GLOBAL MEDICAL DEVICE RISK ASSESSMENT MASTER INDEX

STERILE | NONSTERILE | IMPLANTS | IVD | ACTIVE DEVICES | SaMD | COMBINATION PRODUCTS

ISO 14971 • ISO 13485 • US FDA QMSR • EU MDR / IVDR • MHRA • TGA • CDSCO

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Equipment / process / system topics	909 topic prompts across 35 functional areas
Detailed hazard/failure scenarios	2727 linked prompts in the companion Excel workbook
Document use	Proposed risk-identification index; device-specific approval and applicability required

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EXECUTIVE PURPOSE AND SCOPE

This document is a structured master inventory of potential medical-device risk-assessment subjects across product design and development, manufacturing, assembly, special processes, device testing, sterilization, sterile-barrier packaging, installation and servicing, supply chain and postmarket activities. The scope includes single-use sterile and nonsterile consumables, wound care, catheters, implantable and cardiovascular devices, orthopedic and dental devices, active medical electrical equipment, diagnostic devices and in-vitro diagnostics (IVDs), software as a medical device (SaMD), additive manufacturing, custom devices and drug-device interfaces.

Additional horizontal functions: Product risk management, QA/QMS, Regulatory Affairs, R&D, biocompatibility, usability engineering, physical and microbiological QC, engineering/utilities, qualification/validation, warehouse/logistics, procurement and supplier control, HR/administration, IT/eQMS/CSV, field service and EHS.

Important qualification: These entries are potential hazards / failure-mode prompts only. They do not allege any nonconformity or establish product risk acceptance. A manufacturer must document intended use, actual hazard sequences, persons exposed, severity/probability of harm, verified controls, residual risks and approvals for each relevant device.

RISK METHODOLOGY - ISO 14971 DISTINCTION

1. Identify the medical-device intended purpose, patient/user populations, reasonably foreseeable misuse and clinical environments; form the device risk management plan with approved acceptability criteria.
2. Distinguish a HAZARD (potential source of harm) from a HAZARDOUS SITUATION (people exposed to hazard) and HARM. Model sequences of events, severity of harm and probability of occurrence of harm.
3. Implement controls in priority order: inherently safe design/manufacture, protective measures, and information for safety. Verify implementation and effectiveness, and assess any risks introduced by the controls.
4. After controls, evaluate each individual residual risk, overall residual risk and benefit-risk (where required); document the risk management report and qualified review.
5. Use product/device PHA, FTA, usability risk analysis, FMEA, process FMEA, HAZOP, fault injection, microbial/biological evaluation and cybersecurity threat models as appropriate. Process FMEA RPN and detection are auxiliary methods, not substitutes for harm probability.

6. Update product risk files in response to service, supplier quality, deviations, trend signals, complaints, clinical experience, vigilance, post-market surveillance and regulatory/scientific change.

REGULATORY FRAMEWORK / APPLICABILITY

Core framework: ISO 14971:2019 and ISO/TR 24971:2020; ISO 13485:2016; current US FDA 21 CFR Part 820 Quality Management System Regulation (QMSR, effective 02 February 2026); EU MDR 2017/745, EU IVDR 2017/746; MHRA UK medical-device requirements for the relevant market; Australian TGA Essential Principles; and India Medical Devices Rules, 2017, including Fifth Schedule QMS as applicable. Select product-specific standards for sterility, materials, electrical safety, software, usability and clinical performance; these are not universally applicable to every device.

Examples: ISO 10993 biological evaluation; ISO 11607 sterile-barrier packaging; ISO 11135/11137/17665 sterilization; ISO 11737 bioburden and sterility validation testing; ISO 14644 cleanrooms; IEC 60601 series electrical safety; IEC 62304 software; IEC 62366-1 usability; IEC 81001-5-1 cybersecurity; and relevant product standards.

Pharmaceutical terminology clarification: Schedule M and Schedule Y are not primary medical-device manufacturing QMS requirements. Evaluate their relevance only if a regulated drug or drug-device combination is involved. For Indian medical devices and IVDs apply the Medical Devices Rules 2017 and current amendments according to device class and role.

DEPARTMENT / FUNCTIONAL AREA COVERAGE

Functional area	Topics	Risk scenarios
Additive Manufacturing / 3D Printing	18	54
Analytical Development Laboratory (ADL)	22	66
Biocompatibility & Chemical Safety	25	75
Clinical Evaluation, PMS & Vigilance	24	72
Design, Development & R&D	31	93
Disposable Devices, Syringes & IV Sets	35	105
Drug-Device / Biologic Combination Interfaces	10	30
EHS & Occupational / Process Safety	25	75
Electronics & Active Devices	30	90
Engineering, Utilities & Facilities	31	93
Field Service, Installation & Repair	15	45
HR, Administration & Competence	19	57
IT, ERP, eQMS & Data Integrity	20	60
IVD Reagents & Diagnostics	34	102
Implantable / Cardiovascular Devices	24	72
Medical Gloves, PPE & Protective Barriers	15	45
Medical Imaging, Monitoring & Diagnostics	25	75
Metalworking, Orthopedics & Dental	30	90
Microbiology / Cleanliness QC	20	60
Packaging, Labeling & UDI	30	90
Polymer, Moulding & Tubing	28	84
Product Risk Management	35	105
Production - Nonsterile Assembly	32	96
Purchase, Supplier & Outsourcing	22	66
QC / Test & Metrology	32	96
Quality Assurance / QMS	33	99
Regulatory Affairs & Market Access	25	75
Respiratory, Dialysis & Critical-Care Equipment	30	90
Software, SaMD & Cybersecurity	37	111
Sterile Device Assembly & Cleanrooms	28	84
Sterilization & Decontamination	30	90
Usability & Human Factors	20	60
Validation & Qualification	30	90
Warehouse, Transport & Distribution	24	72
Wound Care, Dressings & Textile Devices	20	60

REGULATORY REFERENCE KEY

Code	Reference	Application / applicability notes
ISO14971	ISO 14971:2019 - Medical devices risk management	Hazard, hazardous situation, risk of harm, control and residual risk across lifecycle
ISO24971	ISO/TR 24971:2020 - Guidance on ISO 14971	Examples, risk methods, probability and benefit-risk guidance (informative)
ISO13485	ISO 13485:2016 - Medical device QMS	Design/manufacture, supplier control, records, PMS and outsourced processes
FDA820	US FDA 21 CFR Part 820 QMSR - effective 2026-02-02	QMSR incorporates ISO 13485:2016 by reference, with US supplemental requirements

Code	Reference	Application / applicability notes
EUMDR	EU MDR Regulation (EU) 2017/745	Annex I general safety/performance & risk management; II/III technical/PMS; Article 10
EU IVDR	EU IVDR Regulation (EU) 2017/746	Risk management, IVD performance evaluation, PMS, and manufacturer obligations
INDMDR	India Medical Devices Rules, 2017 (as amended)	Indian manufacturing/import rules; Fifth Schedule QMS and applicable licensing
UKMDR	MHRA - UK medical device regulatory guidance	UK MDR 2002 as amended; differentiated GB and NI market pathways; PMS obligations
TGA	TGA - Medical Device Essential Principles	Australian safety/performance, manufacturer evidence and benefit-risk requirements
ISO10993	ISO 10993 series - Biological evaluation	Contact-based biological evaluation, chemical characterization and toxicology
ISO11607	ISO 11607-1/-2 - Sterile barrier packaging	Sterile barrier materials, design and forming/sealing/assembly validation
ISO11135	ISO 11135 - Ethylene oxide sterilization	EO development, validation and routine control
ISO11137	ISO 11137 series - Radiation sterilization	Validation and dose-based radiation sterilization
ISO17665	ISO 17665 - Moist heat sterilization	Development, validation and routine control of moist heat
ISO11737	ISO 11737-1/-2 - Microbiological methods	Bioburden and tests of sterility used in sterilization validation
ISO14644	ISO 14644 series - Cleanrooms	Cleanroom classification, monitoring and testing
IEC62304	IEC 62304 - Medical device software lifecycle	Software development and maintenance process
IEC62366	IEC 62366-1 - Usability engineering	Safety-related usability engineering of medical devices
IEC60601	IEC 60601 series - Medical electrical equipment	Basic safety and essential performance of relevant electrical devices
IEC81001	IEC 81001-5-1 - Health software cybersecurity	Secure product lifecycle for health software and IT health systems
ISO17025	ISO/IEC 17025 - Testing/calibration laboratories	Competence, metrology and laboratory risk where applicable
21CFR11	21 CFR Part 11 - Electronic records/signatures	US electronic record/signature requirements when applicable
ASTMISO	Product-specific ISO / ASTM / IEC standards	Select product-specific test standards, geometry, biocompatibility and performance
EHSL	Applicable occupational and environmental legislation	Local EHS/industrial safety law and permit conditions; distinct from device risk

Exact official reference URLs are included in the REGULATORY SOURCES sheet of the Excel workbook.

01 | ADDITIVE MANUFACTURING / 3D PRINTING

18 distinct assessment topics • 54 proposed scenario prompts in companion workbook

Purpose: Evaluate each listed equipment/activity for the applicable device model, intended use, patient hazard, preventive controls and objective evidence. Mark nonapplicable topics with rationale.

Topic ID	Equipment / process / activity	Critical parameter / control point	Possible patient / safety effect
ADD-001	Patient-specific image segmentation	CT/MRI input fidelity and region of interest	custom implant geometry incorrect
ADD-002	Patient anatomical model approval	surgeon sign-off and correct patient identity	wrong patient-specific device implanted
ADD-003	CAD-to-build file conversion	mesh errors and unit scaling	device manufactured to wrong dimensions
ADD-004	3D printer machine calibration	laser/powder bed or optical accuracy	geometric nonconformity
ADD-005	Metal powder lot qualification	chemistry, particle size and flowability	porosity and metal contamination
ADD-006	Powder reuse limits	oxygen pickup, sieving and lot trace	fatigue/corrosion performance degrades
ADD-007	Powder-bed fusion laser energy	power, hatch spacing and layer thickness	porous or weak implant
ADD-008	Build plate leveling / adhesion	warping and layer alignment	device dimension or strength loss
ADD-009	Build orientation and support structure	load-bearing anisotropy and accessibility	unexpected implant fatigue failure
ADD-010	Post-build depowdering	internal channels and trapped powder	foreign particles released into tissue
ADD-011	Hot isostatic pressing / heat treatment	microstructure and residual stress	material remains porous or brittle
ADD-012	Post-process machining and finishing	critical dimensional control	implant does not fit anatomy
ADD-013	3D-printed polymer curing	photopolymer residual monomers	toxic surface and low strength
ADD-014	Printer software version changes	slice algorithm and support structures	validated product differs after update
ADD-015	Custom-device documentation	patient identity, approval and traceability	wrong custom item delivered
ADD-016	Sterilization of porous AM devices	penetration, cleaning and dose suitability	hidden bioburden remains
ADD-017	AM implant mechanical test coupon	witness coupon location and representativeness	defective build lot falsely released
ADD-018	Powder handling fire and inhalation	metal dust control and PPE	flash fire or toxic exposure

Suggested methods: AM process FMEA / material safety

Potential device stream(s): ORTHO;DENTAL;CUSTOM;IMPLANT

02 | ANALYTICAL DEVELOPMENT LABORATORY (ADL)

22 distinct assessment topics • 66 proposed scenario prompts in companion workbook

Purpose: Evaluate each listed equipment/activity for the applicable device model, intended use, patient hazard, preventive controls and objective evidence. Mark nonapplicable topics with rationale.

Topic ID	Equipment / process / activity	Critical parameter / control point	Possible patient / safety effect
ADL-001	Material identification method development	selectivity for medical-grade polymers	wrong resin undetected
ADL-002	Extractables method design	clinically relevant extraction conditions	toxic leachable not detected
ADL-003	Leachables method qualification	LoD/LoQ and matrix response	underestimated chemical exposure
ADL-004	HPLC gradient method development	resolution, carryover and robustness	incorrect chemical characterization
ADL-005	GC-MS volatile method development	blank background and volatile recovery	toxic solvent residue missed
ADL-006	ICP-MS elemental method development	isotope selection and interference	metal ions reported incorrectly
ADL-007	TOC residual carbon method	swab/rinse recovery and sensitivity	surface cleaning residue missed
ADL-008	FTIR spectral library qualification	validated grade match and sampling	wrong material identity accepted
ADL-009	Particle-count methodology	particle type, size and sample recovery	particulate contamination understated
ADL-010	Endotoxin extraction method development	inhibition/enhancement and recovery	false negative pyrogen risk
ADL-011	Chromatographic analytical method transfer	equipment/site equivalence	bias between development and QC
ADL-012	Cleaning agent analytical method	recovery on material and residue stability	cleaning process falsely accepted
ADL-013	Method robustness study	minor method factors and response	unreliable result in routine QC
ADL-014	Measurement uncertainty assessment	decision rules and fit for purpose	incorrect conformance decision
ADL-015	Reference material qualification	traceability and commutability	systematic laboratory bias
ADL-016	Analytical sample stability	storage, hold and container effects	false impurity/bioburden conclusion
ADL-017	Laboratory instrument qualification	IQ/OQ/PQ and method software	invalid method-development data
ADL-018	Electronic raw data and integration	audit trail, version and processing controls	report manipulated or irreproducible
ADL-019	Method change and bridging	statistical equivalence and criticality	changed method gives non-comparable results
ADL-020	Biological test extraction design	surface area/mass and simulated use	patient risk wrongly assessed
ADL-021	Stability indicating diagnostic reagent assay	degradation products and activity loss	IVD expiry unsupported
ADL-022	Analytical protocol/report approval	quality review and deviation handling	unvalidated method accepted

Suggested methods: Analytical method risk / FMEA

Potential device stream(s): ALL;IVD;IMPLANT

03 | BIOCOMPATIBILITY & CHEMICAL SAFETY

25 distinct assessment topics • 75 proposed scenario prompts in companion workbook

Purpose: Evaluate each listed equipment/activity for the applicable device model, intended use, patient hazard, preventive controls and objective evidence. Mark nonapplicable topics with rationale.

