP.	Review	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	Medium
BTV-10-0043	Data analysis	Protocol / design: Use appropriate calculation and limits of assay detection	Preapproved risk-based study design; endpoint: Transparent LRV and uncertainty.	Planning	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0044	Data analysis	Execution / boundary verification: Use appropriate calculation and limits of assay detection	Documented raw observations, calibration, relevant worst cases and defined acceptance for Transparent LRV and uncertainty.	Execution	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0045	Data analysis	Review / lifecycle: Use appropriate calculation and limits of assay detection	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Transparent LRV and uncertainty.	Review	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	Medium
BTV-10-0046	Viral vector exception	Protocol / design: Assess distinct risk of intended viral activity, not blanket clearance	Preapproved risk-based study design; endpoint: Product-specific containment, impurity and potency logic.	Planning	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-10-0047	Viral vector exception	Execution / boundary verification: Assess distinct risk of intended viral activity, not blanket clearance	Documented raw observations, calibration, relevant worst cases and defined acceptance for Product-specific containment, impurity and potency logic.	Execution	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0048	Viral vector exception	Review / lifecycle: Assess distinct risk of intended viral activity, not blanket clearance	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Product-specific containment, impurity and potency logic.	Review	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	Medium
BTV-10-0049	Low-pH viral inactivation tank	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace pH mixing gradients, min temp, agitation, time to product impact on Robust inactivation exposure and protein stability.	URS / DQ	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0050	Low-pH viral inactivation tank	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Low-pH viral inactivation tank.	IQ	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	Medium
BTV-10-0051	Low-pH viral inactivation tank	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of pH mixing gradients, min temp, agitation, time; compare challenge outputs to predefined Robust inactivation exposure and protein stability acceptance.	OQ	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0052	Low-pH viral inactivation tank	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Robust inactivation exposure and protein stability.	OQ	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0053	Low-pH viral inactivation tank	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Robust inactivation exposure and protein stability at relevant pH mixing gradients, min temp, agitation, time; sampling scientifically justified.	PQ	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0054	Low-pH viral inactivation tank	Continued verification / risk-based requalification trigger evaluation	Trend pH mixing gradients, min temp, agitation, time and impact on Robust inactivation exposure and protein stability; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	Medium
BTV-10-0055	Virus removal filter housing	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Pressure distribution, integrity and max area load to product impact on Robust viral filtration conditions.	URS / DQ	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0056	Virus removal filter housing	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Virus removal filter housing.	IQ	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	Medium
BTV-10-0057	Virus removal filter housing	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Pressure distribution, integrity and max area load; compare challenge outputs to predefined Robust viral filtration conditions acceptance.	OQ	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0058	Virus removal filter housing	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Robust viral filtration conditions.	OQ	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0059	Virus removal filter housing	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Robust viral filtration conditions at relevant Pressure distribution, integrity and max area load; sampling scientifically justified.	PQ	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0060	Virus removal filter housing	Continued verification / risk-based requalification trigger evaluation	Trend Pressure distribution, integrity and max area load and impact on Robust viral filtration conditions; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	Medium
BTV-10-0061	Closed viral spiking test rig	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Containment, cleaning, sampling points to product impact on Controlled development-scale virus challenge.	URS / DQ	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0062	Closed viral spiking test rig	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Closed viral spiking test rig.	IQ	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	Medium
BTV-10-0063	Closed viral spiking test rig	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Containment, cleaning, sampling points; compare challenge outputs to predefined Controlled development-scale virus challenge acceptance.	OQ	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0064	Closed viral spiking test rig	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Controlled development-scale virus challenge.	OQ	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0065	Closed viral spiking test rig	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Controlled development-scale virus challenge at relevant Containment, cleaning, sampling points; sampling scientifically justified.	PQ	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0066	Closed viral spiking test rig	Continued verification / risk-based requalification trigger evaluation	Trend Containment, cleaning, sampling points and impact on Controlled development-scale virus challenge; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	Medium
BTV-10-0067	Virus culture assay reader	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Detection sensitivity, positive controls to product impact on Defensible viral infectivity endpoint.	URS / DQ	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-10-0068	Virus culture assay reader	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Virus culture assay reader.	IQ	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	Medium
BTV-10-0069	Virus culture assay reader	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Detection sensitivity, positive controls; compare challenge outputs to predefined Defensible viral infectivity endpoint acceptance.	OQ	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0070	Virus culture assay reader	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Defensible viral infectivity endpoint.	OQ	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0071	Virus culture assay reader	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Defensible viral infectivity endpoint at relevant Detection sensitivity, positive controls; sampling scientifically justified.	PQ	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0072	Virus culture assay reader	Continued verification / risk-based requalification trigger evaluation	Trend Detection sensitivity, positive controls and impact on Defensible viral infectivity endpoint; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	Medium
BTV-10-0073	Viral nucleic acid PCR instrument	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace LOD, specificity, interference to product impact on Sensitive viral safety testing.	URS / DQ	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0074	Viral nucleic acid PCR instrument	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Viral nucleic acid PCR instrument.	IQ	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	Medium
BTV-10-0075	Viral nucleic acid PCR instrument	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of LOD, specificity, interference; compare challenge outputs to predefined Sensitive viral safety testing acceptance.	OQ	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0076	Viral nucleic acid PCR instrument	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Sensitive viral safety testing.	OQ	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0077	Viral nucleic acid PCR instrument	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Sensitive viral safety testing at relevant LOD, specificity, interference; sampling scientifically justified.	PQ	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0078	Viral nucleic acid PCR instrument	Continued verification / risk-based requalification trigger evaluation	Trend LOD, specificity, interference and impact on Sensitive viral safety testing; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	Medium
BTV-10-0079	Mycoplasma qPCR system	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace LOD, inclusivity and sample inhibition to product impact on Adventitious agent test reliability.	URS / DQ	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0080	Mycoplasma qPCR system	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Mycoplasma qPCR system.	IQ	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	Medium
BTV-10-0081	Mycoplasma qPCR system	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of LOD, inclusivity and sample inhibition; compare challenge outputs to predefined Adventitious agent test reliability acceptance.	OQ	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0082	Mycoplasma qPCR system	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Adventitious agent test reliability.	OQ	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0083	Mycoplasma qPCR system	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Adventitious agent test reliability at relevant LOD, inclusivity and sample inhibition; sampling scientifically justified.	PQ	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	High
BTV-10-0084	Mycoplasma qPCR system	Continued verification / risk-based requalification trigger evaluation	Trend LOD, inclusivity and sample inhibition and impact on Adventitious agent test reliability; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Cell-derived biotechnology DS; product-specific	B03 B07 B08 B13 B25	Medium
BTV-10-0085	Viral load challenge	Protocol / design: Justify spiking input relative to process capacity	Preapproved risk-based study design; endpoint: Credible LRV claims.	Planning	Biologics with viral clearance claims	B07 B03	High
BTV-10-0086	Viral load challenge	Execution / boundary verification: Justify spiking input relative to process capacity	Documented raw observations, calibration, relevant worst cases and defined acceptance for Credible LRV claims.	Execution	Biologics with viral clearance claims	B07 B03	High
BTV-10-0087	Viral load challenge	Review / lifecycle: Justify spiking input relative to process capacity	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Credible LRV claims.	Review	Biologics with viral clearance claims	B07 B03	Medium
BTV-10-0088	Viral assay interference	Protocol / design: Demonstrate removal of cytotoxicity and detection interference	Preapproved risk-based study design; endpoint: Unbiased infectivity titers.	Planning	Biologics with viral clearance claims	B07 B03	High
BTV-10-0089	Viral assay interference	Execution / boundary verification: Demonstrate removal of cytotoxicity and detection interference	Documented raw observations, calibration, relevant worst cases and defined acceptance for Unbiased infectivity titers.	Execution	Biologics with viral clearance claims	B07 B03	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-10-0090	Viral assay interference	Review / lifecycle: Demonstrate removal of cytotoxicity and detection interference	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Unbiased infectivity titers.	Review	Biologics with viral clearance claims	B07 B03	Medium
BTV-10-0091	Viral clearance summation	Protocol / design: Evaluate independence and whether additive LRV justified	Preapproved risk-based study design; endpoint: Defensible overall viral safety margin.	Planning	Biologics with viral clearance claims	B07 B03	High
BTV-10-0092	Viral clearance summation	Execution / boundary verification: Evaluate independence and whether additive LRV justified	Documented raw observations, calibration, relevant worst cases and defined acceptance for Defensible overall viral safety margin.	Execution	Biologics with viral clearance claims	B07 B03	High
BTV-10-0093	Viral clearance summation	Review / lifecycle: Evaluate independence and whether additive LRV justified	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Defensible overall viral safety margin.	Review	Biologics with viral clearance claims	B07 B03	Medium
BTV-10-0094	Worst-case viral clearance	Protocol / design: Test boundary pH, conductivity, load and contact	Preapproved risk-based study design; endpoint: Robust viral safety near allowed range.	Planning	Biologics with viral clearance claims	B07 B03	High
BTV-10-0095	Worst-case viral clearance	Execution / boundary verification: Test boundary pH, conductivity, load and contact	Documented raw observations, calibration, relevant worst cases and defined acceptance for Robust viral safety near allowed range.	Execution	Biologics with viral clearance claims	B07 B03	High
BTV-10-0096	Worst-case viral clearance	Review / lifecycle: Test boundary pH, conductivity, load and contact	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Robust viral safety near allowed range.	Review	Biologics with viral clearance claims	B07 B03	Medium
BTV-10-0097	Virus clearance small-scale homology	Protocol / design: Characterize process comparability and scaling factors	Preapproved risk-based study design; endpoint: Relevant commercial extrapolation.	Planning	Biologics with viral clearance claims	B07 B03	High
BTV-10-0098	Virus clearance small-scale homology	Execution / boundary verification: Characterize process comparability and scaling factors	Documented raw observations, calibration, relevant worst cases and defined acceptance for Relevant commercial extrapolation.	Execution	Biologics with viral clearance claims	B07 B03	High
BTV-10-0099	Virus clearance small-scale homology	Review / lifecycle: Characterize process comparability and scaling factors	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Relevant commercial extrapolation.	Review	Biologics with viral clearance claims	B07 B03	Medium

11 BULK DRUG SUBSTANCE, INTERMEDIATE & HOLD TIMES

72 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-11-0001	Intermediate definition	Protocol / design: Set intermediate status and release criteria by process stage	Preapproved risk-based study design; endpoint: Defined quality release points.	Planning	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0002	Intermediate definition	Execution / boundary verification: Set intermediate status and release criteria by process stage	Documented raw observations, calibration, relevant worst cases and defined acceptance for Defined quality release points.	Execution	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0003	Intermediate definition	Review / lifecycle: Set intermediate status and release criteria by process stage	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Defined quality release points.	Review	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	Medium
BTV-11-0004	Bulk DS concentration	Protocol / design: Validate concentration range, pH, excipient and mixing	Preapproved risk-based study design; endpoint: Bulk protein integrity and potency.	Planning	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0005	Bulk DS concentration	Execution / boundary verification: Validate concentration range, pH, excipient and mixing	Documented raw observations, calibration, relevant worst cases and defined acceptance for Bulk protein integrity and potency.	Execution	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0006	Bulk DS concentration	Review / lifecycle: Validate concentration range, pH, excipient and mixing	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Bulk protein integrity and potency.	Review	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	Medium
BTV-11-0007	Hold time in production vessel	Protocol / design: Worst-case time, temperature, headspace and mixing	Preapproved risk-based study design; endpoint: Stable bioburden, potency, aggregation and modifications.	Planning	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0008	Hold time in production vessel	Execution / boundary verification: Worst-case time, temperature, headspace and mixing	Documented raw observations, calibration, relevant worst cases and defined acceptance for Stable bioburden, potency, aggregation and modifications.	Execution	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0009	Hold time in production vessel	Review / lifecycle: Worst-case time, temperature, headspace and mixing	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Stable bioburden, potency, aggregation and modifications.	Review	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	Medium
BTV-11-0010	Freeze-thaw cycles	Protocol / design: Qualify maximum cycles, thaw rate and temperature gradients	Preapproved risk-based study design; endpoint: Potency, particles and aggregate limits.	Planning	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0011	Freeze-thaw cycles	Execution / boundary verification: Qualify maximum cycles, thaw rate and temperature gradients	Documented raw observations, calibration, relevant worst cases and defined acceptance for Potency, particles and aggregate limits.	Execution	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0012	Freeze-thaw cycles	Review / lifecycle: Qualify maximum cycles, thaw rate and temperature gradients	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Potency, particles and aggregate limits.	Review	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	Medium
BTV-11-0013	Frozen DS transport	Protocol / design: Map shippers, thaw exposure and reconciliation	Preapproved risk-based study design; endpoint: No hidden excursion damaging product.	Planning	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0014	Frozen DS transport	Execution / boundary verification: Map shippers, thaw exposure and reconciliation	Documented raw observations, calibration, relevant worst cases and defined acceptance for No hidden excursion damaging product.	Execution	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0015	Frozen DS transport	Review / lifecycle: Map shippers, thaw exposure and reconciliation	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No hidden excursion damaging product.	Review	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	Medium
BTV-11-0016	Pool hold after capture	Protocol / design: Prove protein stability and bioburden at max hold	Preapproved risk-based study design; endpoint: Pool remains process-suitable.	Planning	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-11-0017	Pool hold after capture	Execution / boundary verification: Prove protein stability and bioburden at max hold	Documented raw observations, calibration, relevant worst cases and defined acceptance for Pool remains process-suitable.	Execution	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0018	Pool hold after capture	Review / lifecycle: Prove protein stability and bioburden at max hold	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Pool remains process-suitable.	Review	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	Medium
BTV-11-0019	Pool hold after polishing	Protocol / design: Establish post-polishing bioburden/endotoxin limits	Preapproved risk-based study design; endpoint: Control prior to sterile filtration.	Planning	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0020	Pool hold after polishing	Execution / boundary verification: Establish post-polishing bioburden/endotoxin limits	Documented raw observations, calibration, relevant worst cases and defined acceptance for Control prior to sterile filtration.	Execution	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0021	Pool hold after polishing	Review / lifecycle: Establish post-polishing bioburden/endotoxin limits	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Control prior to sterile filtration.	Review	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	Medium
BTV-11-0022	Concentration excursions	Protocol / design: Challenge adverse concentration and pH windows	Preapproved risk-based study design; endpoint: Defined allowable hold and remedial strategy.	Planning	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0023	Concentration excursions	Execution / boundary verification: Challenge adverse concentration and pH windows	Documented raw observations, calibration, relevant worst cases and defined acceptance for Defined allowable hold and remedial strategy.	Execution	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0024	Concentration excursions	Review / lifecycle: Challenge adverse concentration and pH windows	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Defined allowable hold and remedial strategy.	Review	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	Medium
BTV-11-0025	Bulk container compatibility	Protocol / design: Assess leachables, adsorption and closure integrity	Preapproved risk-based study design; endpoint: Storage container fitness.	Planning	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0026	Bulk container compatibility	Execution / boundary verification: Assess leachables, adsorption and closure integrity	Documented raw observations, calibration, relevant worst cases and defined acceptance for Storage container fitness.	Execution	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0027	Bulk container compatibility	Review / lifecycle: Assess leachables, adsorption and closure integrity	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Storage container fitness.	Review	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	Medium
BTV-11-0028	DS shipping bracketing	Protocol / design: Challenge fill amount, dry ice profile and lane season	Preapproved risk-based study design; endpoint: Controlled physical and chemical product attributes.	Planning	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0029	DS shipping bracketing	Execution / boundary verification: Challenge fill amount, dry ice profile and lane season	Documented raw observations, calibration, relevant worst cases and defined acceptance for Controlled physical and chemical product attributes.	Execution	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0030	DS shipping bracketing	Review / lifecycle: Challenge fill amount, dry ice profile and lane season	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Controlled physical and chemical product attributes.	Review	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	Medium
BTV-11-0031	Bulk sampling	Protocol / design: Qualify top/bottom homogeneity and sample handling	Preapproved risk-based study design; endpoint: Representative identity, purity, potency and bioburden.	Planning	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0032	Bulk sampling	Execution / boundary verification: Qualify top/bottom homogeneity and sample handling	Documented raw observations, calibration, relevant worst cases and defined acceptance for Representative identity, purity, potency and bioburden.	Execution	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0033	Bulk sampling	Review / lifecycle: Qualify top/bottom homogeneity and sample handling	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Representative identity, purity, potency and bioburden.	Review	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	Medium
BTV-11-0034	Batch linkage	Protocol / design: Validate batch genealogy to upstream, resins and raw materials	Preapproved risk-based study design; endpoint: Complete traceability and reconciliation.	Planning	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-11-0035	Batch linkage	Execution / boundary verification: Validate batch genealogy to upstream, resins and raw materials	Documented raw observations, calibration, relevant worst cases and defined acceptance for Complete traceability and reconciliation.	Execution	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0036	Batch linkage	Review / lifecycle: Validate batch genealogy to upstream, resins and raw materials	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Complete traceability and reconciliation.	Review	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	Medium
BTV-11-0037	Bulk product holding vessel	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Temperature, agitation, pressure, transfer to product impact on Protein stability and bioburden.	URS / DQ	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0038	Bulk product holding vessel	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Bulk product holding vessel.	IQ	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	Medium
BTV-11-0039	Bulk product holding vessel	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Temperature, agitation, pressure, transfer; compare challenge outputs to predefined Protein stability and bioburden acceptance.	OQ	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0040	Bulk product holding vessel	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Protein stability and bioburden.	OQ	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0041	Bulk product holding vessel	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Protein stability and bioburden at relevant Temperature, agitation, pressure, transfer; sampling scientifically justified.	PQ	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0042	Bulk product holding vessel	Continued verification / risk-based requalification trigger evaluation	Trend Temperature, agitation, pressure, transfer and impact on Protein stability and bioburden; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	Medium
BTV-11-0043	Cryogenic bulk storage freezer	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Temperature mapping, alarms, recovery to product impact on Frozen DS quality stability.	URS / DQ	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0044	Cryogenic bulk storage freezer	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Cryogenic bulk storage freezer.	IQ	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	Medium
BTV-11-0045	Cryogenic bulk storage freezer	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Temperature mapping, alarms, recovery; compare challenge outputs to predefined Frozen DS quality stability acceptance.	OQ	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0046	Cryogenic bulk storage freezer	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Frozen DS quality stability.	OQ	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0047	Cryogenic bulk storage freezer	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Frozen DS quality stability at relevant Temperature mapping, alarms, recovery; sampling scientifically justified.	PQ	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0048	Cryogenic bulk storage freezer	Continued verification / risk-based requalification trigger evaluation	Trend Temperature mapping, alarms, recovery and impact on Frozen DS quality stability; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	Medium
BTV-11-0049	Bulk bottle filling manifold	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Fill weight, aseptic connection, leak test to product impact on Traceable bulk filling with no contamination.	URS / DQ	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0050	Bulk bottle filling manifold	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Bulk bottle filling manifold.	IQ	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	Medium
BTV-11-0051	Bulk bottle filling manifold	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Fill weight, aseptic connection, leak test; compare challenge outputs to predefined Traceable bulk filling with no contamination acceptance.	OQ	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0052	Bulk bottle filling manifold	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Traceable bulk filling with no contamination.	OQ	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-11-0053	Bulk bottle filling manifold	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Traceable bulk filling with no contamination at relevant Fill weight, aseptic connection, leak test; sampling scientifically justified.	PQ	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0054	Bulk bottle filling manifold	Continued verification / risk-based requalification trigger evaluation	Trend Fill weight, aseptic connection, leak test and impact on Traceable bulk filling with no contamination; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	Medium
BTV-11-0055	Bulk freezing chamber	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Freeze rate, pallet configuration, location to product impact on Reproducible ice formation and product quality.	URS / DQ	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0056	Bulk freezing chamber	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Bulk freezing chamber.	IQ	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	Medium
BTV-11-0057	Bulk freezing chamber	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Freeze rate, pallet configuration, location; compare challenge outputs to predefined Reproducible ice formation and product quality acceptance.	OQ	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0058	Bulk freezing chamber	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Reproducible ice formation and product quality.	OQ	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0059	Bulk freezing chamber	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Reproducible ice formation and product quality at relevant Freeze rate, pallet configuration, location; sampling scientifically justified.	PQ	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0060	Bulk freezing chamber	Continued verification / risk-based requalification trigger evaluation	Trend Freeze rate, pallet configuration, location and impact on Reproducible ice formation and product quality; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	Medium
BTV-11-0061	Controlled thaw station	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Temperature, thaw time, mixing to product impact on Acceptable protein integrity after thaw.	URS / DQ	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0062	Controlled thaw station	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Controlled thaw station.	IQ	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	Medium
BTV-11-0063	Controlled thaw station	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Temperature, thaw time, mixing; compare challenge outputs to predefined Acceptable protein integrity after thaw acceptance.	OQ	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0064	Controlled thaw station	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Acceptable protein integrity after thaw.	OQ	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0065	Controlled thaw station	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Acceptable protein integrity after thaw at relevant Temperature, thaw time, mixing; sampling scientifically justified.	PQ	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0066	Controlled thaw station	Continued verification / risk-based requalification trigger evaluation	Trend Temperature, thaw time, mixing and impact on Acceptable protein integrity after thaw; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	Medium
BTV-11-0067	Product transfer peristaltic pump	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Occlusion, flow and shear to product impact on Low particle generation and product recovery.	URS / DQ	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0068	Product transfer peristaltic pump	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Product transfer peristaltic pump.	IQ	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	Medium
BTV-11-0069	Product transfer peristaltic pump	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Occlusion, flow and shear; compare challenge outputs to predefined Low particle generation and product recovery acceptance.	OQ	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0070	Product transfer peristaltic pump	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Low particle generation and product recovery.	OQ	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-11-0071	Product transfer peristaltic pump	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Low particle generation and product recovery at relevant Occlusion, flow and shear; sampling scientifically justified.	PQ	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	High
BTV-11-0072	Product transfer peristaltic pump	Continued verification / risk-based requalification trigger evaluation	Trend Occlusion, flow and shear and impact on Low particle generation and product recovery; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	mAbs, recombinant proteins, enzymes, antigen bulk	B02 B03 B05 B09 B11 B12	Medium

12 ADCS, HIGH-POTENCY CONJUGATES & CHEMICAL-BIOLOGIC INTERFACES

63 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-12-0001	Conjugation stoichiometry	Protocol / design: Validate linker/payload ratio, pH, time and temperature	Preapproved risk-based study design; endpoint: Drug-to-antibody ratio (DAR) distribution and free payload.	Planning	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0002	Conjugation stoichiometry	Execution / boundary verification: Validate linker/payload ratio, pH, time and temperature	Documented raw observations, calibration, relevant worst cases and defined acceptance for Drug-to-antibody ratio (DAR) distribution and free payload.	Execution	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0003	Conjugation stoichiometry	Review / lifecycle: Validate linker/payload ratio, pH, time and temperature	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Drug-to-antibody ratio (DAR) distribution and free payload.	Review	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	Medium
BTV-12-0004	Conjugation mixing	Protocol / design: Prove reaction homogeneity at scale and low volume	Preapproved risk-based study design; endpoint: Batch DAR and aggregation consistency.	Planning	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0005	Conjugation mixing	Execution / boundary verification: Prove reaction homogeneity at scale and low volume	Documented raw observations, calibration, relevant worst cases and defined acceptance for Batch DAR and aggregation consistency.	Execution	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0006	Conjugation mixing	Review / lifecycle: Prove reaction homogeneity at scale and low volume	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Batch DAR and aggregation consistency.	Review	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	Medium
BTV-12-0007	Quench operation	Protocol / design: Define reagent endpoint and impurity controls	Preapproved risk-based study design; endpoint: No continued uncontrolled conjugation.	Planning	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0008	Quench operation	Execution / boundary verification: Define reagent endpoint and impurity controls	Documented raw observations, calibration, relevant worst cases and defined acceptance for No continued uncontrolled conjugation.	Execution	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0009	Quench operation	Review / lifecycle: Define reagent endpoint and impurity controls	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No continued uncontrolled conjugation.	Review	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	Medium
BTV-12-0010	Free-payload clearance	Protocol / design: Validate chromatographic and filtration removal	Preapproved risk-based study design; endpoint: Residual toxic payload under product-specific limits.	Planning	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0011	Free-payload clearance	Execution / boundary verification: Validate chromatographic and filtration removal	Documented raw observations, calibration, relevant worst cases and defined acceptance for Residual toxic payload under product-specific limits.	Execution	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0012	Free-payload clearance	Review / lifecycle: Validate chromatographic and filtration removal	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Residual toxic payload under product-specific limits.	Review	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	Medium
BTV-12-0013	Occupational containment	Protocol / design: Qualify isolator leak, HEPA, pressure and safe transfer	Preapproved risk-based study design; endpoint: Operator and adjacent process protection.	Planning	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0014	Occupational containment	Execution / boundary verification: Qualify isolator leak, HEPA, pressure and safe transfer	Documented raw observations, calibration, relevant worst cases and defined acceptance for Operator and adjacent process protection.	Execution	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0015	Occupational containment	Review / lifecycle: Qualify isolator leak, HEPA, pressure and safe transfer	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Operator and adjacent process protection.	Review	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	Medium
BTV-12-0016	Cleaning high-potency residues	Protocol / design: Set HBEL/PDE-based limits with validated methods	Preapproved risk-based study design; endpoint: Safe equipment reuse and no carryover.	Planning	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0017	Cleaning high-potency residues	Execution / boundary verification: Set HBEL/PDE-based limits with validated methods	Documented raw observations, calibration, relevant worst cases and defined acceptance for Safe equipment reuse and no carryover.	Execution	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0018	Cleaning high-potency residues	Review / lifecycle: Set HBEL/PDE-based limits with validated methods	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Safe equipment reuse and no carryover.	Review	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	Medium
BTV-12-0019	Conjugate stability	Protocol / design: Challenge light, oxidation, temperature and mechanical handling	Preapproved risk-based study design; endpoint: Preserved DAR, potency and impurities.	Planning	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0020	Conjugate stability	Execution / boundary verification: Challenge light, oxidation, temperature and mechanical handling	Documented raw observations, calibration, relevant worst cases and defined acceptance for Preserved DAR, potency and impurities.	Execution	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0021	Conjugate stability	Review / lifecycle: Challenge light, oxidation, temperature and mechanical handling	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Preserved DAR, potency and impurities.	Review	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	Medium
BTV-12-0022	In-process DAR	Protocol / design: Validate analytical procedure precision and specificity	Preapproved risk-based study design; endpoint: Reliable product/process monitoring.	Planning	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-12-0023	In-process DAR	Execution / boundary verification: Validate analytical procedure precision and specificity	Documented raw observations, calibration, relevant worst cases and defined acceptance for Reliable product/process monitoring.	Execution	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0024	In-process DAR	Review / lifecycle: Validate analytical procedure precision and specificity	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Reliable product/process monitoring.	Review	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	Medium
BTV-12-0025	Chemical intermediate storage	Protocol / design: Qualify retest/expiry, oxygen/light and humidity	Preapproved risk-based study design; endpoint: Stable linker-payload quality.	Planning	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0026	Chemical intermediate storage	Execution / boundary verification: Qualify retest/expiry, oxygen/light and humidity	Documented raw observations, calibration, relevant worst cases and defined acceptance for Stable linker-payload quality.	Execution	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0027	Chemical intermediate storage	Review / lifecycle: Qualify retest/expiry, oxygen/light and humidity	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Stable linker-payload quality.	Review	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	Medium
BTV-12-0028	Waste inactivation	Protocol / design: Validate chemical neutralization/disposal procedures	Preapproved risk-based study design; endpoint: Controlled safety and environmental discharge.	Planning	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0029	Waste inactivation	Execution / boundary verification: Validate chemical neutralization/disposal procedures	Documented raw observations, calibration, relevant worst cases and defined acceptance for Controlled safety and environmental discharge.	Execution	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0030	Waste inactivation	Review / lifecycle: Validate chemical neutralization/disposal procedures	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Controlled safety and environmental discharge.	Review	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	Medium
BTV-12-0031	Containment breach response	Protocol / design: Challenge alarm, line clearance and operator response	Preapproved risk-based study design; endpoint: Exposure and cross-contamination prevention.	Planning	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0032	Containment breach response	Execution / boundary verification: Challenge alarm, line clearance and operator response	Documented raw observations, calibration, relevant worst cases and defined acceptance for Exposure and cross-contamination prevention.	Execution	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0033	Containment breach response	Review / lifecycle: Challenge alarm, line clearance and operator response	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Exposure and cross-contamination prevention.	Review	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	Medium
BTV-12-0034	Conjugation reactor	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Mixing, pH, temperature, addition rate to product impact on Controlled DAR and protein integrity.	URS / DQ	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0035	Conjugation reactor	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Conjugation reactor.	IQ	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	Medium
BTV-12-0036	Conjugation reactor	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Mixing, pH, temperature, addition rate; compare challenge outputs to predefined Controlled DAR and protein integrity acceptance.	OQ	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0037	Conjugation reactor	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Controlled DAR and protein integrity.	OQ	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0038	Conjugation reactor	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Controlled DAR and protein integrity at relevant Mixing, pH, temperature, addition rate; sampling scientifically justified.	PQ	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0039	Conjugation reactor	Continued verification / risk-based requalification trigger evaluation	Trend Mixing, pH, temperature, addition rate and impact on Controlled DAR and protein integrity; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	Medium
BTV-12-0040	HPAPI isolator	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Pressure cascade, glove leak and airflow to product impact on Operator protection and product segregation.	URS / DQ	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0041	HPAPI isolator	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for HPAPI isolator.	IQ	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	Medium
BTV-12-0042	HPAPI isolator	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Pressure cascade, glove leak and airflow; compare challenge outputs to predefined Operator protection and product segregation acceptance.	OQ	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0043	HPAPI isolator	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Operator protection and product segregation.	OQ	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0044	HPAPI isolator	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Operator protection and product segregation at relevant Pressure cascade, glove leak and airflow; sampling scientifically justified.	PQ	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-12-0045	HPAPI isolator	Continued verification / risk-based requalification trigger evaluation	Trend Pressure cascade, glove leak and airflow and impact on Operator protection and product segregation; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	Medium
BTV-12-0046	Conjugate polishing skid	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Flow, fractionation, closed transfer to product impact on Free payload and aggregate clearance.	URS / DQ	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0047	Conjugate polishing skid	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Conjugate polishing skid.	IQ	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	Medium
BTV-12-0048	Conjugate polishing skid	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Flow, fractionation, closed transfer; compare challenge outputs to predefined Free payload and aggregate clearance acceptance.	OQ	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0049	Conjugate polishing skid	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Free payload and aggregate clearance.	OQ	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0050	Conjugate polishing skid	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Free payload and aggregate clearance at relevant Flow, fractionation, closed transfer; sampling scientifically justified.	PQ	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0051	Conjugate polishing skid	Continued verification / risk-based requalification trigger evaluation	Trend Flow, fractionation, closed transfer and impact on Free payload and aggregate clearance; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	Medium
BTV-12-0052	Dedicated high potency balance	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Weighing performance and containment to product impact on Accurate payload dosage with low exposure.	URS / DQ	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0053	Dedicated high potency balance	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Dedicated high potency balance.	IQ	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	Medium
BTV-12-0054	Dedicated high potency balance	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Weighing performance and containment; compare challenge outputs to predefined Accurate payload dosage with low exposure acceptance.	OQ	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0055	Dedicated high potency balance	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Accurate payload dosage with low exposure.	OQ	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0056	Dedicated high potency balance	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Accurate payload dosage with low exposure at relevant Weighing performance and containment; sampling scientifically justified.	PQ	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0057	Dedicated high potency balance	Continued verification / risk-based requalification trigger evaluation	Trend Weighing performance and containment and impact on Accurate payload dosage with low exposure; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	Medium
BTV-12-0058	Conjugation transfer skid	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Tubing integrity and valve routing to product impact on No cross contamination or protein degradation.	URS / DQ	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0059	Conjugation transfer skid	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Conjugation transfer skid.	IQ	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	Medium
BTV-12-0060	Conjugation transfer skid	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Tubing integrity and valve routing; compare challenge outputs to predefined No cross contamination or protein degradation acceptance.	OQ	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0061	Conjugation transfer skid	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect No cross contamination or protein degradation.	OQ	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0062	Conjugation transfer skid	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable No cross contamination or protein degradation at relevant Tubing integrity and valve routing; sampling scientifically justified.	PQ	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	High
BTV-12-0063	Conjugation transfer skid	Continued verification / risk-based requalification trigger evaluation	Trend Tubing integrity and valve routing and impact on No cross contamination or protein degradation; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	ADCs, linkers, payloads, conjugated proteins	B03 B05 B11 B12 B18	Medium

13 MRNA, PLASMID DNA AND LIPID NANOPARTICLES

72 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-13-0001	Plasmid fermentation	Protocol / design: Establish copy number, stability and plasmid isoform control	Preapproved risk-based study design; endpoint: Supercoiled plasmid purity and yield.	Planning	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0002	Plasmid fermentation	Execution / boundary verification: Establish copy number, stability and plasmid isoform control	Documented raw observations, calibration, relevant worst cases and defined acceptance for Supercoiled plasmid purity and yield.	Execution	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0003	Plasmid fermentation	Review / lifecycle: Establish copy number, stability and plasmid isoform control	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Supercoiled plasmid purity and yield.	Review	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	Medium
BTV-13-0004	Plasmid linearization	Protocol / design: Qualify enzyme completeness and residual impurities	Preapproved risk-based study design; endpoint: Suitable linear DNA template.	Planning	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0005	Plasmid linearization	Execution / boundary verification: Qualify enzyme completeness and residual impurities	Documented raw observations, calibration, relevant worst cases and defined acceptance for Suitable linear DNA template.	Execution	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0006	Plasmid linearization	Review / lifecycle: Qualify enzyme completeness and residual impurities	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Suitable linear DNA template.	Review	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	Medium
BTV-13-0007	In vitro transcription	Protocol / design: Control NTP/magnesium, enzyme, pH, temperature	Preapproved risk-based study design; endpoint: Full-length mRNA yield and integrity.	Planning	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0008	In vitro transcription	Execution / boundary verification: Control NTP/magnesium, enzyme, pH, temperature	Documented raw observations, calibration, relevant worst cases and defined acceptance for Full-length mRNA yield and integrity.	Execution	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0009	In vitro transcription	Review / lifecycle: Control NTP/magnesium, enzyme, pH, temperature	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Full-length mRNA yield and integrity.	Review	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	Medium
BTV-13-0010	Capping and poly(A)	Protocol / design: Validate enzymatic/chemical capping and tail distribution	Preapproved risk-based study design; endpoint: Capping efficiency and poly(A) quality.	Planning	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0011	Capping and poly(A)	Execution / boundary verification: Validate enzymatic/chemical capping and tail distribution	Documented raw observations, calibration, relevant worst cases and defined acceptance for Capping efficiency and poly(A) quality.	Execution	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0012	Capping and poly(A)	Review / lifecycle: Validate enzymatic/chemical capping and tail distribution	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Capping efficiency and poly(A) quality.	Review	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	Medium
BTV-13-0013	DNase treatment	Protocol / design: Confirm template DNA digestion and clearance	Preapproved risk-based study design; endpoint: Residual DNA and enzyme control.	Planning	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0014	DNase treatment	Execution / boundary verification: Confirm template DNA digestion and clearance	Documented raw observations, calibration, relevant worst cases and defined acceptance for Residual DNA and enzyme control.	Execution	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0015	DNase treatment	Review / lifecycle: Confirm template DNA digestion and clearance	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Residual DNA and enzyme control.	Review	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	Medium
BTV-13-0016	mRNA purification	Protocol / design: Control dsRNA, truncated transcripts and free nucleotides	Preapproved risk-based study design; endpoint: Impurity specifications and mRNA integrity.	Planning	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0017	mRNA purification	Execution / boundary verification: Control dsRNA, truncated transcripts and free nucleotides	Documented raw observations, calibration, relevant worst cases and defined acceptance for Impurity specifications and mRNA integrity.	Execution	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0018	mRNA purification	Review / lifecycle: Control dsRNA, truncated transcripts and free nucleotides	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Impurity specifications and mRNA integrity.	Review	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	Medium
BTV-13-0019	LNP mixing	Protocol / design: Characterize flow ratio, mixing energy and residence time	Preapproved risk-based study design; endpoint: Particle size, PDI and encapsulation efficiency.	Planning	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0020	LNP mixing	Execution / boundary verification: Characterize flow ratio, mixing energy and residence time	Documented raw observations, calibration, relevant worst cases and defined acceptance for Particle size, PDI and encapsulation efficiency.	Execution	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0021	LNP mixing	Review / lifecycle: Characterize flow ratio, mixing energy and residence time	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Particle size, PDI and encapsulation efficiency.	Review	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	Medium
BTV-13-0022	TFF LNP concentration	Protocol / design: Qualify shear, pressure, membrane adsorption	Preapproved risk-based study design; endpoint: Particle integrity and product recovery.	Planning	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-13-0023	TFF LNP concentration	Execution / boundary verification: Qualify shear, pressure, membrane adsorption	Documented raw observations, calibration, relevant worst cases and defined acceptance for Particle integrity and product recovery.	Execution	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0024	TFF LNP concentration	Review / lifecycle: Qualify shear, pressure, membrane adsorption	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Particle integrity and product recovery.	Review	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	Medium
BTV-13-0025	RNase controls	Protocol / design: Validate cleaning, consumables and personnel practices	Preapproved risk-based study design; endpoint: No RNA degradation during processing.	Planning	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0026	RNase controls	Execution / boundary verification: Validate cleaning, consumables and personnel practices	Documented raw observations, calibration, relevant worst cases and defined acceptance for No RNA degradation during processing.	Execution	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0027	RNase controls	Review / lifecycle: Validate cleaning, consumables and personnel practices	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No RNA degradation during processing.	Review	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	Medium
BTV-13-0028	Cold-chain stability	Protocol / design: Qualify thaw/refreeze, temperature excursions and shipping	Preapproved risk-based study design; endpoint: mRNA integrity and potency.	Planning	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0029	Cold-chain stability	Execution / boundary verification: Qualify thaw/refreeze, temperature excursions and shipping	Documented raw observations, calibration, relevant worst cases and defined acceptance for mRNA integrity and potency.	Execution	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0030	Cold-chain stability	Review / lifecycle: Qualify thaw/refreeze, temperature excursions and shipping	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on mRNA integrity and potency.	Review	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	Medium
BTV-13-0031	Sterile filtration feasibility	Protocol / design: Evaluate filter retention vs nanoparticle product and risk	Preapproved risk-based study design; endpoint: Appropriate aseptic strategy; no blanket assumption.	Planning	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0032	Sterile filtration feasibility	Execution / boundary verification: Evaluate filter retention vs nanoparticle product and risk	Documented raw observations, calibration, relevant worst cases and defined acceptance for Appropriate aseptic strategy; no blanket assumption.	Execution	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0033	Sterile filtration feasibility	Review / lifecycle: Evaluate filter retention vs nanoparticle product and risk	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Appropriate aseptic strategy; no blanket assumption.	Review	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	Medium
BTV-13-0034	Microfluidic scale-up	Protocol / design: Prove flow geometry / mixing equivalence	Preapproved risk-based study design; endpoint: Particle size, encapsulation and potency.	Planning	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0035	Microfluidic scale-up	Execution / boundary verification: Prove flow geometry / mixing equivalence	Documented raw observations, calibration, relevant worst cases and defined acceptance for Particle size, encapsulation and potency.	Execution	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0036	Microfluidic scale-up	Review / lifecycle: Prove flow geometry / mixing equivalence	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Particle size, encapsulation and potency.	Review	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	Medium
BTV-13-0037	In-vitro transcription reactor	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Agitation, temperature, pH, nuclease controls to product impact on mRNA length and yield.	URS / DQ	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0038	In-vitro transcription reactor	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for In-vitro transcription reactor.	IQ	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	Medium
BTV-13-0039	In-vitro transcription reactor	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Agitation, temperature, pH, nuclease controls; compare challenge outputs to predefined mRNA length and yield acceptance.	OQ	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0040	In-vitro transcription reactor	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect mRNA length and yield.	OQ	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0041	In-vitro transcription reactor	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable mRNA length and yield at relevant Agitation, temperature, pH, nuclease controls; sampling scientifically justified.	PQ	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0042	In-vitro transcription reactor	Continued verification / risk-based requalification trigger evaluation	Trend Agitation, temperature, pH, nuclease controls and impact on mRNA length and yield; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	Medium
BTV-13-0043	Plasmid linearization reactor	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Temperature, enzyme addition and sampling to product impact on Complete linearized DNA substrate.	URS / DQ	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0044	Plasmid linearization reactor	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Plasmid linearization reactor.	IQ	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	Medium
BTV-13-0045	Plasmid linearization reactor	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Temperature, enzyme addition and sampling; compare challenge outputs to predefined Complete linearized DNA substrate acceptance.	OQ	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-13-0046	Plasmid linearization reactor	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Complete linearized DNA substrate.	OQ	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0047	Plasmid linearization reactor	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Complete linearized DNA substrate at relevant Temperature, enzyme addition and sampling; sampling scientifically justified.	PQ	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0048	Plasmid linearization reactor	Continued verification / risk-based requalification trigger evaluation	Trend Temperature, enzyme addition and sampling and impact on Complete linearized DNA substrate; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	Medium
BTV-13-0049	Microfluidic LNP mixer	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Flow ratios, pump pulsation, mixing geometry to product impact on Particle size/PDI and encapsulation.	URS / DQ	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0050	Microfluidic LNP mixer	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Microfluidic LNP mixer.	IQ	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	Medium
BTV-13-0051	Microfluidic LNP mixer	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Flow ratios, pump pulsation, mixing geometry; compare challenge outputs to predefined Particle size/PDI and encapsulation acceptance.	OQ	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0052	Microfluidic LNP mixer	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Particle size/PDI and encapsulation.	OQ	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0053	Microfluidic LNP mixer	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Particle size/PDI and encapsulation at relevant Flow ratios, pump pulsation, mixing geometry; sampling scientifically justified.	PQ	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0054	Microfluidic LNP mixer	Continued verification / risk-based requalification trigger evaluation	Trend Flow ratios, pump pulsation, mixing geometry and impact on Particle size/PDI and encapsulation; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	Medium
BTV-13-0055	LNP TFF skid	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace TMP, shear, diafiltration to product impact on LNP recovery and stability.	URS / DQ	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0056	LNP TFF skid	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for LNP TFF skid.	IQ	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	Medium
BTV-13-0057	LNP TFF skid	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of TMP, shear, diafiltration; compare challenge outputs to predefined LNP recovery and stability acceptance.	OQ	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0058	LNP TFF skid	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect LNP recovery and stability.	OQ	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0059	LNP TFF skid	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable LNP recovery and stability at relevant TMP, shear, diafiltration; sampling scientifically justified.	PQ	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0060	LNP TFF skid	Continued verification / risk-based requalification trigger evaluation	Trend TMP, shear, diafiltration and impact on LNP recovery and stability; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	Medium
BTV-13-0061	RNA aseptic transfer set	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Weld, sterile connection, exposure to product impact on Microbiological assurance and RNA integrity.	URS / DQ	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0062	RNA aseptic transfer set	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for RNA aseptic transfer set.	IQ	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	Medium
BTV-13-0063	RNA aseptic transfer set	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Weld, sterile connection, exposure; compare challenge outputs to predefined Microbiological assurance and RNA integrity acceptance.	OQ	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0064	RNA aseptic transfer set	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Microbiological assurance and RNA integrity.	OQ	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0065	RNA aseptic transfer set	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Microbiological assurance and RNA integrity at relevant Weld, sterile connection, exposure; sampling scientifically justified.	PQ	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0066	RNA aseptic transfer set	Continued verification / risk-based requalification trigger evaluation	Trend Weld, sterile connection, exposure and impact on Microbiological assurance and RNA integrity; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-13-0067	RNA ultra-low freezer	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Thermal mapping, alarms and opening time to product impact on Retention of mRNA product quality.	URS / DQ	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0068	RNA ultra-low freezer	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for RNA ultra-low freezer.	IQ	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	Medium
BTV-13-0069	RNA ultra-low freezer	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Thermal mapping, alarms and opening time; compare challenge outputs to predefined Retention of mRNA product quality acceptance.	OQ	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0070	RNA ultra-low freezer	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Retention of mRNA product quality.	OQ	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0071	RNA ultra-low freezer	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Retention of mRNA product quality at relevant Thermal mapping, alarms and opening time; sampling scientifically justified.	PQ	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	High
BTV-13-0072	RNA ultra-low freezer	Continued verification / risk-based requalification trigger evaluation	Trend Thermal mapping, alarms and opening time and impact on Retention of mRNA product quality; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	mRNA / pDNA / LNP products (where applicable)	B03 B05 B11 B12 B22 B23	Medium

14 VACCINE ANTIGENS, ADJUVANTS & FORMULATION

72 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-14-0001	Antigen production	Protocol / design: Qualify expression/propagation profile and scale equivalency	Preapproved risk-based study design; endpoint: Antigen yield, identity and potency.	Planning	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0002	Antigen production	Execution / boundary verification: Qualify expression/propagation profile and scale equivalency	Documented raw observations, calibration, relevant worst cases and defined acceptance for Antigen yield, identity and potency.	Execution	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0003	Antigen production	Review / lifecycle: Qualify expression/propagation profile and scale equivalency	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Antigen yield, identity and potency.	Review	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	Medium
BTV-14-0004	Antigen inactivation	Protocol / design: Validate time, temperature, reagent exposure and residual live agent	Preapproved risk-based study design; endpoint: Demonstrated inactivation where claimed.	Planning	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0005	Antigen inactivation	Execution / boundary verification: Validate time, temperature, reagent exposure and residual live agent	Documented raw observations, calibration, relevant worst cases and defined acceptance for Demonstrated inactivation where claimed.	Execution	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0006	Antigen inactivation	Review / lifecycle: Validate time, temperature, reagent exposure and residual live agent	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Demonstrated inactivation where claimed.	Review	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	Medium
BTV-14-0007	Antigen purification	Protocol / design: Confirm impurity removal and epitope preservation	Preapproved risk-based study design; endpoint: Antigen potency and purity.	Planning	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0008	Antigen purification	Execution / boundary verification: Confirm impurity removal and epitope preservation	Documented raw observations, calibration, relevant worst cases and defined acceptance for Antigen potency and purity.	Execution	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0009	Antigen purification	Review / lifecycle: Confirm impurity removal and epitope preservation	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Antigen potency and purity.	Review	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	Medium
BTV-14-0010	Adjuvant preparation	Protocol / design: Define mixing, particle suspension and concentration limits	Preapproved risk-based study design; endpoint: Uniform adjuvant composition.	Planning	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0011	Adjuvant preparation	Execution / boundary verification: Define mixing, particle suspension and concentration limits	Documented raw observations, calibration, relevant worst cases and defined acceptance for Uniform adjuvant composition.	Execution	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0012	Adjuvant preparation	Review / lifecycle: Define mixing, particle suspension and concentration limits	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Uniform adjuvant composition.	Review	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	Medium
BTV-14-0013	Antigen adsorption	Protocol / design: Validate pH, order, time and mixing for adjuvant binding	Preapproved risk-based study design; endpoint: Consistent adsorption and potency.	Planning	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0014	Antigen adsorption	Execution / boundary verification: Validate pH, order, time and mixing for adjuvant binding	Documented raw observations, calibration, relevant worst cases and defined acceptance for Consistent adsorption and potency.	Execution	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0015	Antigen adsorption	Review / lifecycle: Validate pH, order, time and mixing for adjuvant binding	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Consistent adsorption and potency.	Review	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	Medium
BTV-14-0016	Vaccine formulation	Protocol / design: Evaluate preservative, stabilizer and ionic compatibility	Preapproved risk-based study design; endpoint: Potency and stability through shelf life.	Planning	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-14-0017	Vaccine formulation	Execution / boundary verification: Evaluate preservative, stabilizer and ionic compatibility	Documented raw observations, calibration, relevant worst cases and defined acceptance for Potency and stability through shelf life.	Execution	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0018	Vaccine formulation	Review / lifecycle: Evaluate preservative, stabilizer and ionic compatibility	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Potency and stability through shelf life.	Review	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	Medium
BTV-14-0019	Multi-dose preservative	Protocol / design: Qualify effectiveness when relevant	Preapproved risk-based study design; endpoint: Microbial protection and extractables compatibility.	Planning	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0020	Multi-dose preservative	Execution / boundary verification: Qualify effectiveness when relevant	Documented raw observations, calibration, relevant worst cases and defined acceptance for Microbial protection and extractables compatibility.	Execution	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0021	Multi-dose preservative	Review / lifecycle: Qualify effectiveness when relevant	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Microbial protection and extractables compatibility.	Review	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	Medium
BTV-14-0022	Vaccine potency test	Protocol / design: Qualify species-independent assay where appropriate	Preapproved risk-based study design; endpoint: Precise and sensitive biological potency.	Planning	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0023	Vaccine potency test	Execution / boundary verification: Qualify species-independent assay where appropriate	Documented raw observations, calibration, relevant worst cases and defined acceptance for Precise and sensitive biological potency.	Execution	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0024	Vaccine potency test	Review / lifecycle: Qualify species-independent assay where appropriate	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Precise and sensitive biological potency.	Review	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	Medium
BTV-14-0025	Antigen content	Protocol / design: Characterize immunoassay linearity, accuracy and interference	Preapproved risk-based study design; endpoint: Consistent antigen concentration.	Planning	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0026	Antigen content	Execution / boundary verification: Characterize immunoassay linearity, accuracy and interference	Documented raw observations, calibration, relevant worst cases and defined acceptance for Consistent antigen concentration.	Execution	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0027	Antigen content	Review / lifecycle: Characterize immunoassay linearity, accuracy and interference	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Consistent antigen concentration.	Review	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	Medium
BTV-14-0028	Infectivity titer	Protocol / design: Validate infectious particle or focus forming assay when applicable	Preapproved risk-based study design; endpoint: Validated titer and assay controls.	Planning	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0029	Infectivity titer	Execution / boundary verification: Validate infectious particle or focus forming assay when applicable	Documented raw observations, calibration, relevant worst cases and defined acceptance for Validated titer and assay controls.	Execution	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0030	Infectivity titer	Review / lifecycle: Validate infectious particle or focus forming assay when applicable	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Validated titer and assay controls.	Review	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	Medium
BTV-14-0031	Container integrity	Protocol / design: Qualify vial/stopper and freeze/thaw transport demands	Preapproved risk-based study design; endpoint: Sterility maintained during product life.	Planning	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0032	Container integrity	Execution / boundary verification: Qualify vial/stopper and freeze/thaw transport demands	Documented raw observations, calibration, relevant worst cases and defined acceptance for Sterility maintained during product life.	Execution	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0033	Container integrity	Review / lifecycle: Qualify vial/stopper and freeze/thaw transport demands	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Sterility maintained during product life.	Review	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	Medium
BTV-14-0034	Adjuvant suspension	Protocol / design: Challenge mixing interruption and resuspension	Preapproved risk-based study design; endpoint: Uniform fill potency across batch.	Planning	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-14-0035	Adjuvant suspension	Execution / boundary verification: Challenge mixing interruption and resuspension	Documented raw observations, calibration, relevant worst cases and defined acceptance for Uniform fill potency across batch.	Execution	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0036	Adjuvant suspension	Review / lifecycle: Challenge mixing interruption and resuspension	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Uniform fill potency across batch.	Review	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	Medium
BTV-14-0037	Antigen inactivation reactor	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Chemical concentration, temperature, mixing to product impact on Complete antigen inactivation and preserved epitope.	URS / DQ	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0038	Antigen inactivation reactor	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Antigen inactivation reactor.	IQ	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	Medium
BTV-14-0039	Antigen inactivation reactor	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Chemical concentration, temperature, mixing; compare challenge outputs to predefined Complete antigen inactivation and preserved epitope acceptance.	OQ	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0040	Antigen inactivation reactor	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Complete antigen inactivation and preserved epitope.	OQ	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0041	Antigen inactivation reactor	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Complete antigen inactivation and preserved epitope at relevant Chemical concentration, temperature, mixing; sampling scientifically justified.	PQ	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0042	Antigen inactivation reactor	Continued verification / risk-based requalification trigger evaluation	Trend Chemical concentration, temperature, mixing and impact on Complete antigen inactivation and preserved epitope; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	Medium
BTV-14-0043	Adjuvant blending tank	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Agitation, pH, homogenization to product impact on Uniform antigen adsorption.	URS / DQ	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0044	Adjuvant blending tank	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Adjuvant blending tank.	IQ	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	Medium
BTV-14-0045	Adjuvant blending tank	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Agitation, pH, homogenization; compare challenge outputs to predefined Uniform antigen adsorption acceptance.	OQ	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0046	Adjuvant blending tank	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Uniform antigen adsorption.	OQ	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0047	Adjuvant blending tank	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Uniform antigen adsorption at relevant Agitation, pH, homogenization; sampling scientifically justified.	PQ	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0048	Adjuvant blending tank	Continued verification / risk-based requalification trigger evaluation	Trend Agitation, pH, homogenization and impact on Uniform antigen adsorption; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	Medium
BTV-14-0049	Vaccine aseptic fill line	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Fill precision, stopper position, sterility to product impact on Consistent sterile vaccine dose.	URS / DQ	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0050	Vaccine aseptic fill line	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Vaccine aseptic fill line.	IQ	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	Medium
BTV-14-0051	Vaccine aseptic fill line	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Fill precision, stopper position, sterility; compare challenge outputs to predefined Consistent sterile vaccine dose acceptance.	OQ	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0052	Vaccine aseptic fill line	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Consistent sterile vaccine dose.	OQ	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-14-0053	Vaccine aseptic fill line	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Consistent sterile vaccine dose at relevant Fill precision, stopper position, sterility; sampling scientifically justified.	PQ	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0054	Vaccine aseptic fill line	Continued verification / risk-based requalification trigger evaluation	Trend Fill precision, stopper position, sterility and impact on Consistent sterile vaccine dose; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	Medium
BTV-14-0055	Multi-dose vial crimper	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Seal force, cap feed and CCI to product impact on Container seal integrity.	URS / DQ	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0056	Multi-dose vial crimper	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Multi-dose vial crimper.	IQ	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	Medium
BTV-14-0057	Multi-dose vial crimper	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Seal force, cap feed and CCI; compare challenge outputs to predefined Container seal integrity acceptance.	OQ	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0058	Multi-dose vial crimper	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Container seal integrity.	OQ	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0059	Multi-dose vial crimper	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Container seal integrity at relevant Seal force, cap feed and CCI; sampling scientifically justified.	PQ	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0060	Multi-dose vial crimper	Continued verification / risk-based requalification trigger evaluation	Trend Seal force, cap feed and CCI and impact on Container seal integrity; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	Medium
BTV-14-0061	Antigen potency reader	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Assay calibration, plate effects and controls to product impact on Defensible potency results.	URS / DQ	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0062	Antigen potency reader	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Antigen potency reader.	IQ	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	Medium
BTV-14-0063	Antigen potency reader	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Assay calibration, plate effects and controls; compare challenge outputs to predefined Defensible potency results acceptance.	OQ	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0064	Antigen potency reader	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Defensible potency results.	OQ	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0065	Antigen potency reader	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Defensible potency results at relevant Assay calibration, plate effects and controls; sampling scientifically justified.	PQ	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0066	Antigen potency reader	Continued verification / risk-based requalification trigger evaluation	Trend Assay calibration, plate effects and controls and impact on Defensible potency results; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	Medium
BTV-14-0067	Inactivation sampling manifold	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Aseptic sampling and sample trace to product impact on Representative inactivation assessment.	URS / DQ	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0068	Inactivation sampling manifold	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Inactivation sampling manifold.	IQ	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	Medium
BTV-14-0069	Inactivation sampling manifold	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Aseptic sampling and sample trace; compare challenge outputs to predefined Representative inactivation assessment acceptance.	OQ	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0070	Inactivation sampling manifold	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Representative inactivation assessment.	OQ	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-14-0071	Inactivation sampling manifold	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Representative inactivation assessment at relevant Aseptic sampling and sample trace; sampling scientifically justified.	PQ	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	High
BTV-14-0072	Inactivation sampling manifold	Continued verification / risk-based requalification trigger evaluation	Trend Aseptic sampling and sample trace and impact on Representative inactivation assessment; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Recombinant, inactivated, protein subunit, viral vaccine	B03 B04 B05 B13 B14 B25	Medium