Topic ID	Equipment / process / activity	Critical parameter / control point	Possible patient / safety effect
BIO-001	Biological evaluation plan	nature and duration of patient contact	incomplete endpoint selection
BIO-002	Contact category determination	surface, tissue, implant and blood contact	necessary testing omitted
BIO-003	Material chemical characterization	extractables and composition identification	unknown leachables remain
BIO-004	Toxicological risk assessment	patient exposure dose and limits	toxic leachable accepted without basis
BIO-005	Cytotoxicity assessment	cell viability and extraction conditions	harmful material not detected
BIO-006	Sensitization risk assessment	allergen and sensitizing extractables	allergic reaction in patients
BIO-007	Irritation/intracutaneous reactivity	local inflammatory response	tissue injury after contact
BIO-008	Systemic toxicity screening	route and dose relevance	systemic toxicity missed
BIO-009	Genotoxicity assessment	mutagenic constituent exposure	long-term patient safety unaddressed
BIO-010	Hemocompatibility evaluation	hemolysis, thrombogenicity and platelet activation	blood contact adverse event
BIO-011	Pyrogenicity/endotoxin risk	relevant fever-inducing contaminant	pyrogenic clinical reaction
BIO-012	Implantation response	tissue inflammation and healing	implant integration failure
BIO-013	Degradation-product assessment	wear, corrosion and polymer aging products	late toxic exposure
BIO-014	EO residuals assessment	EO, ECH and EG where relevant	sterilant toxicity at use
BIO-015	Cleaning-agent residual assessment	detergent, lubricant, solvents	patient chemical exposure
BIO-016	Latex allergy assessment	allergen declaration and alternatives	anaphylaxis risk
BIO-017	Nickel/sensitizing metal exposure	alloy constituents and corrosion	contact allergy
BIO-018	Colorants, additives and plasticizer assessment	phthalates and extractable levels	unacceptable toxicological exposure
BIO-019	Biological endpoint scientific justification	use of existing data and gaps	unsupported test omission
BIO-020	Extractables method validation	recovery, sensitivity and simulation solvents	toxic compound concentration underestimated
BIO-021	Leachables shelf-life trend	aging and environmental impact	late exposure exceeds safe limits
BIO-022	Chemical characterization of coatings	bond strength and dissolution	particulates and released chemicals
BIO-023	Risk from animal-origin materials	TSE/BSE and allergen traceability	transmissible agent or immune hazard
BIO-024	Risk from human-derived constituents	donor screening and infectious agent	transmission of infection
BIO-025	Biocompatibility after reprocessing	repeated disinfectant and aging cycles	reprocessed material toxic or weakened

Suggested methods: Biological evaluation / toxicological assessment

Potential device stream(s): INVASIVE;IMPLANT;WOUND;DENTAL

04 | CLINICAL EVALUATION, PMS & VIGILANCE

24 distinct assessment topics • 72 proposed scenario prompts in companion workbook

Purpose: Evaluate each listed equipment/activity for the applicable device model, intended use, patient hazard, preventive controls and objective evidence. Mark nonapplicable topics with rationale.

Topic ID	Equipment / process / activity	Critical parameter / control point	Possible patient / safety effect
PS-001	Clinical evaluation plan and method	indication, endpoint and evidence weighting	clinically important harm not evaluated
PS-002	Clinical evidence sufficiency	trial, literature and real-world evidence	unsupported safety and benefit conclusion
PS-003	Literature surveillance strategy	search terms, update frequency and coverage	new severe hazard undetected
PS-004	Clinical investigation protocol	informed consent, endpoints and safety monitoring	patient exposed without proper oversight
PS-005	Investigational device accountability	investigator site and lot traceability	unsafe unapproved device used
PS-006	Clinical data integrity	source data reconciliation and monitoring	benefit-risk assessment based on erroneous data
PS-007	Clinical trial adverse event reporting	seriousness classification and timeline	patient safety event not reported
PS-008	PMCF plan and study design	known clinical gaps and sampling	emerging safety signal not detected
PS-009	PMS plan linked to risk file	sources, metrics, thresholds and update triggers	risk file grows stale after launch
PS-010	PMS / PMCF report review	periodic analyses and quality approval	field performance decline ignored
PS-011	PSUR / periodic safety report when required	trend, exposure denominator and justification	weak safety evidence for ongoing marketing
PS-012	Complaint severity triage	death, serious injury and malfunction	reportable harm missed
PS-013	Serious incident vigilance decision	jurisdictional criteria and deadlines	regulatory and clinical response delayed
PS-014	Field safety corrective action decision	scope, patient risk and remedy	unsafe devices remain in service
PS-015	Field safety notice comprehension	clinician action and affected devices	field correction not effective
PS-016	UDI/device identification in complaints	lot, serial, software and accessories	investigation cannot identify actual variant
PS-017	Clinical trend normalization	events per exposure and relevant denominator	false reassuring harm-rate signal
PS-018	Service history feedback	repairs, replacement and repeated malfunctions	dangerous design weakness overlooked
PS-019	Complaint-to-CAPA linkage	signal investigation and systemic corrective action	recurring harm without preventive improvement
PS-020	Cybersecurity post-market monitoring	vulnerability, exploit and incident signals	network risk grows after approval
PS-021	Residual risk re-evaluation after new science	updated hazard severity and probability	unacceptable residual risk retained
PS-022	Device recall effectiveness check	accountability and closure of installed base	high-risk devices uncorrected
PS-023	Regulatory safety reporting completeness	different EU/UK/US/India/Australia obligations	reporting missed in one market
PS-024	Implant registry and long-term follow-up	late failure rate and patient outcomes	late implant harm not captured

Suggested methods: Benefit-risk / trend analysis

Potential device stream(s): ALL

05 | DESIGN, DEVELOPMENT & R&D

31 distinct assessment topics • 93 proposed scenario prompts in companion workbook

Purpose: Evaluate each listed equipment/activity for the applicable device model, intended use, patient hazard, preventive controls and objective evidence. Mark nonapplicable topics with rationale.

Topic ID	Equipment / process / activity	Critical parameter / control point	Possible patient / safety effect
RD-001	User needs capture	real user context and stakeholder needs	critical need omitted from intended purpose
RD-002	Design inputs and acceptance criteria	measurable safety/performance requirements	unsafe design ambiguity
RD-003	Design input regulatory mapping	GSPR / Essential Principles traceability	device requirement not addressed
RD-004	Design outputs and specifications	tolerances and testable drawing requirements	unsafe product made to incomplete specs
RD-005	Design review gates	independent specialist and clinical inputs	hazards survive development gates
RD-006	Design verification plan	sufficient test coverage and sample rationale	unverified critical requirement
RD-007	Design validation with intended users	representative use conditions and training	real-world use failure not detected
RD-008	Design transfer to manufacturing	validated process parameters and training	prototype behavior not replicated at scale
RD-009	Design changes after approval	regulatory significance and new hazard evaluation	unassessed modification marketed
RD-010	Design history / technical documentation	revision integrity and traceability	design decisions not reconstructable
RD-011	Risk-based requirements traceability	need → risk → requirement → test	control without evidence of efficacy
RD-012	System architecture review	interfaces, dependencies and common cause failures	system-wide loss of critical function
RD-013	Subassembly integration testing	mechanical-electrical-software interoperability	component works alone but fails in system
RD-014	Worst-case operating envelope	extreme temperature, voltage, humidity, load	device fails outside nominal test setting
RD-015	Failure under single fault condition	protection design and safe-state response	patient exposed to hazardous energy
RD-016	Mechanical tolerance stack-up	assembly fit and worst-case dimensions	leakage or device malfunction
RD-017	Environmental stress screening	transport, shock, vibration and temperature	field failures not predicted
RD-018	Material selection and alternatives	allergy, biocompatibility and aging	unsafe materials substituted
RD-019	Human factors formative testing	confusion, use error and interface discovery	avoidable use hazards incorporated
RD-020	Human factors summative validation	critical task representative test	critical use errors persist to launch
RD-021	Risk-based pilot manufacturing	scaling, operator effects and tooling	production variability unrecognized
RD-022	Reference device / equivalence evaluation	scientific and clinical comparability	unfounded performance claim
RD-023	Design for assembly	error-proofed interfaces and mix-up controls	wrong-way assembly creates latent hazard
RD-024	Design for cleaning/disinfection	soil traps and compatible agents	device infection after reuse
RD-025	Design for serviceability	safe maintenance, spare parts and calibration	incorrect service changes clinical performance
RD-026	Design for cybersecurity	threat modeling and security-by-design	patient risk through unauthorized intervention
RD-027	Device life and wear-out design	reliability targets and failure rates	device fails before claimed lifetime
RD-028	Accessory compatibility specifications	electrical/mechanical/data limits	unapproved accessory causes harm
RD-029	Usability of IFU and symbols	comprehension and language checks	users cannot follow safety steps
RD-030	Design freeze and manufacturing baseline	BOM/CAD/software/labels baseline alignment	mis-matched configuration reaches market
RD-031	Verification of alarms and interlocks	priority, response time and detectability	operator not alerted to hazardous state

Suggested methods: Design FMEA / PHA

Potential device stream(s): ALL

06 | DISPOSABLE DEVICES, SYRINGES & IV SETS

35 distinct assessment topics • 105 proposed scenario prompts in companion workbook

Purpose: Evaluate each listed equipment/activity for the applicable device model, intended use, patient hazard, preventive controls and objective evidence. Mark nonapplicable topics with rationale.

Topic ID	Equipment / process / activity	Critical parameter / control point	Possible patient / safety effect
DISP-001	Syringe barrel injection molding	barrel inside diameter and concentricity	dose delivery inaccurate
DISP-002	Syringe plunger molding	sealing lip, fit and surface finish	leakage, air ingress or high glide force
DISP-003	Syringe piston gasket assembly	gasket fit and lubrication	dose accuracy and seal failure
DISP-004	Syringe graduations printing	scale accuracy, adhesion and readability	incorrect volume measured
DISP-005	Luer lock tip molding	ISO small-bore connector dimensions	syringe detaches during injection
DISP-006	Needle tube cutting and forming	gauge, length and sharp cut	incorrect flow or pain
DISP-007	Needle bevel grinding	bevel geometry and burrs	tissue tearing or insertion failure
DISP-008	Needle cannula siliconization	coating amount and chemistry	particles or toxic residual
DISP-009	Needle hub attachment	pull strength and adhesive cure	needle separation in tissue
DISP-010	Safety needle shield activation	needle lock and feedback	needle stick after use
DISP-011	IV administration set tubing	flow, flexibility and extractables	inaccurate infusion or patient exposure
DISP-012	IV set drip chamber assembly	drop factor and air vent	incorrect infusion rate
DISP-013	IV set roller clamp	occlusion and set-point stability	unexpected fluid delivery
DISP-014	IV set spike connector	fit, strength and microbial barrier	contaminated fluid path
DISP-015	IV extension set stopcock	valve seal and flow orientation	wrong route, leak or air entry
DISP-016	Infusion set injection port	septum puncture and reseal	leakage and microbial ingress
DISP-017	Peripheral IV cannula tip finishing	tip smoothness and catheter retention	vessel trauma or cannula fragment
DISP-018	Peripheral cannula flashback chamber	leak/visibility and correct assembly	unsafe vascular access
DISP-019	Blood collection needle assembly	sharpness, flow and safety guard	hemolysis or needle injury
DISP-020	Vacuum blood collection tube stoppering	vacuum level and additive identity	incorrect diagnostic specimen
DISP-021	Blood bag film extrusion	film strength and material compatibility	bag leak or toxic extractables
DISP-022	Blood bag RF welding	weld seam strength and uniformity	blood contamination or bag rupture
DISP-023	Blood bag tubing seal	closed-system tube integrity	microbial ingress or blood leakage
DISP-024	Blood bag anticoagulant filling	identity, volume and concentration	clotting or cell injury
DISP-025	Blood bag collection needle joining	connector bond and sterility	blood-contact contamination
DISP-026	Enteral feeding bag tubing	small-bore incompatibility control	inadvertent intravenous connection
DISP-027	Enteral connector dimensional control	dedicated connection geometry	unsafe misconnections
DISP-028	Oxygen mask material conversion	ventilation ports and material integrity	hypoxia or chemical irritation
DISP-029	Suction catheter side holes	burrs, patency and suction force	airway trauma or occlusion
DISP-030	Urinary catheter eyelet forming	smoothness and flow	mucosal injury or inadequate drainage
DISP-031	Urinary catheter balloon integrity	volume retention and rupture	catheter dislodgement or trauma
DISP-032	Disposable wound drain assembly	valve flow and reservoir seal	ineffective drainage or infection
DISP-033	Hemodialysis bloodline tubing weld	bond integrity and flow path	blood leak or air embolism
DISP-034	Disposable dialysis filter housing seal	pressure integrity and fiber retention	blood loss or fluid cross leakage
DISP-035	Single-use cannula sterile pack	barrier integrity and aseptic presentation	infection from compromised packaging

Suggested methods: Process FMEA / control plan

Potential device stream(s): DISPOSABLE;STERILE;CATHETER

07 | DRUG-DEVICE / BIOLOGIC COMBINATION INTERFACES

10 distinct assessment topics • 30 proposed scenario prompts in companion workbook

Purpose: Evaluate each listed equipment/activity for the applicable device model, intended use, patient hazard, preventive controls and objective evidence. Mark nonapplicable topics with rationale.