15 PLASMA-DERIVED PRODUCTS AND BLOOD FRACTIONATION

72 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-15-0001	Donor/plasma traceability	Protocol / design: Validate lot pool genealogy, donor eligibility and test linkage	Preapproved risk-based study design; endpoint: Complete viral safety traceability.	Planning	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0002	Donor/plasma traceability	Execution / boundary verification: Validate lot pool genealogy, donor eligibility and test linkage	Documented raw observations, calibration, relevant worst cases and defined acceptance for Complete viral safety traceability.	Execution	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0003	Donor/plasma traceability	Review / lifecycle: Validate lot pool genealogy, donor eligibility and test linkage	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Complete viral safety traceability.	Review	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	Medium
BTV-15-0004	Plasma thawing	Protocol / design: Qualify time, temperature and thaw gradients	Preapproved risk-based study design; endpoint: Stable clotting factors and proteins.	Planning	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0005	Plasma thawing	Execution / boundary verification: Qualify time, temperature and thaw gradients	Documented raw observations, calibration, relevant worst cases and defined acceptance for Stable clotting factors and proteins.	Execution	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0006	Plasma thawing	Review / lifecycle: Qualify time, temperature and thaw gradients	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Stable clotting factors and proteins.	Review	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	Medium
BTV-15-0007	Ethanol fractionation	Protocol / design: Characterize pH, ionic strength, ethanol and subzero control	Preapproved risk-based study design; endpoint: Protein precipitation selectivity and recovery.	Planning	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0008	Ethanol fractionation	Execution / boundary verification: Characterize pH, ionic strength, ethanol and subzero control	Documented raw observations, calibration, relevant worst cases and defined acceptance for Protein precipitation selectivity and recovery.	Execution	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0009	Ethanol fractionation	Review / lifecycle: Characterize pH, ionic strength, ethanol and subzero control	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Protein precipitation selectivity and recovery.	Review	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	Medium
BTV-15-0010	Depth filtration fractionation	Protocol / design: Validate solids handling, flow and pressure limits	Preapproved risk-based study design; endpoint: Desired fraction purity and yield.	Planning	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0011	Depth filtration fractionation	Execution / boundary verification: Validate solids handling, flow and pressure limits	Documented raw observations, calibration, relevant worst cases and defined acceptance for Desired fraction purity and yield.	Execution	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0012	Depth filtration fractionation	Review / lifecycle: Validate solids handling, flow and pressure limits	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Desired fraction purity and yield.	Review	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	Medium
BTV-15-0013	S/D inactivation	Protocol / design: Validate solvent/detergent level, exposure and downstream removal	Preapproved risk-based study design; endpoint: Product-specific viral safety evidence.	Planning	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0014	S/D inactivation	Execution / boundary verification: Validate solvent/detergent level, exposure and downstream removal	Documented raw observations, calibration, relevant worst cases and defined acceptance for Product-specific viral safety evidence.	Execution	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0015	S/D inactivation	Review / lifecycle: Validate solvent/detergent level, exposure and downstream removal	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Product-specific viral safety evidence.	Review	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	Medium
BTV-15-0016	Pasteurization	Protocol / design: Prove time/temperature profile and stabilizer control	Preapproved risk-based study design; endpoint: Appropriate viral inactivation and protein quality.	Planning	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-15-0017	Pasteurization	Execution / boundary verification: Prove time/temperature profile and stabilizer control	Documented raw observations, calibration, relevant worst cases and defined acceptance for Appropriate viral inactivation and protein quality.	Execution	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0018	Pasteurization	Review / lifecycle: Prove time/temperature profile and stabilizer control	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Appropriate viral inactivation and protein quality.	Review	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	Medium
BTV-15-0019	Nanofiltration viral removal	Protocol / design: Qualify capacity and virus-retention when applicable	Preapproved risk-based study design; endpoint: Orthogonal viral safety clearance.	Planning	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0020	Nanofiltration viral removal	Execution / boundary verification: Qualify capacity and virus-retention when applicable	Documented raw observations, calibration, relevant worst cases and defined acceptance for Orthogonal viral safety clearance.	Execution	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0021	Nanofiltration viral removal	Review / lifecycle: Qualify capacity and virus-retention when applicable	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Orthogonal viral safety clearance.	Review	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	Medium
BTV-15-0022	Immunoglobulin aggregates	Protocol / design: Validate process hold and mixing controls	Preapproved risk-based study design; endpoint: Low aggregate/fragment content.	Planning	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0023	Immunoglobulin aggregates	Execution / boundary verification: Validate process hold and mixing controls	Documented raw observations, calibration, relevant worst cases and defined acceptance for Low aggregate/fragment content.	Execution	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0024	Immunoglobulin aggregates	Review / lifecycle: Validate process hold and mixing controls	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Low aggregate/fragment content.	Review	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	Medium
BTV-15-0025	Plasma shipping	Protocol / design: Validate cold chain, thaw duration and traceability	Preapproved risk-based study design; endpoint: Maintained starting material quality.	Planning	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0026	Plasma shipping	Execution / boundary verification: Validate cold chain, thaw duration and traceability	Documented raw observations, calibration, relevant worst cases and defined acceptance for Maintained starting material quality.	Execution	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0027	Plasma shipping	Review / lifecycle: Validate cold chain, thaw duration and traceability	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Maintained starting material quality.	Review	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	Medium
BTV-15-0028	Fraction hold time	Protocol / design: Qualify temperature and microbial constraints	Preapproved risk-based study design; endpoint: No product degradation or contamination.	Planning	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0029	Fraction hold time	Execution / boundary verification: Qualify temperature and microbial constraints	Documented raw observations, calibration, relevant worst cases and defined acceptance for No product degradation or contamination.	Execution	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0030	Fraction hold time	Review / lifecycle: Qualify temperature and microbial constraints	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No product degradation or contamination.	Review	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	Medium
BTV-15-0031	Plasma pooling	Protocol / design: Verify sample identity, test release and pooling recipe	Preapproved risk-based study design; endpoint: No untested pool entry.	Planning	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0032	Plasma pooling	Execution / boundary verification: Verify sample identity, test release and pooling recipe	Documented raw observations, calibration, relevant worst cases and defined acceptance for No untested pool entry.	Execution	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0033	Plasma pooling	Review / lifecycle: Verify sample identity, test release and pooling recipe	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No untested pool entry.	Review	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	Medium
BTV-15-0034	Residual ethanol	Protocol / design: Validate residual assay and stripping conditions	Preapproved risk-based study design; endpoint: Specification compliance.	Planning	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-15-0035	Residual ethanol	Execution / boundary verification: Validate residual assay and stripping conditions	Documented raw observations, calibration, relevant worst cases and defined acceptance for Specification compliance.	Execution	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0036	Residual ethanol	Review / lifecycle: Validate residual assay and stripping conditions	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Specification compliance.	Review	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	Medium
BTV-15-0037	Plasma thawing cabinet	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Temperature mapping, load configuration to product impact on Controlled plasma protein quality.	URS / DQ	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0038	Plasma thawing cabinet	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Plasma thawing cabinet.	IQ	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	Medium
BTV-15-0039	Plasma thawing cabinet	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Temperature mapping, load configuration; compare challenge outputs to predefined Controlled plasma protein quality acceptance.	OQ	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0040	Plasma thawing cabinet	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Controlled plasma protein quality.	OQ	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0041	Plasma thawing cabinet	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Controlled plasma protein quality at relevant Temperature mapping, load configuration; sampling scientifically justified.	PQ	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0042	Plasma thawing cabinet	Continued verification / risk-based requalification trigger evaluation	Trend Temperature mapping, load configuration and impact on Controlled plasma protein quality; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	Medium
BTV-15-0043	Ethanol fractionation vessel	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Temperature, pH, ethanol concentration to product impact on Fraction selectivity and process reproducibility.	URS / DQ	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0044	Ethanol fractionation vessel	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Ethanol fractionation vessel.	IQ	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	Medium
BTV-15-0045	Ethanol fractionation vessel	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Temperature, pH, ethanol concentration; compare challenge outputs to predefined Fraction selectivity and process reproducibility acceptance.	OQ	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0046	Ethanol fractionation vessel	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Fraction selectivity and process reproducibility.	OQ	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0047	Ethanol fractionation vessel	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Fraction selectivity and process reproducibility at relevant Temperature, pH, ethanol concentration; sampling scientifically justified.	PQ	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0048	Ethanol fractionation vessel	Continued verification / risk-based requalification trigger evaluation	Trend Temperature, pH, ethanol concentration and impact on Fraction selectivity and process reproducibility; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	Medium
BTV-15-0049	Plasma centrifuge	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Bowl speed, low temperature and throughput to product impact on Protein fraction recovery.	URS / DQ	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0050	Plasma centrifuge	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Plasma centrifuge.	IQ	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	Medium
BTV-15-0051	Plasma centrifuge	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Bowl speed, low temperature and throughput; compare challenge outputs to predefined Protein fraction recovery acceptance.	OQ	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0052	Plasma centrifuge	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Protein fraction recovery.	OQ	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-15-0053	Plasma centrifuge	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Protein fraction recovery at relevant Bowl speed, low temperature and throughput; sampling scientifically justified.	PQ	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0054	Plasma centrifuge	Continued verification / risk-based requalification trigger evaluation	Trend Bowl speed, low temperature and throughput and impact on Protein fraction recovery; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	Medium
BTV-15-0055	Plasma fraction filtration	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Pressure, flux and solids load to product impact on Fraction clarification.	URS / DQ	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0056	Plasma fraction filtration	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Plasma fraction filtration.	IQ	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	Medium
BTV-15-0057	Plasma fraction filtration	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Pressure, flux and solids load; compare challenge outputs to predefined Fraction clarification acceptance.	OQ	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0058	Plasma fraction filtration	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Fraction clarification.	OQ	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0059	Plasma fraction filtration	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Fraction clarification at relevant Pressure, flux and solids load; sampling scientifically justified.	PQ	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0060	Plasma fraction filtration	Continued verification / risk-based requalification trigger evaluation	Trend Pressure, flux and solids load and impact on Fraction clarification; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	Medium
BTV-15-0061	Solvent-detergent treatment tank	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Contact time, concentration and mixing to product impact on Viral inactivation where applicable.	URS / DQ	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0062	Solvent-detergent treatment tank	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Solvent-detergent treatment tank.	IQ	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	Medium
BTV-15-0063	Solvent-detergent treatment tank	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Contact time, concentration and mixing; compare challenge outputs to predefined Viral inactivation where applicable acceptance.	OQ	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0064	Solvent-detergent treatment tank	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Viral inactivation where applicable.	OQ	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0065	Solvent-detergent treatment tank	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Viral inactivation where applicable at relevant Contact time, concentration and mixing; sampling scientifically justified.	PQ	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0066	Solvent-detergent treatment tank	Continued verification / risk-based requalification trigger evaluation	Trend Contact time, concentration and mixing and impact on Viral inactivation where applicable; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	Medium
BTV-15-0067	Pasteurization vessel	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Temperature uniformity and contact duration to product impact on Defined thermal viral treatment.	URS / DQ	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0068	Pasteurization vessel	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Pasteurization vessel.	IQ	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	Medium
BTV-15-0069	Pasteurization vessel	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Temperature uniformity and contact duration; compare challenge outputs to predefined Defined thermal viral treatment acceptance.	OQ	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0070	Pasteurization vessel	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Defined thermal viral treatment.	OQ	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-15-0071	Pasteurization vessel	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Defined thermal viral treatment at relevant Temperature uniformity and contact duration; sampling scientifically justified.	PQ	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	High
BTV-15-0072	Pasteurization vessel	Continued verification / risk-based requalification trigger evaluation	Trend Temperature uniformity and contact duration and impact on Defined thermal viral treatment; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Plasma proteins, immunoglobulins, albumin; applicable scope	B03 B05 B07 B14 B20	Medium

16 CELL THERAPY, GENE THERAPY, VIRAL VECTORS & ATMPS

93 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-16-0001	ATMP regulatory boundary	Protocol / design: Distinguish EU Part IV and product-specific national rules	Preapproved risk-based study design; endpoint: Applicable classification and manufacturer obligations.	Planning	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0002	ATMP regulatory boundary	Execution / boundary verification: Distinguish EU Part IV and product-specific national rules	Documented raw observations, calibration, relevant worst cases and defined acceptance for Applicable classification and manufacturer obligations.	Execution	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0003	ATMP regulatory boundary	Review / lifecycle: Distinguish EU Part IV and product-specific national rules	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Applicable classification and manufacturer obligations.	Review	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	Medium
BTV-16-0004	Chain of identity / custody	Protocol / design: Validate patient/donor identifiers, labels, eBR interfaces	Preapproved risk-based study design; endpoint: No patient-to-patient or lot mix-up.	Planning	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0005	Chain of identity / custody	Execution / boundary verification: Validate patient/donor identifiers, labels, eBR interfaces	Documented raw observations, calibration, relevant worst cases and defined acceptance for No patient-to-patient or lot mix-up.	Execution	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0006	Chain of identity / custody	Review / lifecycle: Validate patient/donor identifiers, labels, eBR interfaces	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No patient-to-patient or lot mix-up.	Review	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	Medium
BTV-16-0007	Cell isolation	Protocol / design: Qualify sorting/separation yield and cell phenotype	Preapproved risk-based study design; endpoint: Identity and viability retention.	Planning	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0008	Cell isolation	Execution / boundary verification: Qualify sorting/separation yield and cell phenotype	Documented raw observations, calibration, relevant worst cases and defined acceptance for Identity and viability retention.	Execution	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0009	Cell isolation	Review / lifecycle: Qualify sorting/separation yield and cell phenotype	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Identity and viability retention.	Review	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	Medium
BTV-16-0010	Cell activation / expansion	Protocol / design: Establish culture duration, cytokine dosing and cell differentiation	Preapproved risk-based study design; endpoint: Critical cell phenotype and potency.	Planning	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0011	Cell activation / expansion	Execution / boundary verification: Establish culture duration, cytokine dosing and cell differentiation	Documented raw observations, calibration, relevant worst cases and defined acceptance for Critical cell phenotype and potency.	Execution	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0012	Cell activation / expansion	Review / lifecycle: Establish culture duration, cytokine dosing and cell differentiation	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Critical cell phenotype and potency.	Review	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	Medium
BTV-16-0013	Transduction/transfection	Protocol / design: Validate vector MOI, incubation and transfer controls	Preapproved risk-based study design; endpoint: Transduction efficiency, identity and viability.	Planning	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0014	Transduction/transfection	Execution / boundary verification: Validate vector MOI, incubation and transfer controls	Documented raw observations, calibration, relevant worst cases and defined acceptance for Transduction efficiency, identity and viability.	Execution	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0015	Transduction/transfection	Review / lifecycle: Validate vector MOI, incubation and transfer controls	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Transduction efficiency, identity and viability.	Review	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	Medium
BTV-16-0016	Vector residual impurities	Protocol / design: Characterize residual host cell DNA, proteins and process aids	Preapproved risk-based study design; endpoint: Safety-relevant impurity specifications.	Planning	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-16-0017	Vector residual impurities	Execution / boundary verification: Characterize residual host cell DNA, proteins and process aids	Documented raw observations, calibration, relevant worst cases and defined acceptance for Safety-relevant impurity specifications.	Execution	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0018	Vector residual impurities	Review / lifecycle: Characterize residual host cell DNA, proteins and process aids	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Safety-relevant impurity specifications.	Review	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	Medium
BTV-16-0019	Replication competent virus	Protocol / design: Validate test sensitivity where required	Preapproved risk-based study design; endpoint: Contamination control and negative criteria.	Planning	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0020	Replication competent virus	Execution / boundary verification: Validate test sensitivity where required	Documented raw observations, calibration, relevant worst cases and defined acceptance for Contamination control and negative criteria.	Execution	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0021	Replication competent virus	Review / lifecycle: Validate test sensitivity where required	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Contamination control and negative criteria.	Review	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	Medium
BTV-16-0022	AAV capsid quality	Protocol / design: Qualify full/empty ratio, titer and aggregation tests	Preapproved risk-based study design; endpoint: Relevant capsid and genome CQA reproducibility.	Planning	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0023	AAV capsid quality	Execution / boundary verification: Qualify full/empty ratio, titer and aggregation tests	Documented raw observations, calibration, relevant worst cases and defined acceptance for Relevant capsid and genome CQA reproducibility.	Execution	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0024	AAV capsid quality	Review / lifecycle: Qualify full/empty ratio, titer and aggregation tests	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Relevant capsid and genome CQA reproducibility.	Review	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	Medium
BTV-16-0025	Potency cell assay	Protocol / design: Establish biological response linked to mechanism of action	Preapproved risk-based study design; endpoint: Reliable lot-to-lot potency.	Planning	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0026	Potency cell assay	Execution / boundary verification: Establish biological response linked to mechanism of action	Documented raw observations, calibration, relevant worst cases and defined acceptance for Reliable lot-to-lot potency.	Execution	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0027	Potency cell assay	Review / lifecycle: Establish biological response linked to mechanism of action	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Reliable lot-to-lot potency.	Review	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	Medium
BTV-16-0028	Cryopreservation	Protocol / design: Validate cryoprotectant, cooling and thaw recovery	Preapproved risk-based study design; endpoint: Viability, phenotype and post-thaw potency.	Planning	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0029	Cryopreservation	Execution / boundary verification: Validate cryoprotectant, cooling and thaw recovery	Documented raw observations, calibration, relevant worst cases and defined acceptance for Viability, phenotype and post-thaw potency.	Execution	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0030	Cryopreservation	Review / lifecycle: Validate cryoprotectant, cooling and thaw recovery	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Viability, phenotype and post-thaw potency.	Review	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	Medium
BTV-16-0031	Closed process integrity	Protocol / design: Validate tubing, bags, sterile connectors and deviations	Preapproved risk-based study design; endpoint: Aseptic product pathway protection.	Planning	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0032	Closed process integrity	Execution / boundary verification: Validate tubing, bags, sterile connectors and deviations	Documented raw observations, calibration, relevant worst cases and defined acceptance for Aseptic product pathway protection.	Execution	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0033	Closed process integrity	Review / lifecycle: Validate tubing, bags, sterile connectors and deviations	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Aseptic product pathway protection.	Review	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	Medium
BTV-16-0034	Small lot sampling	Protocol / design: Justify destructive test and release-on-time constraints	Preapproved risk-based study design; endpoint: Risk-based sampling for patient-specific products.	Planning	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-16-0035	Small lot sampling	Execution / boundary verification: Justify destructive test and release-on-time constraints	Documented raw observations, calibration, relevant worst cases and defined acceptance for Risk-based sampling for patient-specific products.	Execution	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0036	Small lot sampling	Review / lifecycle: Justify destructive test and release-on-time constraints	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Risk-based sampling for patient-specific products.	Review	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	Medium
BTV-16-0037	Shipment on dry shipper	Protocol / design: Validate nitrogen vapor shipper load and lane	Preapproved risk-based study design; endpoint: Product identity and controlled cryogenic temperature.	Planning	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0038	Shipment on dry shipper	Execution / boundary verification: Validate nitrogen vapor shipper load and lane	Documented raw observations, calibration, relevant worst cases and defined acceptance for Product identity and controlled cryogenic temperature.	Execution	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0039	Shipment on dry shipper	Review / lifecycle: Validate nitrogen vapor shipper load and lane	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Product identity and controlled cryogenic temperature.	Review	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	Medium
BTV-16-0040	Starting material variability	Protocol / design: Define donor variability and process comparability strategy	Preapproved risk-based study design; endpoint: Controlled clinical-product lot quality.	Planning	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0041	Starting material variability	Execution / boundary verification: Define donor variability and process comparability strategy	Documented raw observations, calibration, relevant worst cases and defined acceptance for Controlled clinical-product lot quality.	Execution	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0042	Starting material variability	Review / lifecycle: Define donor variability and process comparability strategy	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Controlled clinical-product lot quality.	Review	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	Medium
BTV-16-0043	Viral vector inactivation exception	Protocol / design: Do not assume removal/inactivation of intended vector is allowable	Preapproved risk-based study design; endpoint: Product-specific adventitious agent controls and biosafety.	Planning	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0044	Viral vector inactivation exception	Execution / boundary verification: Do not assume removal/inactivation of intended vector is allowable	Documented raw observations, calibration, relevant worst cases and defined acceptance for Product-specific adventitious agent controls and biosafety.	Execution	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0045	Viral vector inactivation exception	Review / lifecycle: Do not assume removal/inactivation of intended vector is allowable	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Product-specific adventitious agent controls and biosafety.	Review	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	Medium
BTV-16-0046	Cell processing isolator	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Airflow, pressure, glove integrity, decontamination to product impact on Aseptic closed or controlled processing.	URS / DQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0047	Cell processing isolator	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Cell processing isolator.	IQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	Medium
BTV-16-0048	Cell processing isolator	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Airflow, pressure, glove integrity, decontamination; compare challenge outputs to predefined Aseptic closed or controlled processing acceptance.	OQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0049	Cell processing isolator	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Aseptic closed or controlled processing.	OQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0050	Cell processing isolator	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Aseptic closed or controlled processing at relevant Airflow, pressure, glove integrity, decontamination; sampling scientifically justified.	PQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0051	Cell processing isolator	Continued verification / risk-based requalification trigger evaluation	Trend Airflow, pressure, glove integrity, decontamination and impact on Aseptic closed or controlled processing; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	Medium
BTV-16-0052	Automated cell washer	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace G-force, wash efficiency, recovery to product impact on Cell viability and purity.	URS / DQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-16-0053	Automated cell washer	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Automated cell washer.	IQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	Medium
BTV-16-0054	Automated cell washer	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of G-force, wash efficiency, recovery; compare challenge outputs to predefined Cell viability and purity acceptance.	OQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0055	Automated cell washer	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Cell viability and purity.	OQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0056	Automated cell washer	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Cell viability and purity at relevant G-force, wash efficiency, recovery; sampling scientifically justified.	PQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0057	Automated cell washer	Continued verification / risk-based requalification trigger evaluation	Trend G-force, wash efficiency, recovery and impact on Cell viability and purity; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	Medium
BTV-16-0058	Cell selection sorter	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Marker gating, bead separation, carryover to product impact on Target-cell identity and recovery.	URS / DQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0059	Cell selection sorter	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Cell selection sorter.	IQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	Medium
BTV-16-0060	Cell selection sorter	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Marker gating, bead separation, carryover; compare challenge outputs to predefined Target-cell identity and recovery acceptance.	OQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0061	Cell selection sorter	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Target-cell identity and recovery.	OQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0062	Cell selection sorter	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Target-cell identity and recovery at relevant Marker gating, bead separation, carryover; sampling scientifically justified.	PQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0063	Cell selection sorter	Continued verification / risk-based requalification trigger evaluation	Trend Marker gating, bead separation, carryover and impact on Target-cell identity and recovery; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	Medium
BTV-16-0064	Closed cell expansion instrument	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Culture control and lot traceability to product impact on Consistent phenotype and viability.	URS / DQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0065	Closed cell expansion instrument	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Closed cell expansion instrument.	IQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	Medium
BTV-16-0066	Closed cell expansion instrument	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Culture control and lot traceability; compare challenge outputs to predefined Consistent phenotype and viability acceptance.	OQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0067	Closed cell expansion instrument	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Consistent phenotype and viability.	OQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0068	Closed cell expansion instrument	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Consistent phenotype and viability at relevant Culture control and lot traceability; sampling scientifically justified.	PQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0069	Closed cell expansion instrument	Continued verification / risk-based requalification trigger evaluation	Trend Culture control and lot traceability and impact on Consistent phenotype and viability; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	Medium
BTV-16-0070	Cell cryopreservation freezer	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Cooling profile, vials/bag load to product impact on Post-thaw potency and viability.	URS / DQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-16-0071	Cell cryopreservation freezer	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Cell cryopreservation freezer.	IQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	Medium
BTV-16-0072	Cell cryopreservation freezer	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Cooling profile, vials/bag load; compare challenge outputs to predefined Post-thaw potency and viability acceptance.	OQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0073	Cell cryopreservation freezer	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Post-thaw potency and viability.	OQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0074	Cell cryopreservation freezer	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Post-thaw potency and viability at relevant Cooling profile, vials/bag load; sampling scientifically justified.	PQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0075	Cell cryopreservation freezer	Continued verification / risk-based requalification trigger evaluation	Trend Cooling profile, vials/bag load and impact on Post-thaw potency and viability; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	Medium
BTV-16-0076	AAV vector purification skid	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Chromatography conditions and membrane retention to product impact on Viral vector identity and potency.	URS / DQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0077	AAV vector purification skid	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for AAV vector purification skid.	IQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	Medium
BTV-16-0078	AAV vector purification skid	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Chromatography conditions and membrane retention; compare challenge outputs to predefined Viral vector identity and potency acceptance.	OQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0079	AAV vector purification skid	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Viral vector identity and potency.	OQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0080	AAV vector purification skid	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Viral vector identity and potency at relevant Chromatography conditions and membrane retention; sampling scientifically justified.	PQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0081	AAV vector purification skid	Continued verification / risk-based requalification trigger evaluation	Trend Chromatography conditions and membrane retention and impact on Viral vector identity and potency; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	Medium
BTV-16-0082	Viral vector fill set	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Connection, flow, adsorption, shear to product impact on Recovered functional vector and sterility.	URS / DQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0083	Viral vector fill set	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Viral vector fill set.	IQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	Medium
BTV-16-0084	Viral vector fill set	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Connection, flow, adsorption, shear; compare challenge outputs to predefined Recovered functional vector and sterility acceptance.	OQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0085	Viral vector fill set	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Recovered functional vector and sterility.	OQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0086	Viral vector fill set	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Recovered functional vector and sterility at relevant Connection, flow, adsorption, shear; sampling scientifically justified.	PQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0087	Viral vector fill set	Continued verification / risk-based requalification trigger evaluation	Trend Connection, flow, adsorption, shear and impact on Recovered functional vector and sterility; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	Medium
BTV-16-0088	Cryogenic dry shipper	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Temperature mapping, hold time, shipping loads to product impact on Intact product and traceability.	URS / DQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-16-0089	Cryogenic dry shipper	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Cryogenic dry shipper.	IQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	Medium
BTV-16-0090	Cryogenic dry shipper	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Temperature mapping, hold time, shipping loads; compare challenge outputs to predefined Intact product and traceability acceptance.	OQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0091	Cryogenic dry shipper	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Intact product and traceability.	OQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0092	Cryogenic dry shipper	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Intact product and traceability at relevant Temperature mapping, hold time, shipping loads; sampling scientifically justified.	PQ	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	High
BTV-16-0093	Cryogenic dry shipper	Continued verification / risk-based requalification trigger evaluation	Trend Temperature mapping, hold time, shipping loads and impact on Intact product and traceability; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	ATMPs, CAR-T, AAV, lentiviral vectors (conditional)	B04 B05 B07 B22 B25	Medium

17 BIOSIMILARS, COMPARABILITY & TECHNOLOGY TRANSFERS

66 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-17-0001	Reference product characterization	Protocol / design: Establish qualified lots and appropriate reference storage	Preapproved risk-based study design; endpoint: Valid comparison across quality attribute distributions.	Planning	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0002	Reference product characterization	Execution / boundary verification: Establish qualified lots and appropriate reference storage	Documented raw observations, calibration, relevant worst cases and defined acceptance for Valid comparison across quality attribute distributions.	Execution	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0003	Reference product characterization	Review / lifecycle: Establish qualified lots and appropriate reference storage	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Valid comparison across quality attribute distributions.	Review	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	Medium
BTV-17-0004	Analytical comparability plan	Protocol / design: Select critical functional/structural methods and statistics	Preapproved risk-based study design; endpoint: Meaningful similarity and acceptance framework.	Planning	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0005	Analytical comparability plan	Execution / boundary verification: Select critical functional/structural methods and statistics	Documented raw observations, calibration, relevant worst cases and defined acceptance for Meaningful similarity and acceptance framework.	Execution	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0006	Analytical comparability plan	Review / lifecycle: Select critical functional/structural methods and statistics	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Meaningful similarity and acceptance framework.	Review	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	Medium
BTV-17-0007	Glycan comparability	Protocol / design: Verify glycosylation structures and relative distributions	Preapproved risk-based study design; endpoint: Glycan species/charge profile across process change.	Planning	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0008	Glycan comparability	Execution / boundary verification: Verify glycosylation structures and relative distributions	Documented raw observations, calibration, relevant worst cases and defined acceptance for Glycan species/charge profile across process change.	Execution	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0009	Glycan comparability	Review / lifecycle: Verify glycosylation structures and relative distributions	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Glycan species/charge profile across process change.	Review	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	Medium
BTV-17-0010	Charge variants	Protocol / design: Compare deamidation, sialylation and other isoforms	Preapproved risk-based study design; endpoint: Biological and physicochemical comparability.	Planning	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0011	Charge variants	Execution / boundary verification: Compare deamidation, sialylation and other isoforms	Documented raw observations, calibration, relevant worst cases and defined acceptance for Biological and physicochemical comparability.	Execution	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0012	Charge variants	Review / lifecycle: Compare deamidation, sialylation and other isoforms	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Biological and physicochemical comparability.	Review	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	Medium
BTV-17-0013	Aggregate profile	Protocol / design: Evaluate monomer, HMW and fragments	Preapproved risk-based study design; endpoint: Comparable aggregate levels and mechanism.	Planning	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0014	Aggregate profile	Execution / boundary verification: Evaluate monomer, HMW and fragments	Documented raw observations, calibration, relevant worst cases and defined acceptance for Comparable aggregate levels and mechanism.	Execution	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0015	Aggregate profile	Review / lifecycle: Evaluate monomer, HMW and fragments	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Comparable aggregate levels and mechanism.	Review	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	Medium
BTV-17-0016	Binding affinity	Protocol / design: Qualify antigen/receptor interaction assay equivalence	Preapproved risk-based study design; endpoint: Biological activity comparability.	Planning	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0017	Binding affinity	Execution / boundary verification: Qualify antigen/receptor interaction assay equivalence	Documented raw observations, calibration, relevant worst cases and defined acceptance for Biological activity comparability.	Execution	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0018	Binding affinity	Review / lifecycle: Qualify antigen/receptor interaction assay equivalence	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Biological activity comparability.	Review	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	Medium
BTV-17-0019	Effector function	Protocol / design: Evaluate Fc receptor, ADCC, CDC as applicable	Preapproved risk-based study design; endpoint: Mechanism-related functional similarity.	Planning	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0020	Effector function	Execution / boundary verification: Evaluate Fc receptor, ADCC, CDC as applicable	Documented raw observations, calibration, relevant worst cases and defined acceptance for Mechanism-related functional similarity.	Execution	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0021	Effector function	Review / lifecycle: Evaluate Fc receptor, ADCC, CDC as applicable	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Mechanism-related functional similarity.	Review	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	Medium
BTV-17-0022	Process changes	Protocol / design: Assess resin, cell line, media, equipment and scale changes	Preapproved risk-based study design; endpoint: ICH Q5E comparability evidence.	Planning	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-17-0023	Process changes	Execution / boundary verification: Assess resin, cell line, media, equipment and scale changes	Documented raw observations, calibration, relevant worst cases and defined acceptance for ICH Q5E comparability evidence.	Execution	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0024	Process changes	Review / lifecycle: Assess resin, cell line, media, equipment and scale changes	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on ICH Q5E comparability evidence.	Review	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	Medium
BTV-17-0025	Site transfer	Protocol / design: Qualify tech transfer, gap assessments and parallel runs	Preapproved risk-based study design; endpoint: Commercially comparable output and control strategy.	Planning	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0026	Site transfer	Execution / boundary verification: Qualify tech transfer, gap assessments and parallel runs	Documented raw observations, calibration, relevant worst cases and defined acceptance for Commercially comparable output and control strategy.	Execution	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0027	Site transfer	Review / lifecycle: Qualify tech transfer, gap assessments and parallel runs	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Commercially comparable output and control strategy.	Review	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	Medium
BTV-17-0028	Scale-down model	Protocol / design: Demonstrate relevance to full scale for ranges and impurity clearance	Preapproved risk-based study design; endpoint: Validated scale-down predictions.	Planning	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0029	Scale-down model	Execution / boundary verification: Demonstrate relevance to full scale for ranges and impurity clearance	Documented raw observations, calibration, relevant worst cases and defined acceptance for Validated scale-down predictions.	Execution	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0030	Scale-down model	Review / lifecycle: Demonstrate relevance to full scale for ranges and impurity clearance	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Validated scale-down predictions.	Review	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	Medium
BTV-17-0031	Comparability batch design	Protocol / design: Justify lots, manufacturing ages and stress challenges	Preapproved risk-based study design; endpoint: Sufficient evidence of relevant similarity.	Planning	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0032	Comparability batch design	Execution / boundary verification: Justify lots, manufacturing ages and stress challenges	Documented raw observations, calibration, relevant worst cases and defined acceptance for Sufficient evidence of relevant similarity.	Execution	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0033	Comparability batch design	Review / lifecycle: Justify lots, manufacturing ages and stress challenges	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Sufficient evidence of relevant similarity.	Review	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	Medium
BTV-17-0034	Stability comparability	Protocol / design: Compare degradants, thermal/light/force stability	Preapproved risk-based study design; endpoint: No adverse stability change.	Planning	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0035	Stability comparability	Execution / boundary verification: Compare degradants, thermal/light/force stability	Documented raw observations, calibration, relevant worst cases and defined acceptance for No adverse stability change.	Execution	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0036	Stability comparability	Review / lifecycle: Compare degradants, thermal/light/force stability	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No adverse stability change.	Review	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	Medium
BTV-17-0037	Analytical bridging	Protocol / design: Evaluate assay method and reference-standard changes	Preapproved risk-based study design; endpoint: Equivalent historical vs post-change results.	Planning	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0038	Analytical bridging	Execution / boundary verification: Evaluate assay method and reference-standard changes	Documented raw observations, calibration, relevant worst cases and defined acceptance for Equivalent historical vs post-change results.	Execution	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0039	Analytical bridging	Review / lifecycle: Evaluate assay method and reference-standard changes	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Equivalent historical vs post-change results.	Review	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	Medium
BTV-17-0040	Change filing	Protocol / design: Assess jurisdictional variation / prior approval before implementing	Preapproved risk-based study design; endpoint: Approved regulatory change route.	Planning	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0041	Change filing	Execution / boundary verification: Assess jurisdictional variation / prior approval before implementing	Documented raw observations, calibration, relevant worst cases and defined acceptance for Approved regulatory change route.	Execution	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0042	Change filing	Review / lifecycle: Assess jurisdictional variation / prior approval before implementing	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Approved regulatory change route.	Review	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	Medium
BTV-17-0043	Process development bioreactor	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Scale-down kLa, mixing, CO2 and cell health to product impact on Representative process CQA response.	URS / DQ	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0044	Process development bioreactor	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Process development bioreactor.	IQ	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	Medium
BTV-17-0045	Process development bioreactor	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Scale-down kLa, mixing, CO2 and cell health; compare challenge outputs to predefined Representative process CQA response acceptance.	OQ	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-17-0046	Process development bioreactor	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Representative process CQA response.	OQ	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0047	Process development bioreactor	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Representative process CQA response at relevant Scale-down kLa, mixing, CO2 and cell health; sampling scientifically justified.	PQ	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0048	Process development bioreactor	Continued verification / risk-based requalification trigger evaluation	Trend Scale-down kLa, mixing, CO2 and cell health and impact on Representative process CQA response; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	Medium
BTV-17-0049	Automated micro-bioreactor system	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Control loops and volume effects to product impact on Defensible design space and scale-down model.	URS / DQ	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0050	Automated micro-bioreactor system	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Automated micro-bioreactor system.	IQ	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	Medium
BTV-17-0051	Automated micro-bioreactor system	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Control loops and volume effects; compare challenge outputs to predefined Defensible design space and scale-down model acceptance.	OQ	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0052	Automated micro-bioreactor system	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Defensible design space and scale-down model.	OQ	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0053	Automated micro-bioreactor system	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Defensible design space and scale-down model at relevant Control loops and volume effects; sampling scientifically justified.	PQ	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0054	Automated micro-bioreactor system	Continued verification / risk-based requalification trigger evaluation	Trend Control loops and volume effects and impact on Defensible design space and scale-down model; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	Medium
BTV-17-0055	Protein characterization LC-MS	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Mass accuracy, digestion recovery and suitability to product impact on Structural comparability.	URS / DQ	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0056	Protein characterization LC-MS	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Protein characterization LC-MS.	IQ	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	Medium
BTV-17-0057	Protein characterization LC-MS	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Mass accuracy, digestion recovery and suitability; compare challenge outputs to predefined Structural comparability acceptance.	OQ	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0058	Protein characterization LC-MS	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Structural comparability.	OQ	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0059	Protein characterization LC-MS	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Structural comparability at relevant Mass accuracy, digestion recovery and suitability; sampling scientifically justified.	PQ	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0060	Protein characterization LC-MS	Continued verification / risk-based requalification trigger evaluation	Trend Mass accuracy, digestion recovery and suitability and impact on Structural comparability; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	Medium
BTV-17-0061	Biophysical stability platform	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Temperature, concentration and sample response to product impact on Comparable protein folding/aggregation response.	URS / DQ	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0062	Biophysical stability platform	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Biophysical stability platform.	IQ	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	Medium
BTV-17-0063	Biophysical stability platform	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Temperature, concentration and sample response; compare challenge outputs to predefined Comparable protein folding/aggregation response acceptance.	OQ	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0064	Biophysical stability platform	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Comparable protein folding/aggregation response.	OQ	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High
BTV-17-0065	Biophysical stability platform	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Comparable protein folding/aggregation response at relevant Temperature, concentration and sample response; sampling scientifically justified.	PQ	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-17-0066	Biophysical stability platform	Continued verification / risk-based requalification trigger evaluation	Trend Temperature, concentration and sample response and impact on Comparable protein folding/aggregation response; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biosimilars, post-change comparability, site transfer	B08 B09 B10 B11 B12 B16	Medium

18 CLEANROOMS, FACILITY LAYOUT, HVAC & AHUS

102 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-18-0001	Facility zoning	Protocol / design: Validate segregation between live organism, viral vector and sterile operations	Preapproved risk-based study design; endpoint: Controlled flows and cross-contamination protection.	Planning	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0002	Facility zoning	Execution / boundary verification: Validate segregation between live organism, viral vector and sterile operations	Documented raw observations, calibration, relevant worst cases and defined acceptance for Controlled flows and cross-contamination protection.	Execution	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0003	Facility zoning	Review / lifecycle: Validate segregation between live organism, viral vector and sterile operations	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Controlled flows and cross-contamination protection.	Review	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	Medium
BTV-18-0004	Air classification	Protocol / design: Qualify appropriate classes / grades for actual aseptic steps	Preapproved risk-based study design; endpoint: Particle classification at rest/in operation where required.	Planning	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0005	Air classification	Execution / boundary verification: Qualify appropriate classes / grades for actual aseptic steps	Documented raw observations, calibration, relevant worst cases and defined acceptance for Particle classification at rest/in operation where required.	Execution	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0006	Air classification	Review / lifecycle: Qualify appropriate classes / grades for actual aseptic steps	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Particle classification at rest/in operation where required.	Review	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	Medium
BTV-18-0007	AHU performance	Protocol / design: Verify supply airflow, recovery and stability under occupancy	Preapproved risk-based study design; endpoint: Defined air quality and temperature control.	Planning	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0008	AHU performance	Execution / boundary verification: Verify supply airflow, recovery and stability under occupancy	Documented raw observations, calibration, relevant worst cases and defined acceptance for Defined air quality and temperature control.	Execution	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0009	AHU performance	Review / lifecycle: Verify supply airflow, recovery and stability under occupancy	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Defined air quality and temperature control.	Review	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	Medium
BTV-18-0010	Pressure cascade	Protocol / design: Challenge door opening, pressure reversal and alarms	Preapproved risk-based study design; endpoint: Directional containment / cleanliness protection.	Planning	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0011	Pressure cascade	Execution / boundary verification: Challenge door opening, pressure reversal and alarms	Documented raw observations, calibration, relevant worst cases and defined acceptance for Directional containment / cleanliness protection.	Execution	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0012	Pressure cascade	Review / lifecycle: Challenge door opening, pressure reversal and alarms	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Directional containment / cleanliness protection.	Review	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	Medium
BTV-18-0013	HEPA filter integrity	Protocol / design: Test installed filters and sealing at defined method	Preapproved risk-based study design; endpoint: No detectable bypass above approved limits.	Planning	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0014	HEPA filter integrity	Execution / boundary verification: Test installed filters and sealing at defined method	Documented raw observations, calibration, relevant worst cases and defined acceptance for No detectable bypass above approved limits.	Execution	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0015	HEPA filter integrity	Review / lifecycle: Test installed filters and sealing at defined method	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No detectable bypass above approved limits.	Review	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	Medium
BTV-18-0016	Airflow visualization	Protocol / design: Smoke-study critical interventions and first air protection	Preapproved risk-based study design; endpoint: Unidirectional air protection in critical zones.	Planning	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0017	Airflow visualization	Execution / boundary verification: Smoke-study critical interventions and first air protection	Documented raw observations, calibration, relevant worst cases and defined acceptance for Unidirectional air protection in critical zones.	Execution	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0018	Airflow visualization	Review / lifecycle: Smoke-study critical interventions and first air protection	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Unidirectional air protection in critical zones.	Review	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	Medium
BTV-18-0019	Microbial environment monitoring	Protocol / design: Validate sampling sites, methods and recovery limits	Preapproved risk-based study design; endpoint: Contamination control strategy evidence.	Planning	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0020	Microbial environment monitoring	Execution / boundary verification: Validate sampling sites, methods and recovery limits	Documented raw observations, calibration, relevant worst cases and defined acceptance for Contamination control strategy evidence.	Execution	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0021	Microbial environment monitoring	Review / lifecycle: Validate sampling sites, methods and recovery limits	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Contamination control strategy evidence.	Review	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	Medium
BTV-18-0022	Room recovery	Protocol / design: Test recovery following simulated interventions and doors	Preapproved risk-based study design; endpoint: Rapid return to classified state.	Planning	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-18-0023	Room recovery	Execution / boundary verification: Test recovery following simulated interventions and doors	Documented raw observations, calibration, relevant worst cases and defined acceptance for Rapid return to classified state.	Execution	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0024	Room recovery	Review / lifecycle: Test recovery following simulated interventions and doors	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Rapid return to classified state.	Review	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	Medium
BTV-18-0025	Temperature/RH mapping	Protocol / design: Map occupied and empty zone in seasonal limits	Preapproved risk-based study design; endpoint: Product/process material stability.	Planning	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0026	Temperature/RH mapping	Execution / boundary verification: Map occupied and empty zone in seasonal limits	Documented raw observations, calibration, relevant worst cases and defined acceptance for Product/process material stability.	Execution	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0027	Temperature/RH mapping	Review / lifecycle: Map occupied and empty zone in seasonal limits	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Product/process material stability.	Review	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	Medium
BTV-18-0028	Personnel flow	Protocol / design: Qualify gowning/airlock routines including live vs sterile streams	Preapproved risk-based study design; endpoint: No cross contamination.	Planning	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0029	Personnel flow	Execution / boundary verification: Qualify gowning/airlock routines including live vs sterile streams	Documented raw observations, calibration, relevant worst cases and defined acceptance for No cross contamination.	Execution	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0030	Personnel flow	Review / lifecycle: Qualify gowning/airlock routines including live vs sterile streams	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No cross contamination.	Review	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	Medium
BTV-18-0031	Material flows	Protocol / design: Validate decontamination transfer and airlock interlocks	Preapproved risk-based study design; endpoint: Clean material path protection.	Planning	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0032	Material flows	Execution / boundary verification: Validate decontamination transfer and airlock interlocks	Documented raw observations, calibration, relevant worst cases and defined acceptance for Clean material path protection.	Execution	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0033	Material flows	Review / lifecycle: Validate decontamination transfer and airlock interlocks	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Clean material path protection.	Review	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	Medium
BTV-18-0034	Exhaust and containment	Protocol / design: Challenge infectious aerosols and high-potency routing	Preapproved risk-based study design; endpoint: Operator and environmental safety.	Planning	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0035	Exhaust and containment	Execution / boundary verification: Challenge infectious aerosols and high-potency routing	Documented raw observations, calibration, relevant worst cases and defined acceptance for Operator and environmental safety.	Execution	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0036	Exhaust and containment	Review / lifecycle: Challenge infectious aerosols and high-potency routing	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Operator and environmental safety.	Review	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	Medium
BTV-18-0037	BMS alarm paths	Protocol / design: Verify setpoint alarms, escalation and electronic records	Preapproved risk-based study design; endpoint: Timely responses to excursions.	Planning	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0038	BMS alarm paths	Execution / boundary verification: Verify setpoint alarms, escalation and electronic records	Documented raw observations, calibration, relevant worst cases and defined acceptance for Timely responses to excursions.	Execution	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0039	BMS alarm paths	Review / lifecycle: Verify setpoint alarms, escalation and electronic records	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Timely responses to excursions.	Review	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	Medium
BTV-18-0040	Power failure recovery	Protocol / design: Demonstrate critical zone recovery and restart decisions	Preapproved risk-based study design; endpoint: Aseptic conditions restored and documented.	Planning	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0041	Power failure recovery	Execution / boundary verification: Demonstrate critical zone recovery and restart decisions	Documented raw observations, calibration, relevant worst cases and defined acceptance for Aseptic conditions restored and documented.	Execution	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0042	Power failure recovery	Review / lifecycle: Demonstrate critical zone recovery and restart decisions	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Aseptic conditions restored and documented.	Review	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	Medium
BTV-18-0043	AHU process-grade supply	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Airflow, filters, humidity, heat capacity to product impact on Stable classified environment.	URS / DQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0044	AHU process-grade supply	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for AHU process-grade supply.	IQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	Medium
BTV-18-0045	AHU process-grade supply	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Airflow, filters, humidity, heat capacity; compare challenge outputs to predefined Stable classified environment acceptance.	OQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0046	AHU process-grade supply	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Stable classified environment.	OQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-18-0047	AHU process-grade supply	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Stable classified environment at relevant Airflow, filters, humidity, heat capacity; sampling scientifically justified.	PQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0048	AHU process-grade supply	Continued verification / risk-based requalification trigger evaluation	Trend Airflow, filters, humidity, heat capacity and impact on Stable classified environment; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	Medium
BTV-18-0049	Biosafety laboratory AHU	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Negative pressure, exhaust, failure mode to product impact on Worker and adjacent room protection.	URS / DQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0050	Biosafety laboratory AHU	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Biosafety laboratory AHU.	IQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	Medium
BTV-18-0051	Biosafety laboratory AHU	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Negative pressure, exhaust, failure mode; compare challenge outputs to predefined Worker and adjacent room protection acceptance.	OQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0052	Biosafety laboratory AHU	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Worker and adjacent room protection.	OQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0053	Biosafety laboratory AHU	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Worker and adjacent room protection at relevant Negative pressure, exhaust, failure mode; sampling scientifically justified.	PQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0054	Biosafety laboratory AHU	Continued verification / risk-based requalification trigger evaluation	Trend Negative pressure, exhaust, failure mode and impact on Worker and adjacent room protection; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	Medium
BTV-18-0055	HEPA terminal filter	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Filter leak scan and air face velocity to product impact on Clean air in critical zone.	URS / DQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0056	HEPA terminal filter	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for HEPA terminal filter.	IQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	Medium
BTV-18-0057	HEPA terminal filter	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Filter leak scan and air face velocity; compare challenge outputs to predefined Clean air in critical zone acceptance.	OQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0058	HEPA terminal filter	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Clean air in critical zone.	OQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0059	HEPA terminal filter	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Clean air in critical zone at relevant Filter leak scan and air face velocity; sampling scientifically justified.	PQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0060	HEPA terminal filter	Continued verification / risk-based requalification trigger evaluation	Trend Filter leak scan and air face velocity and impact on Clean air in critical zone; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	Medium
BTV-18-0061	Laminar flow ceiling	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Velocity, uniformity, smoke patterns to product impact on First-air protection.	URS / DQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0062	Laminar flow ceiling	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Laminar flow ceiling.	IQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	Medium
BTV-18-0063	Laminar flow ceiling	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Velocity, uniformity, smoke patterns; compare challenge outputs to predefined First-air protection acceptance.	OQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0064	Laminar flow ceiling	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect First-air protection.	OQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0065	Laminar flow ceiling	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable First-air protection at relevant Velocity, uniformity, smoke patterns; sampling scientifically justified.	PQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0066	Laminar flow ceiling	Continued verification / risk-based requalification trigger evaluation	Trend Velocity, uniformity, smoke patterns and impact on First-air protection; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	Medium
BTV-18-0067	Cleanroom pressure transmitter	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Calibration, pressure cascade, alarm to product impact on Directional flow state monitoring.	URS / DQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0068	Cleanroom pressure transmitter	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Cleanroom pressure transmitter.	IQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-18-0069	Cleanroom pressure transmitter	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Calibration, pressure cascade, alarm; compare challenge outputs to predefined Directional flow state monitoring acceptance.	OQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0070	Cleanroom pressure transmitter	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Directional flow state monitoring.	OQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0071	Cleanroom pressure transmitter	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Directional flow state monitoring at relevant Calibration, pressure cascade, alarm; sampling scientifically justified.	PQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0072	Cleanroom pressure transmitter	Continued verification / risk-based requalification trigger evaluation	Trend Calibration, pressure cascade, alarm and impact on Directional flow state monitoring; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	Medium
BTV-18-0073	Airlock interlock control	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Door logic, fault mode and override to product impact on No simultaneous contradictory door events.	URS / DQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0074	Airlock interlock control	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Airlock interlock control.	IQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	Medium
BTV-18-0075	Airlock interlock control	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Door logic, fault mode and override; compare challenge outputs to predefined No simultaneous contradictory door events acceptance.	OQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0076	Airlock interlock control	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect No simultaneous contradictory door events.	OQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0077	Airlock interlock control	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable No simultaneous contradictory door events at relevant Door logic, fault mode and override; sampling scientifically justified.	PQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0078	Airlock interlock control	Continued verification / risk-based requalification trigger evaluation	Trend Door logic, fault mode and override and impact on No simultaneous contradictory door events; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	Medium
BTV-18-0079	Temperature RH transmitter	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Mapping, accuracy and alarms to product impact on Controlled process environment.	URS / DQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0080	Temperature RH transmitter	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Temperature RH transmitter.	IQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	Medium
BTV-18-0081	Temperature RH transmitter	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Mapping, accuracy and alarms; compare challenge outputs to predefined Controlled process environment acceptance.	OQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0082	Temperature RH transmitter	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Controlled process environment.	OQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0083	Temperature RH transmitter	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Controlled process environment at relevant Mapping, accuracy and alarms; sampling scientifically justified.	PQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0084	Temperature RH transmitter	Continued verification / risk-based requalification trigger evaluation	Trend Mapping, accuracy and alarms and impact on Controlled process environment; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	Medium
BTV-18-0085	Pass box dynamic/static	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Purge, particle recovery, interlock to product impact on Clean transfers.	URS / DQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0086	Pass box dynamic/static	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Pass box dynamic/static.	IQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	Medium
BTV-18-0087	Pass box dynamic/static	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Purge, particle recovery, interlock; compare challenge outputs to predefined Clean transfers acceptance.	OQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0088	Pass box dynamic/static	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Clean transfers.	OQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0089	Pass box dynamic/static	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Clean transfers at relevant Purge, particle recovery, interlock; sampling scientifically justified.	PQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-18-0090	Pass box dynamic/static	Continued verification / risk-based requalification trigger evaluation	Trend Purge, particle recovery, interlock and impact on Clean transfers; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	Medium
BTV-18-0091	Cleanroom BMS controller	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Trend, audit trail, alarm route and backup to product impact on Reliable room state and deviations.	URS / DQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0092	Cleanroom BMS controller	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Cleanroom BMS controller.	IQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	Medium
BTV-18-0093	Cleanroom BMS controller	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Trend, audit trail, alarm route and backup; compare challenge outputs to predefined Reliable room state and deviations acceptance.	OQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0094	Cleanroom BMS controller	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Reliable room state and deviations.	OQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0095	Cleanroom BMS controller	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Reliable room state and deviations at relevant Trend, audit trail, alarm route and backup; sampling scientifically justified.	PQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0096	Cleanroom BMS controller	Continued verification / risk-based requalification trigger evaluation	Trend Trend, audit trail, alarm route and backup and impact on Reliable room state and deviations; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	Medium
BTV-18-0097	Room air shower if installed	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Airflow cycle, emergency stop and door logic to product impact on Justified decontamination support.	URS / DQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0098	Room air shower if installed	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Room air shower if installed.	IQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	Medium
BTV-18-0099	Room air shower if installed	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Airflow cycle, emergency stop and door logic; compare challenge outputs to predefined Justified decontamination support acceptance.	OQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0100	Room air shower if installed	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Justified decontamination support.	OQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0101	Room air shower if installed	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Justified decontamination support at relevant Airflow cycle, emergency stop and door logic; sampling scientifically justified.	PQ	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	High
BTV-18-0102	Room air shower if installed	Continued verification / risk-based requalification trigger evaluation	Trend Airflow cycle, emergency stop and door logic and impact on Justified decontamination support; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Sterile and nonsterile biological facilities	B03 B04 B05 B06 B21	Medium