Topic ID	Equipment / process / activity	Critical parameter / control point	Possible patient / safety effect
COMB-001	Drug-device interface definition	dosage, delivery path and device state	wrong delivered medicinal dose
COMB-002	Pre-filled syringe plunger compatibility	break-loose/glide forces and container closure	under/over delivery or leak
COMB-003	Autoinjector trigger and needle shielding	activation forces, lock and injury protection	failure to inject or needle stick
COMB-004	Infusion set material compatibility	drug adsorption and extractables	wrong active delivered concentration
COMB-005	Drug-coated implant coating uniformity	surface loading, release and adhesion	local toxicity or ineffective drug effect
COMB-006	Drug delivery pump dose algorithm	prescription, rate and limit controls	overdose from software/setting error
COMB-007	Primary container glass or polymer integrity	extractables and closure compatibility	chemical or microbial contamination
COMB-008	Biologic-reagent stability in cartridge	protein aggregation and adsorption	loss of efficacy or unsafe particles
COMB-009	User interface and drug concentration entry	unit conversion and guardrails	dose error from wrong input
COMB-010	Combination product complaint triage	drug versus device root cause and reporting	serious event not investigated correctly

Suggested methods: Integrated risk / interface hazard analysis

Potential device stream(s): COMBINATION;IMPLANT;DRUGDELIVERY

08 | EHS & OCCUPATIONAL / PROCESS SAFETY

25 distinct assessment topics • 75 proposed scenario prompts in companion workbook

Purpose: Evaluate each listed equipment/activity for the applicable device model, intended use, patient hazard, preventive controls and objective evidence. Mark nonapplicable topics with rationale.

Topic ID	Equipment / process / activity	Critical parameter / control point	Possible patient / safety effect
EHS-001	Injection molding machine guarding	hot zone and clamp interlocks	operator crush or burn injury
EHS-002	CNC rotating equipment	guards, emergency stops and work holding	laceration or projectile impact
EHS-003	Laser welding/cutting enclosure	class-rated shielding and eye protection	eye damage or fire
EHS-004	EO storage and leak detection	toxic/explosive atmosphere and ventilation	worker poisoning or explosion
EHS-005	Gamma irradiation facility interlock	radiation shielding and access control	worker radiation exposure
EHS-006	E-beam accelerator shielding	fail-safe interlocks and dosimetry	radiation exposure during operation
EHS-007	Hydrogen peroxide vapor exposure	PPE, ventilation and release monitoring	chemical inhalation injury
EHS-008	Solvent/adhesive handling	LEL and local exhaust ventilation	flash fire or chronic exposure
EHS-009	Acid passivation tank	secondary containment, fumes and PPE	chemical burns and inhalation injury
EHS-010	Metal dust and polishing fumes	local extraction and combustible dust review	respiratory disease or dust fire
EHS-011	Sharps and needles handling	shielding, containers and safe disposal	needle stick / blood-borne exposure
EHS-012	Contaminated IVD cartridge waste	infectious material and segregation	biological occupational exposure
EHS-013	Cleanroom ergonomics / repetitive work	repetitive movement and reach	musculoskeletal injury
EHS-014	Warehouse forklift routes	vehicle/pedestrian segregation	vehicle impact injury
EHS-015	Gas cylinders and oxygen displacement	restraint and O2 alarm where needed	high-pressure release/asphyxiation
EHS-016	Electrical lockout tagout	isolation of stored energy	shock or unexpected motion
EHS-017	Pressurized autoclave safety	relief devices and safe opening	steam burn or rupture
EHS-018	Chemical spill emergency procedure	compatible containment and trained responders	harmful exposure and pollution
EHS-019	Fire detection and evacuation	flammable materials and blocked exits	personnel injury and plant shutdown
EHS-020	Emergency eyewash/safety showers	access and functional testing	chemical injury aggravated
EHS-021	Machine maintenance work permits	confined space, hot work and isolation	severe accident during maintenance
EHS-022	Clinical/biological specimen handling	biosafety and exposure response	infection in laboratory staff
EHS-023	Air emissions and effluent compliance	local permits and waste stream treatment	environmental release or enforcement
EHS-024	Medical surveillance for hazardous agents	appropriate exposure health monitoring	occupational illness undetected
EHS-025	Process risk study of polymer fume	thermal decomposition and ventilation	toxic fumes reach operators

Suggested methods: EHS HAZOP / JSA / bow-tie

Potential device stream(s): ALL

09 | ELECTRONICS & ACTIVE DEVICES

30 distinct assessment topics • 90 proposed scenario prompts in companion workbook

Purpose: Evaluate each listed equipment/activity for the applicable device model, intended use, patient hazard, preventive controls and objective evidence. Mark nonapplicable topics with rationale.

Topic ID	Equipment / process / activity	Critical parameter / control point	Possible patient / safety effect
EL-001	PCB component source authenticity	counterfeit and component traceability	unpredictable device failure
EL-002	PCB SMT solder paste printing	paste deposit and alignment	cold joint and intermittent failure
EL-003	Pick-and-place component placement	polarity and component orientation	device inoperative or hazardous output
EL-004	Reflow oven profile	peak heat and solder joint quality	thermal damage or latent solder cracks
EL-005	Selective soldering	wetting and bridge defects	electrical short or open circuit
EL-006	Conformal coating	coverage and cure	moisture-related electronic malfunction
EL-007	IPC workmanship visual checks	bridging, tombstone and void criteria	latent electrical defect
EL-008	ESD wrist strap and workstation	grounding and handling discipline	hidden semiconductor failure
EL-009	ESD flooring and ionizer	static discharge protection	latent IC damage
EL-010	Power supply electrical safety	overvoltage and protective isolation	shock or unsafe energy delivery
EL-011	Battery pack assembly and BMS	cell matching and protection	thermal runaway or unexpected shutdown
EL-012	Battery charging circuit	current limiting and thermal protection	overheating and fire
EL-013	Battery state of charge estimation	remaining service time under load	therapy interruption
EL-014	Sensor factory calibration	range, accuracy and stability	wrong measured physiologic parameter
EL-015	Sensor aging and drift	periodic performance check	false readings in service
EL-016	Transducer assembly and bonding	seal integrity and response characteristics	inaccurate pressure reading
EL-017	Display and LED feedback	image/brightness and fault reporting	critical information not visible
EL-018	Keypad and user controls	switch bounce and unintended input	incorrect setting accepted
EL-019	Electromagnetic compatibility	immunity and emissions in clinical environment	therapy interruption near other devices
EL-020	Electrical leakage and dielectric strength	creepage, clearance and isolation	electric shock to patient
EL-021	Defibrillator protection circuit	overvoltage and recovery	monitor damaged during shock
EL-022	Thermal management and fan failure	device case temperature and air flow	burn injury or sudden shutdown
EL-023	Ingress protection of enclosure	fluid splash and gasket design	short circuit during cleaning
EL-024	Cable strain relief and connector pinout	pull force and orientation	intermittent function or shock
EL-025	Audio and visual alarm generator	fault indication and sound pressure	unnoticed life-threatening condition
EL-026	Electrical device production test	programmed test limits and coverage	defective device passes
EL-027	Firmware flashing at final assembly	image hash, version and secure boot	wrong firmware delivered
EL-028	Serial-number calibration record	traceable constants and test data	wrong device calibration after service
EL-029	Network/wireless coexistence	radio interference and packet loss	missed alarm or data
EL-030	Cybersecure hardware debug ports	port lock and physical access	unauthorized parameter changes

Suggested methods: System FMEA / fault tree

Potential device stream(s): ACTIVE;MONITOR;THERAPY

10 | ENGINEERING, UTILITIES & FACILITIES

31 distinct assessment topics • 93 proposed scenario prompts in companion workbook

Purpose: Evaluate each listed equipment/activity for the applicable device model, intended use, patient hazard, preventive controls and objective evidence. Mark nonapplicable topics with rationale.

Topic ID	Equipment / process / activity	Critical parameter / control point	Possible patient / safety effect
EN-001	Facility material/personnel flow	clean versus dirty pathways	cross-contamination in device assembly
EN-002	Cleanroom AHU control	temperature, RH, differential pressure	loss of contamination control
EN-003	AHU prefilter / HEPA service	filtration status and integrity	particle/bioburden ingress
EN-004	HVAC BMS alarm hierarchy	sensor thresholds and notification	critical excursions not acted on
EN-005	Air compressor receiver and dryer	pressure stability, oil and dew point	device contamination or process defects
EN-006	Oil-free compressed air point-of-use	filters and monitoring	particles/oil transfer onto components
EN-007	Nitrogen gas supply	purity, pressure and oxygen deficiency	packaging defects or worker asphyxiation
EN-008	Vacuum pump and piping	vacuum strength and oil backstreaming	failure of molding/sealing
EN-009	Purified cleaning water system	quality appropriate to intended use	residue or microbial contamination
EN-010	RO/DI pretreatment and sanitization	membrane performance and microbial load	biofilm in device cleaning supply
EN-011	Process water distribution loop	dead legs and use point quality	microbial challenge at rinsing
EN-012	Electrical power quality	surges, voltage dips and earthing	critical equipment loses parameters
EN-013	UPS backup for critical control	autonomy and switchover	unlogged process interruptions
EN-014	Diesel generator and ATS	startup and critical loads	production/sterilization outage
EN-015	Electrical panels and machine grounding	shock safety and harmonics	unsafe equipment operation
EN-016	BMS / EMS validated configuration	alarm points and audit records	loss of environmental history
EN-017	SCADA/PLC machine interlock	fail-safe and unauthorized change	unsafe cycle bypass
EN-018	Chilled water distribution	temperature/flow stability	dimensional defects in molding
EN-019	Cooling tower water treatment	biofilm control and blowdown	legionella / corrosion risk
EN-020	Boiler / steam service	pressure and dryness	faulty sterilization heat transfer
EN-021	Pressure vessel inspections	relief valve and certification	rupture or hazardous release
EN-022	Nitrogen / oxygen pipeline identification	line label and pressure compatibility	wrong-gas connection
EN-023	Calibration laboratory conditions	temperature and vibration	metrology bias
EN-024	Equipment preventive maintenance	wear parts, interval and history	unexpected critical process failure
EN-025	Predictive maintenance analytics	sensor drift and alarm performance	early failure signal missed
EN-026	Compressed gas particulate filtration	point-of-use grade and maintenance	contamination of device surfaces
EN-027	Facility pest exclusion	loading bay and storage integrity	product contamination in warehouse
EN-028	Facility cleaning chemical storage	segregation and compatible materials	contaminating fumes or spills
EN-029	Critical equipment spare parts	authentic approved parts and qualification	unapproved replacement changes process
EN-030	Cleanroom door seals / airlock	interlock and pressure hold	uncontrolled particle migration
EN-031	Effluent disposal from cleaning	chemical and biological waste streams	environmental exposure and regulatory breach

Suggested methods: Engineering FMEA / HAZOP

Potential device stream(s): ALL

11 | FIELD SERVICE, INSTALLATION & REPAIR

15 distinct assessment topics • 45 proposed scenario prompts in companion workbook

Purpose: Evaluate each listed equipment/activity for the applicable device model, intended use, patient hazard, preventive controls and objective evidence. Mark nonapplicable topics with rationale.

Topic ID	Equipment / process / activity	Critical parameter / control point	Possible patient / safety effect
SRV-001	Site acceptance and installation	power, gas, network and ambient conditions	device unsafe at customer location
SRV-002	User training at handover	critical operation and alarm response	operator introduces hazardous error
SRV-003	Preventive maintenance plan	service interval and safety-critical parts	increased failure in field
SRV-004	Field repair work order	approved parts and correct serial	unapproved modification of therapy device
SRV-005	Calibration after field repair	accuracy traceability and as-left status	wrong measurement used clinically
SRV-006	Post-service safety/function test	electrical safety and functional acceptance	serviced unsafe equipment returned
SRV-007	Remote service and cybersecurity	temporary access and logs	unauthorized settings change
SRV-008	Spare-part traceability	original component and compatibility	counterfeit or wrong part installed
SRV-009	Software upgrade service procedure	approved version and rollback plan	device impaired by update
SRV-010	Complaint capture from service visit	field failure and patient outcome	reportable safety event missed
SRV-011	Preventive replacement before wear-out	service lifetime and wear monitor	unexpected in-use failure
SRV-012	Reprocessing instructions for reusable devices	cleaning, disinfection, sterilization and count	cross-infection on reuse
SRV-013	Cleaning validation after field use	soil and difficult lumen locations	residual blood/tissue remains
SRV-014	Device use-life tracking	number of cycles, repairs and wear	device operated beyond safe life
SRV-015	Decommissioning and secure data wipe	patient records and battery hazards	privacy breach or environmental harm

Suggested methods: Service / maintenance FMEA

Potential device stream(s): ACTIVE;IMPLANT;HOME;IVD

12 | HR, ADMINISTRATION & COMPETENCE

19 distinct assessment topics • 57 proposed scenario prompts in companion workbook

Purpose: Evaluate each listed equipment/activity for the applicable device model, intended use, patient hazard, preventive controls and objective evidence. Mark nonapplicable topics with rationale.