19 PHARMACEUTICAL WATER, WFI & PROCESS UTILITIES

96 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-19-0001	Water system URS	Protocol / design: Define intended use and grade by bioprocess step	Preapproved risk-based study design; endpoint: Fitness of purified water/WFI use points.	Planning	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0002	Water system URS	Execution / boundary verification: Define intended use and grade by bioprocess step	Documented raw observations, calibration, relevant worst cases and defined acceptance for Fitness of purified water/WFI use points.	Execution	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0003	Water system URS	Review / lifecycle: Define intended use and grade by bioprocess step	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Fitness of purified water/WFI use points.	Review	Biotech DS / sterile DP	B03 B04 B05 B06 B15	Medium
BTV-19-0004	Purified water qualification	Protocol / design: Demonstrate chemical and microbial consistency across seasonal operation	Preapproved risk-based study design; endpoint: Conductivity, TOC and microbial trend.	Planning	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0005	Purified water qualification	Execution / boundary verification: Demonstrate chemical and microbial consistency across seasonal operation	Documented raw observations, calibration, relevant worst cases and defined acceptance for Conductivity, TOC and microbial trend.	Execution	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0006	Purified water qualification	Review / lifecycle: Demonstrate chemical and microbial consistency across seasonal operation	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Conductivity, TOC and microbial trend.	Review	Biotech DS / sterile DP	B03 B04 B05 B06 B15	Medium
BTV-19-0007	WFI generation qualification	Protocol / design: Validate temperature / membrane / distillation process controls	Preapproved risk-based study design; endpoint: Compendial quality, endotoxin and microbial controls.	Planning	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0008	WFI generation qualification	Execution / boundary verification: Validate temperature / membrane / distillation process controls	Documented raw observations, calibration, relevant worst cases and defined acceptance for Compendial quality, endotoxin and microbial controls.	Execution	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0009	WFI generation qualification	Review / lifecycle: Validate temperature / membrane / distillation process controls	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Compendial quality, endotoxin and microbial controls.	Review	Biotech DS / sterile DP	B03 B04 B05 B06 B15	Medium
BTV-19-0010	Distribution loop	Protocol / design: Verify velocity, dead legs, point-of-use configuration	Preapproved risk-based study design; endpoint: Prevent microbial proliferation and endotoxin increase.	Planning	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0011	Distribution loop	Execution / boundary verification: Verify velocity, dead legs, point-of-use configuration	Documented raw observations, calibration, relevant worst cases and defined acceptance for Prevent microbial proliferation and endotoxin increase.	Execution	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0012	Distribution loop	Review / lifecycle: Verify velocity, dead legs, point-of-use configuration	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Prevent microbial proliferation and endotoxin increase.	Review	Biotech DS / sterile DP	B03 B04 B05 B06 B15	Medium
BTV-19-0013	Thermal sanitization	Protocol / design: Prove minimum time/temperature across loop	Preapproved risk-based study design; endpoint: Validated biofilm control.	Planning	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0014	Thermal sanitization	Execution / boundary verification: Prove minimum time/temperature across loop	Documented raw observations, calibration, relevant worst cases and defined acceptance for Validated biofilm control.	Execution	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0015	Thermal sanitization	Review / lifecycle: Prove minimum time/temperature across loop	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Validated biofilm control.	Review	Biotech DS / sterile DP	B03 B04 B05 B06 B15	Medium
BTV-19-0016	Ozone sanitization	Protocol / design: Validate ozone dose/contact and residual removal when used	Preapproved risk-based study design; endpoint: Microbial control without product exposure.	Planning	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0017	Ozone sanitization	Execution / boundary verification: Validate ozone dose/contact and residual removal when used	Documented raw observations, calibration, relevant worst cases and defined acceptance for Microbial control without product exposure.	Execution	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0018	Ozone sanitization	Review / lifecycle: Validate ozone dose/contact and residual removal when used	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Microbial control without product exposure.	Review	Biotech DS / sterile DP	B03 B04 B05 B06 B15	Medium
BTV-19-0019	Water hold time	Protocol / design: Demonstrate water quality through max hold and use point	Preapproved risk-based study design; endpoint: Stable chemical and microbial suitability.	Planning	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0020	Water hold time	Execution / boundary verification: Demonstrate water quality through max hold and use point	Documented raw observations, calibration, relevant worst cases and defined acceptance for Stable chemical and microbial suitability.	Execution	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0021	Water hold time	Review / lifecycle: Demonstrate water quality through max hold and use point	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Stable chemical and microbial suitability.	Review	Biotech DS / sterile DP	B03 B04 B05 B06 B15	Medium
BTV-19-0022	RO/EDI performance	Protocol / design: Challenge conductivity, differential pressure and rejection	Preapproved risk-based study design; endpoint: Consistent feed water quality.	Planning	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-19-0023	RO/EDI performance	Execution / boundary verification: Challenge conductivity, differential pressure and rejection	Documented raw observations, calibration, relevant worst cases and defined acceptance for Consistent feed water quality.	Execution	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0024	RO/EDI performance	Review / lifecycle: Challenge conductivity, differential pressure and rejection	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Consistent feed water quality.	Review	Biotech DS / sterile DP	B03 B04 B05 B06 B15	Medium
BTV-19-0025	WFI storage	Protocol / design: Qualify vent filter, temperature and spray-ball coverage	Preapproved risk-based study design; endpoint: No recontamination.	Planning	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0026	WFI storage	Execution / boundary verification: Qualify vent filter, temperature and spray-ball coverage	Documented raw observations, calibration, relevant worst cases and defined acceptance for No recontamination.	Execution	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0027	WFI storage	Review / lifecycle: Qualify vent filter, temperature and spray-ball coverage	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No recontamination.	Review	Biotech DS / sterile DP	B03 B04 B05 B06 B15	Medium
BTV-19-0028	Microbial test method	Protocol / design: Validate sampling neutralizer, sample hold and recoverability	Preapproved risk-based study design; endpoint: Representative microorganism counts.	Planning	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0029	Microbial test method	Execution / boundary verification: Validate sampling neutralizer, sample hold and recoverability	Documented raw observations, calibration, relevant worst cases and defined acceptance for Representative microorganism counts.	Execution	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0030	Microbial test method	Review / lifecycle: Validate sampling neutralizer, sample hold and recoverability	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Representative microorganism counts.	Review	Biotech DS / sterile DP	B03 B04 B05 B06 B15	Medium
BTV-19-0031	Water excursions	Protocol / design: Define investigation, recirculation and product impact	Preapproved risk-based study design; endpoint: Effective response and batch traceability.	Planning	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0032	Water excursions	Execution / boundary verification: Define investigation, recirculation and product impact	Documented raw observations, calibration, relevant worst cases and defined acceptance for Effective response and batch traceability.	Execution	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0033	Water excursions	Review / lifecycle: Define investigation, recirculation and product impact	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Effective response and batch traceability.	Review	Biotech DS / sterile DP	B03 B04 B05 B06 B15	Medium
BTV-19-0034	Water mapping	Protocol / design: Select worst-case ports and seasonal sampling	Preapproved risk-based study design; endpoint: Validated distribution qualification.	Planning	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0035	Water mapping	Execution / boundary verification: Select worst-case ports and seasonal sampling	Documented raw observations, calibration, relevant worst cases and defined acceptance for Validated distribution qualification.	Execution	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0036	Water mapping	Review / lifecycle: Select worst-case ports and seasonal sampling	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Validated distribution qualification.	Review	Biotech DS / sterile DP	B03 B04 B05 B06 B15	Medium
BTV-19-0037	Pretreatment softener	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Breakthrough conductivity and regen cycle to product impact on Controlled feed water quality.	URS / DQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0038	Pretreatment softener	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Pretreatment softener.	IQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	Medium
BTV-19-0039	Pretreatment softener	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Breakthrough conductivity and regen cycle; compare challenge outputs to predefined Controlled feed water quality acceptance.	OQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0040	Pretreatment softener	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Controlled feed water quality.	OQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0041	Pretreatment softener	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Controlled feed water quality at relevant Breakthrough conductivity and regen cycle; sampling scientifically justified.	PQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0042	Pretreatment softener	Continued verification / risk-based requalification trigger evaluation	Trend Breakthrough conductivity and regen cycle and impact on Controlled feed water quality; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biotech DS / sterile DP	B03 B04 B05 B06 B15	Medium
BTV-19-0043	Reverse osmosis system	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Rejection, pressure, flow, membrane integrity to product impact on Purified water feed quality.	URS / DQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0044	Reverse osmosis system	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Reverse osmosis system.	IQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	Medium
BTV-19-0045	Reverse osmosis system	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Rejection, pressure, flow, membrane integrity; compare challenge outputs to predefined Purified water feed quality acceptance.	OQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0046	Reverse osmosis system	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Purified water feed quality.	OQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-19-0047	Reverse osmosis system	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Purified water feed quality at relevant Rejection, pressure, flow, membrane integrity; sampling scientifically justified.	PQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0048	Reverse osmosis system	Continued verification / risk-based requalification trigger evaluation	Trend Rejection, pressure, flow, membrane integrity and impact on Purified water feed quality; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biotech DS / sterile DP	B03 B04 B05 B06 B15	Medium
BTV-19-0049	EDI module	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Resistivity, flow and current to product impact on Stable ionic removal.	URS / DQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0050	EDI module	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for EDI module.	IQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	Medium
BTV-19-0051	EDI module	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Resistivity, flow and current; compare challenge outputs to predefined Stable ionic removal acceptance.	OQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0052	EDI module	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Stable ionic removal.	OQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0053	EDI module	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Stable ionic removal at relevant Resistivity, flow and current; sampling scientifically justified.	PQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0054	EDI module	Continued verification / risk-based requalification trigger evaluation	Trend Resistivity, flow and current and impact on Stable ionic removal; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biotech DS / sterile DP	B03 B04 B05 B06 B15	Medium
BTV-19-0055	WFI generator distillation	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Steam pressure, conductivity, temperature to product impact on WFI compendial quality.	URS / DQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0056	WFI generator distillation	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for WFI generator distillation.	IQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	Medium
BTV-19-0057	WFI generator distillation	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Steam pressure, conductivity, temperature; compare challenge outputs to predefined WFI compendial quality acceptance.	OQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0058	WFI generator distillation	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect WFI compendial quality.	OQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0059	WFI generator distillation	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable WFI compendial quality at relevant Steam pressure, conductivity, temperature; sampling scientifically justified.	PQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0060	WFI generator distillation	Continued verification / risk-based requalification trigger evaluation	Trend Steam pressure, conductivity, temperature and impact on WFI compendial quality; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biotech DS / sterile DP	B03 B04 B05 B06 B15	Medium
BTV-19-0061	WFI membrane system if used	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Membrane integrity, TOC, endotoxin to product impact on Validated WFI quality where allowed.	URS / DQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0062	WFI membrane system if used	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for WFI membrane system if used.	IQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	Medium
BTV-19-0063	WFI membrane system if used	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Membrane integrity, TOC, endotoxin; compare challenge outputs to predefined Validated WFI quality where allowed acceptance.	OQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0064	WFI membrane system if used	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Validated WFI quality where allowed.	OQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0065	WFI membrane system if used	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Validated WFI quality where allowed at relevant Membrane integrity, TOC, endotoxin; sampling scientifically justified.	PQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0066	WFI membrane system if used	Continued verification / risk-based requalification trigger evaluation	Trend Membrane integrity, TOC, endotoxin and impact on Validated WFI quality where allowed; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biotech DS / sterile DP	B03 B04 B05 B06 B15	Medium
BTV-19-0067	WFI storage tank	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Temperature, vent filter, level, spray ball to product impact on Microbial/endotoxin control.	URS / DQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0068	WFI storage tank	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for WFI storage tank.	IQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-19-0069	WFI storage tank	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Temperature, vent filter, level, spray ball; compare challenge outputs to predefined Microbial/endotoxin control acceptance.	OQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0070	WFI storage tank	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Microbial/endotoxin control.	OQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0071	WFI storage tank	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Microbial/endotoxin control at relevant Temperature, vent filter, level, spray ball; sampling scientifically justified.	PQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0072	WFI storage tank	Continued verification / risk-based requalification trigger evaluation	Trend Temperature, vent filter, level, spray ball and impact on Microbial/endotoxin control; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biotech DS / sterile DP	B03 B04 B05 B06 B15	Medium
BTV-19-0073	WFI recirculation loop	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Flow, return temp, use-point stress to product impact on Distributed WFI suitability.	URS / DQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0074	WFI recirculation loop	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for WFI recirculation loop.	IQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	Medium
BTV-19-0075	WFI recirculation loop	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Flow, return temp, use-point stress; compare challenge outputs to predefined Distributed WFI suitability acceptance.	OQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0076	WFI recirculation loop	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Distributed WFI suitability.	OQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0077	WFI recirculation loop	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Distributed WFI suitability at relevant Flow, return temp, use-point stress; sampling scientifically justified.	PQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0078	WFI recirculation loop	Continued verification / risk-based requalification trigger evaluation	Trend Flow, return temp, use-point stress and impact on Distributed WFI suitability; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biotech DS / sterile DP	B03 B04 B05 B06 B15	Medium
BTV-19-0079	Ozone generator	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Concentration, sensor and decay to product impact on Validated sanitization with no residual.	URS / DQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0080	Ozone generator	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Ozone generator.	IQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	Medium
BTV-19-0081	Ozone generator	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Concentration, sensor and decay; compare challenge outputs to predefined Validated sanitization with no residual acceptance.	OQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0082	Ozone generator	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Validated sanitization with no residual.	OQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0083	Ozone generator	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Validated sanitization with no residual at relevant Concentration, sensor and decay; sampling scientifically justified.	PQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0084	Ozone generator	Continued verification / risk-based requalification trigger evaluation	Trend Concentration, sensor and decay and impact on Validated sanitization with no residual; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biotech DS / sterile DP	B03 B04 B05 B06 B15	Medium
BTV-19-0085	UV water treatment unit	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Irradiance, flow and lamp age to product impact on Redundant microbial/TOC control.	URS / DQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0086	UV water treatment unit	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for UV water treatment unit.	IQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	Medium
BTV-19-0087	UV water treatment unit	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Irradiance, flow and lamp age; compare challenge outputs to predefined Redundant microbial/TOC control acceptance.	OQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0088	UV water treatment unit	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Redundant microbial/TOC control.	OQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0089	UV water treatment unit	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Redundant microbial/TOC control at relevant Irradiance, flow and lamp age; sampling scientifically justified.	PQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0090	UV water treatment unit	Continued verification / risk-based requalification trigger evaluation	Trend Irradiance, flow and lamp age and impact on Redundant microbial/TOC control; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biotech DS / sterile DP	B03 B04 B05 B06 B15	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-19-0091	Water sampling port	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Hygienic design, purge and representativeness to product impact on Valid quality results.	URS / DQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0092	Water sampling port	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Water sampling port.	IQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	Medium
BTV-19-0093	Water sampling port	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Hygienic design, purge and representativeness; compare challenge outputs to predefined Valid quality results acceptance.	OQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0094	Water sampling port	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Valid quality results.	OQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0095	Water sampling port	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Valid quality results at relevant Hygienic design, purge and representativeness; sampling scientifically justified.	PQ	Biotech DS / sterile DP	B03 B04 B05 B06 B15	High
BTV-19-0096	Water sampling port	Continued verification / risk-based requalification trigger evaluation	Trend Hygienic design, purge and representativeness and impact on Valid quality results; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biotech DS / sterile DP	B03 B04 B05 B06 B15	Medium

20 CLEAN STEAM, COMPRESSED GASES, VACUUM & HVAC UTILITIES

93 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-20-0001	Clean steam quality	Protocol / design: Validate dryness, noncondensable gases and superheat where relevant	Preapproved risk-based study design; endpoint: Reliable sterilization heat transfer.	Planning	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0002	Clean steam quality	Execution / boundary verification: Validate dryness, noncondensable gases and superheat where relevant	Documented raw observations, calibration, relevant worst cases and defined acceptance for Reliable sterilization heat transfer.	Execution	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0003	Clean steam quality	Review / lifecycle: Validate dryness, noncondensable gases and superheat where relevant	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Reliable sterilization heat transfer.	Review	Biotech process and sterile filling	B03 B04 B05 B06	Medium
BTV-20-0004	Clean steam condensate	Protocol / design: Verify conductivity and compendial attributes as applicable	Preapproved risk-based study design; endpoint: No process contamination from steam.	Planning	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0005	Clean steam condensate	Execution / boundary verification: Verify conductivity and compendial attributes as applicable	Documented raw observations, calibration, relevant worst cases and defined acceptance for No process contamination from steam.	Execution	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0006	Clean steam condensate	Review / lifecycle: Verify conductivity and compendial attributes as applicable	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No process contamination from steam.	Review	Biotech process and sterile filling	B03 B04 B05 B06	Medium
BTV-20-0007	Compressed air quality	Protocol / design: Qualify particles, oil, moisture, microbes where product contact	Preapproved risk-based study design; endpoint: Fit for contact and aseptic operations.	Planning	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0008	Compressed air quality	Execution / boundary verification: Qualify particles, oil, moisture, microbes where product contact	Documented raw observations, calibration, relevant worst cases and defined acceptance for Fit for contact and aseptic operations.	Execution	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0009	Compressed air quality	Review / lifecycle: Qualify particles, oil, moisture, microbes where product contact	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Fit for contact and aseptic operations.	Review	Biotech process and sterile filling	B03 B04 B05 B06	Medium
BTV-20-0010	Nitrogen quality	Protocol / design: Validate oxygen content, moisture, particles and microbes for intended use	Preapproved risk-based study design; endpoint: Oxidation and contamination controlled.	Planning	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0011	Nitrogen quality	Execution / boundary verification: Validate oxygen content, moisture, particles and microbes for intended use	Documented raw observations, calibration, relevant worst cases and defined acceptance for Oxidation and contamination controlled.	Execution	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0012	Nitrogen quality	Review / lifecycle: Validate oxygen content, moisture, particles and microbes for intended use	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Oxidation and contamination controlled.	Review	Biotech process and sterile filling	B03 B04 B05 B06	Medium
BTV-20-0013	CO2 process gas	Protocol / design: Qualify grade, microbial filter and flow accuracy	Preapproved risk-based study design; endpoint: Reproducible culture pH control.	Planning	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0014	CO2 process gas	Execution / boundary verification: Qualify grade, microbial filter and flow accuracy	Documented raw observations, calibration, relevant worst cases and defined acceptance for Reproducible culture pH control.	Execution	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0015	CO2 process gas	Review / lifecycle: Qualify grade, microbial filter and flow accuracy	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Reproducible culture pH control.	Review	Biotech process and sterile filling	B03 B04 B05 B06	Medium
BTV-20-0016	Oxygen process gas	Protocol / design: Verify grade, pressure and flow metering	Preapproved risk-based study design; endpoint: Consistent culture aeration.	Planning	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0017	Oxygen process gas	Execution / boundary verification: Verify grade, pressure and flow metering	Documented raw observations, calibration, relevant worst cases and defined acceptance for Consistent culture aeration.	Execution	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0018	Oxygen process gas	Review / lifecycle: Verify grade, pressure and flow metering	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Consistent culture aeration.	Review	Biotech process and sterile filling	B03 B04 B05 B06	Medium
BTV-20-0019	Gas filter integrity	Protocol / design: Define pre/post use test for sterilizing-grade filter where applicable	Preapproved risk-based study design; endpoint: Control microbial ingress.	Planning	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0020	Gas filter integrity	Execution / boundary verification: Define pre/post use test for sterilizing-grade filter where applicable	Documented raw observations, calibration, relevant worst cases and defined acceptance for Control microbial ingress.	Execution	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0021	Gas filter integrity	Review / lifecycle: Define pre/post use test for sterilizing-grade filter where applicable	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Control microbial ingress.	Review	Biotech process and sterile filling	B03 B04 B05 B06	Medium
BTV-20-0022	Vacuum protection	Protocol / design: Validate backflow prevention and trap function	Preapproved risk-based study design; endpoint: No back contamination during process.	Planning	Biotech process and sterile filling	B03 B04 B05 B06	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-20-0023	Vacuum protection	Execution / boundary verification: Validate backflow prevention and trap function	Documented raw observations, calibration, relevant worst cases and defined acceptance for No back contamination during process.	Execution	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0024	Vacuum protection	Review / lifecycle: Validate backflow prevention and trap function	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No back contamination during process.	Review	Biotech process and sterile filling	B03 B04 B05 B06	Medium
BTV-20-0025	Gas supply redundancy	Protocol / design: Challenge switchover, emergency pressure and alarm	Preapproved risk-based study design; endpoint: No batch loss or unsafe exposure.	Planning	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0026	Gas supply redundancy	Execution / boundary verification: Challenge switchover, emergency pressure and alarm	Documented raw observations, calibration, relevant worst cases and defined acceptance for No batch loss or unsafe exposure.	Execution	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0027	Gas supply redundancy	Review / lifecycle: Challenge switchover, emergency pressure and alarm	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No batch loss or unsafe exposure.	Review	Biotech process and sterile filling	B03 B04 B05 B06	Medium
BTV-20-0028	Steam trap mapping	Protocol / design: Qualify condensate removal and cold spots	Preapproved risk-based study design; endpoint: Effective SIP cycles.	Planning	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0029	Steam trap mapping	Execution / boundary verification: Qualify condensate removal and cold spots	Documented raw observations, calibration, relevant worst cases and defined acceptance for Effective SIP cycles.	Execution	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0030	Steam trap mapping	Review / lifecycle: Qualify condensate removal and cold spots	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Effective SIP cycles.	Review	Biotech process and sterile filling	B03 B04 B05 B06	Medium
BTV-20-0031	Utility instrumentation	Protocol / design: Assure metrology, alarm and recorder validity	Preapproved risk-based study design; endpoint: Traceable CPP records.	Planning	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0032	Utility instrumentation	Execution / boundary verification: Assure metrology, alarm and recorder validity	Documented raw observations, calibration, relevant worst cases and defined acceptance for Traceable CPP records.	Execution	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0033	Utility instrumentation	Review / lifecycle: Assure metrology, alarm and recorder validity	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Traceable CPP records.	Review	Biotech process and sterile filling	B03 B04 B05 B06	Medium
BTV-20-0034	Pure steam generator	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Cleanliness, steam pressure, condensate quality to product impact on Suitable steam sterilization service.	URS / DQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0035	Pure steam generator	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Pure steam generator.	IQ	Biotech process and sterile filling	B03 B04 B05 B06	Medium
BTV-20-0036	Pure steam generator	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Cleanliness, steam pressure, condensate quality; compare challenge outputs to predefined Suitable steam sterilization service acceptance.	OQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0037	Pure steam generator	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Suitable steam sterilization service.	OQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0038	Pure steam generator	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Suitable steam sterilization service at relevant Cleanliness, steam pressure, condensate quality; sampling scientifically justified.	PQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0039	Pure steam generator	Continued verification / risk-based requalification trigger evaluation	Trend Cleanliness, steam pressure, condensate quality and impact on Suitable steam sterilization service; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biotech process and sterile filling	B03 B04 B05 B06	Medium
BTV-20-0040	Pure steam distribution	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Pressure, drains, traps, cold spots to product impact on Adequate SIP exposure.	URS / DQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0041	Pure steam distribution	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Pure steam distribution.	IQ	Biotech process and sterile filling	B03 B04 B05 B06	Medium
BTV-20-0042	Pure steam distribution	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Pressure, drains, traps, cold spots; compare challenge outputs to predefined Adequate SIP exposure acceptance.	OQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0043	Pure steam distribution	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Adequate SIP exposure.	OQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0044	Pure steam distribution	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Adequate SIP exposure at relevant Pressure, drains, traps, cold spots; sampling scientifically justified.	PQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0045	Pure steam distribution	Continued verification / risk-based requalification trigger evaluation	Trend Pressure, drains, traps, cold spots and impact on Adequate SIP exposure; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biotech process and sterile filling	B03 B04 B05 B06	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-20-0046	Clean compressed air station	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Pressure dew point, particles, oil, microbes to product impact on Bioprocess air quality.	URS / DQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0047	Clean compressed air station	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Clean compressed air station.	IQ	Biotech process and sterile filling	B03 B04 B05 B06	Medium
BTV-20-0048	Clean compressed air station	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Pressure dew point, particles, oil, microbes; compare challenge outputs to predefined Bioprocess air quality acceptance.	OQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0049	Clean compressed air station	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Bioprocess air quality.	OQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0050	Clean compressed air station	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Bioprocess air quality at relevant Pressure dew point, particles, oil, microbes; sampling scientifically justified.	PQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0051	Clean compressed air station	Continued verification / risk-based requalification trigger evaluation	Trend Pressure dew point, particles, oil, microbes and impact on Bioprocess air quality; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biotech process and sterile filling	B03 B04 B05 B06	Medium
BTV-20-0052	Process nitrogen skid	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Purity, moisture, pressure to product impact on Biological bulk protection.	URS / DQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0053	Process nitrogen skid	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Process nitrogen skid.	IQ	Biotech process and sterile filling	B03 B04 B05 B06	Medium
BTV-20-0054	Process nitrogen skid	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Purity, moisture, pressure; compare challenge outputs to predefined Biological bulk protection acceptance.	OQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0055	Process nitrogen skid	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Biological bulk protection.	OQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0056	Process nitrogen skid	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Biological bulk protection at relevant Purity, moisture, pressure; sampling scientifically justified.	PQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0057	Process nitrogen skid	Continued verification / risk-based requalification trigger evaluation	Trend Purity, moisture, pressure and impact on Biological bulk protection; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biotech process and sterile filling	B03 B04 B05 B06	Medium
BTV-20-0058	Oxygen supply skid	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Regulator, flow, alarms to product impact on Culture oxygen transfer reliability.	URS / DQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0059	Oxygen supply skid	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Oxygen supply skid.	IQ	Biotech process and sterile filling	B03 B04 B05 B06	Medium
BTV-20-0060	Oxygen supply skid	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Regulator, flow, alarms; compare challenge outputs to predefined Culture oxygen transfer reliability acceptance.	OQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0061	Oxygen supply skid	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Culture oxygen transfer reliability.	OQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0062	Oxygen supply skid	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Culture oxygen transfer reliability at relevant Regulator, flow, alarms; sampling scientifically justified.	PQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0063	Oxygen supply skid	Continued verification / risk-based requalification trigger evaluation	Trend Regulator, flow, alarms and impact on Culture oxygen transfer reliability; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biotech process and sterile filling	B03 B04 B05 B06	Medium
BTV-20-0064	CO2 gas manifold	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Gas purity, flow, switching to product impact on Stable culture pH control.	URS / DQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0065	CO2 gas manifold	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for CO2 gas manifold.	IQ	Biotech process and sterile filling	B03 B04 B05 B06	Medium
BTV-20-0066	CO2 gas manifold	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Gas purity, flow, switching; compare challenge outputs to predefined Stable culture pH control acceptance.	OQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0067	CO2 gas manifold	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Stable culture pH control.	OQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0068	CO2 gas manifold	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Stable culture pH control at relevant Gas purity, flow, switching; sampling scientifically justified.	PQ	Biotech process and sterile filling	B03 B04 B05 B06	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-20-0069	CO2 gas manifold	Continued verification / risk-based requalification trigger evaluation	Trend Gas purity, flow, switching and impact on Stable culture pH control; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biotech process and sterile filling	B03 B04 B05 B06	Medium
BTV-20-0070	Vacuum system	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Vacuum level, leak and backflow to product impact on Contamination-free operations.	URS / DQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0071	Vacuum system	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Vacuum system.	IQ	Biotech process and sterile filling	B03 B04 B05 B06	Medium
BTV-20-0072	Vacuum system	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Vacuum level, leak and backflow; compare challenge outputs to predefined Contamination-free operations acceptance.	OQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0073	Vacuum system	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Contamination-free operations.	OQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0074	Vacuum system	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Contamination-free operations at relevant Vacuum level, leak and backflow; sampling scientifically justified.	PQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0075	Vacuum system	Continued verification / risk-based requalification trigger evaluation	Trend Vacuum level, leak and backflow and impact on Contamination-free operations; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biotech process and sterile filling	B03 B04 B05 B06	Medium
BTV-20-0076	Gas point-of-use filter	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Integrity and pressure loss to product impact on Controlled microorganisms/particles.	URS / DQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0077	Gas point-of-use filter	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Gas point-of-use filter.	IQ	Biotech process and sterile filling	B03 B04 B05 B06	Medium
BTV-20-0078	Gas point-of-use filter	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Integrity and pressure loss; compare challenge outputs to predefined Controlled microorganisms/particles acceptance.	OQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0079	Gas point-of-use filter	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Controlled microorganisms/particles.	OQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0080	Gas point-of-use filter	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Controlled microorganisms/particles at relevant Integrity and pressure loss; sampling scientifically justified.	PQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0081	Gas point-of-use filter	Continued verification / risk-based requalification trigger evaluation	Trend Integrity and pressure loss and impact on Controlled microorganisms/particles; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biotech process and sterile filling	B03 B04 B05 B06	Medium
BTV-20-0082	Plant chilled water	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Supply/return temperature, load capacity to product impact on Controlled bioreactor temperature.	URS / DQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0083	Plant chilled water	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Plant chilled water.	IQ	Biotech process and sterile filling	B03 B04 B05 B06	Medium
BTV-20-0084	Plant chilled water	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Supply/return temperature, load capacity; compare challenge outputs to predefined Controlled bioreactor temperature acceptance.	OQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0085	Plant chilled water	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Controlled bioreactor temperature.	OQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0086	Plant chilled water	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Controlled bioreactor temperature at relevant Supply/return temperature, load capacity; sampling scientifically justified.	PQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0087	Plant chilled water	Continued verification / risk-based requalification trigger evaluation	Trend Supply/return temperature, load capacity and impact on Controlled bioreactor temperature; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biotech process and sterile filling	B03 B04 B05 B06	Medium
BTV-20-0088	Emergency power / UPS	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Load transfer and battery autonomy to product impact on Preserved data and critical controls.	URS / DQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0089	Emergency power / UPS	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Emergency power / UPS.	IQ	Biotech process and sterile filling	B03 B04 B05 B06	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-20-0090	Emergency power / UPS	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Load transfer and battery autonomy; compare challenge outputs to predefined Preserved data and critical controls acceptance.	OQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0091	Emergency power / UPS	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Preserved data and critical controls.	OQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0092	Emergency power / UPS	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Preserved data and critical controls at relevant Load transfer and battery autonomy; sampling scientifically justified.	PQ	Biotech process and sterile filling	B03 B04 B05 B06	High
BTV-20-0093	Emergency power / UPS	Continued verification / risk-based requalification trigger evaluation	Trend Load transfer and battery autonomy and impact on Preserved data and critical controls; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biotech process and sterile filling	B03 B04 B05 B06	Medium

21 CIP, COP, CLEANING VALIDATION AND CROSS-CONTAMINATION

90 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-21-0001	Cleaning worst case	Protocol / design: Select product load, potency, solubility and degradability	Preapproved risk-based study design; endpoint: Product and material worst-case matrix.	Planning	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0002	Cleaning worst case	Execution / boundary verification: Select product load, potency, solubility and degradability	Documented raw observations, calibration, relevant worst cases and defined acceptance for Product and material worst-case matrix.	Execution	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0003	Cleaning worst case	Review / lifecycle: Select product load, potency, solubility and degradability	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Product and material worst-case matrix.	Review	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	Medium
BTV-21-0004	HBEL/PDE based limits	Protocol / design: Establish limits by toxicological assessment where relevant	Preapproved risk-based study design; endpoint: Scientifically justified carryover limits.	Planning	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0005	HBEL/PDE based limits	Execution / boundary verification: Establish limits by toxicological assessment where relevant	Documented raw observations, calibration, relevant worst cases and defined acceptance for Scientifically justified carryover limits.	Execution	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0006	HBEL/PDE based limits	Review / lifecycle: Establish limits by toxicological assessment where relevant	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Scientifically justified carryover limits.	Review	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	Medium
BTV-21-0007	Bioburden and endotoxin	Protocol / design: Define post-clean microbial acceptance criteria	Preapproved risk-based study design; endpoint: Biological contamination controlled.	Planning	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0008	Bioburden and endotoxin	Execution / boundary verification: Define post-clean microbial acceptance criteria	Documented raw observations, calibration, relevant worst cases and defined acceptance for Biological contamination controlled.	Execution	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0009	Bioburden and endotoxin	Review / lifecycle: Define post-clean microbial acceptance criteria	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Biological contamination controlled.	Review	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	Medium
BTV-21-0010	Swab recovery	Protocol / design: Validate recovery on SS316L, elastomer and hard-to-clean areas	Preapproved risk-based study design; endpoint: Representative chemical/protein residue recovery.	Planning	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0011	Swab recovery	Execution / boundary verification: Validate recovery on SS316L, elastomer and hard-to-clean areas	Documented raw observations, calibration, relevant worst cases and defined acceptance for Representative chemical/protein residue recovery.	Execution	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0012	Swab recovery	Review / lifecycle: Validate recovery on SS316L, elastomer and hard-to-clean areas	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Representative chemical/protein residue recovery.	Review	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	Medium
BTV-21-0013	Rinse recovery	Protocol / design: Validate rinse sample representativeness and detection	Preapproved risk-based study design; endpoint: Ability to detect worst-case surface residue.	Planning	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0014	Rinse recovery	Execution / boundary verification: Validate rinse sample representativeness and detection	Documented raw observations, calibration, relevant worst cases and defined acceptance for Ability to detect worst-case surface residue.	Execution	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0015	Rinse recovery	Review / lifecycle: Validate rinse sample representativeness and detection	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Ability to detect worst-case surface residue.	Review	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	Medium
BTV-21-0016	Cleaning analytical assay	Protocol / design: Validate specificity, sensitivity and protein/HCP interference	Preapproved risk-based study design; endpoint: Reliable quantification at established limits.	Planning	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0017	Cleaning analytical assay	Execution / boundary verification: Validate specificity, sensitivity and protein/HCP interference	Documented raw observations, calibration, relevant worst cases and defined acceptance for Reliable quantification at established limits.	Execution	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0018	Cleaning analytical assay	Review / lifecycle: Validate specificity, sensitivity and protein/HCP interference	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Reliable quantification at established limits.	Review	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	Medium
BTV-21-0019	CIP coverage	Protocol / design: Prove spray ball impingement, flow and low-drain locations	Preapproved risk-based study design; endpoint: No residue in worst-case locations.	Planning	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0020	CIP coverage	Execution / boundary verification: Prove spray ball impingement, flow and low-drain locations	Documented raw observations, calibration, relevant worst cases and defined acceptance for No residue in worst-case locations.	Execution	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0021	CIP coverage	Review / lifecycle: Prove spray ball impingement, flow and low-drain locations	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No residue in worst-case locations.	Review	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	Medium
BTV-21-0022	Cleaning agent concentration	Protocol / design: Challenge concentration, minimum temperature and contact time	Preapproved risk-based study design; endpoint: Reproducible residue removal.	Planning	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-21-0023	Cleaning agent concentration	Execution / boundary verification: Challenge concentration, minimum temperature and contact time	Documented raw observations, calibration, relevant worst cases and defined acceptance for Reproducible residue removal.	Execution	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0024	Cleaning agent concentration	Review / lifecycle: Challenge concentration, minimum temperature and contact time	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Reproducible residue removal.	Review	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	Medium
BTV-21-0025	Dirty hold time	Protocol / design: Demonstrate maximum delay before start of cleaning	Preapproved risk-based study design; endpoint: Soil not hardened beyond cleaning capability.	Planning	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0026	Dirty hold time	Execution / boundary verification: Demonstrate maximum delay before start of cleaning	Documented raw observations, calibration, relevant worst cases and defined acceptance for Soil not hardened beyond cleaning capability.	Execution	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0027	Dirty hold time	Review / lifecycle: Demonstrate maximum delay before start of cleaning	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Soil not hardened beyond cleaning capability.	Review	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	Medium
BTV-21-0028	Clean hold time	Protocol / design: Establish post-clean bioburden/chemical limits	Preapproved risk-based study design; endpoint: Clean state maintained until reuse.	Planning	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0029	Clean hold time	Execution / boundary verification: Establish post-clean bioburden/chemical limits	Documented raw observations, calibration, relevant worst cases and defined acceptance for Clean state maintained until reuse.	Execution	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0030	Clean hold time	Review / lifecycle: Establish post-clean bioburden/chemical limits	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Clean state maintained until reuse.	Review	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	Medium
BTV-21-0031	Campaign length	Protocol / design: Validate max consecutive batches before cleaning	Preapproved risk-based study design; endpoint: Controlled accumulation of residues.	Planning	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0032	Campaign length	Execution / boundary verification: Validate max consecutive batches before cleaning	Documented raw observations, calibration, relevant worst cases and defined acceptance for Controlled accumulation of residues.	Execution	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0033	Campaign length	Review / lifecycle: Validate max consecutive batches before cleaning	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Controlled accumulation of residues.	Review	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	Medium
BTV-21-0034	Equipment disassembly	Protocol / design: Qualify component COP/inspection and reassembly	Preapproved risk-based study design; endpoint: No trapped contamination.	Planning	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0035	Equipment disassembly	Execution / boundary verification: Qualify component COP/inspection and reassembly	Documented raw observations, calibration, relevant worst cases and defined acceptance for No trapped contamination.	Execution	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0036	Equipment disassembly	Review / lifecycle: Qualify component COP/inspection and reassembly	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No trapped contamination.	Review	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	Medium
BTV-21-0037	Dedicated vs shared use	Protocol / design: Risk assess reusable product-contact trains and cleaning limitations	Preapproved risk-based study design; endpoint: No unsafe cross-contamination.	Planning	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0038	Dedicated vs shared use	Execution / boundary verification: Risk assess reusable product-contact trains and cleaning limitations	Documented raw observations, calibration, relevant worst cases and defined acceptance for No unsafe cross-contamination.	Execution	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0039	Dedicated vs shared use	Review / lifecycle: Risk assess reusable product-contact trains and cleaning limitations	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No unsafe cross-contamination.	Review	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	Medium
BTV-21-0040	Cleaning agent residue	Protocol / design: Show detergent removal from wetted surfaces	Preapproved risk-based study design; endpoint: Controlled residual cleaning compound.	Planning	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0041	Cleaning agent residue	Execution / boundary verification: Show detergent removal from wetted surfaces	Documented raw observations, calibration, relevant worst cases and defined acceptance for Controlled residual cleaning compound.	Execution	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0042	Cleaning agent residue	Review / lifecycle: Show detergent removal from wetted surfaces	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Controlled residual cleaning compound.	Review	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	Medium
BTV-21-0043	Microbial biofilm	Protocol / design: Evaluate challenging niches and periodic sanitization	Preapproved risk-based study design; endpoint: Sustainable process microbial control.	Planning	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0044	Microbial biofilm	Execution / boundary verification: Evaluate challenging niches and periodic sanitization	Documented raw observations, calibration, relevant worst cases and defined acceptance for Sustainable process microbial control.	Execution	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0045	Microbial biofilm	Review / lifecycle: Evaluate challenging niches and periodic sanitization	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Sustainable process microbial control.	Review	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	Medium
BTV-21-0046	Manual cleaning	Protocol / design: Validate operator variability and training challenge	Preapproved risk-based study design; endpoint: Repeatable manual cleaning outcome.	Planning	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-21-0047	Manual cleaning	Execution / boundary verification: Validate operator variability and training challenge	Documented raw observations, calibration, relevant worst cases and defined acceptance for Repeatable manual cleaning outcome.	Execution	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0048	Manual cleaning	Review / lifecycle: Validate operator variability and training challenge	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Repeatable manual cleaning outcome.	Review	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	Medium
BTV-21-0049	CIP supply skid	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Concentration, return flow, time and temperature to product impact on Reliable cleaning cycle.	URS / DQ	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0050	CIP supply skid	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for CIP supply skid.	IQ	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	Medium
BTV-21-0051	CIP supply skid	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Concentration, return flow, time and temperature; compare challenge outputs to predefined Reliable cleaning cycle acceptance.	OQ	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0052	CIP supply skid	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Reliable cleaning cycle.	OQ	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0053	CIP supply skid	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Reliable cleaning cycle at relevant Concentration, return flow, time and temperature; sampling scientifically justified.	PQ	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0054	CIP supply skid	Continued verification / risk-based requalification trigger evaluation	Trend Concentration, return flow, time and temperature and impact on Reliable cleaning cycle; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	Medium
BTV-21-0055	CIP return conductivity sensor	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Sensor range, response and calibration to product impact on Correct rinse endpoint.	URS / DQ	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0056	CIP return conductivity sensor	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for CIP return conductivity sensor.	IQ	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	Medium
BTV-21-0057	CIP return conductivity sensor	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Sensor range, response and calibration; compare challenge outputs to predefined Correct rinse endpoint acceptance.	OQ	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0058	CIP return conductivity sensor	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Correct rinse endpoint.	OQ	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0059	CIP return conductivity sensor	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Correct rinse endpoint at relevant Sensor range, response and calibration; sampling scientifically justified.	PQ	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0060	CIP return conductivity sensor	Continued verification / risk-based requalification trigger evaluation	Trend Sensor range, response and calibration and impact on Correct rinse endpoint; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	Medium
BTV-21-0061	CIP spray ball	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Coverage, pressure, shadow areas to product impact on Effective surface cleaning.	URS / DQ	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0062	CIP spray ball	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for CIP spray ball.	IQ	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	Medium
BTV-21-0063	CIP spray ball	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Coverage, pressure, shadow areas; compare challenge outputs to predefined Effective surface cleaning acceptance.	OQ	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0064	CIP spray ball	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Effective surface cleaning.	OQ	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0065	CIP spray ball	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Effective surface cleaning at relevant Coverage, pressure, shadow areas; sampling scientifically justified.	PQ	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0066	CIP spray ball	Continued verification / risk-based requalification trigger evaluation	Trend Coverage, pressure, shadow areas and impact on Effective surface cleaning; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	Medium
BTV-21-0067	COP parts washer	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Load arrangement, spray pressure and drying to product impact on Consistent component cleaning.	URS / DQ	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0068	COP parts washer	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for COP parts washer.	IQ	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-21-0069	COP parts washer	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Load arrangement, spray pressure and drying; compare challenge outputs to predefined Consistent component cleaning acceptance.	OQ	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0070	COP parts washer	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Consistent component cleaning.	OQ	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0071	COP parts washer	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Consistent component cleaning at relevant Load arrangement, spray pressure and drying; sampling scientifically justified.	PQ	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0072	COP parts washer	Continued verification / risk-based requalification trigger evaluation	Trend Load arrangement, spray pressure and drying and impact on Consistent component cleaning; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	Medium
BTV-21-0073	CIP return pump	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Flow rate, cavitation and suction to product impact on Complete return and soil transport.	URS / DQ	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0074	CIP return pump	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for CIP return pump.	IQ	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	Medium
BTV-21-0075	CIP return pump	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Flow rate, cavitation and suction; compare challenge outputs to predefined Complete return and soil transport acceptance.	OQ	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0076	CIP return pump	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Complete return and soil transport.	OQ	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0077	CIP return pump	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Complete return and soil transport at relevant Flow rate, cavitation and suction; sampling scientifically justified.	PQ	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0078	CIP return pump	Continued verification / risk-based requalification trigger evaluation	Trend Flow rate, cavitation and suction and impact on Complete return and soil transport; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	Medium
BTV-21-0079	Cleaning swab test kit	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Recovery, stability, LOQ and material to product impact on Defensible residual quantitation.	URS / DQ	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0080	Cleaning swab test kit	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Cleaning swab test kit.	IQ	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	Medium
BTV-21-0081	Cleaning swab test kit	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Recovery, stability, LOQ and material; compare challenge outputs to predefined Defensible residual quantitation acceptance.	OQ	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0082	Cleaning swab test kit	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Defensible residual quantitation.	OQ	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0083	Cleaning swab test kit	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Defensible residual quantitation at relevant Recovery, stability, LOQ and material; sampling scientifically justified.	PQ	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0084	Cleaning swab test kit	Continued verification / risk-based requalification trigger evaluation	Trend Recovery, stability, LOQ and material and impact on Defensible residual quantitation; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	Medium
BTV-21-0085	CIP cycle recorder / PLC	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Recipe lock, alarm, audit trail to product impact on Traceable validated cleaning runs.	URS / DQ	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0086	CIP cycle recorder / PLC	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for CIP cycle recorder / PLC.	IQ	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	Medium
BTV-21-0087	CIP cycle recorder / PLC	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Recipe lock, alarm, audit trail; compare challenge outputs to predefined Traceable validated cleaning runs acceptance.	OQ	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0088	CIP cycle recorder / PLC	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Traceable validated cleaning runs.	OQ	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High
BTV-21-0089	CIP cycle recorder / PLC	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Traceable validated cleaning runs at relevant Recipe lock, alarm, audit trail; sampling scientifically justified.	PQ	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-21-0090	CIP cycle recorder / PLC	Continued verification / risk-based requalification trigger evaluation	Trend Recipe lock, alarm, audit trail and impact on Traceable validated cleaning runs; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Stainless and multi-product biotechnology processing	B03 B05 B06 B12 B15	Medium