Topic ID	Equipment / process / activity	Critical parameter / control point	Possible patient / safety effect
HR-001	Position-specific competence matrix	critical safety task qualifications	unqualified staff conduct device work
HR-002	Gowning operator competency	practical aseptic skill	cleanroom contamination by personnel
HR-003	Welding/bonding operator qualification	demonstrated special process capability	weak joints made by unqualified operator
HR-004	Risk management training	severity, probability of harm and traceability	invalid risk analysis accepted
HR-005	Software safety engineering competence	code and clinical context	unsafe algorithm design
HR-006	IVD laboratory scientist competence	test verification and interpretation	false diagnostic result released
HR-007	Calibration technician competence	traceability and measurement uncertainty	invalid measurement system
HR-008	Independent quality release authority	independence and role cover	production pressure overrides safety
HR-009	Contract-worker onboarding	training and controlled system access	critical SOP bypassed by temporary worker
HR-010	Personnel hygiene and illness reporting	communicable infection and hygiene	clean area microbial contamination
HR-011	Periodic effectiveness assessment	observation and task assessment	training recorded without capability
HR-012	Changeover/shift handover controls	unresolved defects and equipment status	unfinished unsafe assembly continued
HR-013	Staffing levels for critical operation	fatigue, overtime and error likelihood	mistakes in inspections or assembly
HR-014	Emergency staff and evacuation drill	roles, medical attention and access	injury exacerbated during incident
HR-015	Cleanroom behavioral observation	routine audit feedback	persistent contamination practices
HR-016	Human-factors-driven work instructions	visual aids and mistake-proofing	repeated assembly use error
HR-017	Visitor control for clean/secure areas	access and PPE	contamination or unauthorized handling
HR-018	Recruitment vetting for data roles	privilege and security awareness	inappropriate access to medical data
HR-019	Training record retention	certificate, trainer and effectiveness	competence cannot be demonstrated

Suggested methods: Human and organization risk

Potential device stream(s): ALL

13 | IT, ERP, EQMS & DATA INTEGRITY

20 distinct assessment topics • 60 proposed scenario prompts in companion workbook

Purpose: Evaluate each listed equipment/activity for the applicable device model, intended use, patient hazard, preventive controls and objective evidence. Mark nonapplicable topics with rationale.

Topic ID	Equipment / process / activity	Critical parameter / control point	Possible patient / safety effect
IT-001	ERP material status controls	approved/quarantine/rejected block logic	unreleased material issued
IT-002	Electronic device history record	critical workflow and authorized review	incomplete device record approved
IT-003	Electronic design-history system	revision, traceability and backups	obsolete design file released
IT-004	Electronic QMS audit trail	who/what/when and reason for change	unauthorized record alteration undetected
IT-005	LIMS result calculations	method version, precision and acceptance logic	defective device released
IT-006	Calibration management system	due dates and OOT action	overdue instrument used
IT-007	Automated batch/lot traceability	lot/serial relationships and genealogy	recall population inaccurate
IT-008	UDI database and label software	identifier mapping and versions	incorrect labels printed
IT-009	Access roles and segregation of duties	least privilege and release authority	unauthorized approval of device
IT-010	System backup and restore testing	restore time and data completeness	critical production evidence lost
IT-011	Disaster recovery plan	site outages and validated resumption	loss of release/traceability information
IT-012	Cybersecurity of GxP systems	patching, accounts and network segregation	data integrity or manufacturing control compromised
IT-013	Spreadsheet control of risk matrix	formula locking, version and verification	incorrect harm classification
IT-014	Software change control and regression testing	validated baseline and test evidence	critical functionality altered unknowingly
IT-015	Electronic signatures and identity	authenticated signing and linked records	falsified product release record
IT-016	Time synchronization across machines	timestamp and event traceability	wrong event sequence after deviation
IT-017	Remote vendor maintenance access	session approval and logs	unauthorized PLC/SCADA modification
IT-018	Cloud data residency and vendor controls	availability and integrity of records	loss of clinical or quality evidence
IT-019	Data migration after system upgrade	record completeness and field mapping	mislinked lot/device history
IT-020	Device customer/patient data privacy	confidentiality and authorized use	exposure of identifiable medical data

Suggested methods: GxP computer system risk / CSV

Potential device stream(s): ALL

14 | IVD REAGENTS & DIAGNOSTICS

34 distinct assessment topics • 102 proposed scenario prompts in companion workbook

Purpose: Evaluate each listed equipment/activity for the applicable device model, intended use, patient hazard, preventive controls and objective evidence. Mark nonapplicable topics with rationale.

Topic ID	Equipment / process / activity	Critical parameter / control point	Possible patient / safety effect
IVD-001	Intended specimen type	serum, plasma, whole blood and swab compatibility	invalid diagnostic result
IVD-002	Sample collection and transport	stability, container, temperature and time	false positive or false negative
IVD-003	Specimen identification and aliquoting	barcode integrity and cross-contamination	wrong patient result
IVD-004	Reagent raw material traceability	antibodies, enzymes, primers and buffers	lot-dependent assay failure
IVD-005	Reagent formulation and blending	concentration, pH and homogeneity	systematic assay bias
IVD-006	Reagent dispensing and filling	volume, wetting and cross-contamination	incorrect signal intensity
IVD-007	Lyophilized diagnostic reagent	cake/moisture and reconstitution	loss of test sensitivity
IVD-008	Conjugate preparation	label-to-protein ratio and stability	background or signal defect
IVD-009	Antibody capture coating	uniformity, epitope binding and plate orientation	false assay result
IVD-010	Lateral flow membrane striping	line width, concentration and position	weak test line or false result
IVD-011	Lateral flow cassette assembly	strip placement and capillary action	invalid migration and false result
IVD-012	Rapid diagnostic test visual read	line interpretation and cutoff	misdiagnosis through poor readability
IVD-013	PCR primer/probe design	inclusivity, cross-reactivity and mutation effects	missed target or false target
IVD-014	PCR reagent setup	contamination prevention and mixture composition	false positive through amplification contamination
IVD-015	Nucleic acid extraction	recovery and inhibitor removal	false negative due to failed extraction
IVD-016	RT-PCR thermal cycler performance	temperature accuracy and uniformity	amplification failure
IVD-017	PCR positive/negative controls	control acceptance and run validity	unrecognized invalid patient run
IVD-018	Multiplex assay cross-talk	signal bleed and interference	wrong analyte reported
IVD-019	Analytical sensitivity / LoD	statistically justified low-level detection	clinically important low concentration missed
IVD-020	Analytical specificity / cross-reactivity	interferents and related organisms	false positive clinical diagnosis
IVD-021	Diagnostic cutoff / reference interval	clinical performance and population	misclassification of disease status
IVD-022	Clinical performance evaluation	representative subjects and clinical comparison	unsupported diagnostic intended purpose
IVD-023	Lot-to-lot reagent bridging	equivalence and reference panels	new reagent lot shifts results
IVD-024	Analyzer optical detection	lamp aging and photodetector accuracy	biased assay measurements
IVD-025	Analyzer liquid handling	aspirate accuracy, carryover and bubbles	wrong sample/reagent volume
IVD-026	Analyzer wash station	residual cross-contamination and blockages	carryover positive results
IVD-027	Analyzer sample probe crash	position sensor and collision stop	wrong aspirate or hardware breakdown
IVD-028	IVD calibration and QC material	traceability and matrix commutability	biased patient diagnosis
IVD-029	IVD software result flags	out-of-range, invalid and critical value alarms	unreliable patient output
IVD-030	IVD instrument middleware/LIS interface	analyte code, unit and patient identifier	wrong result transmitted
IVD-031	Self-test / home IVD instructions	time window and interpretability	wrong self-diagnosis and delayed treatment
IVD-032	Stability of open-vial reagent	in-use time, humidity and microbial growth	false report after opening
IVD-033	Transport of cold-chain reagents	freeze-thaw exposure and excursions	reagent potency loss
IVD-034	IVD used cartridge disposal	infectious residue and sharps control	cross-infection and occupational exposure

Suggested methods: Analytical risk / process FMEA

Potential device stream(s): IVD;LAB

15 | IMPLANTABLE / CARDIOVASCULAR DEVICES

24 distinct assessment topics • 72 proposed scenario prompts in companion workbook

Purpose: Evaluate each listed equipment/activity for the applicable device model, intended use, patient hazard, preventive controls and objective evidence. Mark nonapplicable topics with rationale.

Topic ID	Equipment / process / activity	Critical parameter / control point	Possible patient / safety effect
IM-001	Implant load-bearing fatigue	cyclic physiologic loading and worst-case size	implant fracture in patient
IM-002	Implantation surgical technique	instrumentation and anatomical access	misplacement causes permanent harm
IM-003	Implant surface particulate	loose coatings and manufacturing debris	inflammatory response or embolism
IM-004	Implant migration resistance	anchoring geometry and deployment	migration or loss of therapy
IM-005	Stent radial strength and recoil	radial force and dimensional recovery	restenosis or vessel injury
IM-006	Stent strut fatigue	bending, pulsation and fracture tolerance	perforation or loss of support
IM-007	Balloon catheter rated burst pressure	pressure limits and burst mode	vessel injury from balloon rupture
IM-008	Balloon catheter rated nominal pressure	deployment dose/diameter accuracy	under-expansion or dissection
IM-009	Guidewire tip retention	weld/adhesive fatigue and pull	vascular foreign body
IM-010	Catheter hydrophilic coating integrity	adhesion and repeated use abrasion	coating emboli or tissue injury
IM-011	Intravascular device extractables	contact duration and blood compatibility	thrombotic or toxic event
IM-012	Venous catheter kink resistance	minimum bend radius under use	therapy interruption or infiltration
IM-013	Implant corrosion fatigue	electrochemical environment and cyclic load	metal ion release and breakage
IM-014	Orthopedic joint wear debris	bearing wear and long-term performance	osteolysis and implant loosening
IM-015	Spinal implant rod connector	lock torque and fatigue	loss of spinal correction
IM-016	Pacemaker lead insulation	pinholes, abrasion and leakage current	loss of pacing or unintended stimulation
IM-017	Cardiac implant battery life	low-battery notification and remaining service time	loss of lifesaving therapy
IM-018	Neurostimulator lead migration	anchor design and strain relief	therapy failure or nerve injury
IM-019	Drug-coated device surface loading	coating uniformity and dose release	local toxicity or poor treatment
IM-020	Absorbable implant degradation	mass loss, strength retention and by-products	premature loss of support
IM-021	Implant MR compatibility	MR-conditional labeling and test limitations	heating or movement in MRI
IM-022	Implant radiopacity markers	position, attachment and imaging visibility	misplacement due to poor visualization
IM-023	Implant traceability by serial/lot	patient-level link and distribution records	ineffective targeted recall
IM-024	Explant analysis process	preservation and failure investigation	emerging failure mechanism missed

Suggested methods: Device hazard analysis / fatigue FMEA

Potential device stream(s): IMPLANT;CARDIO;ORTHO;NEURO

16 | MEDICAL GLOVES, PPE & PROTECTIVE BARRIERS

15 distinct assessment topics • 45 proposed scenario prompts in companion workbook

Purpose: Evaluate each listed equipment/activity for the applicable device model, intended use, patient hazard, preventive controls and objective evidence. Mark nonapplicable topics with rationale.

Topic ID	Equipment / process / activity	Critical parameter / control point	Possible patient / safety effect
PPE-001	Medical examination glove material	allergen and barrier suitability	allergy or pathogen exposure
PPE-002	Glove dip-coating tank	film thickness uniformity and pinholes	fluid penetration through glove
PPE-003	Glove vulcanization/cure	mechanical strength and residual accelerators	glove tears or skin irritation
PPE-004	Glove leaching process	protein/chemical residue removal	user sensitization or irritation
PPE-005	Glove powder-free processing	residual powder and cleanliness	inflammation or tissue contamination
PPE-006	Glove water-leak integrity test	sampling and defect sensitivity	barrier-defective glove accepted
PPE-007	Sterile surgical glove packaging	left-right orientation and barrier	aseptic opening contaminated
PPE-008	Surgical mask filtration efficiency	particle size and test conditions	poor respiratory barrier performance
PPE-009	Surgical mask breathability	pressure differential and fit	wearer intolerance / leakage
PPE-010	Surgical mask ultrasonic weld	ear loop tensile strength	mask loosens during procedure
PPE-011	N95/FFP respirator filter media	filter efficiency and face seal	respiratory exposure despite PPE
PPE-012	Respirator nose clip/strap	seal geometry and durability	poor face fit
PPE-013	Protective gown seam strength	liquid barrier and seam closure	blood/fluid penetration
PPE-014	Protective face shield optics	clarity, fogging and splash coverage	vision reduction or exposure
PPE-015	Protective drape sterile field barrier	fabric defects and aseptic presentation	infection barrier breached

Suggested methods: Product safety / barrier FMEA

Potential device stream(s): DISPOSABLE;WOUND;SURGICAL

17 | MEDICAL IMAGING, MONITORING & DIAGNOSTICS

25 distinct assessment topics • 75 proposed scenario prompts in companion workbook

Purpose: Evaluate each listed equipment/activity for the applicable device model, intended use, patient hazard, preventive controls and objective evidence. Mark nonapplicable topics with rationale.