22 STERILIZATION, SIP, AUTOCLAVES AND DEPYROGENATION

87 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-22-0001	Moist heat sterilization	Protocol / design: Heat distribution and penetration at worst-case load	Preapproved risk-based study design; endpoint: Defined lethality/SAL or bioburden-based cycle where applicable.	Planning	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0002	Moist heat sterilization	Execution / boundary verification: Heat distribution and penetration at worst-case load	Documented raw observations, calibration, relevant worst cases and defined acceptance for Defined lethality/SAL or bioburden-based cycle where applicable.	Execution	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0003	Moist heat sterilization	Review / lifecycle: Heat distribution and penetration at worst-case load	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Defined lethality/SAL or bioburden-based cycle where applicable.	Review	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	Medium
BTV-22-0004	SIP validation	Protocol / design: Demonstrate cold point time, temperature, steam quality and air removal	Preapproved risk-based study design; endpoint: Repeatable sterile product-contact path.	Planning	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0005	SIP validation	Execution / boundary verification: Demonstrate cold point time, temperature, steam quality and air removal	Documented raw observations, calibration, relevant worst cases and defined acceptance for Repeatable sterile product-contact path.	Execution	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0006	SIP validation	Review / lifecycle: Demonstrate cold point time, temperature, steam quality and air removal	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Repeatable sterile product-contact path.	Review	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	Medium
BTV-22-0007	SIP boundaries	Protocol / design: Validate valves, low points and condensate drain	Preapproved risk-based study design; endpoint: All intended surfaces exposed.	Planning	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0008	SIP boundaries	Execution / boundary verification: Validate valves, low points and condensate drain	Documented raw observations, calibration, relevant worst cases and defined acceptance for All intended surfaces exposed.	Execution	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0009	SIP boundaries	Review / lifecycle: Validate valves, low points and condensate drain	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on All intended surfaces exposed.	Review	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	Medium
BTV-22-0010	Load configuration	Protocol / design: Qualify equipment orientation, filters and tubing assemblies	Preapproved risk-based study design; endpoint: Sterilization accessibility.	Planning	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0011	Load configuration	Execution / boundary verification: Qualify equipment orientation, filters and tubing assemblies	Documented raw observations, calibration, relevant worst cases and defined acceptance for Sterilization accessibility.	Execution	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0012	Load configuration	Review / lifecycle: Qualify equipment orientation, filters and tubing assemblies	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Sterilization accessibility.	Review	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	Medium
BTV-22-0013	BI challenge	Protocol / design: Use suitable indicators and locations for cycle type	Preapproved risk-based study design; endpoint: Evidence microbial lethality within cycle limitations.	Planning	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0014	BI challenge	Execution / boundary verification: Use suitable indicators and locations for cycle type	Documented raw observations, calibration, relevant worst cases and defined acceptance for Evidence microbial lethality within cycle limitations.	Execution	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0015	BI challenge	Review / lifecycle: Use suitable indicators and locations for cycle type	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Evidence microbial lethality within cycle limitations.	Review	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	Medium
BTV-22-0016	Poststerile integrity	Protocol / design: Validate closed sterile boundary and post-cycle hold	Preapproved risk-based study design; endpoint: No recontamination before use.	Planning	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0017	Poststerile integrity	Execution / boundary verification: Validate closed sterile boundary and post-cycle hold	Documented raw observations, calibration, relevant worst cases and defined acceptance for No recontamination before use.	Execution	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0018	Poststerile integrity	Review / lifecycle: Validate closed sterile boundary and post-cycle hold	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No recontamination before use.	Review	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	Medium
BTV-22-0019	Autoclave liquid loads	Protocol / design: Challenge slow heat penetration and container pressure	Preapproved risk-based study design; endpoint: Successful product-appropriate sterilization.	Planning	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0020	Autoclave liquid loads	Execution / boundary verification: Challenge slow heat penetration and container pressure	Documented raw observations, calibration, relevant worst cases and defined acceptance for Successful product-appropriate sterilization.	Execution	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0021	Autoclave liquid loads	Review / lifecycle: Challenge slow heat penetration and container pressure	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Successful product-appropriate sterilization.	Review	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	Medium
BTV-22-0022	Depyrogenation	Protocol / design: Validate time-temperature endotoxin reduction for applicable glassware	Preapproved risk-based study design; endpoint: Endotoxin challenge study where justified.	Planning	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-22-0023	Depyrogenation	Execution / boundary verification: Validate time-temperature endotoxin reduction for applicable glassware	Documented raw observations, calibration, relevant worst cases and defined acceptance for Endotoxin challenge study where justified.	Execution	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0024	Depyrogenation	Review / lifecycle: Validate time-temperature endotoxin reduction for applicable glassware	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Endotoxin challenge study where justified.	Review	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	Medium
BTV-22-0025	Dry heat sterilization	Protocol / design: Demonstrate thermal distribution for applicable load	Preapproved risk-based study design; endpoint: Appropriate validated thermal exposure.	Planning	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0026	Dry heat sterilization	Execution / boundary verification: Demonstrate thermal distribution for applicable load	Documented raw observations, calibration, relevant worst cases and defined acceptance for Appropriate validated thermal exposure.	Execution	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0027	Dry heat sterilization	Review / lifecycle: Demonstrate thermal distribution for applicable load	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Appropriate validated thermal exposure.	Review	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	Medium
BTV-22-0028	Sterilizing filtration	Protocol / design: Qualify bacterial retention, filter compatibility and integrity	Preapproved risk-based study design; endpoint: Filtration as a sterile barrier.	Planning	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0029	Sterilizing filtration	Execution / boundary verification: Qualify bacterial retention, filter compatibility and integrity	Documented raw observations, calibration, relevant worst cases and defined acceptance for Filtration as a sterile barrier.	Execution	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0030	Sterilizing filtration	Review / lifecycle: Qualify bacterial retention, filter compatibility and integrity	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Filtration as a sterile barrier.	Review	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	Medium
BTV-22-0031	Filter preuse integrity	Protocol / design: Assess PUPSIT feasibility and Annex 1 expectations when relevant	Preapproved risk-based study design; endpoint: Justified pre/post use filter integrity controls.	Planning	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0032	Filter preuse integrity	Execution / boundary verification: Assess PUPSIT feasibility and Annex 1 expectations when relevant	Documented raw observations, calibration, relevant worst cases and defined acceptance for Justified pre/post use filter integrity controls.	Execution	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0033	Filter preuse integrity	Review / lifecycle: Assess PUPSIT feasibility and Annex 1 expectations when relevant	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Justified pre/post use filter integrity controls.	Review	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	Medium
BTV-22-0034	Sterile connection	Protocol / design: Validate aseptic weld/connector handling after sterilization	Preapproved risk-based study design; endpoint: No compromise in aseptic boundary.	Planning	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0035	Sterile connection	Execution / boundary verification: Validate aseptic weld/connector handling after sterilization	Documented raw observations, calibration, relevant worst cases and defined acceptance for No compromise in aseptic boundary.	Execution	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0036	Sterile connection	Review / lifecycle: Validate aseptic weld/connector handling after sterilization	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No compromise in aseptic boundary.	Review	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	Medium
BTV-22-0037	Sterile hold time	Protocol / design: Define maximum post-SIP idle hold and environmental condition	Preapproved risk-based study design; endpoint: Validated sterile equipment state.	Planning	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0038	Sterile hold time	Execution / boundary verification: Define maximum post-SIP idle hold and environmental condition	Documented raw observations, calibration, relevant worst cases and defined acceptance for Validated sterile equipment state.	Execution	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0039	Sterile hold time	Review / lifecycle: Define maximum post-SIP idle hold and environmental condition	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Validated sterile equipment state.	Review	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	Medium
BTV-22-0040	Steam autoclave	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Heat distribution, penetration, air removal to product impact on Target sterility assurance under validated load.	URS / DQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0041	Steam autoclave	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Steam autoclave.	IQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	Medium
BTV-22-0042	Steam autoclave	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Heat distribution, penetration, air removal; compare challenge outputs to predefined Target sterility assurance under validated load acceptance.	OQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0043	Steam autoclave	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Target sterility assurance under validated load.	OQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0044	Steam autoclave	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Target sterility assurance under validated load at relevant Heat distribution, penetration, air removal; sampling scientifically justified.	PQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0045	Steam autoclave	Continued verification / risk-based requalification trigger evaluation	Trend Heat distribution, penetration, air removal and impact on Target sterility assurance under validated load; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-22-0046	Bioreactor SIP cycle	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Temperature cold points, valves and seals to product impact on Sterile product-contact bioreactor.	URS / DQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0047	Bioreactor SIP cycle	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Bioreactor SIP cycle.	IQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	Medium
BTV-22-0048	Bioreactor SIP cycle	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Temperature cold points, valves and seals; compare challenge outputs to predefined Sterile product-contact bioreactor acceptance.	OQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0049	Bioreactor SIP cycle	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Sterile product-contact bioreactor.	OQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0050	Bioreactor SIP cycle	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Sterile product-contact bioreactor at relevant Temperature cold points, valves and seals; sampling scientifically justified.	PQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0051	Bioreactor SIP cycle	Continued verification / risk-based requalification trigger evaluation	Trend Temperature cold points, valves and seals and impact on Sterile product-contact bioreactor; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	Medium
BTV-22-0052	CIP/SIP integrated skid	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Recipe transition, pressure and time to product impact on Sterile train without process error.	URS / DQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0053	CIP/SIP integrated skid	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for CIP/SIP integrated skid.	IQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	Medium
BTV-22-0054	CIP/SIP integrated skid	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Recipe transition, pressure and time; compare challenge outputs to predefined Sterile train without process error acceptance.	OQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0055	CIP/SIP integrated skid	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Sterile train without process error.	OQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0056	CIP/SIP integrated skid	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Sterile train without process error at relevant Recipe transition, pressure and time; sampling scientifically justified.	PQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0057	CIP/SIP integrated skid	Continued verification / risk-based requalification trigger evaluation	Trend Recipe transition, pressure and time and impact on Sterile train without process error; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	Medium
BTV-22-0058	Dry heat depyrogenation tunnel	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Conveyor speed, thermal penetration, endotoxin challenge to product impact on Endotoxin reduction in glassware.	URS / DQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0059	Dry heat depyrogenation tunnel	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Dry heat depyrogenation tunnel.	IQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	Medium
BTV-22-0060	Dry heat depyrogenation tunnel	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Conveyor speed, thermal penetration, endotoxin challenge; compare challenge outputs to predefined Endotoxin reduction in glassware acceptance.	OQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0061	Dry heat depyrogenation tunnel	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Endotoxin reduction in glassware.	OQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0062	Dry heat depyrogenation tunnel	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Endotoxin reduction in glassware at relevant Conveyor speed, thermal penetration, endotoxin challenge; sampling scientifically justified.	PQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0063	Dry heat depyrogenation tunnel	Continued verification / risk-based requalification trigger evaluation	Trend Conveyor speed, thermal penetration, endotoxin challenge and impact on Endotoxin reduction in glassware; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	Medium
BTV-22-0064	Dry heat oven	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Temperature uniformity and load penetration to product impact on Sterilization/depyrogenation where claimed.	URS / DQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0065	Dry heat oven	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Dry heat oven.	IQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	Medium
BTV-22-0066	Dry heat oven	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Temperature uniformity and load penetration; compare challenge outputs to predefined Sterilization/depyrogenation where claimed acceptance.	OQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-22-0067	Dry heat oven	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Sterilization/depyrogenation where claimed.	OQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0068	Dry heat oven	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Sterilization/depyrogenation where claimed at relevant Temperature uniformity and load penetration; sampling scientifically justified.	PQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0069	Dry heat oven	Continued verification / risk-based requalification trigger evaluation	Trend Temperature uniformity and load penetration and impact on Sterilization/depyrogenation where claimed; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	Medium
BTV-22-0070	Sterilizing filter integrity tester	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Pressure decay, bubble point, diffusion to product impact on Correct filter integrity determination.	URS / DQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0071	Sterilizing filter integrity tester	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Sterilizing filter integrity tester.	IQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	Medium
BTV-22-0072	Sterilizing filter integrity tester	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Pressure decay, bubble point, diffusion; compare challenge outputs to predefined Correct filter integrity determination acceptance.	OQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0073	Sterilizing filter integrity tester	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Correct filter integrity determination.	OQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0074	Sterilizing filter integrity tester	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Correct filter integrity determination at relevant Pressure decay, bubble point, diffusion; sampling scientifically justified.	PQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0075	Sterilizing filter integrity tester	Continued verification / risk-based requalification trigger evaluation	Trend Pressure decay, bubble point, diffusion and impact on Correct filter integrity determination; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	Medium
BTV-22-0076	Component autoclave	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Wrapped load, drying, bioburden control to product impact on Sterile gown/equipment components.	URS / DQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0077	Component autoclave	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Component autoclave.	IQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	Medium
BTV-22-0078	Component autoclave	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Wrapped load, drying, bioburden control; compare challenge outputs to predefined Sterile gown/equipment components acceptance.	OQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0079	Component autoclave	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Sterile gown/equipment components.	OQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0080	Component autoclave	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Sterile gown/equipment components at relevant Wrapped load, drying, bioburden control; sampling scientifically justified.	PQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0081	Component autoclave	Continued verification / risk-based requalification trigger evaluation	Trend Wrapped load, drying, bioburden control and impact on Sterile gown/equipment components; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	Medium
BTV-22-0082	Clean steam condensate sampling skid	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Steam quality and sampling to product impact on Valid clean steam characterization.	URS / DQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0083	Clean steam condensate sampling skid	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Clean steam condensate sampling skid.	IQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	Medium
BTV-22-0084	Clean steam condensate sampling skid	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Steam quality and sampling; compare challenge outputs to predefined Valid clean steam characterization acceptance.	OQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0085	Clean steam condensate sampling skid	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Valid clean steam characterization.	OQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0086	Clean steam condensate sampling skid	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Valid clean steam characterization at relevant Steam quality and sampling; sampling scientifically justified.	PQ	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	High
BTV-22-0087	Clean steam condensate sampling skid	Continued verification / risk-based requalification trigger evaluation	Trend Steam quality and sampling and impact on Valid clean steam characterization; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Aseptic biologics and product contact equipment	B03 B04 B05 B06 B20	Medium

23 ASEPTIC MANUFACTURE, APS/MEDIA FILL & CCS

120 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-23-0001	Contamination Control Strategy	Protocol / design: Map microbial, particulate and endotoxin sources and controls	Preapproved risk-based study design; endpoint: Integrated risk-based CCS and review plan.	Planning	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0002	Contamination Control Strategy	Execution / boundary verification: Map microbial, particulate and endotoxin sources and controls	Documented raw observations, calibration, relevant worst cases and defined acceptance for Integrated risk-based CCS and review plan.	Execution	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0003	Contamination Control Strategy	Review / lifecycle: Map microbial, particulate and endotoxin sources and controls	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Integrated risk-based CCS and review plan.	Review	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	Medium
BTV-23-0004	APS program	Protocol / design: Design process simulation for aseptic operations and representative interventions	Preapproved risk-based study design; endpoint: Meaningful aseptic process simulation, not a blanket nonsterile requirement.	Planning	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0005	APS program	Execution / boundary verification: Design process simulation for aseptic operations and representative interventions	Documented raw observations, calibration, relevant worst cases and defined acceptance for Meaningful aseptic process simulation, not a blanket nonsterile requirement.	Execution	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0006	APS program	Review / lifecycle: Design process simulation for aseptic operations and representative interventions	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Meaningful aseptic process simulation, not a blanket nonsterile requirement.	Review	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	Medium
BTV-23-0007	Worst-case interventions	Protocol / design: Include stopper replenishment, line stoppage, maintenance and samples	Preapproved risk-based study design; endpoint: High-risk manual/automatic aseptic challenges.	Planning	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0008	Worst-case interventions	Execution / boundary verification: Include stopper replenishment, line stoppage, maintenance and samples	Documented raw observations, calibration, relevant worst cases and defined acceptance for High-risk manual/automatic aseptic challenges.	Execution	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0009	Worst-case interventions	Review / lifecycle: Include stopper replenishment, line stoppage, maintenance and samples	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on High-risk manual/automatic aseptic challenges.	Review	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	Medium
BTV-23-0010	APS duration	Protocol / design: Justify production shift, speed, container and operator representation	Preapproved risk-based study design; endpoint: Relevant simulation design and coverage.	Planning	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0011	APS duration	Execution / boundary verification: Justify production shift, speed, container and operator representation	Documented raw observations, calibration, relevant worst cases and defined acceptance for Relevant simulation design and coverage.	Execution	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0012	APS duration	Review / lifecycle: Justify production shift, speed, container and operator representation	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Relevant simulation design and coverage.	Review	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	Medium
BTV-23-0013	APS incubation	Protocol / design: Validate media growth promotion and incubation conditions	Preapproved risk-based study design; endpoint: Ability to detect contamination within study.	Planning	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0014	APS incubation	Execution / boundary verification: Validate media growth promotion and incubation conditions	Documented raw observations, calibration, relevant worst cases and defined acceptance for Ability to detect contamination within study.	Execution	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0015	APS incubation	Review / lifecycle: Validate media growth promotion and incubation conditions	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Ability to detect contamination within study.	Review	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	Medium
BTV-23-0016	APS acceptance	Protocol / design: Apply current Annex 1 investigation and response criteria	Preapproved risk-based study design; endpoint: Contamination triggers investigation and disposition.	Planning	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0017	APS acceptance	Execution / boundary verification: Apply current Annex 1 investigation and response criteria	Documented raw observations, calibration, relevant worst cases and defined acceptance for Contamination triggers investigation and disposition.	Execution	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0018	APS acceptance	Review / lifecycle: Apply current Annex 1 investigation and response criteria	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Contamination triggers investigation and disposition.	Review	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	Medium
BTV-23-0019	Operator gowning qualification	Protocol / design: Challenge aseptic movement, glove monitoring and interventions	Preapproved risk-based study design; endpoint: Competent qualified aseptic staff.	Planning	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0020	Operator gowning qualification	Execution / boundary verification: Challenge aseptic movement, glove monitoring and interventions	Documented raw observations, calibration, relevant worst cases and defined acceptance for Competent qualified aseptic staff.	Execution	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0021	Operator gowning qualification	Review / lifecycle: Challenge aseptic movement, glove monitoring and interventions	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Competent qualified aseptic staff.	Review	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	Medium

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BTV-23-0022	Grade A airflow	Protocol / design: Visualize first air at critical locations and interventions	Preapproved risk-based study design; endpoint: No contamination path to sterile product.	Planning	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0023	Grade A airflow	Execution / boundary verification: Visualize first air at critical locations and interventions	Documented raw observations, calibration, relevant worst cases and defined acceptance for No contamination path to sterile product.	Execution	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0024	Grade A airflow	Review / lifecycle: Visualize first air at critical locations and interventions	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No contamination path to sterile product.	Review	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	Medium
BTV-23-0025	Sterile component transfer	Protocol / design: Qualify disinfection cycles and sterile path traceability	Preapproved risk-based study design; endpoint: Properly sterilized inputs in Grade A/B environment.	Planning	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0026	Sterile component transfer	Execution / boundary verification: Qualify disinfection cycles and sterile path traceability	Documented raw observations, calibration, relevant worst cases and defined acceptance for Properly sterilized inputs in Grade A/B environment.	Execution	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0027	Sterile component transfer	Review / lifecycle: Qualify disinfection cycles and sterile path traceability	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Properly sterilized inputs in Grade A/B environment.	Review	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	Medium
BTV-23-0028	Bioburden before sterilizing filtration	Protocol / design: Set evidence-based limit and sampling point	Preapproved risk-based study design; endpoint: Controlled prefilter microbial burden.	Planning	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0029	Bioburden before sterilizing filtration	Execution / boundary verification: Set evidence-based limit and sampling point	Documented raw observations, calibration, relevant worst cases and defined acceptance for Controlled prefilter microbial burden.	Execution	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0030	Bioburden before sterilizing filtration	Review / lifecycle: Set evidence-based limit and sampling point	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Controlled prefilter microbial burden.	Review	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	Medium
BTV-23-0031	Endotoxin risk	Protocol / design: Establish sources, limits and validated test recovery	Preapproved risk-based study design; endpoint: No pyrogen contamination.	Planning	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0032	Endotoxin risk	Execution / boundary verification: Establish sources, limits and validated test recovery	Documented raw observations, calibration, relevant worst cases and defined acceptance for No pyrogen contamination.	Execution	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0033	Endotoxin risk	Review / lifecycle: Establish sources, limits and validated test recovery	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No pyrogen contamination.	Review	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	Medium
BTV-23-0034	Sterility testing method suitability	Protocol / design: Qualify product inhibition/interference controls	Preapproved risk-based study design; endpoint: Reliable sterility assay.	Planning	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0035	Sterility testing method suitability	Execution / boundary verification: Qualify product inhibition/interference controls	Documented raw observations, calibration, relevant worst cases and defined acceptance for Reliable sterility assay.	Execution	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0036	Sterility testing method suitability	Review / lifecycle: Qualify product inhibition/interference controls	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Reliable sterility assay.	Review	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	Medium
BTV-23-0037	Aseptic environmental monitoring	Protocol / design: Qualify viable/nonviable sampling methods and frequency	Preapproved risk-based study design; endpoint: Representative critical site conditions.	Planning	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0038	Aseptic environmental monitoring	Execution / boundary verification: Qualify viable/nonviable sampling methods and frequency	Documented raw observations, calibration, relevant worst cases and defined acceptance for Representative critical site conditions.	Execution	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0039	Aseptic environmental monitoring	Review / lifecycle: Qualify viable/nonviable sampling methods and frequency	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Representative critical site conditions.	Review	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	Medium
BTV-23-0040	Intervention video review	Protocol / design: Document simulation of manual high-risk tasks	Preapproved risk-based study design; endpoint: Traceability between procedure and APS scope.	Planning	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0041	Intervention video review	Execution / boundary verification: Document simulation of manual high-risk tasks	Documented raw observations, calibration, relevant worst cases and defined acceptance for Traceability between procedure and APS scope.	Execution	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0042	Intervention video review	Review / lifecycle: Document simulation of manual high-risk tasks	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Traceability between procedure and APS scope.	Review	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	Medium
BTV-23-0043	Line restart recovery	Protocol / design: Define validated restart after stop / failure	Preapproved risk-based study design; endpoint: No loss of aseptic state.	Planning	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0044	Line restart recovery	Execution / boundary verification: Define validated restart after stop / failure	Documented raw observations, calibration, relevant worst cases and defined acceptance for No loss of aseptic state.	Execution	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0045	Line restart recovery	Review / lifecycle: Define validated restart after stop / failure	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No loss of aseptic state.	Review	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	Medium

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BTV-23-0046	RABS / isolator decontamination	Protocol / design: Qualify gaseous disinfection and integrity where installed	Preapproved risk-based study design; endpoint: Controlled internal microbial contamination.	Planning	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0047	RABS / isolator decontamination	Execution / boundary verification: Qualify gaseous disinfection and integrity where installed	Documented raw observations, calibration, relevant worst cases and defined acceptance for Controlled internal microbial contamination.	Execution	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0048	RABS / isolator decontamination	Review / lifecycle: Qualify gaseous disinfection and integrity where installed	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Controlled internal microbial contamination.	Review	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	Medium
BTV-23-0049	Sterile hold after final filtration	Protocol / design: Validate allowable hold and connection integrity	Preapproved risk-based study design; endpoint: No sterility loss before filling.	Planning	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0050	Sterile hold after final filtration	Execution / boundary verification: Validate allowable hold and connection integrity	Documented raw observations, calibration, relevant worst cases and defined acceptance for No sterility loss before filling.	Execution	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0051	Sterile hold after final filtration	Review / lifecycle: Validate allowable hold and connection integrity	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No sterility loss before filling.	Review	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	Medium
BTV-23-0052	Aseptic vial filler	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Fill volume, open container exposure, reject handling to product impact on Dose accuracy and aseptic control.	URS / DQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0053	Aseptic vial filler	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Aseptic vial filler.	IQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	Medium
BTV-23-0054	Aseptic vial filler	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Fill volume, open container exposure, reject handling; compare challenge outputs to predefined Dose accuracy and aseptic control acceptance.	OQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0055	Aseptic vial filler	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Dose accuracy and aseptic control.	OQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0056	Aseptic vial filler	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Dose accuracy and aseptic control at relevant Fill volume, open container exposure, reject handling; sampling scientifically justified.	PQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0057	Aseptic vial filler	Continued verification / risk-based requalification trigger evaluation	Trend Fill volume, open container exposure, reject handling and impact on Dose accuracy and aseptic control; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	Medium
BTV-23-0058	Ampoule filling and sealing machine	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Fill accuracy, flame sealing and particles to product impact on Sterile integrity and dose.	URS / DQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0059	Ampoule filling and sealing machine	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Ampoule filling and sealing machine.	IQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	Medium
BTV-23-0060	Ampoule filling and sealing machine	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Fill accuracy, flame sealing and particles; compare challenge outputs to predefined Sterile integrity and dose acceptance.	OQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0061	Ampoule filling and sealing machine	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Sterile integrity and dose.	OQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0062	Ampoule filling and sealing machine	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Sterile integrity and dose at relevant Fill accuracy, flame sealing and particles; sampling scientifically justified.	PQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0063	Ampoule filling and sealing machine	Continued verification / risk-based requalification trigger evaluation	Trend Fill accuracy, flame sealing and particles and impact on Sterile integrity and dose; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	Medium
BTV-23-0064	RABS enclosure	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Glove leak, airflow, transfer and decon to product impact on Controlled critical zone.	URS / DQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0065	RABS enclosure	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for RABS enclosure.	IQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	Medium
BTV-23-0066	RABS enclosure	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Glove leak, airflow, transfer and decon; compare challenge outputs to predefined Controlled critical zone acceptance.	OQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0067	RABS enclosure	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Controlled critical zone.	OQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High

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BTV-23-0068	RABS enclosure	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Controlled critical zone at relevant Glove leak, airflow, transfer and decon; sampling scientifically justified.	PQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0069	RABS enclosure	Continued verification / risk-based requalification trigger evaluation	Trend Glove leak, airflow, transfer and decon and impact on Controlled critical zone; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	Medium
BTV-23-0070	Aseptic isolator	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Bio-decontamination, pressure, glove integrity to product impact on Sterile process boundary.	URS / DQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0071	Aseptic isolator	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Aseptic isolator.	IQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	Medium
BTV-23-0072	Aseptic isolator	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Bio-decontamination, pressure, glove integrity; compare challenge outputs to predefined Sterile process boundary acceptance.	OQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0073	Aseptic isolator	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Sterile process boundary.	OQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0074	Aseptic isolator	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Sterile process boundary at relevant Bio-decontamination, pressure, glove integrity; sampling scientifically justified.	PQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0075	Aseptic isolator	Continued verification / risk-based requalification trigger evaluation	Trend Bio-decontamination, pressure, glove integrity and impact on Sterile process boundary; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	Medium
BTV-23-0076	Closed aseptic transfer skid	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Connections, integrity and flow routing to product impact on Maintained sterile boundary.	URS / DQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0077	Closed aseptic transfer skid	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Closed aseptic transfer skid.	IQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	Medium
BTV-23-0078	Closed aseptic transfer skid	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Connections, integrity and flow routing; compare challenge outputs to predefined Maintained sterile boundary acceptance.	OQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0079	Closed aseptic transfer skid	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Maintained sterile boundary.	OQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0080	Closed aseptic transfer skid	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Maintained sterile boundary at relevant Connections, integrity and flow routing; sampling scientifically justified.	PQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0081	Closed aseptic transfer skid	Continued verification / risk-based requalification trigger evaluation	Trend Connections, integrity and flow routing and impact on Maintained sterile boundary; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	Medium
BTV-23-0082	In-line particle counter	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Sampling flow, calibration, alarm to product impact on Valid classified area trend.	URS / DQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0083	In-line particle counter	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for In-line particle counter.	IQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	Medium
BTV-23-0084	In-line particle counter	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Sampling flow, calibration, alarm; compare challenge outputs to predefined Valid classified area trend acceptance.	OQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0085	In-line particle counter	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Valid classified area trend.	OQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0086	In-line particle counter	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Valid classified area trend at relevant Sampling flow, calibration, alarm; sampling scientifically justified.	PQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0087	In-line particle counter	Continued verification / risk-based requalification trigger evaluation	Trend Sampling flow, calibration, alarm and impact on Valid classified area trend; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	Medium
BTV-23-0088	Viable air sampler	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Flow calibration and sampling recovery to product impact on Representative microbial EM.	URS / DQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0089	Viable air sampler	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Viable air sampler.	IQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	Medium

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BTV-23-0090	Viable air sampler	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Flow calibration and sampling recovery; compare challenge outputs to predefined Representative microbial EM acceptance.	OQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0091	Viable air sampler	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Representative microbial EM.	OQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0092	Viable air sampler	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Representative microbial EM at relevant Flow calibration and sampling recovery; sampling scientifically justified.	PQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0093	Viable air sampler	Continued verification / risk-based requalification trigger evaluation	Trend Flow calibration and sampling recovery and impact on Representative microbial EM; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	Medium
BTV-23-0094	Sterile bulk formulation vessel	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace SIP status, mixing, hold and connections to product impact on Sterile homogeneous bulk.	URS / DQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0095	Sterile bulk formulation vessel	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Sterile bulk formulation vessel.	IQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	Medium
BTV-23-0096	Sterile bulk formulation vessel	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of SIP status, mixing, hold and connections; compare challenge outputs to predefined Sterile homogeneous bulk acceptance.	OQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0097	Sterile bulk formulation vessel	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Sterile homogeneous bulk.	OQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0098	Sterile bulk formulation vessel	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Sterile homogeneous bulk at relevant SIP status, mixing, hold and connections; sampling scientifically justified.	PQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0099	Sterile bulk formulation vessel	Continued verification / risk-based requalification trigger evaluation	Trend SIP status, mixing, hold and connections and impact on Sterile homogeneous bulk; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	Medium
BTV-23-0100	Glove integrity test system	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Leak detection limit and method to product impact on Barrier glove acceptance.	URS / DQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0101	Glove integrity test system	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Glove integrity test system.	IQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	Medium
BTV-23-0102	Glove integrity test system	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Leak detection limit and method; compare challenge outputs to predefined Barrier glove acceptance acceptance.	OQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0103	Glove integrity test system	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Barrier glove acceptance.	OQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0104	Glove integrity test system	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Barrier glove acceptance at relevant Leak detection limit and method; sampling scientifically justified.	PQ	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	High
BTV-23-0105	Glove integrity test system	Continued verification / risk-based requalification trigger evaluation	Trend Leak detection limit and method and impact on Barrier glove acceptance; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Sterile formulation, aseptic bulk and fill finish	B03 B04 B05 B06 B21	Medium
BTV-23-0106	APS line-speed strategy	Protocol / design: Include justified slow and fast filling where risk relevant	Preapproved risk-based study design; endpoint: Representative exposure and interventions.	Planning	Aseptic biologic facilities	B04 B06	High
BTV-23-0107	APS line-speed strategy	Execution / boundary verification: Include justified slow and fast filling where risk relevant	Documented raw observations, calibration, relevant worst cases and defined acceptance for Representative exposure and interventions.	Execution	Aseptic biologic facilities	B04 B06	High
BTV-23-0108	APS line-speed strategy	Review / lifecycle: Include justified slow and fast filling where risk relevant	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Representative exposure and interventions.	Review	Aseptic biologic facilities	B04 B06	Medium
BTV-23-0109	APS response to contamination	Protocol / design: Investigate any positive units and line impact	Preapproved risk-based study design; endpoint: No unexplained positive APS.	Planning	Aseptic biologic facilities	B04 B06	High
BTV-23-0110	APS response to contamination	Execution / boundary verification: Investigate any positive units and line impact	Documented raw observations, calibration, relevant worst cases and defined acceptance for No unexplained positive APS.	Execution	Aseptic biologic facilities	B04 B06	High
BTV-23-0111	APS response to contamination	Review / lifecycle: Investigate any positive units and line impact	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No unexplained positive APS.	Review	Aseptic biologic facilities	B04 B06	Medium
BTV-23-0112	Gowning media challenge	Protocol / design: Reassess competence after failed microbiological qualification	Preapproved risk-based study design; endpoint: Controlled operator recertification.	Planning	Aseptic biologic facilities	B04 B06	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-23-0113	Gowning media challenge	Execution / boundary verification: Reassess competence after failed microbiological qualification	Documented raw observations, calibration, relevant worst cases and defined acceptance for Controlled operator recertification.	Execution	Aseptic biologic facilities	B04 B06	High
BTV-23-0114	Gowning media challenge	Review / lifecycle: Reassess competence after failed microbiological qualification	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Controlled operator recertification.	Review	Aseptic biologic facilities	B04 B06	Medium
BTV-23-0115	Critical intervention qualification	Protocol / design: Qualify glove sanitization and restoration of first air	Preapproved risk-based study design; endpoint: No sterility boundary compromise.	Planning	Aseptic biologic facilities	B04 B06	High
BTV-23-0116	Critical intervention qualification	Execution / boundary verification: Qualify glove sanitization and restoration of first air	Documented raw observations, calibration, relevant worst cases and defined acceptance for No sterility boundary compromise.	Execution	Aseptic biologic facilities	B04 B06	High
BTV-23-0117	Critical intervention qualification	Review / lifecycle: Qualify glove sanitization and restoration of first air	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No sterility boundary compromise.	Review	Aseptic biologic facilities	B04 B06	Medium
BTV-23-0118	EM excursion during filling	Protocol / design: Evaluate product impact based on organism and exposure	Preapproved risk-based study design; endpoint: Scientific aseptic batch disposition.	Planning	Aseptic biologic facilities	B04 B06	High
BTV-23-0119	EM excursion during filling	Execution / boundary verification: Evaluate product impact based on organism and exposure	Documented raw observations, calibration, relevant worst cases and defined acceptance for Scientific aseptic batch disposition.	Execution	Aseptic biologic facilities	B04 B06	High
BTV-23-0120	EM excursion during filling	Review / lifecycle: Evaluate product impact based on organism and exposure	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Scientific aseptic batch disposition.	Review	Aseptic biologic facilities	B04 B06	Medium

24 FILL FINISH, VIAL/AMPOULE, SYRINGES AND LYOPHILIZATION

129 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-24-0001	Protein formulation	Protocol / design: Establish pH, excipients, ionic strength, surfactant and mixing	Preapproved risk-based study design; endpoint: CQA stability / potency in final formula.	Planning	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0002	Protein formulation	Execution / boundary verification: Establish pH, excipients, ionic strength, surfactant and mixing	Documented raw observations, calibration, relevant worst cases and defined acceptance for CQA stability / potency in final formula.	Execution	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0003	Protein formulation	Review / lifecycle: Establish pH, excipients, ionic strength, surfactant and mixing	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on CQA stability / potency in final formula.	Review	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0004	Filling precision	Protocol / design: Qualify low/high fill volume, speed and container size	Preapproved risk-based study design; endpoint: Accurate dose and minimal losses.	Planning	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0005	Filling precision	Execution / boundary verification: Qualify low/high fill volume, speed and container size	Documented raw observations, calibration, relevant worst cases and defined acceptance for Accurate dose and minimal losses.	Execution	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0006	Filling precision	Review / lifecycle: Qualify low/high fill volume, speed and container size	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Accurate dose and minimal losses.	Review	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0007	Product foaming	Protocol / design: Challenge pump type, line pressure, filling height	Preapproved risk-based study design; endpoint: Controlled air entrainment and aggregation.	Planning	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0008	Product foaming	Execution / boundary verification: Challenge pump type, line pressure, filling height	Documented raw observations, calibration, relevant worst cases and defined acceptance for Controlled air entrainment and aggregation.	Execution	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0009	Product foaming	Review / lifecycle: Challenge pump type, line pressure, filling height	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Controlled air entrainment and aggregation.	Review	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0010	Sterile filter sizing	Protocol / design: Validate minimum area, max batch volume and contact	Preapproved risk-based study design; endpoint: Suitable filtration efficiency and recovery.	Planning	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0011	Sterile filter sizing	Execution / boundary verification: Validate minimum area, max batch volume and contact	Documented raw observations, calibration, relevant worst cases and defined acceptance for Suitable filtration efficiency and recovery.	Execution	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0012	Sterile filter sizing	Review / lifecycle: Validate minimum area, max batch volume and contact	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Suitable filtration efficiency and recovery.	Review	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0013	Sterile filtration retention	Protocol / design: Assess bacterial retention in product or appropriate surrogate	Preapproved risk-based study design; endpoint: Validated filter sterility assurance where relevant.	Planning	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0014	Sterile filtration retention	Execution / boundary verification: Assess bacterial retention in product or appropriate surrogate	Documented raw observations, calibration, relevant worst cases and defined acceptance for Validated filter sterility assurance where relevant.	Execution	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0015	Sterile filtration retention	Review / lifecycle: Assess bacterial retention in product or appropriate surrogate	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Validated filter sterility assurance where relevant.	Review	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0016	Filter compatibility	Protocol / design: Validate product binding, extractables and chemical compatibility	Preapproved risk-based study design; endpoint: Acceptable potency and recovery.	Planning	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0017	Filter compatibility	Execution / boundary verification: Validate product binding, extractables and chemical compatibility	Documented raw observations, calibration, relevant worst cases and defined acceptance for Acceptable potency and recovery.	Execution	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0018	Filter compatibility	Review / lifecycle: Validate product binding, extractables and chemical compatibility	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Acceptable potency and recovery.	Review	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0019	Lyophilization freezing	Protocol / design: Characterize nucleation, freezing ramp and shelf gradient	Preapproved risk-based study design; endpoint: Consistent ice morphology and stability.	Planning	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0020	Lyophilization freezing	Execution / boundary verification: Characterize nucleation, freezing ramp and shelf gradient	Documented raw observations, calibration, relevant worst cases and defined acceptance for Consistent ice morphology and stability.	Execution	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0021	Lyophilization freezing	Review / lifecycle: Characterize nucleation, freezing ramp and shelf gradient	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Consistent ice morphology and stability.	Review	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0022	Primary drying	Protocol / design: Qualify chamber pressure, shelf ramp and product temperature	Preapproved risk-based study design; endpoint: Sublimation without collapse.	Planning	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-24-0023	Primary drying	Execution / boundary verification: Qualify chamber pressure, shelf ramp and product temperature	Documented raw observations, calibration, relevant worst cases and defined acceptance for Sublimation without collapse.	Execution	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0024	Primary drying	Review / lifecycle: Qualify chamber pressure, shelf ramp and product temperature	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Sublimation without collapse.	Review	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0025	Secondary drying	Protocol / design: Control desorption, shelf temperature and hold	Preapproved risk-based study design; endpoint: Residual moisture and potency specification.	Planning	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0026	Secondary drying	Execution / boundary verification: Control desorption, shelf temperature and hold	Documented raw observations, calibration, relevant worst cases and defined acceptance for Residual moisture and potency specification.	Execution	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0027	Secondary drying	Review / lifecycle: Control desorption, shelf temperature and hold	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Residual moisture and potency specification.	Review	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0028	Lyophilizer load patterns	Protocol / design: Qualify front/back/top/bottom positions and vial heat transfer	Preapproved risk-based study design; endpoint: Uniform cake and moisture content.	Planning	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0029	Lyophilizer load patterns	Execution / boundary verification: Qualify front/back/top/bottom positions and vial heat transfer	Documented raw observations, calibration, relevant worst cases and defined acceptance for Uniform cake and moisture content.	Execution	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0030	Lyophilizer load patterns	Review / lifecycle: Qualify front/back/top/bottom positions and vial heat transfer	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Uniform cake and moisture content.	Review	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0031	Stoppering under vacuum	Protocol / design: Validate partial/full stopper and chamber release controls	Preapproved risk-based study design; endpoint: Container closure integrity.	Planning	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0032	Stoppering under vacuum	Execution / boundary verification: Validate partial/full stopper and chamber release controls	Documented raw observations, calibration, relevant worst cases and defined acceptance for Container closure integrity.	Execution	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0033	Stoppering under vacuum	Review / lifecycle: Validate partial/full stopper and chamber release controls	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Container closure integrity.	Review	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0034	Leak test/CCI	Protocol / design: Verify product/container combination and defects detection	Preapproved risk-based study design; endpoint: Sterile barrier throughout shelf life.	Planning	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0035	Leak test/CCI	Execution / boundary verification: Verify product/container combination and defects detection	Documented raw observations, calibration, relevant worst cases and defined acceptance for Sterile barrier throughout shelf life.	Execution	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0036	Leak test/CCI	Review / lifecycle: Verify product/container combination and defects detection	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Sterile barrier throughout shelf life.	Review	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0037	Visual inspection	Protocol / design: Qualify manual/automatic defect recognition and particulates	Preapproved risk-based study design; endpoint: Product-specific visible particle performance.	Planning	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0038	Visual inspection	Execution / boundary verification: Qualify manual/automatic defect recognition and particulates	Documented raw observations, calibration, relevant worst cases and defined acceptance for Product-specific visible particle performance.	Execution	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0039	Visual inspection	Review / lifecycle: Qualify manual/automatic defect recognition and particulates	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Product-specific visible particle performance.	Review	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0040	Freeze-dryer cleaning	Protocol / design: Prove CIP/SIP and drainability including condenser	Preapproved risk-based study design; endpoint: No viable contamination or protein residues.	Planning	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0041	Freeze-dryer cleaning	Execution / boundary verification: Prove CIP/SIP and drainability including condenser	Documented raw observations, calibration, relevant worst cases and defined acceptance for No viable contamination or protein residues.	Execution	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0042	Freeze-dryer cleaning	Review / lifecycle: Prove CIP/SIP and drainability including condenser	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No viable contamination or protein residues.	Review	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0043	Container and stopper prep	Protocol / design: Validate wash, siliconization, sterilization and depyro	Preapproved risk-based study design; endpoint: Appropriate sterile primary pack.	Planning	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0044	Container and stopper prep	Execution / boundary verification: Validate wash, siliconization, sterilization and depyro	Documented raw observations, calibration, relevant worst cases and defined acceptance for Appropriate sterile primary pack.	Execution	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0045	Container and stopper prep	Review / lifecycle: Validate wash, siliconization, sterilization and depyro	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Appropriate sterile primary pack.	Review	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0046	PFS plunger movement	Protocol / design: Challenge stopper position / lubricant where applicable	Preapproved risk-based study design; endpoint: Delivery dose and particulate profile.	Planning	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-24-0047	PFS plunger movement	Execution / boundary verification: Challenge stopper position / lubricant where applicable	Documented raw observations, calibration, relevant worst cases and defined acceptance for Delivery dose and particulate profile.	Execution	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0048	PFS plunger movement	Review / lifecycle: Challenge stopper position / lubricant where applicable	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Delivery dose and particulate profile.	Review	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0049	Biologic stability	Protocol / design: Validate light/temperature/agitational challenges during fill	Preapproved risk-based study design; endpoint: No unacceptable aggregation/fragmentation.	Planning	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0050	Biologic stability	Execution / boundary verification: Validate light/temperature/agitational challenges during fill	Documented raw observations, calibration, relevant worst cases and defined acceptance for No unacceptable aggregation/fragmentation.	Execution	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0051	Biologic stability	Review / lifecycle: Validate light/temperature/agitational challenges during fill	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No unacceptable aggregation/fragmentation.	Review	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0052	Sterile vial filler	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Speed, pump pressure, needle position, fill weight to product impact on Fill precision and low particulate.	URS / DQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0053	Sterile vial filler	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Sterile vial filler.	IQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0054	Sterile vial filler	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Speed, pump pressure, needle position, fill weight; compare challenge outputs to predefined Fill precision and low particulate acceptance.	OQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0055	Sterile vial filler	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Fill precision and low particulate.	OQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0056	Sterile vial filler	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Fill precision and low particulate at relevant Speed, pump pressure, needle position, fill weight; sampling scientifically justified.	PQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0057	Sterile vial filler	Continued verification / risk-based requalification trigger evaluation	Trend Speed, pump pressure, needle position, fill weight and impact on Fill precision and low particulate; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0058	Ampoule filling machine	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Fill volume, open exposure and sealing to product impact on Sterile dose and seal integrity.	URS / DQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0059	Ampoule filling machine	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Ampoule filling machine.	IQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0060	Ampoule filling machine	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Fill volume, open exposure and sealing; compare challenge outputs to predefined Sterile dose and seal integrity acceptance.	OQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0061	Ampoule filling machine	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Sterile dose and seal integrity.	OQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0062	Ampoule filling machine	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Sterile dose and seal integrity at relevant Fill volume, open exposure and sealing; sampling scientifically justified.	PQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0063	Ampoule filling machine	Continued verification / risk-based requalification trigger evaluation	Trend Fill volume, open exposure and sealing and impact on Sterile dose and seal integrity; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0064	Pre-filled syringe filling line	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Needle shield, plunger, fill accuracy to product impact on Dose and closure integrity.	URS / DQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0065	Pre-filled syringe filling line	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Pre-filled syringe filling line.	IQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0066	Pre-filled syringe filling line	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Needle shield, plunger, fill accuracy; compare challenge outputs to predefined Dose and closure integrity acceptance.	OQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0067	Pre-filled syringe filling line	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Dose and closure integrity.	OQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0068	Pre-filled syringe filling line	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Dose and closure integrity at relevant Needle shield, plunger, fill accuracy; sampling scientifically justified.	PQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-24-0069	Pre-filled syringe filling line	Continued verification / risk-based requalification trigger evaluation	Trend Needle shield, plunger, fill accuracy and impact on Dose and closure integrity; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0070	Lyophilizer shelf/stack	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Shelf mapping, vacuum, condenser capacity to product impact on Lyophilized cake and residual moisture.	URS / DQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0071	Lyophilizer shelf/stack	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Lyophilizer shelf/stack.	IQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0072	Lyophilizer shelf/stack	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Shelf mapping, vacuum, condenser capacity; compare challenge outputs to predefined Lyophilized cake and residual moisture acceptance.	OQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0073	Lyophilizer shelf/stack	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Lyophilized cake and residual moisture.	OQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0074	Lyophilizer shelf/stack	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Lyophilized cake and residual moisture at relevant Shelf mapping, vacuum, condenser capacity; sampling scientifically justified.	PQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0075	Lyophilizer shelf/stack	Continued verification / risk-based requalification trigger evaluation	Trend Shelf mapping, vacuum, condenser capacity and impact on Lyophilized cake and residual moisture; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0076	Lyophilizer condenser	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Condensing temperature, capacity, frost to product impact on Controlled sublimation and process reproducibility.	URS / DQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0077	Lyophilizer condenser	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Lyophilizer condenser.	IQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0078	Lyophilizer condenser	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Condensing temperature, capacity, frost; compare challenge outputs to predefined Controlled sublimation and process reproducibility acceptance.	OQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0079	Lyophilizer condenser	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Controlled sublimation and process reproducibility.	OQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0080	Lyophilizer condenser	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Controlled sublimation and process reproducibility at relevant Condensing temperature, capacity, frost; sampling scientifically justified.	PQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0081	Lyophilizer condenser	Continued verification / risk-based requalification trigger evaluation	Trend Condensing temperature, capacity, frost and impact on Controlled sublimation and process reproducibility; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0082	Lyophilizer vacuum system	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Vacuum leak, pressure, sensor response to product impact on Stable primary drying.	URS / DQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0083	Lyophilizer vacuum system	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Lyophilizer vacuum system.	IQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0084	Lyophilizer vacuum system	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Vacuum leak, pressure, sensor response; compare challenge outputs to predefined Stable primary drying acceptance.	OQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0085	Lyophilizer vacuum system	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Stable primary drying.	OQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0086	Lyophilizer vacuum system	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Stable primary drying at relevant Vacuum leak, pressure, sensor response; sampling scientifically justified.	PQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0087	Lyophilizer vacuum system	Continued verification / risk-based requalification trigger evaluation	Trend Vacuum leak, pressure, sensor response and impact on Stable primary drying; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0088	Vial washer	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Rinse flow, residue, cleaning coverage to product impact on Low particulate / endotoxin primary pack.	URS / DQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0089	Vial washer	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Vial washer.	IQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-24-0090	Vial washer	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Rinse flow, residue, cleaning coverage; compare challenge outputs to predefined Low particulate / endotoxin primary pack acceptance.	OQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0091	Vial washer	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Low particulate / endotoxin primary pack.	OQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0092	Vial washer	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Low particulate / endotoxin primary pack at relevant Rinse flow, residue, cleaning coverage; sampling scientifically justified.	PQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0093	Vial washer	Continued verification / risk-based requalification trigger evaluation	Trend Rinse flow, residue, cleaning coverage and impact on Low particulate / endotoxin primary pack; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0094	Vial depyrogenation tunnel	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Temperature and conveyor time to product impact on Validated endotoxin reduction.	URS / DQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0095	Vial depyrogenation tunnel	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Vial depyrogenation tunnel.	IQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0096	Vial depyrogenation tunnel	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Temperature and conveyor time; compare challenge outputs to predefined Validated endotoxin reduction acceptance.	OQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0097	Vial depyrogenation tunnel	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Validated endotoxin reduction.	OQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0098	Vial depyrogenation tunnel	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Validated endotoxin reduction at relevant Temperature and conveyor time; sampling scientifically justified.	PQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0099	Vial depyrogenation tunnel	Continued verification / risk-based requalification trigger evaluation	Trend Temperature and conveyor time and impact on Validated endotoxin reduction; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0100	Rubber stopper processor	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Wash, sterilization and drying cycle to product impact on Acceptable sterile stopper quality.	URS / DQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0101	Rubber stopper processor	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Rubber stopper processor.	IQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0102	Rubber stopper processor	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Wash, sterilization and drying cycle; compare challenge outputs to predefined Acceptable sterile stopper quality acceptance.	OQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0103	Rubber stopper processor	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Acceptable sterile stopper quality.	OQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0104	Rubber stopper processor	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Acceptable sterile stopper quality at relevant Wash, sterilization and drying cycle; sampling scientifically justified.	PQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0105	Rubber stopper processor	Continued verification / risk-based requalification trigger evaluation	Trend Wash, sterilization and drying cycle and impact on Acceptable sterile stopper quality; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0106	Crimping/sealing machine	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Crimp force, stopper seat, reject to product impact on Container closure integrity.	URS / DQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0107	Crimping/sealing machine	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Crimping/sealing machine.	IQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0108	Crimping/sealing machine	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Crimp force, stopper seat, reject; compare challenge outputs to predefined Container closure integrity acceptance.	OQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0109	Crimping/sealing machine	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Container closure integrity.	OQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0110	Crimping/sealing machine	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Container closure integrity at relevant Crimp force, stopper seat, reject; sampling scientifically justified.	PQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0111	Crimping/sealing machine	Continued verification / risk-based requalification trigger evaluation	Trend Crimp force, stopper seat, reject and impact on Container closure integrity; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-24-0112	Automated visual inspection	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Sensitivity, camera algorithm, false reject to product impact on Particulate / cosmetic defect control.	URS / DQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0113	Automated visual inspection	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Automated visual inspection.	IQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0114	Automated visual inspection	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Sensitivity, camera algorithm, false reject; compare challenge outputs to predefined Particulate / cosmetic defect control acceptance.	OQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0115	Automated visual inspection	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Particulate / cosmetic defect control.	OQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0116	Automated visual inspection	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Particulate / cosmetic defect control at relevant Sensitivity, camera algorithm, false reject; sampling scientifically justified.	PQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0117	Automated visual inspection	Continued verification / risk-based requalification trigger evaluation	Trend Sensitivity, camera algorithm, false reject and impact on Particulate / cosmetic defect control; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0118	Container closure integrity tester	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Detection sensitivity, pressure / vacuum profile to product impact on CCI accept/reject validity.	URS / DQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0119	Container closure integrity tester	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Container closure integrity tester.	IQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0120	Container closure integrity tester	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Detection sensitivity, pressure / vacuum profile; compare challenge outputs to predefined CCI accept/reject validity acceptance.	OQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0121	Container closure integrity tester	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect CCI accept/reject validity.	OQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0122	Container closure integrity tester	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable CCI accept/reject validity at relevant Detection sensitivity, pressure / vacuum profile; sampling scientifically justified.	PQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0123	Container closure integrity tester	Continued verification / risk-based requalification trigger evaluation	Trend Detection sensitivity, pressure / vacuum profile and impact on CCI accept/reject validity; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0124	Filling checkweigher	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Weighing accuracy and zero stability to product impact on In-process dose accuracy.	URS / DQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0125	Filling checkweigher	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Filling checkweigher.	IQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium
BTV-24-0126	Filling checkweigher	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Weighing accuracy and zero stability; compare challenge outputs to predefined In-process dose accuracy acceptance.	OQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0127	Filling checkweigher	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect In-process dose accuracy.	OQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0128	Filling checkweigher	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable In-process dose accuracy at relevant Weighing accuracy and zero stability; sampling scientifically justified.	PQ	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	High
BTV-24-0129	Filling checkweigher	Continued verification / risk-based requalification trigger evaluation	Trend Weighing accuracy and zero stability and impact on In-process dose accuracy; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biological DS-to-DP and parenteral formats	B02 B03 B04 B05 B09	Medium

25 ANALYTICAL METHOD VALIDATION & ADL

156 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-25-0001	Assay intended use	Protocol / design: Classify qualitative/quantitative, process, release or characterization method	Preapproved risk-based study design; endpoint: Method-specific performance requirement matrix.	Planning	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0002	Assay intended use	Execution / boundary verification: Classify qualitative/quantitative, process, release or characterization method	Documented raw observations, calibration, relevant worst cases and defined acceptance for Method-specific performance requirement matrix.	Execution	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0003	Assay intended use	Review / lifecycle: Classify qualitative/quantitative, process, release or characterization method	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Method-specific performance requirement matrix.	Review	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0004	Specificity/selectivity	Protocol / design: Challenge matrix, process contaminants and related species	Preapproved risk-based study design; endpoint: No interfering peaks or false positives.	Planning	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0005	Specificity/selectivity	Execution / boundary verification: Challenge matrix, process contaminants and related species	Documented raw observations, calibration, relevant worst cases and defined acceptance for No interfering peaks or false positives.	Execution	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0006	Specificity/selectivity	Review / lifecycle: Challenge matrix, process contaminants and related species	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No interfering peaks or false positives.	Review	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0007	Accuracy/recovery	Protocol / design: Qualify bias across defined reportable range	Preapproved risk-based study design; endpoint: Acceptable recovery versus reference.	Planning	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0008	Accuracy/recovery	Execution / boundary verification: Qualify bias across defined reportable range	Documented raw observations, calibration, relevant worst cases and defined acceptance for Acceptable recovery versus reference.	Execution	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0009	Accuracy/recovery	Review / lifecycle: Qualify bias across defined reportable range	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Acceptable recovery versus reference.	Review	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0010	Repeatability	Protocol / design: Evaluate same analyst/day/equipment variability	Preapproved risk-based study design; endpoint: Within-run precision.	Planning	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0011	Repeatability	Execution / boundary verification: Evaluate same analyst/day/equipment variability	Documented raw observations, calibration, relevant worst cases and defined acceptance for Within-run precision.	Execution	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0012	Repeatability	Review / lifecycle: Evaluate same analyst/day/equipment variability	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Within-run precision.	Review	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0013	Intermediate precision	Protocol / design: Evaluate analysts, days, instruments and reagent lots	Preapproved risk-based study design; endpoint: Between-run precision.	Planning	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0014	Intermediate precision	Execution / boundary verification: Evaluate analysts, days, instruments and reagent lots	Documented raw observations, calibration, relevant worst cases and defined acceptance for Between-run precision.	Execution	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0015	Intermediate precision	Review / lifecycle: Evaluate analysts, days, instruments and reagent lots	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Between-run precision.	Review	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0016	Reproducibility	Protocol / design: Assess lab-to-lab variation for cross-site use	Preapproved risk-based study design; endpoint: Method transfer suitability.	Planning	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0017	Reproducibility	Execution / boundary verification: Assess lab-to-lab variation for cross-site use	Documented raw observations, calibration, relevant worst cases and defined acceptance for Method transfer suitability.	Execution	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0018	Reproducibility	Review / lifecycle: Assess lab-to-lab variation for cross-site use	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Method transfer suitability.	Review	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0019	Linearity and range	Protocol / design: Qualify concentration vs signal and reportable intervals	Preapproved risk-based study design; endpoint: Defensible calibration model.	Planning	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0020	Linearity and range	Execution / boundary verification: Qualify concentration vs signal and reportable intervals	Documented raw observations, calibration, relevant worst cases and defined acceptance for Defensible calibration model.	Execution	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0021	Linearity and range	Review / lifecycle: Qualify concentration vs signal and reportable intervals	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Defensible calibration model.	Review	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0022	Quantitation limit	Protocol / design: Qualify LOQ sensitivity and precision for impurities	Preapproved risk-based study design; endpoint: Reliable low-level reporting.	Planning	Biological characterization, release and stability	B11 B20 B23 B12	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-25-0023	Quantitation limit	Execution / boundary verification: Qualify LOQ sensitivity and precision for impurities	Documented raw observations, calibration, relevant worst cases and defined acceptance for Reliable low-level reporting.	Execution	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0024	Quantitation limit	Review / lifecycle: Qualify LOQ sensitivity and precision for impurities	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Reliable low-level reporting.	Review	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0025	Detection limit	Protocol / design: Establish LOD for relevant impurities/pathogens	Preapproved risk-based study design; endpoint: Reliable positive/negative decisions.	Planning	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0026	Detection limit	Execution / boundary verification: Establish LOD for relevant impurities/pathogens	Documented raw observations, calibration, relevant worst cases and defined acceptance for Reliable positive/negative decisions.	Execution	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0027	Detection limit	Review / lifecycle: Establish LOD for relevant impurities/pathogens	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Reliable positive/negative decisions.	Review	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0028	Robustness	Protocol / design: Challenge temperature, reagent, incubation and mobile phase variations	Preapproved risk-based study design; endpoint: Method reliable near operating boundaries.	Planning	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0029	Robustness	Execution / boundary verification: Challenge temperature, reagent, incubation and mobile phase variations	Documented raw observations, calibration, relevant worst cases and defined acceptance for Method reliable near operating boundaries.	Execution	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0030	Robustness	Review / lifecycle: Challenge temperature, reagent, incubation and mobile phase variations	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Method reliable near operating boundaries.	Review	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0031	System suitability	Protocol / design: Define controls, standards and acceptance per run	Preapproved risk-based study design; endpoint: Run invalidation criteria predefined.	Planning	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0032	System suitability	Execution / boundary verification: Define controls, standards and acceptance per run	Documented raw observations, calibration, relevant worst cases and defined acceptance for Run invalidation criteria predefined.	Execution	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0033	System suitability	Review / lifecycle: Define controls, standards and acceptance per run	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Run invalidation criteria predefined.	Review	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0034	Reference standard	Protocol / design: Assign and qualify working standards against primary standard	Preapproved risk-based study design; endpoint: Traceability and potency assignment.	Planning	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0035	Reference standard	Execution / boundary verification: Assign and qualify working standards against primary standard	Documented raw observations, calibration, relevant worst cases and defined acceptance for Traceability and potency assignment.	Execution	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0036	Reference standard	Review / lifecycle: Assign and qualify working standards against primary standard	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Traceability and potency assignment.	Review	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0037	Biological assay statistics	Protocol / design: Establish curve-fitting model and parallelism tests	Preapproved risk-based study design; endpoint: Reliable relative potency calculations.	Planning	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0038	Biological assay statistics	Execution / boundary verification: Establish curve-fitting model and parallelism tests	Documented raw observations, calibration, relevant worst cases and defined acceptance for Reliable relative potency calculations.	Execution	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0039	Biological assay statistics	Review / lifecycle: Establish curve-fitting model and parallelism tests	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Reliable relative potency calculations.	Review	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0040	Method transfer	Protocol / design: Prove receiving lab reproducibility and instrument fit	Preapproved risk-based study design; endpoint: Comparable receiving vs sending lab results.	Planning	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0041	Method transfer	Execution / boundary verification: Prove receiving lab reproducibility and instrument fit	Documented raw observations, calibration, relevant worst cases and defined acceptance for Comparable receiving vs sending lab results.	Execution	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0042	Method transfer	Review / lifecycle: Prove receiving lab reproducibility and instrument fit	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Comparable receiving vs sending lab results.	Review	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0043	Sample stability	Protocol / design: Validate extraction, dilution, freeze-thaw and injection hold	Preapproved risk-based study design; endpoint: No sample decomposition.	Planning	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0044	Sample stability	Execution / boundary verification: Validate extraction, dilution, freeze-thaw and injection hold	Documented raw observations, calibration, relevant worst cases and defined acceptance for No sample decomposition.	Execution	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0045	Sample stability	Review / lifecycle: Validate extraction, dilution, freeze-thaw and injection hold	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No sample decomposition.	Review	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0046	Chromatographic carryover	Protocol / design: Qualify blank injections and wash procedure	Preapproved risk-based study design; endpoint: No false impurity contamination.	Planning	Biological characterization, release and stability	B11 B20 B23 B12	High

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BTV-25-0047	Chromatographic carryover	Execution / boundary verification: Qualify blank injections and wash procedure	Documented raw observations, calibration, relevant worst cases and defined acceptance for No false impurity contamination.	Execution	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0048	Chromatographic carryover	Review / lifecycle: Qualify blank injections and wash procedure	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No false impurity contamination.	Review	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0049	Forced degradation	Protocol / design: Demonstrate stability-indicating method discrimination	Preapproved risk-based study design; endpoint: Degradants separable from parent.	Planning	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0050	Forced degradation	Execution / boundary verification: Demonstrate stability-indicating method discrimination	Documented raw observations, calibration, relevant worst cases and defined acceptance for Degradants separable from parent.	Execution	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0051	Forced degradation	Review / lifecycle: Demonstrate stability-indicating method discrimination	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Degradants separable from parent.	Review	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0052	Data analysis validation	Protocol / design: Qualify integration algorithms, macros and calculations	Preapproved risk-based study design; endpoint: Reproducible reported results.	Planning	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0053	Data analysis validation	Execution / boundary verification: Qualify integration algorithms, macros and calculations	Documented raw observations, calibration, relevant worst cases and defined acceptance for Reproducible reported results.	Execution	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0054	Data analysis validation	Review / lifecycle: Qualify integration algorithms, macros and calculations	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Reproducible reported results.	Review	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0055	Instrument qualification linkage	Protocol / design: Confirm instrument IQ/OQ/PQ/calibration prior to method use	Preapproved risk-based study design; endpoint: Valid measurement system.	Planning	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0056	Instrument qualification linkage	Execution / boundary verification: Confirm instrument IQ/OQ/PQ/calibration prior to method use	Documented raw observations, calibration, relevant worst cases and defined acceptance for Valid measurement system.	Execution	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0057	Instrument qualification linkage	Review / lifecycle: Confirm instrument IQ/OQ/PQ/calibration prior to method use	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Valid measurement system.	Review	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0058	ICH Q2(R2)/Q14 lifecycle	Protocol / design: Evaluate analytical development changes and control strategy	Preapproved risk-based study design; endpoint: Fit-for-intended-use procedure.	Planning	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0059	ICH Q2(R2)/Q14 lifecycle	Execution / boundary verification: Evaluate analytical development changes and control strategy	Documented raw observations, calibration, relevant worst cases and defined acceptance for Fit-for-intended-use procedure.	Execution	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0060	ICH Q2(R2)/Q14 lifecycle	Review / lifecycle: Evaluate analytical development changes and control strategy	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Fit-for-intended-use procedure.	Review	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0061	HPLC UHPLC system	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Pump flow, detector wavelength, injector accuracy to product impact on Reliable purity and impurity assays.	URS / DQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0062	HPLC UHPLC system	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for HPLC UHPLC system.	IQ	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0063	HPLC UHPLC system	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Pump flow, detector wavelength, injector accuracy; compare challenge outputs to predefined Reliable purity and impurity assays acceptance.	OQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0064	HPLC UHPLC system	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Reliable purity and impurity assays.	OQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0065	HPLC UHPLC system	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Reliable purity and impurity assays at relevant Pump flow, detector wavelength, injector accuracy; sampling scientifically justified.	PQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0066	HPLC UHPLC system	Continued verification / risk-based requalification trigger evaluation	Trend Pump flow, detector wavelength, injector accuracy and impact on Reliable purity and impurity assays; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0067	LC-MS/MS analyzer	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Mass accuracy, ionization, sensitivity to product impact on Quantitative residual impurity measurements.	URS / DQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0068	LC-MS/MS analyzer	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for LC-MS/MS analyzer.	IQ	Biological characterization, release and stability	B11 B20 B23 B12	Medium

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BTV-25-0069	LC-MS/MS analyzer	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Mass accuracy, ionization, sensitivity; compare challenge outputs to predefined Quantitative residual impurity measurements acceptance.	OQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0070	LC-MS/MS analyzer	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Quantitative residual impurity measurements.	OQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0071	LC-MS/MS analyzer	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Quantitative residual impurity measurements at relevant Mass accuracy, ionization, sensitivity; sampling scientifically justified.	PQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0072	LC-MS/MS analyzer	Continued verification / risk-based requalification trigger evaluation	Trend Mass accuracy, ionization, sensitivity and impact on Quantitative residual impurity measurements; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0073	High resolution LC-MS	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Mass resolution, accuracy and digest recovery to product impact on Protein sequence and post-translational modification ID.	URS / DQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0074	High resolution LC-MS	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for High resolution LC-MS.	IQ	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0075	High resolution LC-MS	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Mass resolution, accuracy and digest recovery; compare challenge outputs to predefined Protein sequence and post-translational modification ID acceptance.	OQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0076	High resolution LC-MS	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Protein sequence and post-translational modification ID.	OQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0077	High resolution LC-MS	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Protein sequence and post-translational modification ID at relevant Mass resolution, accuracy and digest recovery; sampling scientifically justified.	PQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0078	High resolution LC-MS	Continued verification / risk-based requalification trigger evaluation	Trend Mass resolution, accuracy and digest recovery and impact on Protein sequence and post-translational modification ID; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0079	CE-SDS system	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Migration time, peak reproducibility to product impact on Protein fragmentation/purity.	URS / DQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0080	CE-SDS system	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for CE-SDS system.	IQ	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0081	CE-SDS system	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Migration time, peak reproducibility; compare challenge outputs to predefined Protein fragmentation/purity acceptance.	OQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0082	CE-SDS system	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Protein fragmentation/purity.	OQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0083	CE-SDS system	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Protein fragmentation/purity at relevant Migration time, peak reproducibility; sampling scientifically justified.	PQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0084	CE-SDS system	Continued verification / risk-based requalification trigger evaluation	Trend Migration time, peak reproducibility and impact on Protein fragmentation/purity; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0085	cIEF analyzer	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace pI calibration, reproducibility to product impact on Charge heterogeneity profile.	URS / DQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0086	cIEF analyzer	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for cIEF analyzer.	IQ	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0087	cIEF analyzer	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of pI calibration, reproducibility; compare challenge outputs to predefined Charge heterogeneity profile acceptance.	OQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0088	cIEF analyzer	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Charge heterogeneity profile.	OQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0089	cIEF analyzer	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Charge heterogeneity profile at relevant pI calibration, reproducibility; sampling scientifically justified.	PQ	Biological characterization, release and stability	B11 B20 B23 B12	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-25-0090	cIEF analyzer	Continued verification / risk-based requalification trigger evaluation	Trend pI calibration, reproducibility and impact on Charge heterogeneity profile; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0091	SEC chromatography system	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Detector, retention, recovery to product impact on Aggregates and monomer characterization.	URS / DQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0092	SEC chromatography system	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for SEC chromatography system.	IQ	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0093	SEC chromatography system	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Detector, retention, recovery; compare challenge outputs to predefined Aggregates and monomer characterization acceptance.	OQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0094	SEC chromatography system	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Aggregates and monomer characterization.	OQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0095	SEC chromatography system	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Aggregates and monomer characterization at relevant Detector, retention, recovery; sampling scientifically justified.	PQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0096	SEC chromatography system	Continued verification / risk-based requalification trigger evaluation	Trend Detector, retention, recovery and impact on Aggregates and monomer characterization; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0097	Ion-exchange HPLC	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Gradient accuracy, resolution to product impact on Charge variant analysis.	URS / DQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0098	Ion-exchange HPLC	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Ion-exchange HPLC.	IQ	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0099	Ion-exchange HPLC	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Gradient accuracy, resolution; compare challenge outputs to predefined Charge variant analysis acceptance.	OQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0100	Ion-exchange HPLC	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Charge variant analysis.	OQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0101	Ion-exchange HPLC	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Charge variant analysis at relevant Gradient accuracy, resolution; sampling scientifically justified.	PQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0102	Ion-exchange HPLC	Continued verification / risk-based requalification trigger evaluation	Trend Gradient accuracy, resolution and impact on Charge variant analysis; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0103	UV-Vis spectrophotometer	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Wavelength, photometric response to product impact on Accurate protein concentrations.	URS / DQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0104	UV-Vis spectrophotometer	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for UV-Vis spectrophotometer.	IQ	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0105	UV-Vis spectrophotometer	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Wavelength, photometric response; compare challenge outputs to predefined Accurate protein concentrations acceptance.	OQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0106	UV-Vis spectrophotometer	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Accurate protein concentrations.	OQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0107	UV-Vis spectrophotometer	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Accurate protein concentrations at relevant Wavelength, photometric response; sampling scientifically justified.	PQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0108	UV-Vis spectrophotometer	Continued verification / risk-based requalification trigger evaluation	Trend Wavelength, photometric response and impact on Accurate protein concentrations; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0109	Raman spectrometer	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Wavenumber, spectral preprocessing to product impact on Reproducible process modeling.	URS / DQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0110	Raman spectrometer	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Raman spectrometer.	IQ	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0111	Raman spectrometer	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Wavenumber, spectral preprocessing; compare challenge outputs to predefined Reproducible process modeling acceptance.	OQ	Biological characterization, release and stability	B11 B20 B23 B12	High

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BTV-25-0112	Raman spectrometer	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Reproducible process modeling.	OQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0113	Raman spectrometer	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Reproducible process modeling at relevant Wavenumber, spectral preprocessing; sampling scientifically justified.	PQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0114	Raman spectrometer	Continued verification / risk-based requalification trigger evaluation	Trend Wavenumber, spectral preprocessing and impact on Reproducible process modeling; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0115	FTIR system	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Wavenumber and ATR contact to product impact on Material/reagent identification.	URS / DQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0116	FTIR system	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for FTIR system.	IQ	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0117	FTIR system	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Wavenumber and ATR contact; compare challenge outputs to predefined Material/reagent identification acceptance.	OQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0118	FTIR system	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Material/reagent identification.	OQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0119	FTIR system	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Material/reagent identification at relevant Wavenumber and ATR contact; sampling scientifically justified.	PQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0120	FTIR system	Continued verification / risk-based requalification trigger evaluation	Trend Wavenumber and ATR contact and impact on Material/reagent identification; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0121	Karl Fischer moisture analyzer	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Titrant calibration, drift and recovery to product impact on Residual moisture in lyophilized DP.	URS / DQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0122	Karl Fischer moisture analyzer	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Karl Fischer moisture analyzer.	IQ	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0123	Karl Fischer moisture analyzer	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Titrant calibration, drift and recovery; compare challenge outputs to predefined Residual moisture in lyophilized DP acceptance.	OQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0124	Karl Fischer moisture analyzer	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Residual moisture in lyophilized DP.	OQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0125	Karl Fischer moisture analyzer	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Residual moisture in lyophilized DP at relevant Titrant calibration, drift and recovery; sampling scientifically justified.	PQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0126	Karl Fischer moisture analyzer	Continued verification / risk-based requalification trigger evaluation	Trend Titrant calibration, drift and recovery and impact on Residual moisture in lyophilized DP; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0127	Osmometer	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Osmolality calibration and repeatability to product impact on Correct formulation osmolality.	URS / DQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0128	Osmometer	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Osmometer.	IQ	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0129	Osmometer	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Osmolality calibration and repeatability; compare challenge outputs to predefined Correct formulation osmolality acceptance.	OQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0130	Osmometer	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Correct formulation osmolality.	OQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0131	Osmometer	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Correct formulation osmolality at relevant Osmolality calibration and repeatability; sampling scientifically justified.	PQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0132	Osmometer	Continued verification / risk-based requalification trigger evaluation	Trend Osmolality calibration and repeatability and impact on Correct formulation osmolality; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biological characterization, release and stability	B11 B20 B23 B12	Medium

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BTV-25-0133	DLS particle sizer	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Sizing range, sample concentration, repeatability to product impact on LNP/protein particle size distribution.	URS / DQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0134	DLS particle sizer	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for DLS particle sizer.	IQ	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0135	DLS particle sizer	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Sizing range, sample concentration, repeatability; compare challenge outputs to predefined LNP/protein particle size distribution acceptance.	OQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0136	DLS particle sizer	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect LNP/protein particle size distribution.	OQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0137	DLS particle sizer	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable LNP/protein particle size distribution at relevant Sizing range, sample concentration, repeatability; sampling scientifically justified.	PQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0138	DLS particle sizer	Continued verification / risk-based requalification trigger evaluation	Trend Sizing range, sample concentration, repeatability and impact on LNP/protein particle size distribution; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0139	MALS detector	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Detector calibration and inter-detector alignment to product impact on Aggregate molecular mass.	URS / DQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0140	MALS detector	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for MALS detector.	IQ	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0141	MALS detector	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Detector calibration and inter-detector alignment; compare challenge outputs to predefined Aggregate molecular mass acceptance.	OQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0142	MALS detector	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Aggregate molecular mass.	OQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0143	MALS detector	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Aggregate molecular mass at relevant Detector calibration and inter-detector alignment; sampling scientifically justified.	PQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0144	MALS detector	Continued verification / risk-based requalification trigger evaluation	Trend Detector calibration and inter-detector alignment and impact on Aggregate molecular mass; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0145	pH meter bench	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Slope, offset, temperature compensation to product impact on Accurate buffer and DS pH.	URS / DQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0146	pH meter bench	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for pH meter bench.	IQ	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0147	pH meter bench	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Slope, offset, temperature compensation; compare challenge outputs to predefined Accurate buffer and DS pH acceptance.	OQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0148	pH meter bench	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Accurate buffer and DS pH.	OQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0149	pH meter bench	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Accurate buffer and DS pH at relevant Slope, offset, temperature compensation; sampling scientifically justified.	PQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0150	pH meter bench	Continued verification / risk-based requalification trigger evaluation	Trend Slope, offset, temperature compensation and impact on Accurate buffer and DS pH; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0151	Conductivity meter bench	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Range, reference solution and temp to product impact on Accurate salts/ionic concentration.	URS / DQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0152	Conductivity meter bench	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Conductivity meter bench.	IQ	Biological characterization, release and stability	B11 B20 B23 B12	Medium
BTV-25-0153	Conductivity meter bench	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Range, reference solution and temp; compare challenge outputs to predefined Accurate salts/ionic concentration acceptance.	OQ	Biological characterization, release and stability	B11 B20 B23 B12	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-25-0154	Conductivity meter bench	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Accurate salts/ionic concentration.	OQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0155	Conductivity meter bench	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Accurate salts/ionic concentration at relevant Range, reference solution and temp; sampling scientifically justified.	PQ	Biological characterization, release and stability	B11 B20 B23 B12	High
BTV-25-0156	Conductivity meter bench	Continued verification / risk-based requalification trigger evaluation	Trend Range, reference solution and temp and impact on Accurate salts/ionic concentration; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biological characterization, release and stability	B11 B20 B23 B12	Medium

26 POTENCY BIOASSAYS, IMMUNOASSAYS & CELL-BASED QC

117 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-26-0001	ELISA antigen binding	Protocol / design: Validate plate selection, capture reagent, dynamic range	Preapproved risk-based study design; endpoint: Specific and precise binding measurement.	Planning	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0002	ELISA antigen binding	Execution / boundary verification: Validate plate selection, capture reagent, dynamic range	Documented raw observations, calibration, relevant worst cases and defined acceptance for Specific and precise binding measurement.	Execution	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0003	ELISA antigen binding	Review / lifecycle: Validate plate selection, capture reagent, dynamic range	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Specific and precise binding measurement.	Review	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	Medium
BTV-26-0004	Cell-based potency	Protocol / design: Qualify responsive cell line, passage and viability	Preapproved risk-based study design; endpoint: Relative potency and assay reproducibility.	Planning	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0005	Cell-based potency	Execution / boundary verification: Qualify responsive cell line, passage and viability	Documented raw observations, calibration, relevant worst cases and defined acceptance for Relative potency and assay reproducibility.	Execution	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0006	Cell-based potency	Review / lifecycle: Qualify responsive cell line, passage and viability	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Relative potency and assay reproducibility.	Review	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	Medium
BTV-26-0007	ADCC functional assay	Protocol / design: Characterize target/effector ratio and activation	Preapproved risk-based study design; endpoint: Effector-mediated biological activity.	Planning	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0008	ADCC functional assay	Execution / boundary verification: Characterize target/effector ratio and activation	Documented raw observations, calibration, relevant worst cases and defined acceptance for Effector-mediated biological activity.	Execution	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0009	ADCC functional assay	Review / lifecycle: Characterize target/effector ratio and activation	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Effector-mediated biological activity.	Review	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	Medium
BTV-26-0010	CDC bioassay	Protocol / design: Validate complement lot, cell target and titration	Preapproved risk-based study design; endpoint: Functional complement activity.	Planning	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0011	CDC bioassay	Execution / boundary verification: Validate complement lot, cell target and titration	Documented raw observations, calibration, relevant worst cases and defined acceptance for Functional complement activity.	Execution	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0012	CDC bioassay	Review / lifecycle: Validate complement lot, cell target and titration	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Functional complement activity.	Review	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	Medium
BTV-26-0013	Neutralization assay	Protocol / design: Qualify reference virus / antigen and dose-response	Preapproved risk-based study design; endpoint: Biological neutralization endpoint.	Planning	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0014	Neutralization assay	Execution / boundary verification: Qualify reference virus / antigen and dose-response	Documented raw observations, calibration, relevant worst cases and defined acceptance for Biological neutralization endpoint.	Execution	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0015	Neutralization assay	Review / lifecycle: Qualify reference virus / antigen and dose-response	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Biological neutralization endpoint.	Review	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	Medium
BTV-26-0016	Fc receptor binding	Protocol / design: Validate receptor reagent and detection specificity	Preapproved risk-based study design; endpoint: Fc functional binding.	Planning	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0017	Fc receptor binding	Execution / boundary verification: Validate receptor reagent and detection specificity	Documented raw observations, calibration, relevant worst cases and defined acceptance for Fc functional binding.	Execution	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0018	Fc receptor binding	Review / lifecycle: Validate receptor reagent and detection specificity	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Fc functional binding.	Review	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	Medium
BTV-26-0019	Ligand binding assay	Protocol / design: Study competitive inhibition and matrix interference	Preapproved risk-based study design; endpoint: Biologically relevant affinity.	Planning	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0020	Ligand binding assay	Execution / boundary verification: Study competitive inhibition and matrix interference	Documented raw observations, calibration, relevant worst cases and defined acceptance for Biologically relevant affinity.	Execution	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0021	Ligand binding assay	Review / lifecycle: Study competitive inhibition and matrix interference	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Biologically relevant affinity.	Review	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	Medium
BTV-26-0022	Enzyme activity assay	Protocol / design: Qualify substrate, reaction conditions and extinction	Preapproved risk-based study design; endpoint: Catalytic potency.	Planning	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-26-0023	Enzyme activity assay	Execution / boundary verification: Qualify substrate, reaction conditions and extinction	Documented raw observations, calibration, relevant worst cases and defined acceptance for Catalytic potency.	Execution	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0024	Enzyme activity assay	Review / lifecycle: Qualify substrate, reaction conditions and extinction	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Catalytic potency.	Review	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	Medium
BTV-26-0025	In vitro expression test	Protocol / design: Demonstrate functional expression/purity for gene products	Preapproved risk-based study design; endpoint: Relevant potency mechanism.	Planning	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0026	In vitro expression test	Execution / boundary verification: Demonstrate functional expression/purity for gene products	Documented raw observations, calibration, relevant worst cases and defined acceptance for Relevant potency mechanism.	Execution	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0027	In vitro expression test	Review / lifecycle: Demonstrate functional expression/purity for gene products	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Relevant potency mechanism.	Review	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	Medium
BTV-26-0028	Flow cytometry phenotyping	Protocol / design: Validate antibody panel, gates and compensation	Preapproved risk-based study design; endpoint: Cell identity and composition.	Planning	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0029	Flow cytometry phenotyping	Execution / boundary verification: Validate antibody panel, gates and compensation	Documented raw observations, calibration, relevant worst cases and defined acceptance for Cell identity and composition.	Execution	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0030	Flow cytometry phenotyping	Review / lifecycle: Validate antibody panel, gates and compensation	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Cell identity and composition.	Review	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	Medium
BTV-26-0031	Cell viability assay	Protocol / design: Validate viability dye, instrument gating and repeatability	Preapproved risk-based study design; endpoint: Accurate cells recovery and release.	Planning	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0032	Cell viability assay	Execution / boundary verification: Validate viability dye, instrument gating and repeatability	Documented raw observations, calibration, relevant worst cases and defined acceptance for Accurate cells recovery and release.	Execution	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0033	Cell viability assay	Review / lifecycle: Validate viability dye, instrument gating and repeatability	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Accurate cells recovery and release.	Review	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	Medium
BTV-26-0034	Protein A residual assay	Protocol / design: Qualify high/low concentrations and dilution linearity	Preapproved risk-based study design; endpoint: Residual ligand impurity results.	Planning	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0035	Protein A residual assay	Execution / boundary verification: Qualify high/low concentrations and dilution linearity	Documented raw observations, calibration, relevant worst cases and defined acceptance for Residual ligand impurity results.	Execution	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0036	Protein A residual assay	Review / lifecycle: Qualify high/low concentrations and dilution linearity	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Residual ligand impurity results.	Review	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	Medium
BTV-26-0037	HCP ELISA	Protocol / design: Demonstrate coverage and dilution linearity for manufacturing host	Preapproved risk-based study design; endpoint: Meaningful residual HCP measurement.	Planning	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0038	HCP ELISA	Execution / boundary verification: Demonstrate coverage and dilution linearity for manufacturing host	Documented raw observations, calibration, relevant worst cases and defined acceptance for Meaningful residual HCP measurement.	Execution	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0039	HCP ELISA	Review / lifecycle: Demonstrate coverage and dilution linearity for manufacturing host	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Meaningful residual HCP measurement.	Review	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	Medium
BTV-26-0040	Residual DNA qPCR	Protocol / design: Validate extraction recovery and amplicon sensitivity	Preapproved risk-based study design; endpoint: Residual host cell DNA detection.	Planning	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0041	Residual DNA qPCR	Execution / boundary verification: Validate extraction recovery and amplicon sensitivity	Documented raw observations, calibration, relevant worst cases and defined acceptance for Residual host cell DNA detection.	Execution	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0042	Residual DNA qPCR	Review / lifecycle: Validate extraction recovery and amplicon sensitivity	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Residual host cell DNA detection.	Review	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	Medium
BTV-26-0043	Anti-drug antibody method (where needed)	Protocol / design: Fit-for-purpose specificity and drug tolerance	Preapproved risk-based study design; endpoint: Appropriate characterization or clinical analytical use.	Planning	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0044	Anti-drug antibody method (where needed)	Execution / boundary verification: Fit-for-purpose specificity and drug tolerance	Documented raw observations, calibration, relevant worst cases and defined acceptance for Appropriate characterization or clinical analytical use.	Execution	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0045	Anti-drug antibody method (where needed)	Review / lifecycle: Fit-for-purpose specificity and drug tolerance	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Appropriate characterization or clinical analytical use.	Review	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	Medium
BTV-26-0046	Endotoxin method suitability	Protocol / design: Validate dilution / inhibition / enhancement for product	Preapproved risk-based study design; endpoint: Reliable endotoxin results.	Planning	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-26-0047	Endotoxin method suitability	Execution / boundary verification: Validate dilution / inhibition / enhancement for product	Documented raw observations, calibration, relevant worst cases and defined acceptance for Reliable endotoxin results.	Execution	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0048	Endotoxin method suitability	Review / lifecycle: Validate dilution / inhibition / enhancement for product	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Reliable endotoxin results.	Review	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	Medium
BTV-26-0049	ELISA microplate reader	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Optics, wavelength, uniformity to product impact on Reliable relative potency / HCP results.	URS / DQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0050	ELISA microplate reader	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for ELISA microplate reader.	IQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	Medium
BTV-26-0051	ELISA microplate reader	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Optics, wavelength, uniformity; compare challenge outputs to predefined Reliable relative potency / HCP results acceptance.	OQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0052	ELISA microplate reader	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Reliable relative potency / HCP results.	OQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0053	ELISA microplate reader	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Reliable relative potency / HCP results at relevant Optics, wavelength, uniformity; sampling scientifically justified.	PQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0054	ELISA microplate reader	Continued verification / risk-based requalification trigger evaluation	Trend Optics, wavelength, uniformity and impact on Reliable relative potency / HCP results; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	Medium
BTV-26-0055	ELISA plate washer	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Wash residual volume, reproducibility to product impact on Consistent assay background.	URS / DQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0056	ELISA plate washer	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for ELISA plate washer.	IQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	Medium
BTV-26-0057	ELISA plate washer	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Wash residual volume, reproducibility; compare challenge outputs to predefined Consistent assay background acceptance.	OQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0058	ELISA plate washer	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Consistent assay background.	OQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0059	ELISA plate washer	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Consistent assay background at relevant Wash residual volume, reproducibility; sampling scientifically justified.	PQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0060	ELISA plate washer	Continued verification / risk-based requalification trigger evaluation	Trend Wash residual volume, reproducibility and impact on Consistent assay background; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	Medium
BTV-26-0061	Flow cytometer	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Laser alignment, fluorescence, compensation to product impact on Correct immunophenotyping.	URS / DQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0062	Flow cytometer	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Flow cytometer.	IQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	Medium
BTV-26-0063	Flow cytometer	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Laser alignment, fluorescence, compensation; compare challenge outputs to predefined Correct immunophenotyping acceptance.	OQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0064	Flow cytometer	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Correct immunophenotyping.	OQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0065	Flow cytometer	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Correct immunophenotyping at relevant Laser alignment, fluorescence, compensation; sampling scientifically justified.	PQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0066	Flow cytometer	Continued verification / risk-based requalification trigger evaluation	Trend Laser alignment, fluorescence, compensation and impact on Correct immunophenotyping; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	Medium
BTV-26-0067	Luminescence plate reader	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Signal stability and calibration to product impact on Reproducible cell-based assays.	URS / DQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0068	Luminescence plate reader	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Luminescence plate reader.	IQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-26-0069	Luminescence plate reader	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Signal stability and calibration; compare challenge outputs to predefined Reproducible cell-based assays acceptance.	OQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0070	Luminescence plate reader	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Reproducible cell-based assays.	OQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0071	Luminescence plate reader	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Reproducible cell-based assays at relevant Signal stability and calibration; sampling scientifically justified.	PQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0072	Luminescence plate reader	Continued verification / risk-based requalification trigger evaluation	Trend Signal stability and calibration and impact on Reproducible cell-based assays; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	Medium
BTV-26-0073	CO2 QC cell incubator	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace CO2, humidity and temperature mapping to product impact on Stable test cell performance.	URS / DQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0074	CO2 QC cell incubator	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for CO2 QC cell incubator.	IQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	Medium
BTV-26-0075	CO2 QC cell incubator	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of CO2, humidity and temperature mapping; compare challenge outputs to predefined Stable test cell performance acceptance.	OQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0076	CO2 QC cell incubator	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Stable test cell performance.	OQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0077	CO2 QC cell incubator	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Stable test cell performance at relevant CO2, humidity and temperature mapping; sampling scientifically justified.	PQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0078	CO2 QC cell incubator	Continued verification / risk-based requalification trigger evaluation	Trend CO2, humidity and temperature mapping and impact on Stable test cell performance; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	Medium
BTV-26-0079	qPCR / ddPCR system	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Thermal, optics and assay sensitivity to product impact on Accurate nucleic acid quantitation.	URS / DQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0080	qPCR / ddPCR system	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for qPCR / ddPCR system.	IQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	Medium
BTV-26-0081	qPCR / ddPCR system	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Thermal, optics and assay sensitivity; compare challenge outputs to predefined Accurate nucleic acid quantitation acceptance.	OQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0082	qPCR / ddPCR system	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Accurate nucleic acid quantitation.	OQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0083	qPCR / ddPCR system	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Accurate nucleic acid quantitation at relevant Thermal, optics and assay sensitivity; sampling scientifically justified.	PQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0084	qPCR / ddPCR system	Continued verification / risk-based requalification trigger evaluation	Trend Thermal, optics and assay sensitivity and impact on Accurate nucleic acid quantitation; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	Medium
BTV-26-0085	Biological safety cabinet QC	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Airflow, HEPA integrity and contamination control to product impact on Reliable aseptic bioassay preparation.	URS / DQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0086	Biological safety cabinet QC	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Biological safety cabinet QC.	IQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	Medium
BTV-26-0087	Biological safety cabinet QC	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Airflow, HEPA integrity and contamination control; compare challenge outputs to predefined Reliable aseptic bioassay preparation acceptance.	OQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0088	Biological safety cabinet QC	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Reliable aseptic bioassay preparation.	OQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0089	Biological safety cabinet QC	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Reliable aseptic bioassay preparation at relevant Airflow, HEPA integrity and contamination control; sampling scientifically justified.	PQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-26-0090	Biological safety cabinet QC	Continued verification / risk-based requalification trigger evaluation	Trend Airflow, HEPA integrity and contamination control and impact on Reliable aseptic bioassay preparation; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	Medium
BTV-26-0091	Incubator imaging cell analyzer	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Focus, segmentation and cell density to product impact on Representative viability measurements.	URS / DQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0092	Incubator imaging cell analyzer	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Incubator imaging cell analyzer.	IQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	Medium
BTV-26-0093	Incubator imaging cell analyzer	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Focus, segmentation and cell density; compare challenge outputs to predefined Representative viability measurements acceptance.	OQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0094	Incubator imaging cell analyzer	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Representative viability measurements.	OQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0095	Incubator imaging cell analyzer	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Representative viability measurements at relevant Focus, segmentation and cell density; sampling scientifically justified.	PQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0096	Incubator imaging cell analyzer	Continued verification / risk-based requalification trigger evaluation	Trend Focus, segmentation and cell density and impact on Representative viability measurements; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	Medium
BTV-26-0097	Automated liquid handler	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Pipetting accuracy and cross contamination to product impact on Precise bioassay preparation.	URS / DQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0098	Automated liquid handler	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Automated liquid handler.	IQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	Medium
BTV-26-0099	Automated liquid handler	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Pipetting accuracy and cross contamination; compare challenge outputs to predefined Precise bioassay preparation acceptance.	OQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0100	Automated liquid handler	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Precise bioassay preparation.	OQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0101	Automated liquid handler	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Precise bioassay preparation at relevant Pipetting accuracy and cross contamination; sampling scientifically justified.	PQ	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	High
BTV-26-0102	Automated liquid handler	Continued verification / risk-based requalification trigger evaluation	Trend Pipetting accuracy and cross contamination and impact on Precise bioassay preparation; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	mAbs, recombinant proteins, vaccines, ATMPs	B11 B13 B20 B23	Medium
BTV-26-0103	Cell-based potency parallelism	Protocol / design: Qualify dose-response similarity across reference and test	Preapproved risk-based study design; endpoint: Reliable potency ratio.	Planning	Biologics potency assays	B11 B23	High
BTV-26-0104	Cell-based potency parallelism	Execution / boundary verification: Qualify dose-response similarity across reference and test	Documented raw observations, calibration, relevant worst cases and defined acceptance for Reliable potency ratio.	Execution	Biologics potency assays	B11 B23	High
BTV-26-0105	Cell-based potency parallelism	Review / lifecycle: Qualify dose-response similarity across reference and test	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Reliable potency ratio.	Review	Biologics potency assays	B11 B23	Medium
BTV-26-0106	Relative potency assignment	Protocol / design: Validate standard curve reference and assay acceptance	Preapproved risk-based study design; endpoint: Consistent units/lot potency.	Planning	Biologics potency assays	B11 B23	High
BTV-26-0107	Relative potency assignment	Execution / boundary verification: Validate standard curve reference and assay acceptance	Documented raw observations, calibration, relevant worst cases and defined acceptance for Consistent units/lot potency.	Execution	Biologics potency assays	B11 B23	High
BTV-26-0108	Relative potency assignment	Review / lifecycle: Validate standard curve reference and assay acceptance	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Consistent units/lot potency.	Review	Biologics potency assays	B11 B23	Medium
BTV-26-0109	Assay lot effects	Protocol / design: Characterize reference cells and reagent lot changes	Preapproved risk-based study design; endpoint: Stable functional output.	Planning	Biologics potency assays	B11 B23	High
BTV-26-0110	Assay lot effects	Execution / boundary verification: Characterize reference cells and reagent lot changes	Documented raw observations, calibration, relevant worst cases and defined acceptance for Stable functional output.	Execution	Biologics potency assays	B11 B23	High
BTV-26-0111	Assay lot effects	Review / lifecycle: Characterize reference cells and reagent lot changes	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Stable functional output.	Review	Biologics potency assays	B11 B23	Medium
BTV-26-0112	Potency sample stability	Protocol / design: Validate thaw dilution and plate hold	Preapproved risk-based study design; endpoint: No potency loss before readout.	Planning	Biologics potency assays	B11 B23	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-26-0113	Potency sample stability	Execution / boundary verification: Validate thaw dilution and plate hold	Documented raw observations, calibration, relevant worst cases and defined acceptance for No potency loss before readout.	Execution	Biologics potency assays	B11 B23	High
BTV-26-0114	Potency sample stability	Review / lifecycle: Validate thaw dilution and plate hold	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No potency loss before readout.	Review	Biologics potency assays	B11 B23	Medium
BTV-26-0115	Biological response drift	Protocol / design: Monitor assay control charts and release limits	Preapproved risk-based study design; endpoint: Early drift detection.	Planning	Biologics potency assays	B11 B23	High
BTV-26-0116	Biological response drift	Execution / boundary verification: Monitor assay control charts and release limits	Documented raw observations, calibration, relevant worst cases and defined acceptance for Early drift detection.	Execution	Biologics potency assays	B11 B23	High
BTV-26-0117	Biological response drift	Review / lifecycle: Monitor assay control charts and release limits	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Early drift detection.	Review	Biologics potency assays	B11 B23	Medium

27 QC MICROBIOLOGY, STERILITY, ENDOTOXIN AND EM

102 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-27-0001	Bioburden method suitability	Protocol / design: Validate neutralization, recovery, matrix toxicity and hold	Preapproved risk-based study design; endpoint: Reliable microbial counts.	Planning	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0002	Bioburden method suitability	Execution / boundary verification: Validate neutralization, recovery, matrix toxicity and hold	Documented raw observations, calibration, relevant worst cases and defined acceptance for Reliable microbial counts.	Execution	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0003	Bioburden method suitability	Review / lifecycle: Validate neutralization, recovery, matrix toxicity and hold	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Reliable microbial counts.	Review	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	Medium
BTV-27-0004	Sterility method suitability	Protocol / design: Verify no product inhibition of organism detection	Preapproved risk-based study design; endpoint: Valid sterility test interpretation.	Planning	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0005	Sterility method suitability	Execution / boundary verification: Verify no product inhibition of organism detection	Documented raw observations, calibration, relevant worst cases and defined acceptance for Valid sterility test interpretation.	Execution	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0006	Sterility method suitability	Review / lifecycle: Verify no product inhibition of organism detection	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Valid sterility test interpretation.	Review	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	Medium
BTV-27-0007	Bacterial endotoxin method	Protocol / design: Validate inhibition/enhancement and product dilution limits	Preapproved risk-based study design; endpoint: Compendial endotoxin decision.	Planning	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0008	Bacterial endotoxin method	Execution / boundary verification: Validate inhibition/enhancement and product dilution limits	Documented raw observations, calibration, relevant worst cases and defined acceptance for Compendial endotoxin decision.	Execution	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0009	Bacterial endotoxin method	Review / lifecycle: Validate inhibition/enhancement and product dilution limits	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Compendial endotoxin decision.	Review	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	Medium
BTV-27-0010	Rapid microbiological methods	Protocol / design: Establish equivalence, detection limit and risk	Preapproved risk-based study design; endpoint: Comparable microbial method performance.	Planning	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0011	Rapid microbiological methods	Execution / boundary verification: Establish equivalence, detection limit and risk	Documented raw observations, calibration, relevant worst cases and defined acceptance for Comparable microbial method performance.	Execution	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0012	Rapid microbiological methods	Review / lifecycle: Establish equivalence, detection limit and risk	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Comparable microbial method performance.	Review	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	Medium
BTV-27-0013	Growth promotion	Protocol / design: Validate medium batch and test organism suitability	Preapproved risk-based study design; endpoint: Sensitivity of sterility and APS media.	Planning	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0014	Growth promotion	Execution / boundary verification: Validate medium batch and test organism suitability	Documented raw observations, calibration, relevant worst cases and defined acceptance for Sensitivity of sterility and APS media.	Execution	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0015	Growth promotion	Review / lifecycle: Validate medium batch and test organism suitability	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Sensitivity of sterility and APS media.	Review	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	Medium
BTV-27-0016	Cleanroom EM viable	Protocol / design: Qualify air, settle, surface and personnel sampling	Preapproved risk-based study design; endpoint: Representative contamination trend.	Planning	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0017	Cleanroom EM viable	Execution / boundary verification: Qualify air, settle, surface and personnel sampling	Documented raw observations, calibration, relevant worst cases and defined acceptance for Representative contamination trend.	Execution	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0018	Cleanroom EM viable	Review / lifecycle: Qualify air, settle, surface and personnel sampling	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Representative contamination trend.	Review	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	Medium
BTV-27-0019	Active air sampler	Protocol / design: Validate flow rate, sampling recovery and disinfection	Preapproved risk-based study design; endpoint: Reliable air bioburden samples.	Planning	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0020	Active air sampler	Execution / boundary verification: Validate flow rate, sampling recovery and disinfection	Documented raw observations, calibration, relevant worst cases and defined acceptance for Reliable air bioburden samples.	Execution	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0021	Active air sampler	Review / lifecycle: Validate flow rate, sampling recovery and disinfection	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Reliable air bioburden samples.	Review	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	Medium
BTV-27-0022	Operator monitoring	Protocol / design: Qualify glove/garment sampling and action level	Preapproved risk-based study design; endpoint: Controlled aseptic personnel risk.	Planning	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-27-0023	Operator monitoring	Execution / boundary verification: Qualify glove/garment sampling and action level	Documented raw observations, calibration, relevant worst cases and defined acceptance for Controlled aseptic personnel risk.	Execution	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0024	Operator monitoring	Review / lifecycle: Qualify glove/garment sampling and action level	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Controlled aseptic personnel risk.	Review	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	Medium
BTV-27-0025	Incubation regimes	Protocol / design: Validate incubator temperature/humidity/loading	Preapproved risk-based study design; endpoint: Reproducible detection.	Planning	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0026	Incubation regimes	Execution / boundary verification: Validate incubator temperature/humidity/loading	Documented raw observations, calibration, relevant worst cases and defined acceptance for Reproducible detection.	Execution	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0027	Incubation regimes	Review / lifecycle: Validate incubator temperature/humidity/loading	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Reproducible detection.	Review	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	Medium
BTV-27-0028	Microbial identification	Protocol / design: Qualify MALDI-TOF/sequence library and QC controls	Preapproved risk-based study design; endpoint: Reliable isolate ID / trend.	Planning	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0029	Microbial identification	Execution / boundary verification: Qualify MALDI-TOF/sequence library and QC controls	Documented raw observations, calibration, relevant worst cases and defined acceptance for Reliable isolate ID / trend.	Execution	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0030	Microbial identification	Review / lifecycle: Qualify MALDI-TOF/sequence library and QC controls	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Reliable isolate ID / trend.	Review	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	Medium
BTV-27-0031	Endotoxin recovery	Protocol / design: Challenge LER masking and sample interference if relevant	Preapproved risk-based study design; endpoint: Defensible endotoxin assay result.	Planning	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0032	Endotoxin recovery	Execution / boundary verification: Challenge LER masking and sample interference if relevant	Documented raw observations, calibration, relevant worst cases and defined acceptance for Defensible endotoxin assay result.	Execution	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0033	Endotoxin recovery	Review / lifecycle: Challenge LER masking and sample interference if relevant	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Defensible endotoxin assay result.	Review	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	Medium
BTV-27-0034	Microbial hold times	Protocol / design: Validate time from collection to test across matrix	Preapproved risk-based study design; endpoint: No significant loss/change in counts.	Planning	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0035	Microbial hold times	Execution / boundary verification: Validate time from collection to test across matrix	Documented raw observations, calibration, relevant worst cases and defined acceptance for No significant loss/change in counts.	Execution	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0036	Microbial hold times	Review / lifecycle: Validate time from collection to test across matrix	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No significant loss/change in counts.	Review	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	Medium
BTV-27-0037	Environmental trending	Protocol / design: Establish alert/action limits by zone and microbiology	Preapproved risk-based study design; endpoint: Meaningful CCS trend and escalation.	Planning	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0038	Environmental trending	Execution / boundary verification: Establish alert/action limits by zone and microbiology	Documented raw observations, calibration, relevant worst cases and defined acceptance for Meaningful CCS trend and escalation.	Execution	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0039	Environmental trending	Review / lifecycle: Establish alert/action limits by zone and microbiology	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Meaningful CCS trend and escalation.	Review	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	Medium
BTV-27-0040	Disinfectant effectiveness	Protocol / design: Validate surface/organism/contact and neutralization	Preapproved risk-based study design; endpoint: Effective facility decontamination.	Planning	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0041	Disinfectant effectiveness	Execution / boundary verification: Validate surface/organism/contact and neutralization	Documented raw observations, calibration, relevant worst cases and defined acceptance for Effective facility decontamination.	Execution	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0042	Disinfectant effectiveness	Review / lifecycle: Validate surface/organism/contact and neutralization	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Effective facility decontamination.	Review	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	Medium
BTV-27-0043	Spore kill	Protocol / design: Qualify sporicide concentration and contact	Preapproved risk-based study design; endpoint: Reliable periodic spore control.	Planning	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0044	Spore kill	Execution / boundary verification: Qualify sporicide concentration and contact	Documented raw observations, calibration, relevant worst cases and defined acceptance for Reliable periodic spore control.	Execution	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0045	Spore kill	Review / lifecycle: Qualify sporicide concentration and contact	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Reliable periodic spore control.	Review	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	Medium
BTV-27-0046	Mycoplasma test	Protocol / design: Qualify assay matrix interference and detection sensitivity	Preapproved risk-based study design; endpoint: Correct mycoplasma decision.	Planning	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-27-0047	Mycoplasma test	Execution / boundary verification: Qualify assay matrix interference and detection sensitivity	Documented raw observations, calibration, relevant worst cases and defined acceptance for Correct mycoplasma decision.	Execution	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0048	Mycoplasma test	Review / lifecycle: Qualify assay matrix interference and detection sensitivity	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Correct mycoplasma decision.	Review	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	Medium
BTV-27-0049	Sterility test isolator	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Decontamination cycle, integrity, airflow to product impact on Aseptic test conditions.	URS / DQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0050	Sterility test isolator	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Sterility test isolator.	IQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	Medium
BTV-27-0051	Sterility test isolator	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Decontamination cycle, integrity, airflow; compare challenge outputs to predefined Aseptic test conditions acceptance.	OQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0052	Sterility test isolator	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Aseptic test conditions.	OQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0053	Sterility test isolator	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Aseptic test conditions at relevant Decontamination cycle, integrity, airflow; sampling scientifically justified.	PQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0054	Sterility test isolator	Continued verification / risk-based requalification trigger evaluation	Trend Decontamination cycle, integrity, airflow and impact on Aseptic test conditions; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	Medium
BTV-27-0055	Microbial incubator	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Multi-point thermal mapping and alarm to product impact on Suitable incubation ranges.	URS / DQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0056	Microbial incubator	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Microbial incubator.	IQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	Medium
BTV-27-0057	Microbial incubator	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Multi-point thermal mapping and alarm; compare challenge outputs to predefined Suitable incubation ranges acceptance.	OQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0058	Microbial incubator	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Suitable incubation ranges.	OQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0059	Microbial incubator	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Suitable incubation ranges at relevant Multi-point thermal mapping and alarm; sampling scientifically justified.	PQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0060	Microbial incubator	Continued verification / risk-based requalification trigger evaluation	Trend Multi-point thermal mapping and alarm and impact on Suitable incubation ranges; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	Medium
BTV-27-0061	Endotoxin kinetic reader	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Temperature control, OD reproducibility to product impact on Valid LAL or recombinant method results.	URS / DQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0062	Endotoxin kinetic reader	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Endotoxin kinetic reader.	IQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	Medium
BTV-27-0063	Endotoxin kinetic reader	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Temperature control, OD reproducibility; compare challenge outputs to predefined Valid LAL or recombinant method results acceptance.	OQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0064	Endotoxin kinetic reader	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Valid LAL or recombinant method results.	OQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0065	Endotoxin kinetic reader	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Valid LAL or recombinant method results at relevant Temperature control, OD reproducibility; sampling scientifically justified.	PQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0066	Endotoxin kinetic reader	Continued verification / risk-based requalification trigger evaluation	Trend Temperature control, OD reproducibility and impact on Valid LAL or recombinant method results; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	Medium
BTV-27-0067	Environmental air sampler	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Flow accuracy and sampling efficiency to product impact on Representative viable air results.	URS / DQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0068	Environmental air sampler	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Environmental air sampler.	IQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-27-0069	Environmental air sampler	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Flow accuracy and sampling efficiency; compare challenge outputs to predefined Representative viable air results acceptance.	OQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0070	Environmental air sampler	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Representative viable air results.	OQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0071	Environmental air sampler	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Representative viable air results at relevant Flow accuracy and sampling efficiency; sampling scientifically justified.	PQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0072	Environmental air sampler	Continued verification / risk-based requalification trigger evaluation	Trend Flow accuracy and sampling efficiency and impact on Representative viable air results; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	Medium
BTV-27-0073	Colony counter	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Counting accuracy and discrimination to product impact on Consistent CFU results.	URS / DQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0074	Colony counter	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Colony counter.	IQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	Medium
BTV-27-0075	Colony counter	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Counting accuracy and discrimination; compare challenge outputs to predefined Consistent CFU results acceptance.	OQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0076	Colony counter	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Consistent CFU results.	OQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0077	Colony counter	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Consistent CFU results at relevant Counting accuracy and discrimination; sampling scientifically justified.	PQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0078	Colony counter	Continued verification / risk-based requalification trigger evaluation	Trend Counting accuracy and discrimination and impact on Consistent CFU results; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	Medium
BTV-27-0079	Rapid microbial detector	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Sensitivity and method equivalence to product impact on Defensible microbial results.	URS / DQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0080	Rapid microbial detector	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Rapid microbial detector.	IQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	Medium
BTV-27-0081	Rapid microbial detector	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Sensitivity and method equivalence; compare challenge outputs to predefined Defensible microbial results acceptance.	OQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0082	Rapid microbial detector	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Defensible microbial results.	OQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0083	Rapid microbial detector	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Defensible microbial results at relevant Sensitivity and method equivalence; sampling scientifically justified.	PQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0084	Rapid microbial detector	Continued verification / risk-based requalification trigger evaluation	Trend Sensitivity and method equivalence and impact on Defensible microbial results; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	Medium
BTV-27-0085	MALDI-TOF identifier	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Calibration, library, reference strains to product impact on Reliable isolate identities.	URS / DQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0086	MALDI-TOF identifier	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for MALDI-TOF identifier.	IQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	Medium
BTV-27-0087	MALDI-TOF identifier	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Calibration, library, reference strains; compare challenge outputs to predefined Reliable isolate identities acceptance.	OQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0088	MALDI-TOF identifier	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Reliable isolate identities.	OQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0089	MALDI-TOF identifier	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Reliable isolate identities at relevant Calibration, library, reference strains; sampling scientifically justified.	PQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0090	MALDI-TOF identifier	Continued verification / risk-based requalification trigger evaluation	Trend Calibration, library, reference strains and impact on Reliable isolate identities; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-27-0091	Anaerobic incubator	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Oxygen exclusion and uniform temperature to product impact on Recovery where required.	URS / DQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0092	Anaerobic incubator	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Anaerobic incubator.	IQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	Medium
BTV-27-0093	Anaerobic incubator	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Oxygen exclusion and uniform temperature; compare challenge outputs to predefined Recovery where required acceptance.	OQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0094	Anaerobic incubator	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Recovery where required.	OQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0095	Anaerobic incubator	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Recovery where required at relevant Oxygen exclusion and uniform temperature; sampling scientifically justified.	PQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0096	Anaerobic incubator	Continued verification / risk-based requalification trigger evaluation	Trend Oxygen exclusion and uniform temperature and impact on Recovery where required; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	Medium
BTV-27-0097	Autoclave microbiology lab	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Lethality and waste decontamination to product impact on Sterile media and inactivated biohazard waste.	URS / DQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0098	Autoclave microbiology lab	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Autoclave microbiology lab.	IQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	Medium
BTV-27-0099	Autoclave microbiology lab	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Lethality and waste decontamination; compare challenge outputs to predefined Sterile media and inactivated biohazard waste acceptance.	OQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0100	Autoclave microbiology lab	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Sterile media and inactivated biohazard waste.	OQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0101	Autoclave microbiology lab	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Sterile media and inactivated biohazard waste at relevant Lethality and waste decontamination; sampling scientifically justified.	PQ	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	High
BTV-27-0102	Autoclave microbiology lab	Continued verification / risk-based requalification trigger evaluation	Trend Lethality and waste decontamination and impact on Sterile media and inactivated biohazard waste; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	All biologics; sterile DS/DP as applicable	B03 B04 B05 B13 B20 B21	Medium