Topic ID	Equipment / process / activity	Critical parameter / control point	Possible patient / safety effect
IMAGING-001	Ultrasound transducer acoustic output	thermal/mechanical indices and controls	tissue heating or injury
IMAGING-002	Ultrasound transducer array integrity	dead elements and beam quality	missed clinical structure
IMAGING-003	Ultrasound probe cable insulation	patient isolation and fluid ingress	shock or inadequate image
IMAGING-004	Ultrasound gel/probe compatibility	chemical degradation and cleaning	infection or equipment failure
IMAGING-005	X-ray generator exposure control	kVp/mAs accuracy and exposure interlocks	unnecessary radiation dose
IMAGING-006	X-ray image detector uniformity	calibration and defective pixel correction	diagnostic lesion missed
IMAGING-007	X-ray collimation and shielding	beam area and leakage radiation	radiation exposure outside target
IMAGING-008	Radiography operator emergency stop	exposure stop and fail-safe action	continued unintended irradiation
IMAGING-009	CT scanner dose modulation	algorithm settings and patient characteristics	excessive patient radiation
IMAGING-010	CT scanner gantry motion interlocks	collision detection and limits	patient impact injury
IMAGING-011	MRI-compatible accessory screening	ferromagnetic materials and labeling	projectile or RF burn
IMAGING-012	MRI patient temperature management	SAR controls and thermal monitoring	heating injury
IMAGING-013	ECG lead-wire connector compatibility	misconnection and patient applied part	wrong reading or shock
IMAGING-014	ECG signal filtering algorithms	artifact and ST segment preservation	ischemia signal not recognized
IMAGING-015	ECG heart rate alarm setting	limits, reset and alarm routing	arrhythmia response delayed
IMAGING-016	Pulse oximeter calibration populations	skin pigmentation, perfusion and motion	hypoxemia under-recognized
IMAGING-017	Pulse oximeter probe optical path	ambient light and sensor displacement	false oxygen saturation
IMAGING-018	NIBP cuff/pressure sensor	cuff size and sensor range	incorrect blood pressure reading
IMAGING-019	Continuous patient monitoring central station	network availability and patient mapping	critical alarm displayed for wrong patient
IMAGING-020	Bedside multiparameter monitor alarm delay	latency, priority and silence	clinical emergency missed
IMAGING-021	Fetal monitor transducer placement	signal dropout and maternal/foetal separation	fetal distress not detected
IMAGING-022	EEG electrode signal artifact	contact impedance and filtering	neurological event not recognized
IMAGING-023	Thermal imaging patient measurement	emissivity and calibration	fever incorrectly assessed
IMAGING-024	PACS / imaging transfer system	image-patient identifier and compression	wrong image used for diagnosis
IMAGING-025	DICOM interface conformance	metadata, orientation and pixel mapping	diagnostic image misinterpreted

Suggested methods: System hazard / functional FMEA

Potential device stream(s): ACTIVE;MONITOR;THERAPY

18 | METALWORKING, ORTHOPEDICS & DENTAL

30 distinct assessment topics • 90 proposed scenario prompts in companion workbook

Purpose: Evaluate each listed equipment/activity for the applicable device model, intended use, patient hazard, preventive controls and objective evidence. Mark nonapplicable topics with rationale.

Topic ID	Equipment / process / activity	Critical parameter / control point	Possible patient / safety effect
MT-001	Medical-grade metal material certificate	alloy grade, composition and melt traceability	wrong alloy corrodes or fractures
MT-002	Material segregation by alloy	separation of titanium, SS and cobalt chromium	material mix-up in implant
MT-003	CNC turning of implant	diameters, surface finish and tool wear	component fails fit or strength
MT-004	CNC milling of orthopedic component	feature position, depth and burrs	implant misfit or injury
MT-005	Electrical discharge machining	recast layer and surface damage	fatigue initiation and fracture
MT-006	Laser cutting of stent/tube	kerf quality, heat-affected zone	strut fracture or sharp edge
MT-007	Laser welding metal components	weld integrity and porosity	detachment under clinical load
MT-008	Metal forging	grain flow, defects and temperature	fatigue strength compromised
MT-009	Metal stamping / punching	edge burr and dimensional repeatability	cutting injury or assembly misfit
MT-010	Metal deep drawing	wall thickness and residual stress	rupture under load
MT-011	Wire drawing and annealing	diameter, surface roughness and tensile strength	needle / guidewire fracture
MT-012	Guidewire tip joining	flexibility gradient and pull strength	distal tip detaches
MT-013	Orthopedic screw threading	pitch, major/minor diameter and burr	screw strips or fractures
MT-014	Implant press fitting	fit interference and cold-work	stress crack or migration
MT-015	Deburring and polishing	surface defects and retained particles	tissue damage / particles
MT-016	Electropolishing	electrolyte residue, metal dissolution and surface	corrosion or toxic exposure
MT-017	Passivation	acid chemistry, dwell and rinse	pitting corrosion in patient
MT-018	Anodizing implant surfaces	coating thickness, porosity and adhesion	coating release or wear
MT-019	Surface roughening / blasting	media contamination and microcracks	particles or fatigue cracks
MT-020	Hydroxyapatite / porous coating	bond strength and porosity	delamination and inflammation
MT-021	Ceramic coating application	coating thickness and cracking	abrasive particles in joint
MT-022	Implant cleanroom transfer	handling, fiber shedding and residues	patient inflammation or infection
MT-023	Ultrasonic metal cleaning	detergent, cavitation and rinse quality	residual machining fluid remains
MT-024	Critical metallic dimensions	CMM programme and gauge uncertainty	malfit of implant geometry
MT-025	Fatigue verification for implants	load spectrum and sample rationale	early mechanical fracture
MT-026	Wear simulation of bearings	particle generation and tribology	osteolysis and implant failure
MT-027	Corrosion and galvanic compatibility	alloy combinations and electrolytes	implant release and revision surgery
MT-028	Bone-contact surface roughness	Ra/Rz and topography	poor osseointegration or loosening
MT-029	Surgical instrument cutting edges	sharpness, hardness and edge stability	tissue trauma or instrument failure
MT-030	Dental implant abutment fit	microgap and torque retention	infection or screw loosening

Suggested methods: Process FMEA / material risk

Potential device stream(s): ORTHO;IMPLANT;SURGICAL;DENTAL

19 | MICROBIOLOGY / CLEANLINESS QC

20 distinct assessment topics • 60 proposed scenario prompts in companion workbook

Purpose: Evaluate each listed equipment/activity for the applicable device model, intended use, patient hazard, preventive controls and objective evidence. Mark nonapplicable topics with rationale.

Topic ID	Equipment / process / activity	Critical parameter / control point	Possible patient / safety effect
MIC-001	Bioburden recovery efficiency	extraction method and organism recovery	microbial load undercounted
MIC-002	Bioburden sampling locations	worst case device construction	hidden contaminated surfaces missed
MIC-003	Bioburden growth media suitability	organism growth and incubation	false negative result
MIC-004	Microbial identification and trending	recurring organisms and excursion response	persistent contamination source missed
MIC-005	Environmental viable air sampling	volume, placement and equipment	unrepresentative room monitoring
MIC-006	Environmental settle plates	exposure location and time	aerosol fall-out underestimated
MIC-007	Surface contact plates and swabs	recovery and selected sites	high-risk surfaces not evaluated
MIC-008	Personnel glove and gown monitoring	sampling timing and limits	operator source not identified
MIC-009	Environmental particle counting	instrument calibration and monitoring condition	cleanroom status falsely accepted
MIC-010	Product cleanliness / particulate count	nonvolatile residues and particle size	patient inflammatory or embolic reaction
MIC-011	Endotoxin testing LAL/rFC	inhibition/enhancement and suitability	false low endotoxin release
MIC-012	Endotoxin limits determination	device route and patient exposure	limit not appropriate to clinical use
MIC-013	Sterility test in-process handling	aseptic technique and controls	false positive / negative results
MIC-014	Sterility test method suitability	bacteriostasis and fungistasis	inhibitory product masks survivors
MIC-015	Water microbial monitoring	sample point and stagnation	biofilm contamination in cleaning
MIC-016	Cleaning validation microbial acceptance	worst-case surfaces and residues	post-clean device contaminated
MIC-017	Culture media growth promotion	qualified media lots	failing media used in QC
MIC-018	Incubator mapping / alarm	temperature uniformity and excursions	invalid microbial incubation
MIC-019	Microbiological lab contamination control	positive controls and segregated zones	invalid sterility/bioburden findings
MIC-020	Microbial result electronic data integrity	colony records and audit trail	incorrect batch decisions

Suggested methods: Method risk / FMEA

Potential device stream(s): STERILE;IMPLANT;WOUND;IVD

20 | PACKAGING, LABELING & UDI

30 distinct assessment topics • 90 proposed scenario prompts in companion workbook

Purpose: Evaluate each listed equipment/activity for the applicable device model, intended use, patient hazard, preventive controls and objective evidence. Mark nonapplicable topics with rationale.

Topic ID	Equipment / process / activity	Critical parameter / control point	Possible patient / safety effect
PK-001	Packaging material qualification	material identity, permeability and compatibility	device damaged or barrier ineffective
PK-002	Pouch film and Tyvek acceptance	porosity, coat and sealability	microbial barrier failure
PK-003	Tray thermoforming	critical dimensions, corners and thinning	device punctures sterile barrier
PK-004	Blister package mold	pocket fit and device restraint	device damaged in distribution
PK-005	Heat-seal temperature control	temperature and uniformity	weak or burnt seal
PK-006	Heat-seal dwell and pressure	force and dwell time	incomplete seal or channel leak
PK-007	Sealing jaw flatness and wear	seal alignment, contamination and pressure	unsealed sections remain
PK-008	Rotary pouch sealer line speed	contact time and seal quality	sterile barrier breach
PK-009	Ultrasonic package sealing	energy and weld uniformity	leak path at seal
PK-010	Tray lid placement and sealing	lid orientation and peelability	barrier or aseptic opening failure
PK-011	Sealing process IQ/OQ/PQ	worst-case corners and material lots	unvalidated sealing window
PK-012	Seal strength test	sample conditioning and test method	weak seals pass acceptance
PK-013	Dye penetration / bubble leak test	validated leak sensitivity	channels or punctures escape
PK-014	Package visual inspection	creases, foreign matter and seal defects	undetected sterile barrier failures
PK-015	Aseptic presentation usability	controlled opening and device transfer	user contaminates sterile item
PK-016	Distribution simulation ASTM/ISTA	vibration, shock and compression	barrier/device failure in transit
PK-017	Accelerated aging of sterile barrier	material degradation and real-time correlation	barrier fails before labeled shelf-life
PK-018	Real-time aging program	sterile barrier and device performance	unsupported expiry date
PK-019	Carton labeling version	artwork approval and market-specific text	wrong instructions or contraindication
PK-020	Primary pouch labeling	sterility, single-use and storage instructions	unsafe device use
PK-021	UDI-DI and production identifier	GS1/HIBCC or other issuing system validity	field tracing fails
PK-022	UDI scanning verification	barcode readability and data format	wrong or unreadable identity code
PK-023	Serialization and lot linkage	device-to-lot/serial traceability	incomplete recall population
PK-024	Label reconciliation	label roll issuance, destruction and waste	mislabeling between SKUs
PK-025	Variable-data printer qualification	correct serial, date and UDI	wrong identity or expiry printed
PK-026	Print verification cameras	OCR/OCV and fail-safe reject	misprint escapes automated control
PK-027	IFU folding and inclusion	correct language and version in box	device used without correct warnings
PK-028	Pack quantity and accessory checks	count and correct model	incomplete kit reduces treatment
PK-029	Tamper evidence and traceability	seal state and intended use	reused/tampered product undetected
PK-030	Sterile/nonsterile label separation	status and package visual distinction	nonsterile device assumed sterile

Suggested methods: Packaging FMEA / transport risk

Potential device stream(s): ALL

21 | POLYMER, MOULDING & TUBING

28 distinct assessment topics • 84 proposed scenario prompts in companion workbook

Purpose: Evaluate each listed equipment/activity for the applicable device model, intended use, patient hazard, preventive controls and objective evidence. Mark nonapplicable topics with rationale.

Topic ID	Equipment / process / activity	Critical parameter / control point	Possible patient / safety effect
PL-001	Polymer resin identification	grade, lot, colorant and medical-use approvals	wrong polymer causes toxicity or fracture
PL-002	Resin moisture conditioning	drying temperature and time	voids and brittleness
PL-003	Resin regrind content	validated recycled-material ratio	inconsistent properties or contamination
PL-004	Injection molding barrel temperatures	melt stability and degradation	weak / leachable part
PL-005	Mold temperature and cooling	shrinkage, crystallinity and warpage	dimension out of tolerance
PL-006	Injection pressure and hold time	fill, pack and sink marks	incomplete or weak component
PL-007	Mold cavitation and tool wear	cavity-specific dimensional variation	intermittent flash and misfit
PL-008	Molding gate/flash trimming	sharp edge and particulate release	tissue injury or embolic particles
PL-009	Mold release agent residue	agent type, amount and cleaning	patient chemical exposure
PL-010	Insert molding / overmolding	bond integrity and mismatch	component separates in use
PL-011	Microinjection molding	small feature completeness and precision	microscale channel blocked
PL-012	Extruder barrel heat zones	polymer thermal history	tube mechanical weakness
PL-013	Screw speed and melt pressure	diameter consistency and gel formation	catheter flow obstruction
PL-014	Extrusion die alignment	OD / ID concentricity and lumen shape	incorrect flow or kink
PL-015	Tubing wall thickness	laser gauge and puller speed	rupture or occlusion
PL-016	Multi-lumen extrusion	lumen location and continuity	cross-flow or incorrect device channel
PL-017	Braided catheter reinforcement	wire pitch, braid tension and pattern	catheter kinks or collapses
PL-018	Tubing annealing and stress relief	heat/time and stress relaxation	tube shrinks or cracks later
PL-019	Silicone extrusion and curing	crosslink completeness and volatiles	mechanical failure or extractables
PL-020	PVC tube plasticizer control	formulation and leachability	patient chemical exposure
PL-021	TPE weld and compatibility	bond strength and sterilization stability	fluid leak under pressure
PL-022	Balloon blowing / forming	diameter and burst performance	balloon rupture or under-inflation
PL-023	Tip forming / thermal bonding	tip shape and smoothness	vessel trauma
PL-024	Tube laser marking	mark depth and polymer damage	device weakened at marking
PL-025	Particulate washing of polymer parts	water quality and cleanliness	particle entry into patient
PL-026	Polymers under sterilization	dose/heat/EO compatibility	post-sterilization degradation
PL-027	Accelerated aging of polymers	time-temperature assumptions	unexpected late-life cracking
PL-028	Polymer additive migration	plasticizer, stabilizer and extractables	delayed toxicity

Suggested methods: Process FMEA / SPC

Potential device stream(s): DISPOSABLE;CATHETER;IVD;IMPLANT

22 | PRODUCT RISK MANAGEMENT

35 distinct assessment topics • 105 proposed scenario prompts in companion workbook

Purpose: Evaluate each listed equipment/activity for the applicable device model, intended use, patient hazard, preventive controls and objective evidence. Mark nonapplicable topics with rationale.