28 PHYSICAL CHEMISTRY, STABILITY AND STRUCTURAL CHARACTERIZATION

108 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-28-0001	Primary structure	Protocol / design: Qualify sequence confirmation and peptide coverage	Preapproved risk-based study design; endpoint: Identity and structure consistency.	Planning	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0002	Primary structure	Execution / boundary verification: Qualify sequence confirmation and peptide coverage	Documented raw observations, calibration, relevant worst cases and defined acceptance for Identity and structure consistency.	Execution	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0003	Primary structure	Review / lifecycle: Qualify sequence confirmation and peptide coverage	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Identity and structure consistency.	Review	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	Medium
BTV-28-0004	Disulfide mapping	Protocol / design: Validate preparation and fragmentation interpretation	Preapproved risk-based study design; endpoint: Correct bridging assessment.	Planning	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0005	Disulfide mapping	Execution / boundary verification: Validate preparation and fragmentation interpretation	Documented raw observations, calibration, relevant worst cases and defined acceptance for Correct bridging assessment.	Execution	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0006	Disulfide mapping	Review / lifecycle: Validate preparation and fragmentation interpretation	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Correct bridging assessment.	Review	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	Medium
BTV-28-0007	Glycosylation profile	Protocol / design: Demonstrate glycan labeling/detection and reproducibility	Preapproved risk-based study design; endpoint: Relevant glycan distribution.	Planning	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0008	Glycosylation profile	Execution / boundary verification: Demonstrate glycan labeling/detection and reproducibility	Documented raw observations, calibration, relevant worst cases and defined acceptance for Relevant glycan distribution.	Execution	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0009	Glycosylation profile	Review / lifecycle: Demonstrate glycan labeling/detection and reproducibility	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Relevant glycan distribution.	Review	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	Medium
BTV-28-0010	Higher order structure	Protocol / design: Characterize DSC/CD/FTIR repeatability and orthogonality	Preapproved risk-based study design; endpoint: Comparability of conformation.	Planning	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0011	Higher order structure	Execution / boundary verification: Characterize DSC/CD/FTIR repeatability and orthogonality	Documented raw observations, calibration, relevant worst cases and defined acceptance for Comparability of conformation.	Execution	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0012	Higher order structure	Review / lifecycle: Characterize DSC/CD/FTIR repeatability and orthogonality	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Comparability of conformation.	Review	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	Medium
BTV-28-0013	Size variant	Protocol / design: Validate SEC-MALS/CE-SDS for HMW/LMW species	Preapproved risk-based study design; endpoint: Aggregate and fragment assay.	Planning	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0014	Size variant	Execution / boundary verification: Validate SEC-MALS/CE-SDS for HMW/LMW species	Documented raw observations, calibration, relevant worst cases and defined acceptance for Aggregate and fragment assay.	Execution	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0015	Size variant	Review / lifecycle: Validate SEC-MALS/CE-SDS for HMW/LMW species	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Aggregate and fragment assay.	Review	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	Medium
BTV-28-0016	Charge variant	Protocol / design: Validate icIEF/CEX for acidic/basic isoforms	Preapproved risk-based study design; endpoint: Charge heterogeneity monitoring.	Planning	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-28-0017	Charge variant	Execution / boundary verification: Validate icIEF/CEX for acidic/basic isoforms	Documented raw observations, calibration, relevant worst cases and defined acceptance for Charge heterogeneity monitoring.	Execution	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0018	Charge variant	Review / lifecycle: Validate icIEF/CEX for acidic/basic isoforms	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Charge heterogeneity monitoring.	Review	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	Medium
BTV-28-0019	Oxidation assay	Protocol / design: Qualify oxidation-site sensitivity and forced stress	Preapproved risk-based study design; endpoint: Degradation monitoring.	Planning	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0020	Oxidation assay	Execution / boundary verification: Qualify oxidation-site sensitivity and forced stress	Documented raw observations, calibration, relevant worst cases and defined acceptance for Degradation monitoring.	Execution	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0021	Oxidation assay	Review / lifecycle: Qualify oxidation-site sensitivity and forced stress	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Degradation monitoring.	Review	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	Medium
BTV-28-0022	Deamidation assay	Protocol / design: Establish method specificity and stability-indicating behavior	Preapproved risk-based study design; endpoint: Relevant modification quantitation.	Planning	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0023	Deamidation assay	Execution / boundary verification: Establish method specificity and stability-indicating behavior	Documented raw observations, calibration, relevant worst cases and defined acceptance for Relevant modification quantitation.	Execution	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0024	Deamidation assay	Review / lifecycle: Establish method specificity and stability-indicating behavior	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Relevant modification quantitation.	Review	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	Medium
BTV-28-0025	Particle distribution	Protocol / design: Qualify subvisible particle detection and sample preparation	Preapproved risk-based study design; endpoint: Biologics particle safety.	Planning	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0026	Particle distribution	Execution / boundary verification: Qualify subvisible particle detection and sample preparation	Documented raw observations, calibration, relevant worst cases and defined acceptance for Biologics particle safety.	Execution	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0027	Particle distribution	Review / lifecycle: Qualify subvisible particle detection and sample preparation	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Biologics particle safety.	Review	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	Medium
BTV-28-0028	Oligomerization	Protocol / design: Assess concentration-dependent aggregation behavior	Preapproved risk-based study design; endpoint: CQA stability during storage.	Planning	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0029	Oligomerization	Execution / boundary verification: Assess concentration-dependent aggregation behavior	Documented raw observations, calibration, relevant worst cases and defined acceptance for CQA stability during storage.	Execution	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0030	Oligomerization	Review / lifecycle: Assess concentration-dependent aggregation behavior	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on CQA stability during storage.	Review	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	Medium
BTV-28-0031	Forced degradation	Protocol / design: Qualify heat, light, pH, oxidation and agitation stress coverage	Preapproved risk-based study design; endpoint: Validated stability indicating methods.	Planning	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0032	Forced degradation	Execution / boundary verification: Qualify heat, light, pH, oxidation and agitation stress coverage	Documented raw observations, calibration, relevant worst cases and defined acceptance for Validated stability indicating methods.	Execution	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0033	Forced degradation	Review / lifecycle: Qualify heat, light, pH, oxidation and agitation stress coverage	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Validated stability indicating methods.	Review	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	Medium
BTV-28-0034	Stability chambers	Protocol / design: Map all shelf positions, alarm and recovery	Preapproved risk-based study design; endpoint: Controlled ICH storage conditions.	Planning	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-28-0035	Stability chambers	Execution / boundary verification: Map all shelf positions, alarm and recovery	Documented raw observations, calibration, relevant worst cases and defined acceptance for Controlled ICH storage conditions.	Execution	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0036	Stability chambers	Review / lifecycle: Map all shelf positions, alarm and recovery	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Controlled ICH storage conditions.	Review	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	Medium
BTV-28-0037	Reference storage	Protocol / design: Validate aliquot stability and reuse policy	Preapproved risk-based study design; endpoint: Reliable assay controls.	Planning	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0038	Reference storage	Execution / boundary verification: Validate aliquot stability and reuse policy	Documented raw observations, calibration, relevant worst cases and defined acceptance for Reliable assay controls.	Execution	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0039	Reference storage	Review / lifecycle: Validate aliquot stability and reuse policy	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Reliable assay controls.	Review	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	Medium
BTV-28-0040	Freeze-thaw stability	Protocol / design: Qualify max handling cycles under routine product handling	Preapproved risk-based study design; endpoint: Preserved product quality and potency.	Planning	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0041	Freeze-thaw stability	Execution / boundary verification: Qualify max handling cycles under routine product handling	Documented raw observations, calibration, relevant worst cases and defined acceptance for Preserved product quality and potency.	Execution	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0042	Freeze-thaw stability	Review / lifecycle: Qualify max handling cycles under routine product handling	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Preserved product quality and potency.	Review	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	Medium
BTV-28-0043	In-use stability	Protocol / design: Challenge reconstitution/dilution and delivery period	Preapproved risk-based study design; endpoint: Maintained specified product quality.	Planning	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0044	In-use stability	Execution / boundary verification: Challenge reconstitution/dilution and delivery period	Documented raw observations, calibration, relevant worst cases and defined acceptance for Maintained specified product quality.	Execution	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0045	In-use stability	Review / lifecycle: Challenge reconstitution/dilution and delivery period	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Maintained specified product quality.	Review	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	Medium
BTV-28-0046	Real-time shelf-life	Protocol / design: Link stability protocol, storage and statistically justified expiry	Preapproved risk-based study design; endpoint: Supported registered shelf life.	Planning	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0047	Real-time shelf-life	Execution / boundary verification: Link stability protocol, storage and statistically justified expiry	Documented raw observations, calibration, relevant worst cases and defined acceptance for Supported registered shelf life.	Execution	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0048	Real-time shelf-life	Review / lifecycle: Link stability protocol, storage and statistically justified expiry	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Supported registered shelf life.	Review	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	Medium
BTV-28-0049	Container compatibility	Protocol / design: Evaluate protein adsorption, extractables, leachables and integrity	Preapproved risk-based study design; endpoint: Stable DS and DP attributes.	Planning	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0050	Container compatibility	Execution / boundary verification: Evaluate protein adsorption, extractables, leachables and integrity	Documented raw observations, calibration, relevant worst cases and defined acceptance for Stable DS and DP attributes.	Execution	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0051	Container compatibility	Review / lifecycle: Evaluate protein adsorption, extractables, leachables and integrity	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Stable DS and DP attributes.	Review	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	Medium
BTV-28-0052	Stress studies	Protocol / design: Test transport vibration, temperature and photostability	Preapproved risk-based study design; endpoint: Product stability risk controls.	Planning	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-28-0053	Stress studies	Execution / boundary verification: Test transport vibration, temperature and photostability	Documented raw observations, calibration, relevant worst cases and defined acceptance for Product stability risk controls.	Execution	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0054	Stress studies	Review / lifecycle: Test transport vibration, temperature and photostability	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Product stability risk controls.	Review	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	Medium
BTV-28-0055	Stability chamber refrigerated	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Temperature mapping, door openings, alarm to product impact on Correct ICH storage.	URS / DQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0056	Stability chamber refrigerated	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Stability chamber refrigerated.	IQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	Medium
BTV-28-0057	Stability chamber refrigerated	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Temperature mapping, door openings, alarm; compare challenge outputs to predefined Correct ICH storage acceptance.	OQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0058	Stability chamber refrigerated	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Correct ICH storage.	OQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0059	Stability chamber refrigerated	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Correct ICH storage at relevant Temperature mapping, door openings, alarm; sampling scientifically justified.	PQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0060	Stability chamber refrigerated	Continued verification / risk-based requalification trigger evaluation	Trend Temperature mapping, door openings, alarm and impact on Correct ICH storage; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	Medium
BTV-28-0061	Stability chamber ambient	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Humidity and temperature mapping to product impact on Controlled long term studies.	URS / DQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0062	Stability chamber ambient	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Stability chamber ambient.	IQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	Medium
BTV-28-0063	Stability chamber ambient	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Humidity and temperature mapping; compare challenge outputs to predefined Controlled long term studies acceptance.	OQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0064	Stability chamber ambient	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Controlled long term studies.	OQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0065	Stability chamber ambient	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Controlled long term studies at relevant Humidity and temperature mapping; sampling scientifically justified.	PQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0066	Stability chamber ambient	Continued verification / risk-based requalification trigger evaluation	Trend Humidity and temperature mapping and impact on Controlled long term studies; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	Medium
BTV-28-0067	Ultra-low stability freezer	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Temperature mapping, backup alarm to product impact on Frozen product stability.	URS / DQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0068	Ultra-low stability freezer	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Ultra-low stability freezer.	IQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	Medium
BTV-28-0069	Ultra-low stability freezer	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Temperature mapping, backup alarm; compare challenge outputs to predefined Frozen product stability acceptance.	OQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0070	Ultra-low stability freezer	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Frozen product stability.	OQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-28-0071	Ultra-low stability freezer	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Frozen product stability at relevant Temperature mapping, backup alarm; sampling scientifically justified.	PQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0072	Ultra-low stability freezer	Continued verification / risk-based requalification trigger evaluation	Trend Temperature mapping, backup alarm and impact on Frozen product stability; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	Medium
BTV-28-0073	DSC instrument	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Heat flow calibration and reproducibility to product impact on Protein unfolding profile.	URS / DQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0074	DSC instrument	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for DSC instrument.	IQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	Medium
BTV-28-0075	DSC instrument	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Heat flow calibration and reproducibility; compare challenge outputs to predefined Protein unfolding profile acceptance.	OQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0076	DSC instrument	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Protein unfolding profile.	OQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0077	DSC instrument	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Protein unfolding profile at relevant Heat flow calibration and reproducibility; sampling scientifically justified.	PQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0078	DSC instrument	Continued verification / risk-based requalification trigger evaluation	Trend Heat flow calibration and reproducibility and impact on Protein unfolding profile; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	Medium
BTV-28-0079	Circular dichroism spectrometer	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Wavelength and pathlength performance to product impact on Secondary structure profile.	URS / DQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0080	Circular dichroism spectrometer	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Circular dichroism spectrometer.	IQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	Medium
BTV-28-0081	Circular dichroism spectrometer	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Wavelength and pathlength performance; compare challenge outputs to predefined Secondary structure profile acceptance.	OQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0082	Circular dichroism spectrometer	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Secondary structure profile.	OQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0083	Circular dichroism spectrometer	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Secondary structure profile at relevant Wavelength and pathlength performance; sampling scientifically justified.	PQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0084	Circular dichroism spectrometer	Continued verification / risk-based requalification trigger evaluation	Trend Wavelength and pathlength performance and impact on Secondary structure profile; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	Medium
BTV-28-0085	Subvisible particle counter	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Size calibration and counting precision to product impact on Particle specification result.	URS / DQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0086	Subvisible particle counter	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Subvisible particle counter.	IQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	Medium
BTV-28-0087	Subvisible particle counter	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Size calibration and counting precision; compare challenge outputs to predefined Particle specification result acceptance.	OQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0088	Subvisible particle counter	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Particle specification result.	OQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-28-0089	Subvisible particle counter	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Particle specification result at relevant Size calibration and counting precision; sampling scientifically justified.	PQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0090	Subvisible particle counter	Continued verification / risk-based requalification trigger evaluation	Trend Size calibration and counting precision and impact on Particle specification result; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	Medium
BTV-28-0091	Micro-flow imaging analyzer	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Illumination, sizing and image classification to product impact on Particle morphology result.	URS / DQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0092	Micro-flow imaging analyzer	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Micro-flow imaging analyzer.	IQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	Medium
BTV-28-0093	Micro-flow imaging analyzer	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Illumination, sizing and image classification; compare challenge outputs to predefined Particle morphology result acceptance.	OQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0094	Micro-flow imaging analyzer	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Particle morphology result.	OQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0095	Micro-flow imaging analyzer	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Particle morphology result at relevant Illumination, sizing and image classification; sampling scientifically justified.	PQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0096	Micro-flow imaging analyzer	Continued verification / risk-based requalification trigger evaluation	Trend Illumination, sizing and image classification and impact on Particle morphology result; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	Medium
BTV-28-0097	Zeta potential analyzer	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Mobility calibration and sample conditions to product impact on Colloidal stability profile.	URS / DQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0098	Zeta potential analyzer	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Zeta potential analyzer.	IQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	Medium
BTV-28-0099	Zeta potential analyzer	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Mobility calibration and sample conditions; compare challenge outputs to predefined Colloidal stability profile acceptance.	OQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0100	Zeta potential analyzer	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Colloidal stability profile.	OQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0101	Zeta potential analyzer	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Colloidal stability profile at relevant Mobility calibration and sample conditions; sampling scientifically justified.	PQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0102	Zeta potential analyzer	Continued verification / risk-based requalification trigger evaluation	Trend Mobility calibration and sample conditions and impact on Colloidal stability profile; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	Medium
BTV-28-0103	Analytical ultracentrifuge	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Speed, temperature and optical measurement to product impact on Molecular mass distributions.	URS / DQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0104	Analytical ultracentrifuge	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Analytical ultracentrifuge.	IQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	Medium
BTV-28-0105	Analytical ultracentrifuge	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Speed, temperature and optical measurement; compare challenge outputs to predefined Molecular mass distributions acceptance.	OQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0106	Analytical ultracentrifuge	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Molecular mass distributions.	OQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-28-0107	Analytical ultracentrifuge	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Molecular mass distributions at relevant Speed, temperature and optical measurement; sampling scientifically justified.	PQ	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	High
BTV-28-0108	Analytical ultracentrifuge	Continued verification / risk-based requalification trigger evaluation	Trend Speed, temperature and optical measurement and impact on Molecular mass distributions; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	DS and DP biologics including proteins and nucleic acids	B09 B11 B20 B23	Medium

29 INSTRUMENTS, METROLOGY AND CALIBRATION

84 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-29-0001	Metrology master list	Protocol / design: Assign each critical instrument accuracy and calibration interval	Preapproved risk-based study design; endpoint: Traceable standard and planned calibration.	Planning	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0002	Metrology master list	Execution / boundary verification: Assign each critical instrument accuracy and calibration interval	Documented raw observations, calibration, relevant worst cases and defined acceptance for Traceable standard and planned calibration.	Execution	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0003	Metrology master list	Review / lifecycle: Assign each critical instrument accuracy and calibration interval	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Traceable standard and planned calibration.	Review	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	Medium
BTV-29-0004	Calibration tolerance	Protocol / design: Define process critical error margin and acceptance	Preapproved risk-based study design; endpoint: Fit-for-intended-use calibration limits.	Planning	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0005	Calibration tolerance	Execution / boundary verification: Define process critical error margin and acceptance	Documented raw observations, calibration, relevant worst cases and defined acceptance for Fit-for-intended-use calibration limits.	Execution	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0006	Calibration tolerance	Review / lifecycle: Define process critical error margin and acceptance	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Fit-for-intended-use calibration limits.	Review	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	Medium
BTV-29-0007	Out of tolerance	Protocol / design: Validate impact evaluation and lookback to prior lots	Preapproved risk-based study design; endpoint: Batch impact and sensor maintenance.	Planning	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0008	Out of tolerance	Execution / boundary verification: Validate impact evaluation and lookback to prior lots	Documented raw observations, calibration, relevant worst cases and defined acceptance for Batch impact and sensor maintenance.	Execution	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0009	Out of tolerance	Review / lifecycle: Validate impact evaluation and lookback to prior lots	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Batch impact and sensor maintenance.	Review	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	Medium
BTV-29-0010	Measurement uncertainty	Protocol / design: Characterize uncertainty for critical reporting where relevant	Preapproved risk-based study design; endpoint: Defensible specifications and results.	Planning	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0011	Measurement uncertainty	Execution / boundary verification: Characterize uncertainty for critical reporting where relevant	Documented raw observations, calibration, relevant worst cases and defined acceptance for Defensible specifications and results.	Execution	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0012	Measurement uncertainty	Review / lifecycle: Characterize uncertainty for critical reporting where relevant	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Defensible specifications and results.	Review	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	Medium
BTV-29-0013	Sensor placement	Protocol / design: Validate representative and worst-case probe locations	Preapproved risk-based study design; endpoint: Measurements reflect batch-critical conditions.	Planning	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0014	Sensor placement	Execution / boundary verification: Validate representative and worst-case probe locations	Documented raw observations, calibration, relevant worst cases and defined acceptance for Measurements reflect batch-critical conditions.	Execution	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0015	Sensor placement	Review / lifecycle: Validate representative and worst-case probe locations	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Measurements reflect batch-critical conditions.	Review	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	Medium
BTV-29-0016	Data loggers	Protocol / design: Qualify timestamps, calibration, buffer storage and downloads	Preapproved risk-based study design; endpoint: Complete temperature / pressure history.	Planning	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0017	Data loggers	Execution / boundary verification: Qualify timestamps, calibration, buffer storage and downloads	Documented raw observations, calibration, relevant worst cases and defined acceptance for Complete temperature / pressure history.	Execution	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0018	Data loggers	Review / lifecycle: Qualify timestamps, calibration, buffer storage and downloads	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Complete temperature / pressure history.	Review	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	Medium
BTV-29-0019	Load cell calibration	Protocol / design: Challenge span, linearity, creep and corner load	Preapproved risk-based study design; endpoint: Accurate dosing and batch mass balance.	Planning	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0020	Load cell calibration	Execution / boundary verification: Challenge span, linearity, creep and corner load	Documented raw observations, calibration, relevant worst cases and defined acceptance for Accurate dosing and batch mass balance.	Execution	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0021	Load cell calibration	Review / lifecycle: Challenge span, linearity, creep and corner load	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Accurate dosing and batch mass balance.	Review	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	Medium
BTV-29-0022	Flowmeter metrology	Protocol / design: Check low/high flow range and fluid properties	Preapproved risk-based study design; endpoint: Reliable process delivery.	Planning	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-29-0023	Flowmeter metrology	Execution / boundary verification: Check low/high flow range and fluid properties	Documented raw observations, calibration, relevant worst cases and defined acceptance for Reliable process delivery.	Execution	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0024	Flowmeter metrology	Review / lifecycle: Check low/high flow range and fluid properties	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Reliable process delivery.	Review	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	Medium
BTV-29-0025	Gas analysis	Protocol / design: Compare process gas analyzers to reference standards	Preapproved risk-based study design; endpoint: Correct dissolved/offgas decisions.	Planning	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0026	Gas analysis	Execution / boundary verification: Compare process gas analyzers to reference standards	Documented raw observations, calibration, relevant worst cases and defined acceptance for Correct dissolved/offgas decisions.	Execution	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0027	Gas analysis	Review / lifecycle: Compare process gas analyzers to reference standards	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Correct dissolved/offgas decisions.	Review	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	Medium
BTV-29-0028	Pressure calibration	Protocol / design: Verify gauge span, impulse lines and alarm limits	Preapproved risk-based study design; endpoint: Dependable sterile filter and TFF pressure.	Planning	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0029	Pressure calibration	Execution / boundary verification: Verify gauge span, impulse lines and alarm limits	Documented raw observations, calibration, relevant worst cases and defined acceptance for Dependable sterile filter and TFF pressure.	Execution	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0030	Pressure calibration	Review / lifecycle: Verify gauge span, impulse lines and alarm limits	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Dependable sterile filter and TFF pressure.	Review	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	Medium
BTV-29-0031	Torque calibration	Protocol / design: Qualify stirrer / fill cap torque devices	Preapproved risk-based study design; endpoint: Controlled mixing and closure performance.	Planning	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0032	Torque calibration	Execution / boundary verification: Qualify stirrer / fill cap torque devices	Documented raw observations, calibration, relevant worst cases and defined acceptance for Controlled mixing and closure performance.	Execution	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0033	Torque calibration	Review / lifecycle: Qualify stirrer / fill cap torque devices	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Controlled mixing and closure performance.	Review	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	Medium
BTV-29-0034	Optical analyzer	Protocol / design: Verify wavelength and photometric metrology	Preapproved risk-based study design; endpoint: Reliable critical QC data.	Planning	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0035	Optical analyzer	Execution / boundary verification: Verify wavelength and photometric metrology	Documented raw observations, calibration, relevant worst cases and defined acceptance for Reliable critical QC data.	Execution	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0036	Optical analyzer	Review / lifecycle: Verify wavelength and photometric metrology	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Reliable critical QC data.	Review	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	Medium
BTV-29-0037	Critical temperature sensors	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Accuracy, response, sensor drift to product impact on Correct CPP temperature evidence.	URS / DQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0038	Critical temperature sensors	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Critical temperature sensors.	IQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	Medium
BTV-29-0039	Critical temperature sensors	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Accuracy, response, sensor drift; compare challenge outputs to predefined Correct CPP temperature evidence acceptance.	OQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0040	Critical temperature sensors	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Correct CPP temperature evidence.	OQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0041	Critical temperature sensors	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Correct CPP temperature evidence at relevant Accuracy, response, sensor drift; sampling scientifically justified.	PQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0042	Critical temperature sensors	Continued verification / risk-based requalification trigger evaluation	Trend Accuracy, response, sensor drift and impact on Correct CPP temperature evidence; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	Medium
BTV-29-0043	Pressure transmitters	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Zero, span, hysteresis, response to product impact on Correct process pressure.	URS / DQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0044	Pressure transmitters	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Pressure transmitters.	IQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	Medium
BTV-29-0045	Pressure transmitters	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Zero, span, hysteresis, response; compare challenge outputs to predefined Correct process pressure acceptance.	OQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-29-0046	Pressure transmitters	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Correct process pressure.	OQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0047	Pressure transmitters	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Correct process pressure at relevant Zero, span, hysteresis, response; sampling scientifically justified.	PQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0048	Pressure transmitters	Continued verification / risk-based requalification trigger evaluation	Trend Zero, span, hysteresis, response and impact on Correct process pressure; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	Medium
BTV-29-0049	Load cells	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Linearity, repeatability and eccentricity to product impact on Correct bioreactor feed weight.	URS / DQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0050	Load cells	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Load cells.	IQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	Medium
BTV-29-0051	Load cells	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Linearity, repeatability and eccentricity; compare challenge outputs to predefined Correct bioreactor feed weight acceptance.	OQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0052	Load cells	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Correct bioreactor feed weight.	OQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0053	Load cells	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Correct bioreactor feed weight at relevant Linearity, repeatability and eccentricity; sampling scientifically justified.	PQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0054	Load cells	Continued verification / risk-based requalification trigger evaluation	Trend Linearity, repeatability and eccentricity and impact on Correct bioreactor feed weight; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	Medium
BTV-29-0055	Mass flow controllers	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Accuracy and mixing ratio to product impact on Correct gas dosing.	URS / DQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0056	Mass flow controllers	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Mass flow controllers.	IQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	Medium
BTV-29-0057	Mass flow controllers	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Accuracy and mixing ratio; compare challenge outputs to predefined Correct gas dosing acceptance.	OQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0058	Mass flow controllers	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Correct gas dosing.	OQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0059	Mass flow controllers	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Correct gas dosing at relevant Accuracy and mixing ratio; sampling scientifically justified.	PQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0060	Mass flow controllers	Continued verification / risk-based requalification trigger evaluation	Trend Accuracy and mixing ratio and impact on Correct gas dosing; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	Medium
BTV-29-0061	Analytical balances	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Repeatability, minimum weight, drift to product impact on Accurate sampling/dosing.	URS / DQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0062	Analytical balances	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Analytical balances.	IQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	Medium
BTV-29-0063	Analytical balances	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Repeatability, minimum weight, drift; compare challenge outputs to predefined Accurate sampling/dosing acceptance.	OQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0064	Analytical balances	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Accurate sampling/dosing.	OQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0065	Analytical balances	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Accurate sampling/dosing at relevant Repeatability, minimum weight, drift; sampling scientifically justified.	PQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0066	Analytical balances	Continued verification / risk-based requalification trigger evaluation	Trend Repeatability, minimum weight, drift and impact on Accurate sampling/dosing; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	Medium
BTV-29-0067	Pipettes and dispensers	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Volume accuracy, precision and tip effects to product impact on Valid assay preparation.	URS / DQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0068	Pipettes and dispensers	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Pipettes and dispensers.	IQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-29-0069	Pipettes and dispensers	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Volume accuracy, precision and tip effects; compare challenge outputs to predefined Valid assay preparation acceptance.	OQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0070	Pipettes and dispensers	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Valid assay preparation.	OQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0071	Pipettes and dispensers	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Valid assay preparation at relevant Volume accuracy, precision and tip effects; sampling scientifically justified.	PQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0072	Pipettes and dispensers	Continued verification / risk-based requalification trigger evaluation	Trend Volume accuracy, precision and tip effects and impact on Valid assay preparation; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	Medium
BTV-29-0073	Particle monitoring systems	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Flow, optics and particle count verification to product impact on Reliable cleanroom particle trends.	URS / DQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0074	Particle monitoring systems	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Particle monitoring systems.	IQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	Medium
BTV-29-0075	Particle monitoring systems	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Flow, optics and particle count verification; compare challenge outputs to predefined Reliable cleanroom particle trends acceptance.	OQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0076	Particle monitoring systems	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Reliable cleanroom particle trends.	OQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0077	Particle monitoring systems	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Reliable cleanroom particle trends at relevant Flow, optics and particle count verification; sampling scientifically justified.	PQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0078	Particle monitoring systems	Continued verification / risk-based requalification trigger evaluation	Trend Flow, optics and particle count verification and impact on Reliable cleanroom particle trends; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	Medium
BTV-29-0079	Recording chart/DAQ systems	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Timestamp, accuracy and buffer integrity to product impact on Complete critical process trace.	URS / DQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0080	Recording chart/DAQ systems	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Recording chart/DAQ systems.	IQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	Medium
BTV-29-0081	Recording chart/DAQ systems	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Timestamp, accuracy and buffer integrity; compare challenge outputs to predefined Complete critical process trace acceptance.	OQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0082	Recording chart/DAQ systems	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Complete critical process trace.	OQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0083	Recording chart/DAQ systems	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Complete critical process trace at relevant Timestamp, accuracy and buffer integrity; sampling scientifically justified.	PQ	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	High
BTV-29-0084	Recording chart/DAQ systems	Continued verification / risk-based requalification trigger evaluation	Trend Timestamp, accuracy and buffer integrity and impact on Complete critical process trace; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	All equipment monitoring and laboratories	B02 B03 B05 B12 B20	Medium

30 CSV, SCADA, PLC, LIMS AND DATA INTEGRITY

105 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-30-0001	GxP inventory	Protocol / design: Classify computerized systems by product quality and patient impact	Preapproved risk-based study design; endpoint: Controlled CSV scope.	Planning	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0002	GxP inventory	Execution / boundary verification: Classify computerized systems by product quality and patient impact	Documented raw observations, calibration, relevant worst cases and defined acceptance for Controlled CSV scope.	Execution	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0003	GxP inventory	Review / lifecycle: Classify computerized systems by product quality and patient impact	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Controlled CSV scope.	Review	GxP computerized biologics systems	B01 B02 B03 B05 B19	Medium
BTV-30-0004	User requirements	Protocol / design: Translate intended use into testable functional and data controls	Preapproved risk-based study design; endpoint: Documented URS acceptance.	Planning	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0005	User requirements	Execution / boundary verification: Translate intended use into testable functional and data controls	Documented raw observations, calibration, relevant worst cases and defined acceptance for Documented URS acceptance.	Execution	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0006	User requirements	Review / lifecycle: Translate intended use into testable functional and data controls	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Documented URS acceptance.	Review	GxP computerized biologics systems	B01 B02 B03 B05 B19	Medium
BTV-30-0007	Configuration control	Protocol / design: Qualify recipes, accounts, role access, e-signatures and configuration	Preapproved risk-based study design; endpoint: Authorized process and secure audit trail.	Planning	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0008	Configuration control	Execution / boundary verification: Qualify recipes, accounts, role access, e-signatures and configuration	Documented raw observations, calibration, relevant worst cases and defined acceptance for Authorized process and secure audit trail.	Execution	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0009	Configuration control	Review / lifecycle: Qualify recipes, accounts, role access, e-signatures and configuration	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Authorized process and secure audit trail.	Review	GxP computerized biologics systems	B01 B02 B03 B05 B19	Medium
BTV-30-0010	Supplier assessment	Protocol / design: Assess vendor QMS, testing and maintenance evidence	Preapproved risk-based study design; endpoint: Credible supplier validation leverage.	Planning	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0011	Supplier assessment	Execution / boundary verification: Assess vendor QMS, testing and maintenance evidence	Documented raw observations, calibration, relevant worst cases and defined acceptance for Credible supplier validation leverage.	Execution	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0012	Supplier assessment	Review / lifecycle: Assess vendor QMS, testing and maintenance evidence	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Credible supplier validation leverage.	Review	GxP computerized biologics systems	B01 B02 B03 B05 B19	Medium
BTV-30-0013	Software lifecycle	Protocol / design: Verify requirements, risk, code/config tests and release	Preapproved risk-based study design; endpoint: Controlled automated system function.	Planning	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0014	Software lifecycle	Execution / boundary verification: Verify requirements, risk, code/config tests and release	Documented raw observations, calibration, relevant worst cases and defined acceptance for Controlled automated system function.	Execution	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0015	Software lifecycle	Review / lifecycle: Verify requirements, risk, code/config tests and release	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Controlled automated system function.	Review	GxP computerized biologics systems	B01 B02 B03 B05 B19	Medium
BTV-30-0016	Audit trails	Protocol / design: Validate protected change/event logging and reviewability	Preapproved risk-based study design; endpoint: Electronic raw data reconstruction.	Planning	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0017	Audit trails	Execution / boundary verification: Validate protected change/event logging and reviewability	Documented raw observations, calibration, relevant worst cases and defined acceptance for Electronic raw data reconstruction.	Execution	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0018	Audit trails	Review / lifecycle: Validate protected change/event logging and reviewability	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Electronic raw data reconstruction.	Review	GxP computerized biologics systems	B01 B02 B03 B05 B19	Medium
BTV-30-0019	Electronic signatures	Protocol / design: Qualify meaning, unique identity and record link	Preapproved risk-based study design; endpoint: Compliant sign-off where applicable.	Planning	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0020	Electronic signatures	Execution / boundary verification: Qualify meaning, unique identity and record link	Documented raw observations, calibration, relevant worst cases and defined acceptance for Compliant sign-off where applicable.	Execution	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0021	Electronic signatures	Review / lifecycle: Qualify meaning, unique identity and record link	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Compliant sign-off where applicable.	Review	GxP computerized biologics systems	B01 B02 B03 B05 B19	Medium
BTV-30-0022	Data backups	Protocol / design: Prove restoration and archive retrieval within business requirements	Preapproved risk-based study design; endpoint: Recoverable original GxP data.	Planning	GxP computerized biologics systems	B01 B02 B03 B05 B19	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-30-0023	Data backups	Execution / boundary verification: Prove restoration and archive retrieval within business requirements	Documented raw observations, calibration, relevant worst cases and defined acceptance for Recoverable original GxP data.	Execution	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0024	Data backups	Review / lifecycle: Prove restoration and archive retrieval within business requirements	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Recoverable original GxP data.	Review	GxP computerized biologics systems	B01 B02 B03 B05 B19	Medium
BTV-30-0025	Disaster recovery	Protocol / design: Challenge loss of server, power, comms and network	Preapproved risk-based study design; endpoint: Controlled process safe state and recovery.	Planning	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0026	Disaster recovery	Execution / boundary verification: Challenge loss of server, power, comms and network	Documented raw observations, calibration, relevant worst cases and defined acceptance for Controlled process safe state and recovery.	Execution	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0027	Disaster recovery	Review / lifecycle: Challenge loss of server, power, comms and network	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Controlled process safe state and recovery.	Review	GxP computerized biologics systems	B01 B02 B03 B05 B19	Medium
BTV-30-0028	Recipe management	Protocol / design: Validate version, approval, batch execution and edit security	Preapproved risk-based study design; endpoint: No unauthorized manufacturing change.	Planning	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0029	Recipe management	Execution / boundary verification: Validate version, approval, batch execution and edit security	Documented raw observations, calibration, relevant worst cases and defined acceptance for No unauthorized manufacturing change.	Execution	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0030	Recipe management	Review / lifecycle: Validate version, approval, batch execution and edit security	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No unauthorized manufacturing change.	Review	GxP computerized biologics systems	B01 B02 B03 B05 B19	Medium
BTV-30-0031	Instrument integrations	Protocol / design: Challenge transfer, units, missing data and interface failure	Preapproved risk-based study design; endpoint: Complete intact QC and production records.	Planning	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0032	Instrument integrations	Execution / boundary verification: Challenge transfer, units, missing data and interface failure	Documented raw observations, calibration, relevant worst cases and defined acceptance for Complete intact QC and production records.	Execution	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0033	Instrument integrations	Review / lifecycle: Challenge transfer, units, missing data and interface failure	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Complete intact QC and production records.	Review	GxP computerized biologics systems	B01 B02 B03 B05 B19	Medium
BTV-30-0034	Automated calculation	Protocol / design: Verify formulas, rounding, units and report templates	Preapproved risk-based study design; endpoint: Reliable critical batch/QC result.	Planning	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0035	Automated calculation	Execution / boundary verification: Verify formulas, rounding, units and report templates	Documented raw observations, calibration, relevant worst cases and defined acceptance for Reliable critical batch/QC result.	Execution	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0036	Automated calculation	Review / lifecycle: Verify formulas, rounding, units and report templates	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Reliable critical batch/QC result.	Review	GxP computerized biologics systems	B01 B02 B03 B05 B19	Medium
BTV-30-0037	Alarm escalation	Protocol / design: Validate routing and acknowledgement timeliness	Preapproved risk-based study design; endpoint: GMP excursions handled correctly.	Planning	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0038	Alarm escalation	Execution / boundary verification: Validate routing and acknowledgement timeliness	Documented raw observations, calibration, relevant worst cases and defined acceptance for GMP excursions handled correctly.	Execution	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0039	Alarm escalation	Review / lifecycle: Validate routing and acknowledgement timeliness	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on GMP excursions handled correctly.	Review	GxP computerized biologics systems	B01 B02 B03 B05 B19	Medium
BTV-30-0040	Computerized change	Protocol / design: Evaluate patches, backup, regression and permission	Preapproved risk-based study design; endpoint: Maintained validated state.	Planning	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0041	Computerized change	Execution / boundary verification: Evaluate patches, backup, regression and permission	Documented raw observations, calibration, relevant worst cases and defined acceptance for Maintained validated state.	Execution	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0042	Computerized change	Review / lifecycle: Evaluate patches, backup, regression and permission	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Maintained validated state.	Review	GxP computerized biologics systems	B01 B02 B03 B05 B19	Medium
BTV-30-0043	Cloud vendor oversight	Protocol / design: Assure SLA, data location, access, retention and continuity	Preapproved risk-based study design; endpoint: Reliable external GxP service.	Planning	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0044	Cloud vendor oversight	Execution / boundary verification: Assure SLA, data location, access, retention and continuity	Documented raw observations, calibration, relevant worst cases and defined acceptance for Reliable external GxP service.	Execution	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0045	Cloud vendor oversight	Review / lifecycle: Assure SLA, data location, access, retention and continuity	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Reliable external GxP service.	Review	GxP computerized biologics systems	B01 B02 B03 B05 B19	Medium
BTV-30-0046	Cybersecurity process risks	Protocol / design: Assess PLC network segregation and ransomware continuity	Preapproved risk-based study design; endpoint: No product safety or data integrity failure.	Planning	GxP computerized biologics systems	B01 B02 B03 B05 B19	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-30-0047	Cybersecurity process risks	Execution / boundary verification: Assess PLC network segregation and ransomware continuity	Documented raw observations, calibration, relevant worst cases and defined acceptance for No product safety or data integrity failure.	Execution	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0048	Cybersecurity process risks	Review / lifecycle: Assess PLC network segregation and ransomware continuity	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No product safety or data integrity failure.	Review	GxP computerized biologics systems	B01 B02 B03 B05 B19	Medium
BTV-30-0049	AI/ML model use	Protocol / design: Define model version, intended use, performance drift and human oversight	Preapproved risk-based study design; endpoint: Validated analytical/process inference if GxP use.	Planning	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0050	AI/ML model use	Execution / boundary verification: Define model version, intended use, performance drift and human oversight	Documented raw observations, calibration, relevant worst cases and defined acceptance for Validated analytical/process inference if GxP use.	Execution	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0051	AI/ML model use	Review / lifecycle: Define model version, intended use, performance drift and human oversight	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Validated analytical/process inference if GxP use.	Review	GxP computerized biologics systems	B01 B02 B03 B05 B19	Medium
BTV-30-0052	Bioreactor PLC / SCADA	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Recipe execution, I/O, interlocks, time sync to product impact on Correct critical control actions.	URS / DQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0053	Bioreactor PLC / SCADA	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Bioreactor PLC / SCADA.	IQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	Medium
BTV-30-0054	Bioreactor PLC / SCADA	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Recipe execution, I/O, interlocks, time sync; compare challenge outputs to predefined Correct critical control actions acceptance.	OQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0055	Bioreactor PLC / SCADA	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Correct critical control actions.	OQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0056	Bioreactor PLC / SCADA	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Correct critical control actions at relevant Recipe execution, I/O, interlocks, time sync; sampling scientifically justified.	PQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0057	Bioreactor PLC / SCADA	Continued verification / risk-based requalification trigger evaluation	Trend Recipe execution, I/O, interlocks, time sync and impact on Correct critical control actions; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	GxP computerized biologics systems	B01 B02 B03 B05 B19	Medium
BTV-30-0058	Chromatography CDS	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Integration, user privileges, audit trail to product impact on Trustworthy purification process records.	URS / DQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0059	Chromatography CDS	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Chromatography CDS.	IQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	Medium
BTV-30-0060	Chromatography CDS	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Integration, user privileges, audit trail; compare challenge outputs to predefined Trustworthy purification process records acceptance.	OQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0061	Chromatography CDS	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Trustworthy purification process records.	OQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0062	Chromatography CDS	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Trustworthy purification process records at relevant Integration, user privileges, audit trail; sampling scientifically justified.	PQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0063	Chromatography CDS	Continued verification / risk-based requalification trigger evaluation	Trend Integration, user privileges, audit trail and impact on Trustworthy purification process records; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	GxP computerized biologics systems	B01 B02 B03 B05 B19	Medium
BTV-30-0064	LIMS QC system	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Sample status, test limits, audit trail to product impact on Correct QC batch disposition.	URS / DQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0065	LIMS QC system	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for LIMS QC system.	IQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	Medium
BTV-30-0066	LIMS QC system	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Sample status, test limits, audit trail; compare challenge outputs to predefined Correct QC batch disposition acceptance.	OQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0067	LIMS QC system	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Correct QC batch disposition.	OQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0068	LIMS QC system	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Correct QC batch disposition at relevant Sample status, test limits, audit trail; sampling scientifically justified.	PQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-30-0069	LIMS QC system	Continued verification / risk-based requalification trigger evaluation	Trend Sample status, test limits, audit trail and impact on Correct QC batch disposition; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	GxP computerized biologics systems	B01 B02 B03 B05 B19	Medium
BTV-30-0070	MES / electronic batch record	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Workflows, signature, lot genealogy to product impact on Traceable GMP batch history.	URS / DQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0071	MES / electronic batch record	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for MES / electronic batch record.	IQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	Medium
BTV-30-0072	MES / electronic batch record	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Workflows, signature, lot genealogy; compare challenge outputs to predefined Traceable GMP batch history acceptance.	OQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0073	MES / electronic batch record	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Traceable GMP batch history.	OQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0074	MES / electronic batch record	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Traceable GMP batch history at relevant Workflows, signature, lot genealogy; sampling scientifically justified.	PQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0075	MES / electronic batch record	Continued verification / risk-based requalification trigger evaluation	Trend Workflows, signature, lot genealogy and impact on Traceable GMP batch history; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	GxP computerized biologics systems	B01 B02 B03 B05 B19	Medium
BTV-30-0076	Historian / process data archive	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Tags, timestamps, integrity, failover to product impact on Complete process trend.	URS / DQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0077	Historian / process data archive	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Historian / process data archive.	IQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	Medium
BTV-30-0078	Historian / process data archive	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Tags, timestamps, integrity, failover; compare challenge outputs to predefined Complete process trend acceptance.	OQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0079	Historian / process data archive	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Complete process trend.	OQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0080	Historian / process data archive	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Complete process trend at relevant Tags, timestamps, integrity, failover; sampling scientifically justified.	PQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0081	Historian / process data archive	Continued verification / risk-based requalification trigger evaluation	Trend Tags, timestamps, integrity, failover and impact on Complete process trend; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	GxP computerized biologics systems	B01 B02 B03 B05 B19	Medium
BTV-30-0082	Stability data management	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Schedule, limits, result and audit trail to product impact on Reliable stability reports.	URS / DQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0083	Stability data management	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Stability data management.	IQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	Medium
BTV-30-0084	Stability data management	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Schedule, limits, result and audit trail; compare challenge outputs to predefined Reliable stability reports acceptance.	OQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0085	Stability data management	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Reliable stability reports.	OQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0086	Stability data management	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Reliable stability reports at relevant Schedule, limits, result and audit trail; sampling scientifically justified.	PQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0087	Stability data management	Continued verification / risk-based requalification trigger evaluation	Trend Schedule, limits, result and audit trail and impact on Reliable stability reports; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	GxP computerized biologics systems	B01 B02 B03 B05 B19	Medium
BTV-30-0088	Automated EM monitoring	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Sampler integrations and excursion alerts to product impact on Timely aseptic EM response.	URS / DQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0089	Automated EM monitoring	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Automated EM monitoring.	IQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	Medium
BTV-30-0090	Automated EM monitoring	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Sampler integrations and excursion alerts; compare challenge outputs to predefined Timely aseptic EM response acceptance.	OQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0091	Automated EM monitoring	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Timely aseptic EM response.	OQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-30-0092	Automated EM monitoring	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Timely aseptic EM response at relevant Sampler integrations and excursion alerts; sampling scientifically justified.	PQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0093	Automated EM monitoring	Continued verification / risk-based requalification trigger evaluation	Trend Sampler integrations and excursion alerts and impact on Timely aseptic EM response; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	GxP computerized biologics systems	B01 B02 B03 B05 B19	Medium
BTV-30-0094	Enterprise quality system	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Deviation/CAPA/change permissions and traceability to product impact on Controlled quality decisions.	URS / DQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0095	Enterprise quality system	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Enterprise quality system.	IQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	Medium
BTV-30-0096	Enterprise quality system	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Deviation/CAPA/change permissions and traceability; compare challenge outputs to predefined Controlled quality decisions acceptance.	OQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0097	Enterprise quality system	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Controlled quality decisions.	OQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0098	Enterprise quality system	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Controlled quality decisions at relevant Deviation/CAPA/change permissions and traceability; sampling scientifically justified.	PQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0099	Enterprise quality system	Continued verification / risk-based requalification trigger evaluation	Trend Deviation/CAPA/change permissions and traceability and impact on Controlled quality decisions; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	GxP computerized biologics systems	B01 B02 B03 B05 B19	Medium
BTV-30-0100	Cold-chain temperature logger software	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Alarm, download, timestamps and reports to product impact on Accurate shipment evidence.	URS / DQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0101	Cold-chain temperature logger software	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Cold-chain temperature logger software.	IQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	Medium
BTV-30-0102	Cold-chain temperature logger software	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Alarm, download, timestamps and reports; compare challenge outputs to predefined Accurate shipment evidence acceptance.	OQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0103	Cold-chain temperature logger software	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Accurate shipment evidence.	OQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0104	Cold-chain temperature logger software	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Accurate shipment evidence at relevant Alarm, download, timestamps and reports; sampling scientifically justified.	PQ	GxP computerized biologics systems	B01 B02 B03 B05 B19	High
BTV-30-0105	Cold-chain temperature logger software	Continued verification / risk-based requalification trigger evaluation	Trend Alarm, download, timestamps and reports and impact on Accurate shipment evidence; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	GxP computerized biologics systems	B01 B02 B03 B05 B19	Medium

31 WAREHOUSE, SUPPLIER MANAGEMENT & COLD CHAIN

99 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-31-0001	Warehouse temperature mapping	Protocol / design: Qualify summer/winter profiles, full/empty and opening conditions	Preapproved risk-based study design; endpoint: Proven storage zones.	Planning	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0002	Warehouse temperature mapping	Execution / boundary verification: Qualify summer/winter profiles, full/empty and opening conditions	Documented raw observations, calibration, relevant worst cases and defined acceptance for Proven storage zones.	Execution	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0003	Warehouse temperature mapping	Review / lifecycle: Qualify summer/winter profiles, full/empty and opening conditions	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Proven storage zones.	Review	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	Medium
BTV-31-0004	Refrigerated warehouse	Protocol / design: Validate 2-8 C (where required) range, alarms and excursions	Preapproved risk-based study design; endpoint: Stable biologic raw materials and DP.	Planning	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0005	Refrigerated warehouse	Execution / boundary verification: Validate 2-8 C (where required) range, alarms and excursions	Documented raw observations, calibration, relevant worst cases and defined acceptance for Stable biologic raw materials and DP.	Execution	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0006	Refrigerated warehouse	Review / lifecycle: Validate 2-8 C (where required) range, alarms and excursions	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Stable biologic raw materials and DP.	Review	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	Medium
BTV-31-0007	Frozen storage	Protocol / design: Prove -20/-80 or product-specific storage performance	Preapproved risk-based study design; endpoint: Maintained material stability.	Planning	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0008	Frozen storage	Execution / boundary verification: Prove -20/-80 or product-specific storage performance	Documented raw observations, calibration, relevant worst cases and defined acceptance for Maintained material stability.	Execution	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0009	Frozen storage	Review / lifecycle: Prove -20/-80 or product-specific storage performance	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Maintained material stability.	Review	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	Medium
BTV-31-0010	LN2 storage	Protocol / design: Qualify vapor-phase temperature and level alarms	Preapproved risk-based study design; endpoint: Cell banks / ATMP viability.	Planning	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0011	LN2 storage	Execution / boundary verification: Qualify vapor-phase temperature and level alarms	Documented raw observations, calibration, relevant worst cases and defined acceptance for Cell banks / ATMP viability.	Execution	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0012	LN2 storage	Review / lifecycle: Qualify vapor-phase temperature and level alarms	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Cell banks / ATMP viability.	Review	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	Medium
BTV-31-0013	Temperature mapping study	Protocol / design: Select worst-case probe locations and logging intervals	Preapproved risk-based study design; endpoint: Defensible distribution.	Planning	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0014	Temperature mapping study	Execution / boundary verification: Select worst-case probe locations and logging intervals	Documented raw observations, calibration, relevant worst cases and defined acceptance for Defensible distribution.	Execution	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0015	Temperature mapping study	Review / lifecycle: Select worst-case probe locations and logging intervals	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Defensible distribution.	Review	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	Medium
BTV-31-0016	Cold-chain transport lane	Protocol / design: Qualify packaging duration, season, shock and delay	Preapproved risk-based study design; endpoint: Product exposure within acceptance limits.	Planning	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-31-0017	Cold-chain transport lane	Execution / boundary verification: Qualify packaging duration, season, shock and delay	Documented raw observations, calibration, relevant worst cases and defined acceptance for Product exposure within acceptance limits.	Execution	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0018	Cold-chain transport lane	Review / lifecycle: Qualify packaging duration, season, shock and delay	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Product exposure within acceptance limits.	Review	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	Medium
BTV-31-0019	Excursion handling	Protocol / design: Validate quarantine/status logic and product-impact assessment	Preapproved risk-based study design; endpoint: No unauthorized use of compromised lots.	Planning	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0020	Excursion handling	Execution / boundary verification: Validate quarantine/status logic and product-impact assessment	Documented raw observations, calibration, relevant worst cases and defined acceptance for No unauthorized use of compromised lots.	Execution	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0021	Excursion handling	Review / lifecycle: Validate quarantine/status logic and product-impact assessment	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No unauthorized use of compromised lots.	Review	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	Medium
BTV-31-0022	Material receiving	Protocol / design: Qualify sampling and quarantine identity controls	Preapproved risk-based study design; endpoint: No wrong or unreleased input material.	Planning	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0023	Material receiving	Execution / boundary verification: Qualify sampling and quarantine identity controls	Documented raw observations, calibration, relevant worst cases and defined acceptance for No wrong or unreleased input material.	Execution	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0024	Material receiving	Review / lifecycle: Qualify sampling and quarantine identity controls	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No wrong or unreleased input material.	Review	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	Medium
BTV-31-0025	Supplier criticality	Protocol / design: Qualify single-use, sterile component, media and resin suppliers	Preapproved risk-based study design; endpoint: Raw material controls / change notice.	Planning	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0026	Supplier criticality	Execution / boundary verification: Qualify single-use, sterile component, media and resin suppliers	Documented raw observations, calibration, relevant worst cases and defined acceptance for Raw material controls / change notice.	Execution	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0027	Supplier criticality	Review / lifecycle: Qualify single-use, sterile component, media and resin suppliers	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Raw material controls / change notice.	Review	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	Medium
BTV-31-0028	Animal-derived raw materials	Protocol / design: Validate traceability, pathogen-risk assurance and CoA verification	Preapproved risk-based study design; endpoint: Controlled animal origin risks.	Planning	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0029	Animal-derived raw materials	Execution / boundary verification: Validate traceability, pathogen-risk assurance and CoA verification	Documented raw observations, calibration, relevant worst cases and defined acceptance for Controlled animal origin risks.	Execution	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0030	Animal-derived raw materials	Review / lifecycle: Validate traceability, pathogen-risk assurance and CoA verification	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Controlled animal origin risks.	Review	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	Medium
BTV-31-0031	Cold chain inventory software	Protocol / design: Validate temperature logger integration and alarms	Preapproved risk-based study design; endpoint: Complete sample and lot storage genealogy.	Planning	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0032	Cold chain inventory software	Execution / boundary verification: Validate temperature logger integration and alarms	Documented raw observations, calibration, relevant worst cases and defined acceptance for Complete sample and lot storage genealogy.	Execution	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0033	Cold chain inventory software	Review / lifecycle: Validate temperature logger integration and alarms	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Complete sample and lot storage genealogy.	Review	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	Medium
BTV-31-0034	Expiry/retest	Protocol / design: Qualify FEFO and electronic status controls	Preapproved risk-based study design; endpoint: Prevent expired material use.	Planning	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-31-0035	Expiry/retest	Execution / boundary verification: Qualify FEFO and electronic status controls	Documented raw observations, calibration, relevant worst cases and defined acceptance for Prevent expired material use.	Execution	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0036	Expiry/retest	Review / lifecycle: Qualify FEFO and electronic status controls	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Prevent expired material use.	Review	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	Medium
BTV-31-0037	Shipping verification	Protocol / design: Challenge seal, logger, packing and documentation	Preapproved risk-based study design; endpoint: Correct release and transit monitoring.	Planning	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0038	Shipping verification	Execution / boundary verification: Challenge seal, logger, packing and documentation	Documented raw observations, calibration, relevant worst cases and defined acceptance for Correct release and transit monitoring.	Execution	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0039	Shipping verification	Review / lifecycle: Challenge seal, logger, packing and documentation	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Correct release and transit monitoring.	Review	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	Medium
BTV-31-0040	Supplier site changes	Protocol / design: Evaluate material film, resin, plastic and formulation change	Preapproved risk-based study design; endpoint: Comparability / E&L re-evaluation.	Planning	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0041	Supplier site changes	Execution / boundary verification: Evaluate material film, resin, plastic and formulation change	Documented raw observations, calibration, relevant worst cases and defined acceptance for Comparability / E&L re-evaluation.	Execution	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0042	Supplier site changes	Review / lifecycle: Evaluate material film, resin, plastic and formulation change	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Comparability / E&L re-evaluation.	Review	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	Medium
BTV-31-0043	Transportation validation	Protocol / design: Validate transport impact on CQA, container and stability	Preapproved risk-based study design; endpoint: Qualified shipments, not only temperature logging.	Planning	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0044	Transportation validation	Execution / boundary verification: Validate transport impact on CQA, container and stability	Documented raw observations, calibration, relevant worst cases and defined acceptance for Qualified shipments, not only temperature logging.	Execution	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0045	Transportation validation	Review / lifecycle: Validate transport impact on CQA, container and stability	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Qualified shipments, not only temperature logging.	Review	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	Medium
BTV-31-0046	Cold room 2-8 C	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Spatial mapping, door challenge and backup to product impact on Stable refrigerated stocks.	URS / DQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0047	Cold room 2-8 C	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Cold room 2-8 C.	IQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	Medium
BTV-31-0048	Cold room 2-8 C	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Spatial mapping, door challenge and backup; compare challenge outputs to predefined Stable refrigerated stocks acceptance.	OQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0049	Cold room 2-8 C	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Stable refrigerated stocks.	OQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0050	Cold room 2-8 C	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Stable refrigerated stocks at relevant Spatial mapping, door challenge and backup; sampling scientifically justified.	PQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0051	Cold room 2-8 C	Continued verification / risk-based requalification trigger evaluation	Trend Spatial mapping, door challenge and backup and impact on Stable refrigerated stocks; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	Medium
BTV-31-0052	Deep freezer -20 C	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Temperature mapping and alarms to product impact on Stable intermediate / reagent storage.	URS / DQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-31-0053	Deep freezer -20 C	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Deep freezer -20 C.	IQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	Medium
BTV-31-0054	Deep freezer -20 C	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Temperature mapping and alarms; compare challenge outputs to predefined Stable intermediate / reagent storage acceptance.	OQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0055	Deep freezer -20 C	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Stable intermediate / reagent storage.	OQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0056	Deep freezer -20 C	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Stable intermediate / reagent storage at relevant Temperature mapping and alarms; sampling scientifically justified.	PQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0057	Deep freezer -20 C	Continued verification / risk-based requalification trigger evaluation	Trend Temperature mapping and alarms and impact on Stable intermediate / reagent storage; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	Medium
BTV-31-0058	Ultra-low freezer -80 C	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Temperature mapping, restart and power failure to product impact on Protected biological products.	URS / DQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0059	Ultra-low freezer -80 C	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Ultra-low freezer -80 C.	IQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	Medium
BTV-31-0060	Ultra-low freezer -80 C	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Temperature mapping, restart and power failure; compare challenge outputs to predefined Protected biological products acceptance.	OQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0061	Ultra-low freezer -80 C	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Protected biological products.	OQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0062	Ultra-low freezer -80 C	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Protected biological products at relevant Temperature mapping, restart and power failure; sampling scientifically justified.	PQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0063	Ultra-low freezer -80 C	Continued verification / risk-based requalification trigger evaluation	Trend Temperature mapping, restart and power failure and impact on Protected biological products; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	Medium
BTV-31-0064	Liquid nitrogen bank tank	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Vapor phase profile, fill alarms to product impact on Preserved cell banks.	URS / DQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0065	Liquid nitrogen bank tank	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Liquid nitrogen bank tank.	IQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	Medium
BTV-31-0066	Liquid nitrogen bank tank	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Vapor phase profile, fill alarms; compare challenge outputs to predefined Preserved cell banks acceptance.	OQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0067	Liquid nitrogen bank tank	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Preserved cell banks.	OQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0068	Liquid nitrogen bank tank	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Preserved cell banks at relevant Vapor phase profile, fill alarms; sampling scientifically justified.	PQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0069	Liquid nitrogen bank tank	Continued verification / risk-based requalification trigger evaluation	Trend Vapor phase profile, fill alarms and impact on Preserved cell banks; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	Medium
BTV-31-0070	Cold-chain shipper	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Loaded duration and ambient profiles to product impact on In-specification in transit.	URS / DQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-31-0071	Cold-chain shipper	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Cold-chain shipper.	IQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	Medium
BTV-31-0072	Cold-chain shipper	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Loaded duration and ambient profiles; compare challenge outputs to predefined In-specification in transit acceptance.	OQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0073	Cold-chain shipper	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect In-specification in transit.	OQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0074	Cold-chain shipper	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable In-specification in transit at relevant Loaded duration and ambient profiles; sampling scientifically justified.	PQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0075	Cold-chain shipper	Continued verification / risk-based requalification trigger evaluation	Trend Loaded duration and ambient profiles and impact on In-specification in transit; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	Medium
BTV-31-0076	Warehouse BMS logger	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Calibration, alarm route and retrieval to product impact on Reliable storage history.	URS / DQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0077	Warehouse BMS logger	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Warehouse BMS logger.	IQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	Medium
BTV-31-0078	Warehouse BMS logger	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Calibration, alarm route and retrieval; compare challenge outputs to predefined Reliable storage history acceptance.	OQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0079	Warehouse BMS logger	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Reliable storage history.	OQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0080	Warehouse BMS logger	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Reliable storage history at relevant Calibration, alarm route and retrieval; sampling scientifically justified.	PQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0081	Warehouse BMS logger	Continued verification / risk-based requalification trigger evaluation	Trend Calibration, alarm route and retrieval and impact on Reliable storage history; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	Medium
BTV-31-0082	Refrigerated truck	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Thermal mapping, stop/start, door opening to product impact on Qualified shipment lane.	URS / DQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0083	Refrigerated truck	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Refrigerated truck.	IQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	Medium
BTV-31-0084	Refrigerated truck	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Thermal mapping, stop/start, door opening; compare challenge outputs to predefined Qualified shipment lane acceptance.	OQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0085	Refrigerated truck	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Qualified shipment lane.	OQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0086	Refrigerated truck	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Qualified shipment lane at relevant Thermal mapping, stop/start, door opening; sampling scientifically justified.	PQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0087	Refrigerated truck	Continued verification / risk-based requalification trigger evaluation	Trend Thermal mapping, stop/start, door opening and impact on Qualified shipment lane; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	Medium
BTV-31-0088	Temperature controlled sampling booth	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Air cleanliness, pressure and temp to product impact on Representative uncontaminated sampling.	URS / DQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-31-0089	Temperature controlled sampling booth	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Temperature controlled sampling booth.	IQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	Medium
BTV-31-0090	Temperature controlled sampling booth	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Air cleanliness, pressure and temp; compare challenge outputs to predefined Representative uncontaminated sampling acceptance.	OQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0091	Temperature controlled sampling booth	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Representative uncontaminated sampling.	OQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0092	Temperature controlled sampling booth	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Representative uncontaminated sampling at relevant Air cleanliness, pressure and temp; sampling scientifically justified.	PQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0093	Temperature controlled sampling booth	Continued verification / risk-based requalification trigger evaluation	Trend Air cleanliness, pressure and temp and impact on Representative uncontaminated sampling; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	Medium
BTV-31-0094	Barcode/ERP warehouse system	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Status labels, lot trace and access to product impact on Correct inventory/release segregation.	URS / DQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0095	Barcode/ERP warehouse system	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Barcode/ERP warehouse system.	IQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	Medium
BTV-31-0096	Barcode/ERP warehouse system	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Status labels, lot trace and access; compare challenge outputs to predefined Correct inventory/release segregation acceptance.	OQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0097	Barcode/ERP warehouse system	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Correct inventory/release segregation.	OQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0098	Barcode/ERP warehouse system	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Correct inventory/release segregation at relevant Status labels, lot trace and access; sampling scientifically justified.	PQ	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	High
BTV-31-0099	Barcode/ERP warehouse system	Continued verification / risk-based requalification trigger evaluation	Trend Status labels, lot trace and access and impact on Correct inventory/release segregation; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Raw materials, intermediates, DS/DP and kits	B03 B05 B09 B12 B17	Medium

32 PACKAGING, CCIT, EXTRACTABLES/LEACHABLES & DISTRIBUTION

84 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-32-0001	Container closure integrity	Protocol / design: Establish deterministic test sensitivity and worst-case defects	Preapproved risk-based study design; endpoint: Sterile barrier maintained throughout product life.	Planning	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0002	Container closure integrity	Execution / boundary verification: Establish deterministic test sensitivity and worst-case defects	Documented raw observations, calibration, relevant worst cases and defined acceptance for Sterile barrier maintained throughout product life.	Execution	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0003	Container closure integrity	Review / lifecycle: Establish deterministic test sensitivity and worst-case defects	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Sterile barrier maintained throughout product life.	Review	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	Medium
BTV-32-0004	CCIT aging	Protocol / design: Validate after real-time/accelerated aging when appropriate	Preapproved risk-based study design; endpoint: Integrity over shelf life.	Planning	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0005	CCIT aging	Execution / boundary verification: Validate after real-time/accelerated aging when appropriate	Documented raw observations, calibration, relevant worst cases and defined acceptance for Integrity over shelf life.	Execution	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0006	CCIT aging	Review / lifecycle: Validate after real-time/accelerated aging when appropriate	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Integrity over shelf life.	Review	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	Medium
BTV-32-0007	Container closure compatibility	Protocol / design: Study glass/elastomer adsorption, silicone and pH impact	Preapproved risk-based study design; endpoint: Preserved potency and low particles.	Planning	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0008	Container closure compatibility	Execution / boundary verification: Study glass/elastomer adsorption, silicone and pH impact	Documented raw observations, calibration, relevant worst cases and defined acceptance for Preserved potency and low particles.	Execution	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0009	Container closure compatibility	Review / lifecycle: Study glass/elastomer adsorption, silicone and pH impact	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Preserved potency and low particles.	Review	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	Medium
BTV-32-0010	Extractables/leachables	Protocol / design: Design chemistry study based on materials/contact conditions	Preapproved risk-based study design; endpoint: Product-specific leachable safety and CQA evaluation.	Planning	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0011	Extractables/leachables	Execution / boundary verification: Design chemistry study based on materials/contact conditions	Documented raw observations, calibration, relevant worst cases and defined acceptance for Product-specific leachable safety and CQA evaluation.	Execution	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0012	Extractables/leachables	Review / lifecycle: Design chemistry study based on materials/contact conditions	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Product-specific leachable safety and CQA evaluation.	Review	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	Medium
BTV-32-0013	Stopper selection	Protocol / design: Qualify formulation compatibility and puncture / reseal	Preapproved risk-based study design; endpoint: Reliable container function.	Planning	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0014	Stopper selection	Execution / boundary verification: Qualify formulation compatibility and puncture / reseal	Documented raw observations, calibration, relevant worst cases and defined acceptance for Reliable container function.	Execution	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0015	Stopper selection	Review / lifecycle: Qualify formulation compatibility and puncture / reseal	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Reliable container function.	Review	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	Medium
BTV-32-0016	Silicone oil sensitivity	Protocol / design: Challenge PFS siliconization and agitation	Preapproved risk-based study design; endpoint: No unacceptable particles/aggregation.	Planning	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0017	Silicone oil sensitivity	Execution / boundary verification: Challenge PFS siliconization and agitation	Documented raw observations, calibration, relevant worst cases and defined acceptance for No unacceptable particles/aggregation.	Execution	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0018	Silicone oil sensitivity	Review / lifecycle: Challenge PFS siliconization and agitation	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No unacceptable particles/aggregation.	Review	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	Medium
BTV-32-0019	Vial seal crimp	Protocol / design: Study sealing window and dimensional tolerance	Preapproved risk-based study design; endpoint: Correct closure integrity.	Planning	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0020	Vial seal crimp	Execution / boundary verification: Study sealing window and dimensional tolerance	Documented raw observations, calibration, relevant worst cases and defined acceptance for Correct closure integrity.	Execution	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0021	Vial seal crimp	Review / lifecycle: Study sealing window and dimensional tolerance	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Correct closure integrity.	Review	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	Medium
BTV-32-0022	Container surface defects	Protocol / design: Prove glass particle detection and crack controls	Preapproved risk-based study design; endpoint: Low glass delamination / defects.	Planning	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-32-0023	Container surface defects	Execution / boundary verification: Prove glass particle detection and crack controls	Documented raw observations, calibration, relevant worst cases and defined acceptance for Low glass delamination / defects.	Execution	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0024	Container surface defects	Review / lifecycle: Prove glass particle detection and crack controls	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Low glass delamination / defects.	Review	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	Medium
BTV-32-0025	Label & serialization	Protocol / design: Validate correct lot, expiry and data matrix after packing	Preapproved risk-based study design; endpoint: No product mix-up.	Planning	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0026	Label & serialization	Execution / boundary verification: Validate correct lot, expiry and data matrix after packing	Documented raw observations, calibration, relevant worst cases and defined acceptance for No product mix-up.	Execution	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0027	Label & serialization	Review / lifecycle: Validate correct lot, expiry and data matrix after packing	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No product mix-up.	Review	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	Medium
BTV-32-0028	Tamper evidence	Protocol / design: Qualify seal integrity and consumer removal where applicable	Preapproved risk-based study design; endpoint: Appropriate visible tamper proof.	Planning	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0029	Tamper evidence	Execution / boundary verification: Qualify seal integrity and consumer removal where applicable	Documented raw observations, calibration, relevant worst cases and defined acceptance for Appropriate visible tamper proof.	Execution	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0030	Tamper evidence	Review / lifecycle: Qualify seal integrity and consumer removal where applicable	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Appropriate visible tamper proof.	Review	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	Medium
BTV-32-0031	Distribution	Protocol / design: Validate drop, vibration, altitude, thermal and pallet load	Preapproved risk-based study design; endpoint: Product and sterile barrier preserved.	Planning	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0032	Distribution	Execution / boundary verification: Validate drop, vibration, altitude, thermal and pallet load	Documented raw observations, calibration, relevant worst cases and defined acceptance for Product and sterile barrier preserved.	Execution	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0033	Distribution	Review / lifecycle: Validate drop, vibration, altitude, thermal and pallet load	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Product and sterile barrier preserved.	Review	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	Medium
BTV-32-0034	Transport packout	Protocol / design: Qualify dry ice, gel packs, void and logger position	Preapproved risk-based study design; endpoint: Controlled physical / thermal risk.	Planning	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0035	Transport packout	Execution / boundary verification: Qualify dry ice, gel packs, void and logger position	Documented raw observations, calibration, relevant worst cases and defined acceptance for Controlled physical / thermal risk.	Execution	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0036	Transport packout	Review / lifecycle: Qualify dry ice, gel packs, void and logger position	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Controlled physical / thermal risk.	Review	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	Medium
BTV-32-0037	Shipping temperature excursions	Protocol / design: Define stability-based excursion evaluation model	Preapproved risk-based study design; endpoint: Scientific disposition criteria.	Planning	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0038	Shipping temperature excursions	Execution / boundary verification: Define stability-based excursion evaluation model	Documented raw observations, calibration, relevant worst cases and defined acceptance for Scientific disposition criteria.	Execution	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0039	Shipping temperature excursions	Review / lifecycle: Define stability-based excursion evaluation model	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Scientific disposition criteria.	Review	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	Medium
BTV-32-0040	Packaging line clearance	Protocol / design: Validate reconciliation and barcode inspection interlocks	Preapproved risk-based study design; endpoint: No label/product mix-ups.	Planning	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0041	Packaging line clearance	Execution / boundary verification: Validate reconciliation and barcode inspection interlocks	Documented raw observations, calibration, relevant worst cases and defined acceptance for No label/product mix-ups.	Execution	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0042	Packaging line clearance	Review / lifecycle: Validate reconciliation and barcode inspection interlocks	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No label/product mix-ups.	Review	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	Medium
BTV-32-0043	Vial crimper	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Seal compression and head spacing to product impact on Closure integrity.	URS / DQ	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0044	Vial crimper	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Vial crimper.	IQ	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	Medium
BTV-32-0045	Vial crimper	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Seal compression and head spacing; compare challenge outputs to predefined Closure integrity acceptance.	OQ	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0046	Vial crimper	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Closure integrity.	OQ	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-32-0047	Vial crimper	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Closure integrity at relevant Seal compression and head spacing; sampling scientifically justified.	PQ	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0048	Vial crimper	Continued verification / risk-based requalification trigger evaluation	Trend Seal compression and head spacing and impact on Closure integrity; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	Medium
BTV-32-0049	Pre-filled syringe stopper inserter	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Insertion force, depth and lubricant to product impact on Functional sealing and dose.	URS / DQ	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0050	Pre-filled syringe stopper inserter	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Pre-filled syringe stopper inserter.	IQ	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	Medium
BTV-32-0051	Pre-filled syringe stopper inserter	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Insertion force, depth and lubricant; compare challenge outputs to predefined Functional sealing and dose acceptance.	OQ	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0052	Pre-filled syringe stopper inserter	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Functional sealing and dose.	OQ	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0053	Pre-filled syringe stopper inserter	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Functional sealing and dose at relevant Insertion force, depth and lubricant; sampling scientifically justified.	PQ	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0054	Pre-filled syringe stopper inserter	Continued verification / risk-based requalification trigger evaluation	Trend Insertion force, depth and lubricant and impact on Functional sealing and dose; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	Medium
BTV-32-0055	Labeling machine	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Vision OCR, serialization and reject to product impact on Correct product identity.	URS / DQ	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0056	Labeling machine	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Labeling machine.	IQ	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	Medium
BTV-32-0057	Labeling machine	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Vision OCR, serialization and reject; compare challenge outputs to predefined Correct product identity acceptance.	OQ	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0058	Labeling machine	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Correct product identity.	OQ	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0059	Labeling machine	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Correct product identity at relevant Vision OCR, serialization and reject; sampling scientifically justified.	PQ	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0060	Labeling machine	Continued verification / risk-based requalification trigger evaluation	Trend Vision OCR, serialization and reject and impact on Correct product identity; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	Medium
BTV-32-0061	Leak/CCIT analyzer	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Reference leaks, limit of detection, sensitivity to product impact on Valid closure test decision.	URS / DQ	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0062	Leak/CCIT analyzer	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Leak/CCIT analyzer.	IQ	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	Medium
BTV-32-0063	Leak/CCIT analyzer	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Reference leaks, limit of detection, sensitivity; compare challenge outputs to predefined Valid closure test decision acceptance.	OQ	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0064	Leak/CCIT analyzer	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Valid closure test decision.	OQ	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0065	Leak/CCIT analyzer	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Valid closure test decision at relevant Reference leaks, limit of detection, sensitivity; sampling scientifically justified.	PQ	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0066	Leak/CCIT analyzer	Continued verification / risk-based requalification trigger evaluation	Trend Reference leaks, limit of detection, sensitivity and impact on Valid closure test decision; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	Medium
BTV-32-0067	Cold-chain case packer	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Pack geometry, case weight and label to product impact on Traceable protected shipments.	URS / DQ	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0068	Cold-chain case packer	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Cold-chain case packer.	IQ	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-32-0069	Cold-chain case packer	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Pack geometry, case weight and label; compare challenge outputs to predefined Traceable protected shipments acceptance.	OQ	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0070	Cold-chain case packer	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Traceable protected shipments.	OQ	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0071	Cold-chain case packer	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Traceable protected shipments at relevant Pack geometry, case weight and label; sampling scientifically justified.	PQ	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0072	Cold-chain case packer	Continued verification / risk-based requalification trigger evaluation	Trend Pack geometry, case weight and label and impact on Traceable protected shipments; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	Medium
BTV-32-0073	Tamper-evident cartoner	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Fold, glue, serial print and inspection to product impact on Correct product packaging.	URS / DQ	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0074	Tamper-evident cartoner	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Tamper-evident cartoner.	IQ	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	Medium
BTV-32-0075	Tamper-evident cartoner	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Fold, glue, serial print and inspection; compare challenge outputs to predefined Correct product packaging acceptance.	OQ	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0076	Tamper-evident cartoner	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Correct product packaging.	OQ	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0077	Tamper-evident cartoner	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Correct product packaging at relevant Fold, glue, serial print and inspection; sampling scientifically justified.	PQ	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0078	Tamper-evident cartoner	Continued verification / risk-based requalification trigger evaluation	Trend Fold, glue, serial print and inspection and impact on Correct product packaging; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	Medium
BTV-32-0079	Container visual inspection system	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Defect sizes, camera resolution to product impact on Validated reject sensitivity.	URS / DQ	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0080	Container visual inspection system	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Container visual inspection system.	IQ	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	Medium
BTV-32-0081	Container visual inspection system	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Defect sizes, camera resolution; compare challenge outputs to predefined Validated reject sensitivity acceptance.	OQ	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0082	Container visual inspection system	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Validated reject sensitivity.	OQ	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0083	Container visual inspection system	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Validated reject sensitivity at relevant Defect sizes, camera resolution; sampling scientifically justified.	PQ	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	High
BTV-32-0084	Container visual inspection system	Continued verification / risk-based requalification trigger evaluation	Trend Defect sizes, camera resolution and impact on Validated reject sensitivity; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biologics primary packs, bulk containers, syringes	B04 B05 B09 B11 B12	Medium

33 ENGINEERING MAINTENANCE, UTILITIES AND CHANGE CONTROL

84 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-33-0001	Preventive maintenance	Protocol / design: Link high-risk PM to validated equipment parameters	Preapproved risk-based study design; endpoint: Qualified maintained condition.	Planning	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0002	Preventive maintenance	Execution / boundary verification: Link high-risk PM to validated equipment parameters	Documented raw observations, calibration, relevant worst cases and defined acceptance for Qualified maintained condition.	Execution	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0003	Preventive maintenance	Review / lifecycle: Link high-risk PM to validated equipment parameters	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Qualified maintained condition.	Review	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	Medium
BTV-33-0004	Unplanned maintenance	Protocol / design: Assess product contact, disassembly and aseptic boundary risks	Preapproved risk-based study design; endpoint: Required return-to-service requalification.	Planning	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0005	Unplanned maintenance	Execution / boundary verification: Assess product contact, disassembly and aseptic boundary risks	Documented raw observations, calibration, relevant worst cases and defined acceptance for Required return-to-service requalification.	Execution	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0006	Unplanned maintenance	Review / lifecycle: Assess product contact, disassembly and aseptic boundary risks	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Required return-to-service requalification.	Review	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	Medium
BTV-33-0007	Critical spare parts	Protocol / design: Qualify substitute materials, sensors, seals and software	Preapproved risk-based study design; endpoint: No unassessed CQA impact.	Planning	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0008	Critical spare parts	Execution / boundary verification: Qualify substitute materials, sensors, seals and software	Documented raw observations, calibration, relevant worst cases and defined acceptance for No unassessed CQA impact.	Execution	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0009	Critical spare parts	Review / lifecycle: Qualify substitute materials, sensors, seals and software	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No unassessed CQA impact.	Review	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	Medium
BTV-33-0010	Calibration deviations	Protocol / design: Perform affected-batch impact before returning equipment to use	Preapproved risk-based study design; endpoint: Documented batch lookback.	Planning	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0011	Calibration deviations	Execution / boundary verification: Perform affected-batch impact before returning equipment to use	Documented raw observations, calibration, relevant worst cases and defined acceptance for Documented batch lookback.	Execution	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0012	Calibration deviations	Review / lifecycle: Perform affected-batch impact before returning equipment to use	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Documented batch lookback.	Review	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	Medium
BTV-33-0013	Design change review	Protocol / design: Trace modification through drawings, URS and OQ/PQ as needed	Preapproved risk-based study design; endpoint: Controlled technical baseline.	Planning	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0014	Design change review	Execution / boundary verification: Trace modification through drawings, URS and OQ/PQ as needed	Documented raw observations, calibration, relevant worst cases and defined acceptance for Controlled technical baseline.	Execution	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0015	Design change review	Review / lifecycle: Trace modification through drawings, URS and OQ/PQ as needed	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Controlled technical baseline.	Review	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	Medium
BTV-33-0016	Equipment relocation	Protocol / design: Validate reconnection and changed environmental interface	Preapproved risk-based study design; endpoint: New site as-installed state.	Planning	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0017	Equipment relocation	Execution / boundary verification: Validate reconnection and changed environmental interface	Documented raw observations, calibration, relevant worst cases and defined acceptance for New site as-installed state.	Execution	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0018	Equipment relocation	Review / lifecycle: Validate reconnection and changed environmental interface	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on New site as-installed state.	Review	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	Medium
BTV-33-0019	Utility outage response	Protocol / design: Assess safe-state, batch impact and cleanroom recovery	Preapproved risk-based study design; endpoint: Controlled operations after loss.	Planning	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0020	Utility outage response	Execution / boundary verification: Assess safe-state, batch impact and cleanroom recovery	Documented raw observations, calibration, relevant worst cases and defined acceptance for Controlled operations after loss.	Execution	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0021	Utility outage response	Review / lifecycle: Assess safe-state, batch impact and cleanroom recovery	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Controlled operations after loss.	Review	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	Medium
BTV-33-0022	HVAC filter change	Protocol / design: Assess leak test, airflow and particulate recovery after work	Preapproved risk-based study design; endpoint: Classified state restored.	Planning	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-33-0023	HVAC filter change	Execution / boundary verification: Assess leak test, airflow and particulate recovery after work	Documented raw observations, calibration, relevant worst cases and defined acceptance for Classified state restored.	Execution	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0024	HVAC filter change	Review / lifecycle: Assess leak test, airflow and particulate recovery after work	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Classified state restored.	Review	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	Medium
BTV-33-0025	PLC recipe change	Protocol / design: Validate regression, audit trail and alarm logic	Preapproved risk-based study design; endpoint: No unintended change to manufacturing CPP.	Planning	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0026	PLC recipe change	Execution / boundary verification: Validate regression, audit trail and alarm logic	Documented raw observations, calibration, relevant worst cases and defined acceptance for No unintended change to manufacturing CPP.	Execution	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0027	PLC recipe change	Review / lifecycle: Validate regression, audit trail and alarm logic	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No unintended change to manufacturing CPP.	Review	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	Medium
BTV-33-0028	Supplier parts obsolescence	Protocol / design: Evaluate alternate part fit, quality and maintainability	Preapproved risk-based study design; endpoint: Qualified change and spare management.	Planning	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0029	Supplier parts obsolescence	Execution / boundary verification: Evaluate alternate part fit, quality and maintainability	Documented raw observations, calibration, relevant worst cases and defined acceptance for Qualified change and spare management.	Execution	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0030	Supplier parts obsolescence	Review / lifecycle: Evaluate alternate part fit, quality and maintainability	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Qualified change and spare management.	Review	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	Medium
BTV-33-0031	Facility renovation	Protocol / design: Qualify construction containment, EM and cleaning clearance	Preapproved risk-based study design; endpoint: No microbial or particle cross contamination.	Planning	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0032	Facility renovation	Execution / boundary verification: Qualify construction containment, EM and cleaning clearance	Documented raw observations, calibration, relevant worst cases and defined acceptance for No microbial or particle cross contamination.	Execution	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0033	Facility renovation	Review / lifecycle: Qualify construction containment, EM and cleaning clearance	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No microbial or particle cross contamination.	Review	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	Medium
BTV-33-0034	CMMS electronic workflow	Protocol / design: Validate service release gates and approvals	Preapproved risk-based study design; endpoint: No overdue/unqualified asset used.	Planning	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0035	CMMS electronic workflow	Execution / boundary verification: Validate service release gates and approvals	Documented raw observations, calibration, relevant worst cases and defined acceptance for No overdue/unqualified asset used.	Execution	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0036	CMMS electronic workflow	Review / lifecycle: Validate service release gates and approvals	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No overdue/unqualified asset used.	Review	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	Medium
BTV-33-0037	Engineering turnover	Protocol / design: Require as-built evidence, O&M manuals and acceptance	Preapproved risk-based study design; endpoint: Controlled handover and qualified asset.	Planning	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0038	Engineering turnover	Execution / boundary verification: Require as-built evidence, O&M manuals and acceptance	Documented raw observations, calibration, relevant worst cases and defined acceptance for Controlled handover and qualified asset.	Execution	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0039	Engineering turnover	Review / lifecycle: Require as-built evidence, O&M manuals and acceptance	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Controlled handover and qualified asset.	Review	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	Medium
BTV-33-0040	Biological waste skid	Protocol / design: Qualify pressure, temperature, inactivation process	Preapproved risk-based study design; endpoint: No uncontrolled organism release.	Planning	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0041	Biological waste skid	Execution / boundary verification: Qualify pressure, temperature, inactivation process	Documented raw observations, calibration, relevant worst cases and defined acceptance for No uncontrolled organism release.	Execution	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0042	Biological waste skid	Review / lifecycle: Qualify pressure, temperature, inactivation process	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No uncontrolled organism release.	Review	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	Medium
BTV-33-0043	Process chiller	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Rated heat load, delivery temp and alarms to product impact on Stable culture/purification temperatures.	URS / DQ	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0044	Process chiller	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Process chiller.	IQ	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	Medium
BTV-33-0045	Process chiller	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Rated heat load, delivery temp and alarms; compare challenge outputs to predefined Stable culture/purification temperatures acceptance.	OQ	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-33-0046	Process chiller	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Stable culture/purification temperatures.	OQ	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0047	Process chiller	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Stable culture/purification temperatures at relevant Rated heat load, delivery temp and alarms; sampling scientifically justified.	PQ	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0048	Process chiller	Continued verification / risk-based requalification trigger evaluation	Trend Rated heat load, delivery temp and alarms and impact on Stable culture/purification temperatures; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	Medium
BTV-33-0049	Central utility BMS	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Sensor mappings, alarm and trend records to product impact on Reliable critical service oversight.	URS / DQ	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0050	Central utility BMS	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Central utility BMS.	IQ	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	Medium
BTV-33-0051	Central utility BMS	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Sensor mappings, alarm and trend records; compare challenge outputs to predefined Reliable critical service oversight acceptance.	OQ	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0052	Central utility BMS	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Reliable critical service oversight.	OQ	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0053	Central utility BMS	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Reliable critical service oversight at relevant Sensor mappings, alarm and trend records; sampling scientifically justified.	PQ	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0054	Central utility BMS	Continued verification / risk-based requalification trigger evaluation	Trend Sensor mappings, alarm and trend records and impact on Reliable critical service oversight; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	Medium
BTV-33-0055	CIP return/drain pump	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Flow, backflow and cleanability to product impact on Complete cleaning drain performance.	URS / DQ	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0056	CIP return/drain pump	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for CIP return/drain pump.	IQ	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	Medium
BTV-33-0057	CIP return/drain pump	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Flow, backflow and cleanability; compare challenge outputs to predefined Complete cleaning drain performance acceptance.	OQ	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0058	CIP return/drain pump	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Complete cleaning drain performance.	OQ	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0059	CIP return/drain pump	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Complete cleaning drain performance at relevant Flow, backflow and cleanability; sampling scientifically justified.	PQ	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0060	CIP return/drain pump	Continued verification / risk-based requalification trigger evaluation	Trend Flow, backflow and cleanability and impact on Complete cleaning drain performance; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	Medium
BTV-33-0061	Generator automatic transfer	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Transfer time, load and UPS coordination to product impact on No critical process loss.	URS / DQ	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0062	Generator automatic transfer	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Generator automatic transfer.	IQ	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	Medium
BTV-33-0063	Generator automatic transfer	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Transfer time, load and UPS coordination; compare challenge outputs to predefined No critical process loss acceptance.	OQ	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0064	Generator automatic transfer	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect No critical process loss.	OQ	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0065	Generator automatic transfer	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable No critical process loss at relevant Transfer time, load and UPS coordination; sampling scientifically justified.	PQ	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0066	Generator automatic transfer	Continued verification / risk-based requalification trigger evaluation	Trend Transfer time, load and UPS coordination and impact on No critical process loss; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-33-0067	Biological liquid waste kill system	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Cycle temperature/time and microbial challenge to product impact on Validated biological inactivation.	URS / DQ	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0068	Biological liquid waste kill system	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Biological liquid waste kill system.	IQ	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	Medium
BTV-33-0069	Biological liquid waste kill system	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Cycle temperature/time and microbial challenge; compare challenge outputs to predefined Validated biological inactivation acceptance.	OQ	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0070	Biological liquid waste kill system	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Validated biological inactivation.	OQ	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0071	Biological liquid waste kill system	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Validated biological inactivation at relevant Cycle temperature/time and microbial challenge; sampling scientifically justified.	PQ	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0072	Biological liquid waste kill system	Continued verification / risk-based requalification trigger evaluation	Trend Cycle temperature/time and microbial challenge and impact on Validated biological inactivation; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	Medium
BTV-33-0073	Emergency shutdown system	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Interlocks, safe state and alarms to product impact on Safe protection of cultures/personnel.	URS / DQ	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0074	Emergency shutdown system	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Emergency shutdown system.	IQ	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	Medium
BTV-33-0075	Emergency shutdown system	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Interlocks, safe state and alarms; compare challenge outputs to predefined Safe protection of cultures/personnel acceptance.	OQ	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0076	Emergency shutdown system	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Safe protection of cultures/personnel.	OQ	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0077	Emergency shutdown system	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Safe protection of cultures/personnel at relevant Interlocks, safe state and alarms; sampling scientifically justified.	PQ	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0078	Emergency shutdown system	Continued verification / risk-based requalification trigger evaluation	Trend Interlocks, safe state and alarms and impact on Safe protection of cultures/personnel; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	Medium
BTV-33-0079	Process heat exchanger	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Heat transfer, pressure tightness and leak to product impact on No utility-to-product cross contamination.	URS / DQ	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0080	Process heat exchanger	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Process heat exchanger.	IQ	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	Medium
BTV-33-0081	Process heat exchanger	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Heat transfer, pressure tightness and leak; compare challenge outputs to predefined No utility-to-product cross contamination acceptance.	OQ	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0082	Process heat exchanger	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect No utility-to-product cross contamination.	OQ	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0083	Process heat exchanger	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable No utility-to-product cross contamination at relevant Heat transfer, pressure tightness and leak; sampling scientifically justified.	PQ	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	High
BTV-33-0084	Process heat exchanger	Continued verification / risk-based requalification trigger evaluation	Trend Heat transfer, pressure tightness and leak and impact on No utility-to-product cross contamination; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Facility engineering and process lifecycle	B02 B03 B05 B06 B12	Medium

34 HR, TRAINING, GOWNING, ADMIN & EHS/BIOSAFETY

99 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-34-0001	Competency matrix	Protocol / design: Qualify personnel for aseptic tasks and high-risk operations	Preapproved risk-based study design; endpoint: Training and practical demonstration.	Planning	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0002	Competency matrix	Execution / boundary verification: Qualify personnel for aseptic tasks and high-risk operations	Documented raw observations, calibration, relevant worst cases and defined acceptance for Training and practical demonstration.	Execution	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0003	Competency matrix	Review / lifecycle: Qualify personnel for aseptic tasks and high-risk operations	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Training and practical demonstration.	Review	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	Medium
BTV-34-0004	Gowning qualification	Protocol / design: Challenge initial/periodic gowning and microbiological monitoring	Preapproved risk-based study design; endpoint: Aseptic cleanroom competence.	Planning	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0005	Gowning qualification	Execution / boundary verification: Challenge initial/periodic gowning and microbiological monitoring	Documented raw observations, calibration, relevant worst cases and defined acceptance for Aseptic cleanroom competence.	Execution	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0006	Gowning qualification	Review / lifecycle: Challenge initial/periodic gowning and microbiological monitoring	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Aseptic cleanroom competence.	Review	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	Medium
BTV-34-0007	Aseptic behavior	Protocol / design: Qualify interventions and line-side corrective practices	Preapproved risk-based study design; endpoint: Controlled aseptic risk.	Planning	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0008	Aseptic behavior	Execution / boundary verification: Qualify interventions and line-side corrective practices	Documented raw observations, calibration, relevant worst cases and defined acceptance for Controlled aseptic risk.	Execution	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0009	Aseptic behavior	Review / lifecycle: Qualify interventions and line-side corrective practices	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Controlled aseptic risk.	Review	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	Medium
BTV-34-0010	Biological safety assessment	Protocol / design: Determine biosafety classification and containment controls	Preapproved risk-based study design; endpoint: Appropriate local biosafety compliance.	Planning	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0011	Biological safety assessment	Execution / boundary verification: Determine biosafety classification and containment controls	Documented raw observations, calibration, relevant worst cases and defined acceptance for Appropriate local biosafety compliance.	Execution	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0012	Biological safety assessment	Review / lifecycle: Determine biosafety classification and containment controls	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Appropriate local biosafety compliance.	Review	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	Medium
BTV-34-0013	Operator exposure assessment	Protocol / design: Validate controls for sensitizers, toxins and high potency conjugates	Preapproved risk-based study design; endpoint: Safe occupational exposure management.	Planning	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0014	Operator exposure assessment	Execution / boundary verification: Validate controls for sensitizers, toxins and high potency conjugates	Documented raw observations, calibration, relevant worst cases and defined acceptance for Safe occupational exposure management.	Execution	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0015	Operator exposure assessment	Review / lifecycle: Validate controls for sensitizers, toxins and high potency conjugates	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Safe occupational exposure management.	Review	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	Medium
BTV-34-0016	Biological waste kill	Protocol / design: Validate autoclave/inactivation for GM organisms and viral agents	Preapproved risk-based study design; endpoint: No viable release.	Planning	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0017	Biological waste kill	Execution / boundary verification: Validate autoclave/inactivation for GM organisms and viral agents	Documented raw observations, calibration, relevant worst cases and defined acceptance for No viable release.	Execution	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0018	Biological waste kill	Review / lifecycle: Validate autoclave/inactivation for GM organisms and viral agents	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No viable release.	Review	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	Medium
BTV-34-0019	Spill response	Protocol / design: Simulate infectious/HPAPI spill and PPE response	Preapproved risk-based study design; endpoint: Effective hazard containment.	Planning	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0020	Spill response	Execution / boundary verification: Simulate infectious/HPAPI spill and PPE response	Documented raw observations, calibration, relevant worst cases and defined acceptance for Effective hazard containment.	Execution	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0021	Spill response	Review / lifecycle: Simulate infectious/HPAPI spill and PPE response	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Effective hazard containment.	Review	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	Medium
BTV-34-0022	Decontamination of reusable PPE	Protocol / design: Validate process compatibility and microbiological control	Preapproved risk-based study design; endpoint: Safe reuse without cross-contamination.	Planning	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-34-0023	Decontamination of reusable PPE	Execution / boundary verification: Validate process compatibility and microbiological control	Documented raw observations, calibration, relevant worst cases and defined acceptance for Safe reuse without cross-contamination.	Execution	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0024	Decontamination of reusable PPE	Review / lifecycle: Validate process compatibility and microbiological control	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Safe reuse without cross-contamination.	Review	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	Medium
BTV-34-0025	Emergency evacuation	Protocol / design: Qualify alarm visibility, muster and safe equipment shutdown	Preapproved risk-based study design; endpoint: Safe life-safety protection.	Planning	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0026	Emergency evacuation	Execution / boundary verification: Qualify alarm visibility, muster and safe equipment shutdown	Documented raw observations, calibration, relevant worst cases and defined acceptance for Safe life-safety protection.	Execution	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0027	Emergency evacuation	Review / lifecycle: Qualify alarm visibility, muster and safe equipment shutdown	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Safe life-safety protection.	Review	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	Medium
BTV-34-0028	Contractor access	Protocol / design: Train construction/maintenance visitors on GMP and biohazards	Preapproved risk-based study design; endpoint: No contamination from uncontrolled work.	Planning	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0029	Contractor access	Execution / boundary verification: Train construction/maintenance visitors on GMP and biohazards	Documented raw observations, calibration, relevant worst cases and defined acceptance for No contamination from uncontrolled work.	Execution	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0030	Contractor access	Review / lifecycle: Train construction/maintenance visitors on GMP and biohazards	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No contamination from uncontrolled work.	Review	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	Medium
BTV-34-0031	Personnel monitoring	Protocol / design: Evaluate microbiological and behavior trend and retraining	Preapproved risk-based study design; endpoint: Adequate aseptic competence.	Planning	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0032	Personnel monitoring	Execution / boundary verification: Evaluate microbiological and behavior trend and retraining	Documented raw observations, calibration, relevant worst cases and defined acceptance for Adequate aseptic competence.	Execution	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0033	Personnel monitoring	Review / lifecycle: Evaluate microbiological and behavior trend and retraining	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Adequate aseptic competence.	Review	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	Medium
BTV-34-0034	HVAC containment breach drill	Protocol / design: Challenge engineering EHS coordinated response	Preapproved risk-based study design; endpoint: Safe response to pressure loss.	Planning	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0035	HVAC containment breach drill	Execution / boundary verification: Challenge engineering EHS coordinated response	Documented raw observations, calibration, relevant worst cases and defined acceptance for Safe response to pressure loss.	Execution	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0036	HVAC containment breach drill	Review / lifecycle: Challenge engineering EHS coordinated response	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Safe response to pressure loss.	Review	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	Medium
BTV-34-0037	Ergonomic intervention	Protocol / design: Evaluate manual handling of cryogenic liquids and bags	Preapproved risk-based study design; endpoint: No personnel injury / loss of lot.	Planning	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0038	Ergonomic intervention	Execution / boundary verification: Evaluate manual handling of cryogenic liquids and bags	Documented raw observations, calibration, relevant worst cases and defined acceptance for No personnel injury / loss of lot.	Execution	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0039	Ergonomic intervention	Review / lifecycle: Evaluate manual handling of cryogenic liquids and bags	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No personnel injury / loss of lot.	Review	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	Medium
BTV-34-0040	GMP records training	Protocol / design: Verify data entry, review, electronic sign-off and deviations	Preapproved risk-based study design; endpoint: ALCOA+ compliant practices.	Planning	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0041	GMP records training	Execution / boundary verification: Verify data entry, review, electronic sign-off and deviations	Documented raw observations, calibration, relevant worst cases and defined acceptance for ALCOA+ compliant practices.	Execution	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0042	GMP records training	Review / lifecycle: Verify data entry, review, electronic sign-off and deviations	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on ALCOA+ compliant practices.	Review	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	Medium
BTV-34-0043	Biosafety cabinet production	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Airflow, filter integrity, containment to product impact on Safe product/worker handling.	URS / DQ	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0044	Biosafety cabinet production	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Biosafety cabinet production.	IQ	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	Medium
BTV-34-0045	Biosafety cabinet production	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Airflow, filter integrity, containment; compare challenge outputs to predefined Safe product/worker handling acceptance.	OQ	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0046	Biosafety cabinet production	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Safe product/worker handling.	OQ	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-34-0047	Biosafety cabinet production	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Safe product/worker handling at relevant Airflow, filter integrity, containment; sampling scientifically justified.	PQ	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0048	Biosafety cabinet production	Continued verification / risk-based requalification trigger evaluation	Trend Airflow, filter integrity, containment and impact on Safe product/worker handling; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	Medium
BTV-34-0049	Chemical fume hood	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Face velocity, airflow alarm, containment to product impact on Exposure protection.	URS / DQ	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0050	Chemical fume hood	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Chemical fume hood.	IQ	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	Medium
BTV-34-0051	Chemical fume hood	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Face velocity, airflow alarm, containment; compare challenge outputs to predefined Exposure protection acceptance.	OQ	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0052	Chemical fume hood	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Exposure protection.	OQ	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0053	Chemical fume hood	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Exposure protection at relevant Face velocity, airflow alarm, containment; sampling scientifically justified.	PQ	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0054	Chemical fume hood	Continued verification / risk-based requalification trigger evaluation	Trend Face velocity, airflow alarm, containment and impact on Exposure protection; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	Medium
BTV-34-0055	Biohazard autoclave	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Lethality, load configuration and test indicators to product impact on Validated waste decontamination.	URS / DQ	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0056	Biohazard autoclave	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Biohazard autoclave.	IQ	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	Medium
BTV-34-0057	Biohazard autoclave	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Lethality, load configuration and test indicators; compare challenge outputs to predefined Validated waste decontamination acceptance.	OQ	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0058	Biohazard autoclave	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Validated waste decontamination.	OQ	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0059	Biohazard autoclave	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Validated waste decontamination at relevant Lethality, load configuration and test indicators; sampling scientifically justified.	PQ	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0060	Biohazard autoclave	Continued verification / risk-based requalification trigger evaluation	Trend Lethality, load configuration and test indicators and impact on Validated waste decontamination; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	Medium
BTV-34-0061	Eyewash safety shower	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Flow, access and inspection tests to product impact on Emergency response ready.	URS / DQ	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0062	Eyewash safety shower	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Eyewash safety shower.	IQ	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	Medium
BTV-34-0063	Eyewash safety shower	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Flow, access and inspection tests; compare challenge outputs to predefined Emergency response ready acceptance.	OQ	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0064	Eyewash safety shower	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Emergency response ready.	OQ	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0065	Eyewash safety shower	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Emergency response ready at relevant Flow, access and inspection tests; sampling scientifically justified.	PQ	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0066	Eyewash safety shower	Continued verification / risk-based requalification trigger evaluation	Trend Flow, access and inspection tests and impact on Emergency response ready; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	Medium
BTV-34-0067	Cryogenic oxygen deficiency alarm	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Detector calibration and response to product impact on LN2 exposure protection.	URS / DQ	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0068	Cryogenic oxygen deficiency alarm	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Cryogenic oxygen deficiency alarm.	IQ	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-34-0069	Cryogenic oxygen deficiency alarm	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Detector calibration and response; compare challenge outputs to predefined LN2 exposure protection acceptance.	OQ	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0070	Cryogenic oxygen deficiency alarm	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect LN2 exposure protection.	OQ	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0071	Cryogenic oxygen deficiency alarm	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable LN2 exposure protection at relevant Detector calibration and response; sampling scientifically justified.	PQ	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0072	Cryogenic oxygen deficiency alarm	Continued verification / risk-based requalification trigger evaluation	Trend Detector calibration and response and impact on LN2 exposure protection; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	Medium
BTV-34-0073	Biological effluent deactivation tank	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Heat/chemical exposure and mixing to product impact on Contained microorganism release.	URS / DQ	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0074	Biological effluent deactivation tank	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Biological effluent deactivation tank.	IQ	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	Medium
BTV-34-0075	Biological effluent deactivation tank	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Heat/chemical exposure and mixing; compare challenge outputs to predefined Contained microorganism release acceptance.	OQ	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0076	Biological effluent deactivation tank	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Contained microorganism release.	OQ	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0077	Biological effluent deactivation tank	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Contained microorganism release at relevant Heat/chemical exposure and mixing; sampling scientifically justified.	PQ	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0078	Biological effluent deactivation tank	Continued verification / risk-based requalification trigger evaluation	Trend Heat/chemical exposure and mixing and impact on Contained microorganism release; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	Medium
BTV-34-0079	Personnel air shower if present	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Operation, emergency exits and interlock to product impact on Validated safety and facility interface.	URS / DQ	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0080	Personnel air shower if present	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Personnel air shower if present.	IQ	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	Medium
BTV-34-0081	Personnel air shower if present	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Operation, emergency exits and interlock; compare challenge outputs to predefined Validated safety and facility interface acceptance.	OQ	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0082	Personnel air shower if present	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Validated safety and facility interface.	OQ	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0083	Personnel air shower if present	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Validated safety and facility interface at relevant Operation, emergency exits and interlock; sampling scientifically justified.	PQ	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	High
BTV-34-0084	Personnel air shower if present	Continued verification / risk-based requalification trigger evaluation	Trend Operation, emergency exits and interlock and impact on Validated safety and facility interface; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	All personnel, biosafety and sterile operations	B03 B04 B05 B12 B18	Medium
BTV-34-0085	Sterile operator APS qualification	Protocol / design: Qualify individual operator participation and interventions	Preapproved risk-based study design; endpoint: Documented sterile technique.	Planning	Personnel and biosafety	B03 B04 B18	High
BTV-34-0086	Sterile operator APS qualification	Execution / boundary verification: Qualify individual operator participation and interventions	Documented raw observations, calibration, relevant worst cases and defined acceptance for Documented sterile technique.	Execution	Personnel and biosafety	B03 B04 B18	High
BTV-34-0087	Sterile operator APS qualification	Review / lifecycle: Qualify individual operator participation and interventions	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Documented sterile technique.	Review	Personnel and biosafety	B03 B04 B18	Medium
BTV-34-0088	Aseptic line mentor training	Protocol / design: Assess trainer competence and observation records	Preapproved risk-based study design; endpoint: Reliable operator qualification.	Planning	Personnel and biosafety	B03 B04 B18	High
BTV-34-0089	Aseptic line mentor training	Execution / boundary verification: Assess trainer competence and observation records	Documented raw observations, calibration, relevant worst cases and defined acceptance for Reliable operator qualification.	Execution	Personnel and biosafety	B03 B04 B18	High
BTV-34-0090	Aseptic line mentor training	Review / lifecycle: Assess trainer competence and observation records	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Reliable operator qualification.	Review	Personnel and biosafety	B03 B04 B18	Medium
BTV-34-0091	Material transfer gowning	Protocol / design: Validate changing PPE across class boundaries	Preapproved risk-based study design; endpoint: No personnel mediated cross contamination.	Planning	Personnel and biosafety	B03 B04 B18	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-34-0092	Material transfer gowning	Execution / boundary verification: Validate changing PPE across class boundaries	Documented raw observations, calibration, relevant worst cases and defined acceptance for No personnel mediated cross contamination.	Execution	Personnel and biosafety	B03 B04 B18	High
BTV-34-0093	Material transfer gowning	Review / lifecycle: Validate changing PPE across class boundaries	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No personnel mediated cross contamination.	Review	Personnel and biosafety	B03 B04 B18	Medium
BTV-34-0094	LN2 oxygen depletion	Protocol / design: Challenge alarms and evacuation procedure	Preapproved risk-based study design; endpoint: Safe cryogenic room response.	Planning	Personnel and biosafety	B03 B04 B18	High
BTV-34-0095	LN2 oxygen depletion	Execution / boundary verification: Challenge alarms and evacuation procedure	Documented raw observations, calibration, relevant worst cases and defined acceptance for Safe cryogenic room response.	Execution	Personnel and biosafety	B03 B04 B18	High
BTV-34-0096	LN2 oxygen depletion	Review / lifecycle: Challenge alarms and evacuation procedure	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Safe cryogenic room response.	Review	Personnel and biosafety	B03 B04 B18	Medium
BTV-34-0097	Genetically modified organism records	Protocol / design: Validate permit, shipment and kill traceability	Preapproved risk-based study design; endpoint: Regulatory biosafety evidence.	Planning	Personnel and biosafety	B03 B04 B18	High
BTV-34-0098	Genetically modified organism records	Execution / boundary verification: Validate permit, shipment and kill traceability	Documented raw observations, calibration, relevant worst cases and defined acceptance for Regulatory biosafety evidence.	Execution	Personnel and biosafety	B03 B04 B18	High
BTV-34-0099	Genetically modified organism records	Review / lifecycle: Validate permit, shipment and kill traceability	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Regulatory biosafety evidence.	Review	Personnel and biosafety	B03 B04 B18	Medium