Topic ID	Equipment / process / activity	Critical parameter / control point	Possible patient / safety effect
RM-001	Device risk management policy	documented risk governance and responsibilities	inconsistent risk acceptability across device families
RM-002	Device-level risk management plan	risk criteria, scope, activities and approvers	significant use and patient risks omitted
RM-003	Defined intended purpose	medical indication and use population	hazards missed for unintended indications
RM-004	User population definition	training, literacy, capabilities and accessibility	unsafe handling or diagnostic interpretation
RM-005	Patient population assumptions	pediatric, elderly, pregnancy and comorbid groups	underestimated harm for vulnerable patients
RM-006	Operating environment definition	home, ambulance, surgery and ICU conditions	unanticipated failure under actual use
RM-007	Reasonably foreseeable misuse	foreseeable abnormal use and user error	patient injury in common misuse sequences
RM-008	Known and foreseeable hazards	energy, biological, chemical, data and usability hazards	incomplete hazard identification
RM-009	Sequences of events to harm	initiating events, safeguards and exposures	probability of harm estimated without causal basis
RM-010	Hazardous situation descriptions	who is exposed and in which context	hazard confused with failure or device defect
RM-011	Benefit versus risk criterion	clinical benefit evidence and residual harm	unsupported acceptance of hazardous product
RM-012	Risk analysis data sources	complaints, literature, similar devices and bench tests	rare but severe events omitted
RM-013	Probability of occurrence of harm	evidence for exposure and progression to injury	misleading risk score without underlying probabilities
RM-014	Severity classification	clinical consequence including delayed diagnosis	underestimation of patient impact
RM-015	Risk acceptability matrix	preapproved objective criteria and escalation	inconsistent acceptance of equivalent risks
RM-016	Risk control hierarchy	inherent safety, protective measures, information	warnings substituted for feasible design controls
RM-017	Risk control implementation	design output traceability and documented proof	controls remain theoretical
RM-018	Risk control verification	verification that mitigation is actually implemented	safety feature missing in delivered device
RM-019	Risk control effectiveness	validation that harm reduction works in real use	control provides false assurance
RM-020	New risks from controls	side effects of safeguards and design changes	mitigation creates new hazardous situation
RM-021	Residual risk analysis	severity and probability after controls	unacceptable remaining risk not recognized
RM-022	Individual residual risk evaluation	each identified hazardous situation	one severe risk hidden by average scoring
RM-023	Overall residual risk evaluation	totality of residual risks and benefit-risk	cumulative risk not accepted on defensible grounds
RM-024	Production information feedback	production escapes, scrap and NC signals	risk estimates not revised after manufacturing issues
RM-025	Post-production information feedback	vigilance, service, complaints and literature	new hazards missed after launch
RM-026	Risk management review/report	completeness and release sign-off	device released without accepted overall residual risk
RM-027	Risk file traceability	hazard to control to V&V and PMS	risk control cannot be proven to operate
RM-028	Risk file version and change control	alignment to drawings, BOM and IFU revision	current device differs from risk assessment
RM-029	Cross-functional risk team competence	clinicians, QA, design, human factors, microbiology	single discipline overlooks important harm paths
RM-030	Risk of lack of clinical data	uncertainty and evidence sufficiency	benefit-risk conclusion overstated
RM-031	Trend thresholds triggering risk review	defined complaint/NC/cybersecurity triggers	weak signals of harm ignored
RM-032	Risk-based family grouping	similarity justification for variants and accessories	unassessed variant inherits inappropriate controls
RM-033	Fault tree top-event selection	patient harm or loss of critical function	top events do not reflect actual patient outcomes
RM-034	Interface hazard analysis	accessories, consumables and external systems	unsafe interaction not addressed
RM-035	Lifecycle decommissioning hazards	battery disposal, disposal and data erasure	harm to users and environment after use

Suggested methods: Risk file / PHA / FTA

Potential device stream(s): ALL

23 | PRODUCTION - NONSTERILE ASSEMBLY

32 distinct assessment topics • 96 proposed scenario prompts in companion workbook

Purpose: Evaluate each listed equipment/activity for the applicable device model, intended use, patient hazard, preventive controls and objective evidence. Mark nonapplicable topics with rationale.

Topic ID	Equipment / process / activity	Critical parameter / control point	Possible patient / safety effect
PM-001	Work order release to line	revision and approved BOM	wrong device variant assembled
PM-002	Line clearance and product changeover	material, label and tool identification	product mix-up between orders
PM-003	Controlled work instruction at station	visual steps and correct parameters	latent assembly defect
PM-004	Incoming kit preparation	part/lot ID and count	unverified component used
PM-005	Manual mechanical assembly	force, alignment and torque	joint fails in clinical use
PM-006	Torque-controlled fastening	calibrated tools and traceability	fasteners loosen or crack
PM-007	Adhesive bonding	mix ratio, cure and bond-area control	joint debonds during use
PM-008	Ultrasonic welding	energy, horn pressure and weld geometry	leaking/weak fused joint
PM-009	Laser welding of assemblies	beam power and seam continuity	weld leak or fracture
PM-010	Heat staking / riveting	depth and temperature	loose or weakened component
PM-011	Press-fit insert assembly	interference and insertion force	cracking or pull-out
PM-012	Snap-fit closure assembly	fit geometry and click confirmation	housing unexpectedly opens
PM-013	O-ring installation	size, damage and lubrication	fluid/gas leakage to patient
PM-014	Gasket seal compression	compression set and dimension	device leakage in service
PM-015	Silicone gasket dispensing	cure, adhesion and contamination	sealing reliability compromised
PM-016	Tubing barbed connection	insertion depth and pull force	tube disconnection during infusion
PM-017	Luer / small-bore connector assembly	lock engagement and dimensional conformity	fluid path disconnection or misconnection
PM-018	Filter element insertion	correct grade and orientation	particle/bacterial ingress
PM-019	Valve assembly and seat setting	cracking pressure and leakage	incorrect fluid flow
PM-020	Needle-to-hub bonding	adhesive cure, bond strength	needle separates from hub
PM-021	Suture needle swaging	swage diameter and pull strength	needle separates under clinical load
PM-022	Balloon catheter folding/wrapping	fold geometry and surface damage	balloon fails to deploy
PM-023	Pump cassette assembly	occlusion and mechanical alignment	over/under-delivery
PM-024	Pump head roller assembly	occlusion and drive tolerance	flow-rate failure
PM-025	Final assembly ESD handling	electrostatic sensitive parts	hidden electronics damage
PM-026	Operator visual inspection	trained defect limits and lighting	critical defect accepted
PM-027	In-process dimensional inspection	sample plan and gauge suitability	out-of-tolerance part continues
PM-028	Automated vision inspection	image algorithm and false-negative rate	visual defect escapes automated test
PM-029	End-of-line functional testing	simulation of critical use	unsafe performance escapes
PM-030	Rework / repair decision	approved limits and repeat verification	unqualified rework reaches market
PM-031	Batch/lot reconciliation	issued, rejected and packed quantity	untraceable component mixing
PM-032	Kitting and accessory matching	compatible accessories and language	incompatible kit used

Suggested methods: Process FMEA / control plan

Potential device stream(s): GENERAL;DISPOSABLE;ORTHO;DENTAL

24 | PURCHASE, SUPPLIER & OUTSOURCING

22 distinct assessment topics • 66 proposed scenario prompts in companion workbook

Purpose: Evaluate each listed equipment/activity for the applicable device model, intended use, patient hazard, preventive controls and objective evidence. Mark nonapplicable topics with rationale.

Topic ID	Equipment / process / activity	Critical parameter / control point	Possible patient / safety effect
SUP-001	Supplier criticality classification	risk of supplied item to device	high-risk supplier insufficiently audited
SUP-002	Approved supplier list controls	authorization and ERP master data	unapproved material purchased
SUP-003	Supplier QMS evaluation	relevant processes and ISO13485 evidence	systematic defects from supplier
SUP-004	Supplier process audits	special process controls and capability	supplier variation reaches patient
SUP-005	Supplier quality agreement	change notification, nonconformance and records	unannounced critical specification change
SUP-006	Supplier corrective actions	root cause and effectiveness	repeat component defects
SUP-007	Raw polymer grade purchasing	medical-use resin and composition	incompatible polymer received
SUP-008	Metal alloy certificate verification	chemistry, heat number and traceability	wrong implant material accepted
SUP-009	Electronic component counterfeit protection	authorized channels and traceability	latent electrical device fault
SUP-010	Single source critical part	contingency, capacity and second source	unsafe substitution after shortage
SUP-011	Sterilization supplier qualification	cycle validation and technical responsibilities	outsourced sterilization fails
SUP-012	Biocompatibility test laboratory selection	accreditation, test method and GLP where relevant	unreliable test evidence accepted
SUP-013	Clinical service provider oversight	data completeness and monitoring	clinical harms not captured
SUP-014	Contract manufacturer change control	drawing/software/material revisions	nonconforming outsourced configuration
SUP-015	Software supplier / OSS governance	licence, SBOM and vulnerability intake	known high-severity exploit not addressed
SUP-016	Cloud platform service-level controls	availability, disaster recovery and access	medical data or therapy function compromised
SUP-017	Supplier risk monitoring	scrap, escapes, recalls and delivery risk	deteriorating supplier undetected
SUP-018	Incoming acceptance criteria	CTQ linked to supplier controls	critical component falsely released
SUP-019	Material substitution approval	biocompatibility, sterility and functional impact	non-equivalent device shipped
SUP-020	Supplier business continuity	qualification of alternate plants	unverified alternate supply introduced
SUP-021	Outsourced calibration provider	traceable measurement and uncertainties	incorrect release measurements
SUP-022	Outsourced transport qualification	actual thermal profile and chain of custody	degraded IVD reagents distributed

Suggested methods: Supplier/process FMEA

Potential device stream(s): ALL

25 | QC / TEST & METROLOGY

32 distinct assessment topics • 96 proposed scenario prompts in companion workbook

Purpose: Evaluate each listed equipment/activity for the applicable device model, intended use, patient hazard, preventive controls and objective evidence. Mark nonapplicable topics with rationale.

Topic ID	Equipment / process / activity	Critical parameter / control point	Possible patient / safety effect
QC-001	Test method development and validation	accuracy, precision and relevant range	false acceptance of unsafe device
QC-002	Inspection plan and critical features	drawing CTQ and sample plan	critical characteristic not tested
QC-003	Calibration status and label control	time interval and approved use	wrong measurement used for release
QC-004	Measurement system analysis / GR&R	repeatability, reproducibility and resolution	testing cannot discriminate defects
QC-005	Digital micrometers and calipers	resolution, operator effects and zero	dimensional defects missed
QC-006	Coordinate measuring machine	probe calibration and programme version	false tolerance acceptance
QC-007	Optical profile projector	magnification and edge definition	misread geometry
QC-008	Vision measurement systems	lighting, threshold and lens calibration	edge/burr defects missed
QC-009	Surface roughness tester	filter, stylus and calibration	surface unsuitable for tissue contact
QC-010	Tensile / universal testing machine	load-cell calibration and specimen grip	low strength accepted
QC-011	Compression testing	fixture alignment and repeatability	device collapses under normal load
QC-012	Burst pressure tester	rate, medium and sensor calibration	weak balloon/tube accepted
QC-013	Leak test apparatus	test pressure and leak sensitivity	fluid/air leak escapes
QC-014	Flow-rate test bench	fluid viscosity and pressure simulation	infusion rate error missed
QC-015	Torque tester	fixture alignment and traceable units	fastener failure risk accepted
QC-016	Hardness tester	surface preparation and scale	incorrect implant mechanical properties
QC-017	Electrical safety analyzer	leakage test and ground continuity	electric shock hazard missed
QC-018	ECG / patient simulator	waveform accuracy and configuration	false patient monitoring approval
QC-019	Infusion pump analyzer	measurement accuracy and occlusion simulation	over/under-delivery risk missed
QC-020	Temperature/pressure data loggers	sensor placement, drift and clock	process excursions not detected
QC-021	Balance / microbalance	minimum weighing and daily calibration	wrong assay mass
QC-022	FTIR material identification	library suitability and sample surface	wrong polymer/adhesive accepted
QC-023	HPLC / GC extractables testing	carryover, sensitivity and integration	toxic residue level missed
QC-024	UV/Vis spectrophotometer	wavelength and concentration accuracy	reagent strength error
QC-025	ICP-MS metal release testing	background correction and contamination	corrosion/ion exposure misreported
QC-026	Sterile barrier peel tester	grip speed, angle and specimen width	weak seals pass testing
QC-027	Software-controlled QC rigs	configuration, audit trail and limit integrity	wrong acceptance algorithm releases device
QC-028	Reference standards and certified materials	traceability, storage and expiry	unreliable acceptance measurements
QC-029	Product functional performance test	worst-case configuration and limits	device fails in intended use
QC-030	Environmental reliability chamber	humidity/thermal calibration and spatial uniformity	invalid aging/reliability data
QC-031	Destructive sampling control	lot size and justified sampling fraction	defects not statistically detected
QC-032	QC data audit trail / raw records	original data and revision explanation	unreliable release record

Suggested methods: Test method FMEA / measurement uncertainty

Potential device stream(s): ALL

26 | QUALITY ASSURANCE / QMS

33 distinct assessment topics • 99 proposed scenario prompts in companion workbook

Purpose: Evaluate each listed equipment/activity for the applicable device model, intended use, patient hazard, preventive controls and objective evidence. Mark nonapplicable topics with rationale.

Topic ID	Equipment / process / activity	Critical parameter / control point	Possible patient / safety effect
QA-001	Quality manual and process interaction map	QMS scope, outsourced activities and exclusions	systemic quality gaps
QA-002	Document control of SOPs and forms	revision, approval and point-of-use access	obsolete work method used
QA-003	Record retention policy	product lifetime and market obligation	loss of traceability and conformity evidence
QA-004	Device master file / medical device file	specifications, production, labels and servicing records	unclear approved device configuration
QA-005	Device history records / lot records	actual production, inspections and operator identity	defective lot not traceable
QA-006	Management review	PMS, nonconformities, objectives and resources	persistent hazards not escalated
QA-007	Internal audit programme	risk-based scope and auditor independence	critical process gap remains undetected
QA-008	CAPA initiation and prioritization	patient harm and systemic recurrence	harmful nonconformity persists
QA-009	CAPA root cause verification	causal mechanism and contributing factors	superficial corrective action recurs
QA-010	CAPA effectiveness confirmation	objective test and monitoring interval	ineffective risk reduction closed prematurely
QA-011	Nonconforming product control	segregation, concession, rework and scrap	out-of-spec product released
QA-012	Deviation assessment	unplanned production/inspection variation	change to safety controls unnoticed
QA-013	Product release and acceptance authority	review of required acceptance records	nonconforming device reaches patient
QA-014	Change control review	design, manufacturing, supplier and regulatory impact	risk file and technical documentation not updated
QA-015	Risk-based complaint escalation	serious incident indicators and review time	reportable event not recognized
QA-016	Traceability and UDI governance	UDI-DI/PI, serial/lot links to distribution	field correction unable to locate devices
QA-017	Critical supplier oversight	quality agreements and audit findings	supplier escape reaches assembly
QA-018	Calibration and metrology oversight	critical measurement traceability	false release results
QA-019	Training system	role competence and effectiveness	operator introduces latent error
QA-020	Cleanroom and microbial risk oversight	EM, bioburden and critical changes	sterile assurance breach not escalated
QA-021	Statistical sampling policy	AQL/acceptance criteria linked to harm	critical defect hidden by inappropriate sampling
QA-022	Outsourced process control	sterilization, testing, machining and software	key risks delegated without oversight
QA-023	Risk-based quality metrics	complaints, FPY, NCR, supplier escapes	degrading patient safety overlooked
QA-024	Regulatory inspection commitments	observation responses and closure evidence	repeat major compliance findings
QA-025	Customer technical and quality agreements	change notices and responsibilities	ambiguous field action ownership
QA-026	Product configuration release	drawings, BOM, software, package and labeling versions	mixed configuration shipped
QA-027	Shelf-life and labeling claim governance	validated claims versus marketed text	expired or unsupported product use
QA-028	Feedback and advisory notices	feedback capture and vigilance linkage	harm signals not handled promptly
QA-029	Returned goods / field-return evaluation	tampering, contamination and investigation integrity	hazardous device reintroduced
QA-030	Reprocessing / rework authorization	validated instructions and retest requirements	reworked device performance compromised
QA-031	Device-specific checklist review	risk control measures actually released	pre-release checks omit critical safety feature
QA-032	Complaint trend and signal detection	statistical action levels by device family	increasing serious incidents undetected
QA-033	Quality culture and escalation	speak-up safety, independent QA authority	deviations concealed under production pressure

Suggested methods: Process FMEA

Potential device stream(s): ALL

27 | REGULATORY AFFAIRS & MARKET ACCESS

25 distinct assessment topics • 75 proposed scenario prompts in companion workbook

Purpose: Evaluate each listed equipment/activity for the applicable device model, intended use, patient hazard, preventive controls and objective evidence. Mark nonapplicable topics with rationale.

Topic ID	Equipment / process / activity	Critical parameter / control point	Possible patient / safety effect
REG-001	Device intended purpose claims	medical indication and promotional wording	unlicensed or unsafe use
REG-002	Device classification by market	risk class, classification rule and rationale	incorrect conformity assessment route
REG-003	India licence/exemption determination	MDR 2017 schedule and applicable amendments	manufacture or import without required authorization
REG-004	US FDA product code and pathway	510(k), De Novo, PMA or exemption logic	incorrect premarket route
REG-005	EU MDR conformity route	Class I/IIa/IIb/III and notified body scope	CE marking without appropriate assessment
REG-006	EU IVDR pathway	IVD class A/B/C/D and conformity evidence	insufficient diagnostic performance dossier
REG-007	UK market route	GB versus NI, UK MDR and transitional provisions	misleading certification or registration
REG-008	Australian ARTG pathway	classification and sponsor/evidence obligations	nonconforming product supplied
REG-009	GSPR essential requirements checklist	linked technical evidence for each requirement	unproven safety and performance
REG-010	Technical documentation version control	risk, V&V, CER/PER, PMS alignment	nonconformity in technical file
REG-011	Authorized representative / importer obligations	economic operator role and agreements	field safety notifications delayed
REG-012	UDI regulatory data and registration	Basic UDI-DI and appropriate device IDs	device cannot be tracked across markets
REG-013	Device listings and establishment registrations	site, model and market details	unregistered product distribution
REG-014	Declaration of conformity	approved scope, standards and signatures	invalid marketing declaration
REG-015	Notified body change / certification cycle	scope, expiry and substantial changes	lapse or invalid certification
REG-016	Vigilance and serious incident rules	reportability, time frames and geographic scope	regulatory non-reporting of harm
REG-017	FSCA / recall regulatory notices	field safety notice and authority communication	unsafe product remains in use
REG-018	Clinical evaluation report lifecycle	current state of art and benefit-risk evidence	unsupported clinical performance
REG-019	Post-market clinical follow-up	PMS-generated clinical evidence gaps	emerging harm or performance drift missed
REG-020	Performance evaluation plan for IVD	scientific validity, analytical/clinical performance	diagnostic claims not substantiated
REG-021	Device-label symbols and language rules	country language and local identifiers	unsafe instructions / mislabeling
REG-022	Promotional claims control	approved labeling and substantiation	off-label recommendation creates harm
REG-023	Changes requiring regulatory approval	assessment of design/sterilization/software changes	unapproved significant changes
REG-024	Device certificate and licence tracking	renewal and authorized scope monitoring	expired authorization overlooked
REG-025	Risk class update monitoring	new classification lists and guidance	incorrect historical class retained

Suggested methods: Compliance gap assessment

Potential device stream(s): ALL

28 | RESPIRATORY, DIALYSIS & CRITICAL-CARE EQUIPMENT

30 distinct assessment topics • 90 proposed scenario prompts in companion workbook

Purpose: Evaluate each listed equipment/activity for the applicable device model, intended use, patient hazard, preventive controls and objective evidence. Mark nonapplicable topics with rationale.

Topic ID	Equipment / process / activity	Critical parameter / control point	Possible patient / safety effect
RESP-001	Ventilator inspiratory pressure sensor	calibration drift and alarm threshold	barotrauma or inadequate ventilation
RESP-002	Ventilator expiratory flow sensor	contamination and accuracy	incorrect tidal volume control
RESP-003	Ventilator oxygen blending valve	FiO2 accuracy and failure position	hypoxia or oxygen toxicity
RESP-004	Ventilator disconnection alarm	response time and fail-safe alarm	unnoticed ventilatory failure
RESP-005	Ventilator battery backup	switchover and duration	therapy failure during power loss
RESP-006	Ventilator humidifier heater	temperature sensor and overtemperature trip	airway thermal injury
RESP-007	Anesthesia machine vaporizer	agent concentration and interlock	anesthetic overdose or awareness
RESP-008	Anesthesia machine gas flowmeters	gas identity and flow accuracy	hypoxic mixture administered
RESP-009	Anesthesia breathing circuit connectors	leak and misconnections	inadequate ventilation
RESP-010	Anesthesia scavenging system	negative pressure and disposal	occupational anesthetic gas exposure
RESP-011	Medical oxygen concentrator	oxygen purity alarm and sieve degradation	insufficient oxygen delivery
RESP-012	Medical oxygen regulator	pressure control and outlet compatibility	overpressure or wrong flow
RESP-013	Nebulizer aerosol generation	droplet size and dose output	underdosing or pulmonary exposure
RESP-014	Infusion pump occlusion alarm	threshold and response time	delayed infusion or overpressure
RESP-015	Infusion pump free-flow prevention	anti-free-flow mechanism and door interlock	uncontrolled medication delivery
RESP-016	Syringe pump drive calibration	pusher speed and travel	incorrect dose or concentration
RESP-017	Syringe pump line identification	channel name and patient mapping	wrong infusion route or rate
RESP-018	Dialysis machine ultrafiltration control	fluid balance accuracy and alarms	hypotension or fluid overload
RESP-019	Dialysis machine conductivity sensor	dialysate concentration and temperature	electrolyte disturbance
RESP-020	Dialysis blood leak detector	sensor response and test performance	blood loss or dialysate contamination
RESP-021	Dialysis dialyzer fiber integrity	membrane leakage and biocompatibility	cross-contamination of blood
RESP-022	Dialysis water treatment	microbial/endotoxin and chemical standards	pyrogen or toxic exposure
RESP-023	Dialysis anticoagulant pump	rate and line integrity	clotting or bleeding
RESP-024	Suction pump vacuum limit	negative pressure and overflow protection	mucosal trauma or loss of suction
RESP-025	CPAP/BiPAP pressure controller	pressure accuracy and mask leakage	ineffective respiratory therapy
RESP-026	CPAP humidifier reservoir	material and cleanability	microbial aerosol exposure
RESP-027	Patient warming blanket control	heat distribution and temperature feedback	thermal burns
RESP-028	Defibrillator energy delivery circuit	charged energy and synchronization	inadequate treatment or myocardial injury
RESP-029	AED arrhythmia detection algorithm	rhythm discrimination and shock advice	inappropriate shock/no-shock
RESP-030	Medical bed actuator and guardrails	limit switches and entrapment zone	patient falls or entrapment

Suggested methods: System hazard / electrical FMEA

Potential device stream(s): ACTIVE;THERAPY;DISPOSABLE

29 | SOFTWARE, SAMD & CYBERSECURITY

37 distinct assessment topics • 111 proposed scenario prompts in companion workbook

Purpose: Evaluate each listed equipment/activity for the applicable device model, intended use, patient hazard, preventive controls and objective evidence. Mark nonapplicable topics with rationale.

Topic ID	Equipment / process / activity	Critical parameter / control point	Possible patient / safety effect
SW-001	Software safety class rationale	classification and hazardous function	insufficient lifecycle controls
SW-002	Software system requirements	complete algorithms and numerical limits	incorrect diagnostic/therapy decision
SW-003	Software architecture modularity	fault isolation and dependencies	single error affects multiple safety features
SW-004	Safety-critical code review	coding standards and independent review	undetected safety defect
SW-005	Static analysis and vulnerability scan	coverage of critical code paths	unsafe implementation not discovered
SW-006	Software unit testing	boundary values and negative paths	edge-case wrong output
SW-007	Software integration testing	interfaces and timing assumptions	unsafe data transfer or state
SW-008	Software system validation	real clinical workflows and end-to-end outputs	incorrect clinical decisions
SW-009	Software configuration management	versioning, build reproducibility and signing	unapproved build installed
SW-010	Software problem resolution process	defect severity and patient risk	known safety defect not addressed
SW-011	Algorithm performance drift	data and operating condition changes	clinical performance degrades
SW-012	AI/ML training data provenance	representative populations and labeling	biased or incorrect predictions
SW-013	AI/ML validation by subgroup	demographic and clinical subgroup performance	higher harm for underrepresented users
SW-014	Algorithm threshold selection	sensitivity, specificity and clinical tradeoffs	misdiagnosis due to poor cutoff
SW-015	False-negative diagnostic alert logic	safe action in error states	dangerous condition unflagged
SW-016	Software alarm/event management	priority, suppression and acknowledgement	critical event lost
SW-017	Time and date synchronization	timestamps and event order	wrong clinical trend interpretation
SW-018	Network availability / offline mode	safe degraded operation	therapy interrupted on link loss
SW-019	Cloud-hosted clinical algorithm	availability, integrity and change control	remote update changes performance
SW-020	Access control and authentication	role-based privileges and least access	unauthorized clinical parameter changes
SW-021	Hardcoded credential and debug access	secret management and disablement	device compromise and patient harm
SW-022	Secure software update	signatures, rollback and failed-update recovery	device bricked or malicious update
SW-023	Vulnerability disclosure response	intake, triage, remediation and communication	exploitable device remains in use
SW-024	SBOM and third-party dependencies	component tracking and vulnerability inventory	untracked exploit exposure
SW-025	Encryption of data in motion	transport security and key handling	clinical data altered in transit
SW-026	Encryption of data at rest	local data and cryptographic key lifecycle	patient data exposure and device manipulation
SW-027	Interoperability with hospital systems	HL7/FHIR or device interface specification	wrong patient data or alarm routing
SW-028	Data quality / missing values	input validation and physiologic plausibility	algorithm produces wrong output
SW-029	Patient-device association	positive patient identity binding	clinical result attached to wrong patient
SW-030	Medical data export/import	format, units and rounding	diagnosis based on corrupted measurements
SW-031	Watchdog, fail-safe and recovery	safe state and alarm on software crash	uncontrolled therapy output
SW-032	Penetration testing	attack surfaces under plausible attacker	unauthorized therapeutic control
SW-033	Security patches and end-of-support	lifecycle maintenance and field deployment	unmitigated high-risk vulnerabilities
SW-034	Remote service access	authorization and session audit	clinical setting changed remotely
SW-035	Software hazard traceability	hazard → requirement → test → released build	critical mitigation omitted
SW-036	Mobile app platform compatibility	OS updates, permissions, device variation	display/connection failure after update
SW-037	Usability of software warnings	clinical comprehension and action	unsafe user response to false confidence

Suggested methods: Software FMEA / threat model / STPA

Potential device stream(s): SAMD;ACTIVE;IVD

30 | STERILE DEVICE ASSEMBLY & CLEANROOMS

28 distinct assessment topics • 84 proposed scenario prompts in companion workbook

Purpose: Evaluate each listed equipment/activity for the applicable device model, intended use, patient hazard, preventive controls and objective evidence. Mark nonapplicable topics with rationale.