35 PPQ, CONTINUED PROCESS VERIFICATION AND ANNUAL REVIEWS

72 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-35-0001	Process design studies	Protocol / design: Link development knowledge to commercial operating ranges	Preapproved risk-based study design; endpoint: Approved science/risk basis of CPP/CQA limits.	Planning	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0002	Process design studies	Execution / boundary verification: Link development knowledge to commercial operating ranges	Documented raw observations, calibration, relevant worst cases and defined acceptance for Approved science/risk basis of CPP/CQA limits.	Execution	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0003	Process design studies	Review / lifecycle: Link development knowledge to commercial operating ranges	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Approved science/risk basis of CPP/CQA limits.	Review	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	Medium
BTV-35-0004	Qualification to PPQ linkage	Protocol / design: Verify facilities/utilities/equipment ready before production runs	Preapproved risk-based study design; endpoint: Stage 1/2 readiness and approval.	Planning	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0005	Qualification to PPQ linkage	Execution / boundary verification: Verify facilities/utilities/equipment ready before production runs	Documented raw observations, calibration, relevant worst cases and defined acceptance for Stage 1/2 readiness and approval.	Execution	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0006	Qualification to PPQ linkage	Review / lifecycle: Verify facilities/utilities/equipment ready before production runs	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Stage 1/2 readiness and approval.	Review	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	Medium
BTV-35-0007	PPQ lot plan	Protocol / design: Justify count by biology complexity/variability and prior knowledge	Preapproved risk-based study design; endpoint: Risk/statistics driven PPQ lots, not blanket three.	Planning	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0008	PPQ lot plan	Execution / boundary verification: Justify count by biology complexity/variability and prior knowledge	Documented raw observations, calibration, relevant worst cases and defined acceptance for Risk/statistics driven PPQ lots, not blanket three.	Execution	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0009	PPQ lot plan	Review / lifecycle: Justify count by biology complexity/variability and prior knowledge	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Risk/statistics driven PPQ lots, not blanket three.	Review	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	Medium
BTV-35-0010	PPQ scale / site	Protocol / design: Define representative equipment geometry and worst-case conditions	Preapproved risk-based study design; endpoint: Comparable scale parameters and quality.	Planning	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0011	PPQ scale / site	Execution / boundary verification: Define representative equipment geometry and worst-case conditions	Documented raw observations, calibration, relevant worst cases and defined acceptance for Comparable scale parameters and quality.	Execution	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0012	PPQ scale / site	Review / lifecycle: Define representative equipment geometry and worst-case conditions	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Comparable scale parameters and quality.	Review	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	Medium
BTV-35-0013	Raw material lots	Protocol / design: Include relevant multiple media/resin/component lots in strategy	Preapproved risk-based study design; endpoint: Supply variability represented.	Planning	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0014	Raw material lots	Execution / boundary verification: Include relevant multiple media/resin/component lots in strategy	Documented raw observations, calibration, relevant worst cases and defined acceptance for Supply variability represented.	Execution	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0015	Raw material lots	Review / lifecycle: Include relevant multiple media/resin/component lots in strategy	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Supply variability represented.	Review	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	Medium
BTV-35-0016	Operator/shift	Protocol / design: Justify human and shift variability in qualification	Preapproved risk-based study design; endpoint: Realistic operating conditions.	Planning	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0017	Operator/shift	Execution / boundary verification: Justify human and shift variability in qualification	Documented raw observations, calibration, relevant worst cases and defined acceptance for Realistic operating conditions.	Execution	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0018	Operator/shift	Review / lifecycle: Justify human and shift variability in qualification	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Realistic operating conditions.	Review	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	Medium
BTV-35-0019	PPQ sampling	Protocol / design: Select within-run and between-run coverage at high-risk points	Preapproved risk-based study design; endpoint: Enough data to characterize variability.	Planning	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0020	PPQ sampling	Execution / boundary verification: Select within-run and between-run coverage at high-risk points	Documented raw observations, calibration, relevant worst cases and defined acceptance for Enough data to characterize variability.	Execution	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0021	PPQ sampling	Review / lifecycle: Select within-run and between-run coverage at high-risk points	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Enough data to characterize variability.	Review	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	Medium
BTV-35-0022	PPQ acceptance	Protocol / design: Define CQA, CPP, yield and impurity bounds before execution	Preapproved risk-based study design; endpoint: Preapproved measurable limits.	Planning	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-35-0023	PPQ acceptance	Execution / boundary verification: Define CQA, CPP, yield and impurity bounds before execution	Documented raw observations, calibration, relevant worst cases and defined acceptance for Preapproved measurable limits.	Execution	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0024	PPQ acceptance	Review / lifecycle: Define CQA, CPP, yield and impurity bounds before execution	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Preapproved measurable limits.	Review	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	Medium
BTV-35-0025	Deviation management	Protocol / design: Investigate deviations and process capability implications	Preapproved risk-based study design; endpoint: Transparent validation disposition.	Planning	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0026	Deviation management	Execution / boundary verification: Investigate deviations and process capability implications	Documented raw observations, calibration, relevant worst cases and defined acceptance for Transparent validation disposition.	Execution	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0027	Deviation management	Review / lifecycle: Investigate deviations and process capability implications	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Transparent validation disposition.	Review	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	Medium
BTV-35-0028	CPV monitoring	Protocol / design: Trend bioreactor, chromatography, TFF and fill attributes	Preapproved risk-based study design; endpoint: Statistical state-of-control measures.	Planning	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0029	CPV monitoring	Execution / boundary verification: Trend bioreactor, chromatography, TFF and fill attributes	Documented raw observations, calibration, relevant worst cases and defined acceptance for Statistical state-of-control measures.	Execution	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0030	CPV monitoring	Review / lifecycle: Trend bioreactor, chromatography, TFF and fill attributes	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Statistical state-of-control measures.	Review	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	Medium
BTV-35-0031	Process capability	Protocol / design: Assess drift, variability, process shifts and control limits	Preapproved risk-based study design; endpoint: Proactive intervention before CQA failure.	Planning	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0032	Process capability	Execution / boundary verification: Assess drift, variability, process shifts and control limits	Documented raw observations, calibration, relevant worst cases and defined acceptance for Proactive intervention before CQA failure.	Execution	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0033	Process capability	Review / lifecycle: Assess drift, variability, process shifts and control limits	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Proactive intervention before CQA failure.	Review	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	Medium
BTV-35-0034	Ongoing viral clearance assumptions	Protocol / design: Monitor CPPs controlling validated clearance steps	Preapproved risk-based study design; endpoint: Clearance model assumptions preserved.	Planning	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0035	Ongoing viral clearance assumptions	Execution / boundary verification: Monitor CPPs controlling validated clearance steps	Documented raw observations, calibration, relevant worst cases and defined acceptance for Clearance model assumptions preserved.	Execution	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0036	Ongoing viral clearance assumptions	Review / lifecycle: Monitor CPPs controlling validated clearance steps	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Clearance model assumptions preserved.	Review	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	Medium
BTV-35-0037	Ongoing resin lifetime	Protocol / design: Trend performance versus reuse cycle	Preapproved risk-based study design; endpoint: No hidden impurity trend.	Planning	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0038	Ongoing resin lifetime	Execution / boundary verification: Trend performance versus reuse cycle	Documented raw observations, calibration, relevant worst cases and defined acceptance for No hidden impurity trend.	Execution	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0039	Ongoing resin lifetime	Review / lifecycle: Trend performance versus reuse cycle	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No hidden impurity trend.	Review	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	Medium
BTV-35-0040	APR / PQR	Protocol / design: Integrate assay, yield, deviations, complaints and quality metrics	Preapproved risk-based study design; endpoint: Periodic commercial process review.	Planning	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0041	APR / PQR	Execution / boundary verification: Integrate assay, yield, deviations, complaints and quality metrics	Documented raw observations, calibration, relevant worst cases and defined acceptance for Periodic commercial process review.	Execution	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0042	APR / PQR	Review / lifecycle: Integrate assay, yield, deviations, complaints and quality metrics	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Periodic commercial process review.	Review	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	Medium
BTV-35-0043	Revalidation triggers	Protocol / design: Evaluate major scale/equipment/media changes and excursions	Preapproved risk-based study design; endpoint: Documented approval and additional validation need.	Planning	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0044	Revalidation triggers	Execution / boundary verification: Evaluate major scale/equipment/media changes and excursions	Documented raw observations, calibration, relevant worst cases and defined acceptance for Documented approval and additional validation need.	Execution	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0045	Revalidation triggers	Review / lifecycle: Evaluate major scale/equipment/media changes and excursions	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Documented approval and additional validation need.	Review	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	Medium
BTV-35-0046	Statistical trending model	Protocol / design: Validate limits, missing-data handling and alert rules	Preapproved risk-based study design; endpoint: Correct CPV decisions.	Planning	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-35-0047	Statistical trending model	Execution / boundary verification: Validate limits, missing-data handling and alert rules	Documented raw observations, calibration, relevant worst cases and defined acceptance for Correct CPV decisions.	Execution	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0048	Statistical trending model	Review / lifecycle: Validate limits, missing-data handling and alert rules	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Correct CPV decisions.	Review	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	Medium
BTV-35-0049	Production shutdown	Protocol / design: Qualify restart after lengthy idle period based on risk	Preapproved risk-based study design; endpoint: State-of-control after recommissioning.	Planning	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0050	Production shutdown	Execution / boundary verification: Qualify restart after lengthy idle period based on risk	Documented raw observations, calibration, relevant worst cases and defined acceptance for State-of-control after recommissioning.	Execution	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0051	Production shutdown	Review / lifecycle: Qualify restart after lengthy idle period based on risk	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on State-of-control after recommissioning.	Review	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	Medium
BTV-35-0052	Regulatory comparability	Protocol / design: Link process changes to CMC variation pathway	Preapproved risk-based study design; endpoint: No unapproved change to filed commercial process.	Planning	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0053	Regulatory comparability	Execution / boundary verification: Link process changes to CMC variation pathway	Documented raw observations, calibration, relevant worst cases and defined acceptance for No unapproved change to filed commercial process.	Execution	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0054	Regulatory comparability	Review / lifecycle: Link process changes to CMC variation pathway	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No unapproved change to filed commercial process.	Review	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	Medium
BTV-35-0055	CPV data historian	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Tag mapping, retention, trending alarms to product impact on Reliable CPP trend dataset.	URS / DQ	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0056	CPV data historian	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for CPV data historian.	IQ	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	Medium
BTV-35-0057	CPV data historian	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Tag mapping, retention, trending alarms; compare challenge outputs to predefined Reliable CPP trend dataset acceptance.	OQ	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0058	CPV data historian	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Reliable CPP trend dataset.	OQ	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0059	CPV data historian	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Reliable CPP trend dataset at relevant Tag mapping, retention, trending alarms; sampling scientifically justified.	PQ	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0060	CPV data historian	Continued verification / risk-based requalification trigger evaluation	Trend Tag mapping, retention, trending alarms and impact on Reliable CPP trend dataset; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	Medium
BTV-35-0061	Process analytics PAT platform	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Calibrated prediction model and maintenance to product impact on Defensible model-informed controls.	URS / DQ	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0062	Process analytics PAT platform	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Process analytics PAT platform.	IQ	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	Medium
BTV-35-0063	Process analytics PAT platform	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Calibrated prediction model and maintenance; compare challenge outputs to predefined Defensible model-informed controls acceptance.	OQ	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0064	Process analytics PAT platform	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Defensible model-informed controls.	OQ	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0065	Process analytics PAT platform	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Defensible model-informed controls at relevant Calibrated prediction model and maintenance; sampling scientifically justified.	PQ	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0066	Process analytics PAT platform	Continued verification / risk-based requalification trigger evaluation	Trend Calibrated prediction model and maintenance and impact on Defensible model-informed controls; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	Medium
BTV-35-0067	Automated batch review workflow	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Data transfer and exception alerts to product impact on Complete batch disposition evidence.	URS / DQ	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0068	Automated batch review workflow	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Automated batch review workflow.	IQ	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-35-0069	Automated batch review workflow	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Data transfer and exception alerts; compare challenge outputs to predefined Complete batch disposition evidence acceptance.	OQ	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0070	Automated batch review workflow	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Complete batch disposition evidence.	OQ	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0071	Automated batch review workflow	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Complete batch disposition evidence at relevant Data transfer and exception alerts; sampling scientifically justified.	PQ	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	High
BTV-35-0072	Automated batch review workflow	Continued verification / risk-based requalification trigger evaluation	Trend Data transfer and exception alerts and impact on Complete batch disposition evidence; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biotechnology commercial PPQ and ongoing control	B02 B03 B05 B06 B10 B12	Medium

36 CONTAMINATION PREVENTION, BIOSAFETY & PEST/ENVIRONMENT

72 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-36-0001	Contamination control map	Protocol / design: Link premises, raw materials, operators and process open steps	Preapproved risk-based study design; endpoint: Integrated microbiological and viral protection.	Planning	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0002	Contamination control map	Execution / boundary verification: Link premises, raw materials, operators and process open steps	Documented raw observations, calibration, relevant worst cases and defined acceptance for Integrated microbiological and viral protection.	Execution	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0003	Contamination control map	Review / lifecycle: Link premises, raw materials, operators and process open steps	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Integrated microbiological and viral protection.	Review	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	Medium
BTV-36-0004	Microbial transfer	Protocol / design: Assess line clearance and human/material entry pathways	Preapproved risk-based study design; endpoint: No contamination at critical transfer steps.	Planning	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0005	Microbial transfer	Execution / boundary verification: Assess line clearance and human/material entry pathways	Documented raw observations, calibration, relevant worst cases and defined acceptance for No contamination at critical transfer steps.	Execution	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0006	Microbial transfer	Review / lifecycle: Assess line clearance and human/material entry pathways	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No contamination at critical transfer steps.	Review	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	Medium
BTV-36-0007	Product cross contamination	Protocol / design: Set segregation and campaign/dedicated process design by risk	Preapproved risk-based study design; endpoint: No accidental product/organism carryover.	Planning	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0008	Product cross contamination	Execution / boundary verification: Set segregation and campaign/dedicated process design by risk	Documented raw observations, calibration, relevant worst cases and defined acceptance for No accidental product/organism carryover.	Execution	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0009	Product cross contamination	Review / lifecycle: Set segregation and campaign/dedicated process design by risk	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No accidental product/organism carryover.	Review	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	Medium
BTV-36-0010	Personnel movement	Protocol / design: Qualify gowning/wash-in between upstream and sterile zones	Preapproved risk-based study design; endpoint: No live culture into sterile areas.	Planning	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0011	Personnel movement	Execution / boundary verification: Qualify gowning/wash-in between upstream and sterile zones	Documented raw observations, calibration, relevant worst cases and defined acceptance for No live culture into sterile areas.	Execution	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0012	Personnel movement	Review / lifecycle: Qualify gowning/wash-in between upstream and sterile zones	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No live culture into sterile areas.	Review	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	Medium
BTV-36-0013	Airborne biocontainment	Protocol / design: Assess exhaust, negative pressure and HEPA performance	Preapproved risk-based study design; endpoint: No release of hazardous biological aerosols.	Planning	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0014	Airborne biocontainment	Execution / boundary verification: Assess exhaust, negative pressure and HEPA performance	Documented raw observations, calibration, relevant worst cases and defined acceptance for No release of hazardous biological aerosols.	Execution	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0015	Airborne biocontainment	Review / lifecycle: Assess exhaust, negative pressure and HEPA performance	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No release of hazardous biological aerosols.	Review	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	Medium
BTV-36-0016	Environmental disinfection	Protocol / design: Validate contact times for organisms and relevant surfaces	Preapproved risk-based study design; endpoint: Demonstrated microbial reduction.	Planning	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0017	Environmental disinfection	Execution / boundary verification: Validate contact times for organisms and relevant surfaces	Documented raw observations, calibration, relevant worst cases and defined acceptance for Demonstrated microbial reduction.	Execution	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0018	Environmental disinfection	Review / lifecycle: Validate contact times for organisms and relevant surfaces	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Demonstrated microbial reduction.	Review	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	Medium
BTV-36-0019	Bioburden escalation	Protocol / design: Qualify excursion investigation, organism ID and trend	Preapproved risk-based study design; endpoint: Effective CCS corrective actions.	Planning	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0020	Bioburden escalation	Execution / boundary verification: Qualify excursion investigation, organism ID and trend	Documented raw observations, calibration, relevant worst cases and defined acceptance for Effective CCS corrective actions.	Execution	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0021	Bioburden escalation	Review / lifecycle: Qualify excursion investigation, organism ID and trend	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Effective CCS corrective actions.	Review	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	Medium
BTV-36-0022	Pest management	Protocol / design: Evaluate supplier service impact and protected areas	Preapproved risk-based study design; endpoint: No pesticide contamination or pest vector.	Planning	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-36-0023	Pest management	Execution / boundary verification: Evaluate supplier service impact and protected areas	Documented raw observations, calibration, relevant worst cases and defined acceptance for No pesticide contamination or pest vector.	Execution	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0024	Pest management	Review / lifecycle: Evaluate supplier service impact and protected areas	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No pesticide contamination or pest vector.	Review	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	Medium
BTV-36-0025	Waste segregation	Protocol / design: Validate live organism and hazardous waste classification	Preapproved risk-based study design; endpoint: Safe compliant waste pathways.	Planning	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0026	Waste segregation	Execution / boundary verification: Validate live organism and hazardous waste classification	Documented raw observations, calibration, relevant worst cases and defined acceptance for Safe compliant waste pathways.	Execution	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0027	Waste segregation	Review / lifecycle: Validate live organism and hazardous waste classification	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Safe compliant waste pathways.	Review	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	Medium
BTV-36-0028	Surface monitoring	Protocol / design: Qualify sponge/swab recovery and neutralization	Preapproved risk-based study design; endpoint: Representative facility burden.	Planning	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0029	Surface monitoring	Execution / boundary verification: Qualify sponge/swab recovery and neutralization	Documented raw observations, calibration, relevant worst cases and defined acceptance for Representative facility burden.	Execution	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0030	Surface monitoring	Review / lifecycle: Qualify sponge/swab recovery and neutralization	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Representative facility burden.	Review	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	Medium
BTV-36-0031	Equipment cleaning segregation	Protocol / design: Verify shared equipment postcampaign validated clearance	Preapproved risk-based study design; endpoint: No detectable unsafe carryover.	Planning	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0032	Equipment cleaning segregation	Execution / boundary verification: Verify shared equipment postcampaign validated clearance	Documented raw observations, calibration, relevant worst cases and defined acceptance for No detectable unsafe carryover.	Execution	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0033	Equipment cleaning segregation	Review / lifecycle: Verify shared equipment postcampaign validated clearance	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No detectable unsafe carryover.	Review	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	Medium
BTV-36-0034	Water ingress control	Protocol / design: Validate facility response to leak / condensate	Preapproved risk-based study design; endpoint: No microbial proliferation.	Planning	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0035	Water ingress control	Execution / boundary verification: Validate facility response to leak / condensate	Documented raw observations, calibration, relevant worst cases and defined acceptance for No microbial proliferation.	Execution	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0036	Water ingress control	Review / lifecycle: Validate facility response to leak / condensate	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No microbial proliferation.	Review	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	Medium
BTV-36-0037	Filter condensate	Protocol / design: Assess filter housing and exhaust condensation risks	Preapproved risk-based study design; endpoint: No filter wetting and microbial transfer.	Planning	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0038	Filter condensate	Execution / boundary verification: Assess filter housing and exhaust condensation risks	Documented raw observations, calibration, relevant worst cases and defined acceptance for No filter wetting and microbial transfer.	Execution	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0039	Filter condensate	Review / lifecycle: Assess filter housing and exhaust condensation risks	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No filter wetting and microbial transfer.	Review	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	Medium
BTV-36-0040	Organism kill challenge	Protocol / design: Prove waste kill efficacy with qualified surrogate	Preapproved risk-based study design; endpoint: Demonstrated inactivation under worst case.	Planning	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0041	Organism kill challenge	Execution / boundary verification: Prove waste kill efficacy with qualified surrogate	Documented raw observations, calibration, relevant worst cases and defined acceptance for Demonstrated inactivation under worst case.	Execution	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0042	Organism kill challenge	Review / lifecycle: Prove waste kill efficacy with qualified surrogate	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Demonstrated inactivation under worst case.	Review	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	Medium
BTV-36-0043	Waste decontamination autoclave	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Load uniformity and lethality to product impact on No viable discharge.	URS / DQ	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0044	Waste decontamination autoclave	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Waste decontamination autoclave.	IQ	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	Medium
BTV-36-0045	Waste decontamination autoclave	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Load uniformity and lethality; compare challenge outputs to predefined No viable discharge acceptance.	OQ	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0046	Waste decontamination autoclave	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect No viable discharge.	OQ	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-36-0047	Waste decontamination autoclave	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable No viable discharge at relevant Load uniformity and lethality; sampling scientifically justified.	PQ	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0048	Waste decontamination autoclave	Continued verification / risk-based requalification trigger evaluation	Trend Load uniformity and lethality and impact on No viable discharge; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	Medium
BTV-36-0049	Pressure cascade monitoring panel	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Pressure accuracy, trend and alarm to product impact on Maintained isolation / contamination barrier.	URS / DQ	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0050	Pressure cascade monitoring panel	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Pressure cascade monitoring panel.	IQ	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	Medium
BTV-36-0051	Pressure cascade monitoring panel	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Pressure accuracy, trend and alarm; compare challenge outputs to predefined Maintained isolation / contamination barrier acceptance.	OQ	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0052	Pressure cascade monitoring panel	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Maintained isolation / contamination barrier.	OQ	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0053	Pressure cascade monitoring panel	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Maintained isolation / contamination barrier at relevant Pressure accuracy, trend and alarm; sampling scientifically justified.	PQ	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0054	Pressure cascade monitoring panel	Continued verification / risk-based requalification trigger evaluation	Trend Pressure accuracy, trend and alarm and impact on Maintained isolation / contamination barrier; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	Medium
BTV-36-0055	Disinfectant preparation skid	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Dilution accuracy and shelf life to product impact on Effective sporicidal/concentrated disinfectant.	URS / DQ	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0056	Disinfectant preparation skid	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Disinfectant preparation skid.	IQ	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	Medium
BTV-36-0057	Disinfectant preparation skid	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Dilution accuracy and shelf life; compare challenge outputs to predefined Effective sporicidal/concentrated disinfectant acceptance.	OQ	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0058	Disinfectant preparation skid	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Effective sporicidal/concentrated disinfectant.	OQ	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0059	Disinfectant preparation skid	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Effective sporicidal/concentrated disinfectant at relevant Dilution accuracy and shelf life; sampling scientifically justified.	PQ	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0060	Disinfectant preparation skid	Continued verification / risk-based requalification trigger evaluation	Trend Dilution accuracy and shelf life and impact on Effective sporicidal/concentrated disinfectant; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	Medium
BTV-36-0061	Pest exclusion door seals	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Barrier inspection and recovery to product impact on Restricted pest entry.	URS / DQ	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0062	Pest exclusion door seals	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Pest exclusion door seals.	IQ	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	Medium
BTV-36-0063	Pest exclusion door seals	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Barrier inspection and recovery; compare challenge outputs to predefined Restricted pest entry acceptance.	OQ	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0064	Pest exclusion door seals	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Restricted pest entry.	OQ	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0065	Pest exclusion door seals	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Restricted pest entry at relevant Barrier inspection and recovery; sampling scientifically justified.	PQ	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0066	Pest exclusion door seals	Continued verification / risk-based requalification trigger evaluation	Trend Barrier inspection and recovery and impact on Restricted pest entry; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	Medium
BTV-36-0067	Biohazard transfer hatch	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Door interlock, decontamination and cleaning to product impact on Controlled movement of biological material.	URS / DQ	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0068	Biohazard transfer hatch	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Biohazard transfer hatch.	IQ	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-36-0069	Biohazard transfer hatch	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Door interlock, decontamination and cleaning; compare challenge outputs to predefined Controlled movement of biological material acceptance.	OQ	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0070	Biohazard transfer hatch	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Controlled movement of biological material.	OQ	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0071	Biohazard transfer hatch	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Controlled movement of biological material at relevant Door interlock, decontamination and cleaning; sampling scientifically justified.	PQ	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	High
BTV-36-0072	Biohazard transfer hatch	Continued verification / risk-based requalification trigger evaluation	Trend Door interlock, decontamination and cleaning and impact on Controlled movement of biological material; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Multi-product biological facilities and laboratory	B03 B04 B05 B14 B18	Medium

37 REGULATORY, SITE LICENSING, VALIDATION RECORDS & INSPECTION

45 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-37-0001	Regulatory applicability	Protocol / design: Determine destination authority and product classification	Preapproved risk-based study design; endpoint: Correct legally adopted GMP regime.	Planning	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	High
BTV-37-0002	Regulatory applicability	Execution / boundary verification: Determine destination authority and product classification	Documented raw observations, calibration, relevant worst cases and defined acceptance for Correct legally adopted GMP regime.	Execution	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	High
BTV-37-0003	Regulatory applicability	Review / lifecycle: Determine destination authority and product classification	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Correct legally adopted GMP regime.	Review	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	Medium
BTV-37-0004	Biologics dossier	Protocol / design: Link validation outcomes to product-process CMC sections	Preapproved risk-based study design; endpoint: Accurate CTD/ACTD descriptions and controls.	Planning	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	High
BTV-37-0005	Biologics dossier	Execution / boundary verification: Link validation outcomes to product-process CMC sections	Documented raw observations, calibration, relevant worst cases and defined acceptance for Accurate CTD/ACTD descriptions and controls.	Execution	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	High
BTV-37-0006	Biologics dossier	Review / lifecycle: Link validation outcomes to product-process CMC sections	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Accurate CTD/ACTD descriptions and controls.	Review	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	Medium
BTV-37-0007	Process registration	Protocol / design: Identify registered cell line, media, resin, scale and fill parameters	Preapproved risk-based study design; endpoint: No undocumented divergence from dossier.	Planning	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	High
BTV-37-0008	Process registration	Execution / boundary verification: Identify registered cell line, media, resin, scale and fill parameters	Documented raw observations, calibration, relevant worst cases and defined acceptance for No undocumented divergence from dossier.	Execution	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	High
BTV-37-0009	Process registration	Review / lifecycle: Identify registered cell line, media, resin, scale and fill parameters	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No undocumented divergence from dossier.	Review	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	Medium
BTV-37-0010	CDSCO authorization	Protocol / design: Determine required Indian manufacturing/test and biologics permissions	Preapproved risk-based study design; endpoint: Licenses and registered scope align.	Planning	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	High
BTV-37-0011	CDSCO authorization	Execution / boundary verification: Determine required Indian manufacturing/test and biologics permissions	Documented raw observations, calibration, relevant worst cases and defined acceptance for Licenses and registered scope align.	Execution	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	High
BTV-37-0012	CDSCO authorization	Review / lifecycle: Determine required Indian manufacturing/test and biologics permissions	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Licenses and registered scope align.	Review	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	Medium
BTV-37-0013	Clinical material vs commercial	Protocol / design: Differentiate phase-appropriate validation and GMP demands	Preapproved risk-based study design; endpoint: No blanket commercial PPQ requirement for early clinical lots.	Planning	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	High
BTV-37-0014	Clinical material vs commercial	Execution / boundary verification: Differentiate phase-appropriate validation and GMP demands	Documented raw observations, calibration, relevant worst cases and defined acceptance for No blanket commercial PPQ requirement for early clinical lots.	Execution	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	High
BTV-37-0015	Clinical material vs commercial	Review / lifecycle: Differentiate phase-appropriate validation and GMP demands	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No blanket commercial PPQ requirement for early clinical lots.	Review	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	Medium
BTV-37-0016	Technology transfer	Protocol / design: Maintain receiving-site qualification evidence	Preapproved risk-based study design; endpoint: Dossier-comparable manufacturing process.	Planning	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	High
BTV-37-0017	Technology transfer	Execution / boundary verification: Maintain receiving-site qualification evidence	Documented raw observations, calibration, relevant worst cases and defined acceptance for Dossier-comparable manufacturing process.	Execution	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	High
BTV-37-0018	Technology transfer	Review / lifecycle: Maintain receiving-site qualification evidence	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Dossier-comparable manufacturing process.	Review	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	Medium
BTV-37-0019	Comparability filing	Protocol / design: Assess postapproval process change and regional filing category	Preapproved risk-based study design; endpoint: Controlled approval before batch supply.	Planning	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	High
BTV-37-0020	Comparability filing	Execution / boundary verification: Assess postapproval process change and regional filing category	Documented raw observations, calibration, relevant worst cases and defined acceptance for Controlled approval before batch supply.	Execution	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	High
BTV-37-0021	Comparability filing	Review / lifecycle: Assess postapproval process change and regional filing category	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Controlled approval before batch supply.	Review	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	Medium
BTV-37-0022	Batch release	Protocol / design: Link validated status, QP/QA and release testing	Preapproved risk-based study design; endpoint: No release outside authorized state.	Planning	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-37-0023	Batch release	Execution / boundary verification: Link validated status, QP/QA and release testing	Documented raw observations, calibration, relevant worst cases and defined acceptance for No release outside authorized state.	Execution	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	High
BTV-37-0024	Batch release	Review / lifecycle: Link validated status, QP/QA and release testing	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on No release outside authorized state.	Review	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	Medium
BTV-37-0025	GMP inspection traceability	Protocol / design: Reconstruct critical tests from raw data and exceptions	Preapproved risk-based study design; endpoint: Inspection-ready protocol/report package.	Planning	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	High
BTV-37-0026	GMP inspection traceability	Execution / boundary verification: Reconstruct critical tests from raw data and exceptions	Documented raw observations, calibration, relevant worst cases and defined acceptance for Inspection-ready protocol/report package.	Execution	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	High
BTV-37-0027	GMP inspection traceability	Review / lifecycle: Reconstruct critical tests from raw data and exceptions	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Inspection-ready protocol/report package.	Review	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	Medium
BTV-37-0028	Data retention	Protocol / design: Validate records, backup, paper/electronic archive and retrieval	Preapproved risk-based study design; endpoint: Defined retention and reconstruction.	Planning	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	High
BTV-37-0029	Data retention	Execution / boundary verification: Validate records, backup, paper/electronic archive and retrieval	Documented raw observations, calibration, relevant worst cases and defined acceptance for Defined retention and reconstruction.	Execution	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	High
BTV-37-0030	Data retention	Review / lifecycle: Validate records, backup, paper/electronic archive and retrieval	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Defined retention and reconstruction.	Review	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	Medium
BTV-37-0031	Contractual responsibilities	Protocol / design: Define MAH/CMO/QP/testing lab responsibility splits	Preapproved risk-based study design; endpoint: Complete written technical/quality agreements.	Planning	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	High
BTV-37-0032	Contractual responsibilities	Execution / boundary verification: Define MAH/CMO/QP/testing lab responsibility splits	Documented raw observations, calibration, relevant worst cases and defined acceptance for Complete written technical/quality agreements.	Execution	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	High
BTV-37-0033	Contractual responsibilities	Review / lifecycle: Define MAH/CMO/QP/testing lab responsibility splits	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Complete written technical/quality agreements.	Review	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	Medium
BTV-37-0034	Biosafety permits	Protocol / design: Assess jurisdictional import / containment / GMO controls	Preapproved risk-based study design; endpoint: Required external permissions in place.	Planning	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	High
BTV-37-0035	Biosafety permits	Execution / boundary verification: Assess jurisdictional import / containment / GMO controls	Documented raw observations, calibration, relevant worst cases and defined acceptance for Required external permissions in place.	Execution	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	High
BTV-37-0036	Biosafety permits	Review / lifecycle: Assess jurisdictional import / containment / GMO controls	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Required external permissions in place.	Review	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	Medium
BTV-37-0037	Product exclusions	Protocol / design: Distinguish ATMP, human tissue, veterinary vaccines and plasma rules	Preapproved risk-based study design; endpoint: Correct framework instead of Annex 2 blanket.	Planning	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	High
BTV-37-0038	Product exclusions	Execution / boundary verification: Distinguish ATMP, human tissue, veterinary vaccines and plasma rules	Documented raw observations, calibration, relevant worst cases and defined acceptance for Correct framework instead of Annex 2 blanket.	Execution	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	High
BTV-37-0039	Product exclusions	Review / lifecycle: Distinguish ATMP, human tissue, veterinary vaccines and plasma rules	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Correct framework instead of Annex 2 blanket.	Review	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	Medium
BTV-37-0040	Deviation/CAPA records	Protocol / design: Verify corrective action effectiveness and validation impact	Preapproved risk-based study design; endpoint: Closed evidence and trend controls.	Planning	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	High
BTV-37-0041	Deviation/CAPA records	Execution / boundary verification: Verify corrective action effectiveness and validation impact	Documented raw observations, calibration, relevant worst cases and defined acceptance for Closed evidence and trend controls.	Execution	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	High
BTV-37-0042	Deviation/CAPA records	Review / lifecycle: Verify corrective action effectiveness and validation impact	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Closed evidence and trend controls.	Review	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	Medium
BTV-37-0043	Periodic standards update	Protocol / design: Screen new annex/ICH/PIC/S versions and legal adoption	Preapproved risk-based study design; endpoint: Current compliance crosswalk.	Planning	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	High
BTV-37-0044	Periodic standards update	Execution / boundary verification: Screen new annex/ICH/PIC/S versions and legal adoption	Documented raw observations, calibration, relevant worst cases and defined acceptance for Current compliance crosswalk.	Execution	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	High
BTV-37-0045	Periodic standards update	Review / lifecycle: Screen new annex/ICH/PIC/S versions and legal adoption	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Current compliance crosswalk.	Review	Global commercial biologics manufacturing	B01 B03 B05 B06 B13 B15 B16 B17 B18	Medium

38 SPECIALIZED BIOTECH MODALITY & NOVEL PROCESSING

69 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-38-0001	Continuous biomanufacturing	Protocol / design: Validate residence-time distribution and lot definition	Preapproved risk-based study design; endpoint: Traceable acceptance for continuous output.	Planning	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0002	Continuous biomanufacturing	Execution / boundary verification: Validate residence-time distribution and lot definition	Documented raw observations, calibration, relevant worst cases and defined acceptance for Traceable acceptance for continuous output.	Execution	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0003	Continuous biomanufacturing	Review / lifecycle: Validate residence-time distribution and lot definition	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Traceable acceptance for continuous output.	Review	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	Medium
BTV-38-0004	Continuous chromatography	Protocol / design: Qualify column switching, cycling and pooling	Preapproved risk-based study design; endpoint: Impurity and yield consistency across campaigns.	Planning	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0005	Continuous chromatography	Execution / boundary verification: Qualify column switching, cycling and pooling	Documented raw observations, calibration, relevant worst cases and defined acceptance for Impurity and yield consistency across campaigns.	Execution	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0006	Continuous chromatography	Review / lifecycle: Qualify column switching, cycling and pooling	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Impurity and yield consistency across campaigns.	Review	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	Medium
BTV-38-0007	Real-time release	Protocol / design: Qualify PAT models and regulatory acceptability before use	Preapproved risk-based study design; endpoint: Trusted release criteria and controls.	Planning	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0008	Real-time release	Execution / boundary verification: Qualify PAT models and regulatory acceptability before use	Documented raw observations, calibration, relevant worst cases and defined acceptance for Trusted release criteria and controls.	Execution	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0009	Real-time release	Review / lifecycle: Qualify PAT models and regulatory acceptability before use	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Trusted release criteria and controls.	Review	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	Medium
BTV-38-0010	Protein refolding	Protocol / design: Establish redox agents, dilution rate, oxygen and pH	Preapproved risk-based study design; endpoint: Functional correctly folded protein.	Planning	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0011	Protein refolding	Execution / boundary verification: Establish redox agents, dilution rate, oxygen and pH	Documented raw observations, calibration, relevant worst cases and defined acceptance for Functional correctly folded protein.	Execution	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0012	Protein refolding	Review / lifecycle: Establish redox agents, dilution rate, oxygen and pH	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Functional correctly folded protein.	Review	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	Medium
BTV-38-0013	Inclusion body solubilization	Protocol / design: Validate solubilization strength and impurity profile	Preapproved risk-based study design; endpoint: Controlled recovery and refolding yield.	Planning	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0014	Inclusion body solubilization	Execution / boundary verification: Validate solubilization strength and impurity profile	Documented raw observations, calibration, relevant worst cases and defined acceptance for Controlled recovery and refolding yield.	Execution	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0015	Inclusion body solubilization	Review / lifecycle: Validate solubilization strength and impurity profile	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Controlled recovery and refolding yield.	Review	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	Medium
BTV-38-0016	Enzymatic bioconversion	Protocol / design: Qualify substrate, enzyme activity, conversion and impurity	Preapproved risk-based study design; endpoint: Reproducible bio-converted intermediate.	Planning	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0017	Enzymatic bioconversion	Execution / boundary verification: Qualify substrate, enzyme activity, conversion and impurity	Documented raw observations, calibration, relevant worst cases and defined acceptance for Reproducible bio-converted intermediate.	Execution	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0018	Enzymatic bioconversion	Review / lifecycle: Qualify substrate, enzyme activity, conversion and impurity	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Reproducible bio-converted intermediate.	Review	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	Medium
BTV-38-0019	Transgenic expression	Protocol / design: Control species, harvest, pathogen screen and containment	Preapproved risk-based study design; endpoint: Biological material consistency and safety.	Planning	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0020	Transgenic expression	Execution / boundary verification: Control species, harvest, pathogen screen and containment	Documented raw observations, calibration, relevant worst cases and defined acceptance for Biological material consistency and safety.	Execution	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0021	Transgenic expression	Review / lifecycle: Control species, harvest, pathogen screen and containment	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Biological material consistency and safety.	Review	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	Medium
BTV-38-0022	Bacterial endotoxin removal	Protocol / design: Characterize specific removal process for endotoxin risk	Preapproved risk-based study design; endpoint: Acceptable bulk endotoxin.	Planning	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-38-0023	Bacterial endotoxin removal	Execution / boundary verification: Characterize specific removal process for endotoxin risk	Documented raw observations, calibration, relevant worst cases and defined acceptance for Acceptable bulk endotoxin.	Execution	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0024	Bacterial endotoxin removal	Review / lifecycle: Characterize specific removal process for endotoxin risk	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Acceptable bulk endotoxin.	Review	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	Medium
BTV-38-0025	High viscosity formulation	Protocol / design: Qualify syringeability, mixing and filtration where feasible	Preapproved risk-based study design; endpoint: Dose functionality and CQA maintenance.	Planning	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0026	High viscosity formulation	Execution / boundary verification: Qualify syringeability, mixing and filtration where feasible	Documented raw observations, calibration, relevant worst cases and defined acceptance for Dose functionality and CQA maintenance.	Execution	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0027	High viscosity formulation	Review / lifecycle: Qualify syringeability, mixing and filtration where feasible	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Dose functionality and CQA maintenance.	Review	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	Medium
BTV-38-0028	Nanoparticle / exosome products	Protocol / design: Define identity, purity, potency and process monitoring	Preapproved risk-based study design; endpoint: Fit-for-purpose particle product controls.	Planning	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0029	Nanoparticle / exosome products	Execution / boundary verification: Define identity, purity, potency and process monitoring	Documented raw observations, calibration, relevant worst cases and defined acceptance for Fit-for-purpose particle product controls.	Execution	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0030	Nanoparticle / exosome products	Review / lifecycle: Define identity, purity, potency and process monitoring	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Fit-for-purpose particle product controls.	Review	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	Medium
BTV-38-0031	Protein crystallization	Protocol / design: Validate seeding, size distribution and crystal harvest	Preapproved risk-based study design; endpoint: Stable protein solid-state specification.	Planning	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0032	Protein crystallization	Execution / boundary verification: Validate seeding, size distribution and crystal harvest	Documented raw observations, calibration, relevant worst cases and defined acceptance for Stable protein solid-state specification.	Execution	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0033	Protein crystallization	Review / lifecycle: Validate seeding, size distribution and crystal harvest	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Stable protein solid-state specification.	Review	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	Medium
BTV-38-0034	Bioconjugation alternate sites	Protocol / design: Verify site-specific conjugation uniformity and impurity	Preapproved risk-based study design; endpoint: Correct product structure and potency.	Planning	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0035	Bioconjugation alternate sites	Execution / boundary verification: Verify site-specific conjugation uniformity and impurity	Documented raw observations, calibration, relevant worst cases and defined acceptance for Correct product structure and potency.	Execution	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0036	Bioconjugation alternate sites	Review / lifecycle: Verify site-specific conjugation uniformity and impurity	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Correct product structure and potency.	Review	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	Medium
BTV-38-0037	Genetic identity NGS	Protocol / design: Qualify library preparation, read depth, contamination metrics	Preapproved risk-based study design; endpoint: Defensible vector identity / genome analysis.	Planning	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0038	Genetic identity NGS	Execution / boundary verification: Qualify library preparation, read depth, contamination metrics	Documented raw observations, calibration, relevant worst cases and defined acceptance for Defensible vector identity / genome analysis.	Execution	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0039	Genetic identity NGS	Review / lifecycle: Qualify library preparation, read depth, contamination metrics	QA-approved report, deviations and ongoing monitoring/revalidation triggers; focus on Defensible vector identity / genome analysis.	Review	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	Medium
BTV-38-0040	Continuous chromatography array	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Valve switching, cycles and interlock to product impact on Uniform purity and yield.	URS / DQ	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0041	Continuous chromatography array	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Continuous chromatography array.	IQ	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	Medium
BTV-38-0042	Continuous chromatography array	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Valve switching, cycles and interlock; compare challenge outputs to predefined Uniform purity and yield acceptance.	OQ	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0043	Continuous chromatography array	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Uniform purity and yield.	OQ	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0044	Continuous chromatography array	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Uniform purity and yield at relevant Valve switching, cycles and interlock; sampling scientifically justified.	PQ	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0045	Continuous chromatography array	Continued verification / risk-based requalification trigger evaluation	Trend Valve switching, cycles and interlock and impact on Uniform purity and yield; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	Medium
BTV-38-0046	Continuous perfusion harvest	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Residence distribution and flow to product impact on Stable CQA and batch traceability.	URS / DQ	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-38-0047	Continuous perfusion harvest	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Continuous perfusion harvest.	IQ	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	Medium
BTV-38-0048	Continuous perfusion harvest	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Residence distribution and flow; compare challenge outputs to predefined Stable CQA and batch traceability acceptance.	OQ	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0049	Continuous perfusion harvest	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Stable CQA and batch traceability.	OQ	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0050	Continuous perfusion harvest	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Stable CQA and batch traceability at relevant Residence distribution and flow; sampling scientifically justified.	PQ	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0051	Continuous perfusion harvest	Continued verification / risk-based requalification trigger evaluation	Trend Residence distribution and flow and impact on Stable CQA and batch traceability; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	Medium
BTV-38-0052	Protein refolding vessel	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace pH, redox control, residence and mixing to product impact on Correctly folded active protein.	URS / DQ	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0053	Protein refolding vessel	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Protein refolding vessel.	IQ	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	Medium
BTV-38-0054	Protein refolding vessel	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of pH, redox control, residence and mixing; compare challenge outputs to predefined Correctly folded active protein acceptance.	OQ	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0055	Protein refolding vessel	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Correctly folded active protein.	OQ	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0056	Protein refolding vessel	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Correctly folded active protein at relevant pH, redox control, residence and mixing; sampling scientifically justified.	PQ	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0057	Protein refolding vessel	Continued verification / risk-based requalification trigger evaluation	Trend pH, redox control, residence and mixing and impact on Correctly folded active protein; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	Medium
BTV-38-0058	High viscosity protein mixer	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Mixing torque and temperature to product impact on Homogeneous high concentration drug product.	URS / DQ	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0059	High viscosity protein mixer	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for High viscosity protein mixer.	IQ	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	Medium
BTV-38-0060	High viscosity protein mixer	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Mixing torque and temperature; compare challenge outputs to predefined Homogeneous high concentration drug product acceptance.	OQ	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0061	High viscosity protein mixer	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Homogeneous high concentration drug product.	OQ	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0062	High viscosity protein mixer	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Homogeneous high concentration drug product at relevant Mixing torque and temperature; sampling scientifically justified.	PQ	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0063	High viscosity protein mixer	Continued verification / risk-based requalification trigger evaluation	Trend Mixing torque and temperature and impact on Homogeneous high concentration drug product; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	Medium
BTV-38-0064	Nanoparticle size analyzer	URS/DQ: define intended process use, CPP/CQA link and engineering safeguards	URS and DQ trace Detector stability and size range to product impact on Relevant particle specification.	URS / DQ	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0065	Nanoparticle size analyzer	IQ: verify installation, design materials, instrumentation and service interfaces	Asset/tag, drawings, critical wetted surfaces, utilities, software configuration and instrument calibrations confirmed for Nanoparticle size analyzer.	IQ	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	Medium
BTV-38-0066	Nanoparticle size analyzer	OQ: challenge approved range, response and worst-case operational limits	Challenge high / low / normal levels of Detector stability and size range; compare challenge outputs to predefined Relevant particle specification acceptance.	OQ	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0067	Nanoparticle size analyzer	OQ: challenge applicable alarms, sensor faults, loss of power and recovery	Interlocks, permissives, fault logging, safe state and batch-recovery records protect Relevant particle specification.	OQ	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
BTV-38-0068	Nanoparticle size analyzer	PQ: demonstrate routine performance on justified representative process loads	Multi-run/operator/load or lot matrix supports repeatable Relevant particle specification at relevant Detector stability and size range; sampling scientifically justified.	PQ	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	High
BTV-38-0069	Nanoparticle size analyzer	Continued verification / risk-based requalification trigger evaluation	Trend Detector stability and size range and impact on Relevant particle specification; assess deviations, repair, replacement, configuration changes and calibration drift.	CPV	Biologics modality-specific optional processes	B03 B07 B10 B11 B14 B22	Medium

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