Topic ID	Equipment / process / activity	Critical parameter / control point	Possible patient / safety effect
ST-001	Sterile device cleanroom design	risk-based classification and cleanroom layout	uncontrolled microbiological and particle contamination
ST-002	Environmental classification at rest/operation	room particle performance and occupancy	underestimated contamination during actual use
ST-003	HEPA installation and leak testing	filter integrity and air distribution	particle/bioburden ingress
ST-004	Differential room pressure cascade	airflow from clean to less clean	reverse contamination pathway
ST-005	Airflow visualization / smoke studies	protection of product and critical zones	contaminating airflow not discovered
ST-006	Personnel gowning qualification	gowning technique and requalification	operator-borne microbial contamination
ST-007	Cleanroom garment laundering/sterilization	fabric integrity and bioburden	gown sheds fibers or microbes
ST-008	Operator behavior and movement	aseptic working practices and interventions	uncontrolled contamination near product
ST-009	Material transfer airlocks	interlocked doors and decontamination	environmental contamination introduced
ST-010	Material disinfection transfer	validated disinfectant and contact time	bioburden on supplies enters clean area
ST-011	Cleanroom surface disinfection	rotation, concentration and coverage	persistent resistant microorganisms
ST-012	Cleanroom housekeeping frequency	tools, wet cleaning and responsibility	biofilm and particulate buildup
ST-013	Cleanroom trend review	viable/nonviable alerts and interventions	increasing contamination unnoticed
ST-014	Routine viable monitoring	sites, frequency and recoveries	microbial contamination trend missed
ST-015	Non-viable particle monitoring	sample locations, action limits	particle excursions not addressed
ST-016	Critical assembly under laminar airflow	first-air protection and manipulation	product contaminated during assembly
ST-017	Unidirectional flow bench qualification	velocity uniformity and integrity	loss of contamination control
ST-018	Cleanroom operator interventions	planned/unplanned exposure pathways	critical contamination not captured
ST-019	Cleanroom equipment cleaning	niches, inaccessible surfaces and residues	cross-contamination between lots
ST-020	Product contact component handling	sterile/low-bioburden parts and gloves	microbial transfer to sterile device
ST-021	Particle and fiber shedding controls	equipment and packaging surfaces	implant or catheter particulate load
ST-022	Water in cleaning and rinse systems	bioburden, conductivity and endotoxin	pyrogen/contamination remains on device
ST-023	Sterile barrier before sterilization	bioburden load prior to cycle	sterilization challenge exceeds validated condition
ST-024	Aseptic assembly process validation	representative manipulations and conditions	assurance based on unvalidated setup
ST-025	Unplanned cleanroom shutdown	HVAC recovery and materials disposition	exposed product retained after excursion
ST-026	Temperature/humidity critical controls	process/material and bioburden implications	product/process deviates after excursion
ST-027	Sterile device product flow segregation	dirty-to-clean material flow	bioburden recontamination
ST-028	Contamination control strategy for devices	link to device risk and monitoring	disconnected controls leave infection hazard

Suggested methods: Contamination risk analysis / FMEA

Potential device stream(s): STERILE;IMPLANT;DISPOSABLE

31 | STERILIZATION & DECONTAMINATION

30 distinct assessment topics • 90 proposed scenario prompts in companion workbook

Purpose: Evaluate each listed equipment/activity for the applicable device model, intended use, patient hazard, preventive controls and objective evidence. Mark nonapplicable topics with rationale.

Topic ID	Equipment / process / activity	Critical parameter / control point	Possible patient / safety effect
STER-001	Sterilization modality selection	device material, packaging and required SAL	ineffective method selected for device
STER-002	Bioburden method and recovery	representative locations, organisms and recovery	validation understates microbial challenge
STER-003	Bioburden periodic monitoring	lot history and alert limits	bioburden increase exceeds validated state
STER-004	EO preconditioning	humidity, temperature and time	EO penetration insufficient
STER-005	EO gas concentration	chamber concentration and exposure time	inadequate microbial inactivation
STER-006	EO humidity control	microbial resistance and load conditions	sterilization efficacy compromised
STER-007	EO load configuration	worst-case density and aeration access	pockets of unsterilized product
STER-008	EO biological indicators	placement and resistance suitability	sterilization cycle false pass
STER-009	EO parametric/process release	critical parameters and evidence	insufficient exposure accepted
STER-010	EO aeration and residual testing	material sorption and removal time	toxic EO/ECH/Ethylene glycol remains
STER-011	EO abator/off-gas management	gas scrubbing and exposure controls	worker toxic exposure and emissions
STER-012	Gamma irradiation dose mapping	minimum/maximum absorbed dose	underdose or material overexposure
STER-013	Electron beam dose mapping	penetration limits and loading pattern	unsterilized dense areas
STER-014	X-ray sterilization dosimetry	dose uniformity and validated limits	insufficient or excessive dose
STER-015	Radiation dose audit	bioburden trend and verification dose	sterilization claim unsupported
STER-016	Radiation effects on materials	polymer discoloration, brittleness and shelf-life	device fails after sterilization
STER-017	Moist heat sterilizer OQ / PQ	heat distribution and equilibration	cold spot fails sterilization
STER-018	Moist heat load mapping	load configuration and biological challenge	sterilization cycle incomplete
STER-019	Dry heat / depyrogenation where applicable	time-temperature and heat penetration	inadequate thermal challenge
STER-020	Low-temperature plasma sterilization	device compatibility and lumen restrictions	non-sterile product after processing
STER-021	Vaporized H2O2 sterilization	permeation and dwell concentration	device not properly sterilized
STER-022	Sterilization service provider selection	accreditation, quality agreement and changes	contract sterilizer fails process ownership
STER-023	Sterilization load segregation	processed/unprocessed status identification	nonsterile inventory shipped
STER-024	Sterilization batch record review	parameters, monitors and deviation actions	failed cycle erroneously released
STER-025	Re-sterilization policy	effects of repeated cycles	package/device degraded after reprocessing
STER-026	Sterility maintenance handling	post-cycle package integrity	sterility lost before delivery
STER-027	Sterilization validation requalification	periodic and change-triggered review	validated condition no longer representative
STER-028	Sterilization indicator interpretation	BI/CI placement and acceptance	wrong load disposition
STER-029	ISO 11737-2 test suitability	test contamination and method sensitivity	false sterile test confidence
STER-030	Endotoxin control for implants / vascular	limits, assay method and source controls	pyrogenic response despite sterilization

Suggested methods: Sterilization validation / FMEA

Potential device stream(s): STERILE;DISPOSABLE;IMPLANT;SURGICAL

32 | USABILITY & HUMAN FACTORS

20 distinct assessment topics • 60 proposed scenario prompts in companion workbook

Purpose: Evaluate each listed equipment/activity for the applicable device model, intended use, patient hazard, preventive controls and objective evidence. Mark nonapplicable topics with rationale.

Topic ID	Equipment / process / activity	Critical parameter / control point	Possible patient / safety effect
HF-001	User interface hazard analysis	critical tasks and error paths	unsafe user action unaddressed
HF-002	Display legibility and contrast	lighting, vision and language	important alarm or value missed
HF-003	Control knob/button differentiation	shape, color and tactile recognition	wrong function selected
HF-004	Connector and tubing misconnections	physical compatibility and keying	wrong fluid/gas route to patient
HF-005	Alarm volume and priority	hearing and alarm fatigue	operator misses high-priority hazard
HF-006	Alarm silence and reset behavior	duration and persistence	critical fault remains hidden
HF-007	Instructions for use comprehension	plain-language directions and graphics	user misinterprets safe use
HF-008	Home-user onboarding	novice user and caregiver capabilities	incorrect setup causes injury
HF-009	Emergency use scenario	stress, gloves, low light and limited time	critical therapy delayed
HF-010	Use after maintenance	re-commissioning and status confirmation	device used in unsafe state
HF-011	Screen navigation and confirmation	dangerous parameter confirmation	incorrect dosage or mode selection
HF-012	Label location and durability	visibility after wear and cleaning	critical warning lost
HF-013	Color and symbol interpretation	cross-market symbols and color ambiguity	incorrect device function inferred
HF-014	Calibration / zeroing by users	guided workflow and error prompts	incorrect clinical measurement
HF-015	Battery change and charging instructions	charging safety and battery polarity	device shutdown during therapy
HF-016	Cleaning/disinfection instructions	validated reprocessing steps	cross-infection during reuse
HF-017	Consumable replacement workflow	correct part and orientation	wrong consumable causes malfunction
HF-018	Clinical workflow interoperability	handoffs and device placement	care interruption and incorrect response
HF-019	Use of personal protective equipment	glove dexterity and visibility	incorrect operation in clinical PPE
HF-020	Summative validation critical-task coverage	representative user set and scenarios	foreseeable critical use error missed

Suggested methods: Use-related risk analysis / task analysis

Potential device stream(s): ALL;HOME;ACTIVE

33 | VALIDATION & QUALIFICATION

30 distinct assessment topics • 90 proposed scenario prompts in companion workbook

Purpose: Evaluate each listed equipment/activity for the applicable device model, intended use, patient hazard, preventive controls and objective evidence. Mark nonapplicable topics with rationale.

Topic ID	Equipment / process / activity	Critical parameter / control point	Possible patient / safety effect
VAL-001	Validation master plan	risk based scope, ownership and deliverables	critical process not validated
VAL-002	Equipment user requirements	safety and performance critical parameters	wrong machine purchased
VAL-003	Design qualification / design review	critical functional requirements	equipment cannot reliably make conforming device
VAL-004	Factory acceptance testing	representative challenges and exceptions	fault discovered after commissioning
VAL-005	Site acceptance testing	installed utilities and safety interface	unsafe process integration
VAL-006	Installation qualification	as-built components, utilities and calibration	unqualified setup used
VAL-007	Operational qualification	operating parameter edge and alarm limits	process fails outside nominal setting
VAL-008	Performance qualification	normal production, operators and lots	process not reproducible over real conditions
VAL-009	Process validation sample rationale	worst-case, variability and statistical logic	sparse sampling hides failures
VAL-010	Validation of automated assembly	force, time, temperature and interlocks	uncontrolled joint integrity
VAL-011	Validation of laser welding	bond characteristics and pull tests	weld strength not established
VAL-012	Validation of adhesive bonding	mix ratio, dwell and environmental control	latent bond failure
VAL-013	Validation of thermal sealing	seal window, worst-case materials and shifts	sterile barrier fails
VAL-014	Validation of CNC special process	surface and heat-treat outcomes	subsurface defect not detected
VAL-015	Validation of cleanroom operation	occupancy, airflow and recovery	claimed classification not maintained
VAL-016	Sterilization validation ownership	site-to-vendor responsibilities and records	unverified sterility release
VAL-017	Cleaning validation for implant surfaces	residues, particles, microbial load	patient inflammation after implantation
VAL-018	Reprocessing validation	number of cycles, drying and disinfection	cross infection after reuse
VAL-019	Packaging distribution testing	shipment hazard and stacking	sterile barrier damaged in transit
VAL-020	Software validation of QMS system	intended use, records and permissions	GxP records wrongly processed
VAL-021	Spreadsheet formula validation	protected calculations and configuration	wrong QC result or trending
VAL-022	Machine vision algorithm validation	false accept/reject and image conditions	defective product passes
VAL-023	Test method validation/verification	measurement uncertainty and suitability	false conformity decision
VAL-024	Measurement system capability studies	resolution and operator variation	inspection cannot detect critical defect
VAL-025	Hold-time studies of cleaned components	bioburden and particulate growth	cleaned device no longer acceptable
VAL-026	Shelf-life validation	real-time and accelerated evidence	unfounded expiry and degraded performance
VAL-027	Shipping qualification	pack, temperature and excursion effects	damaged or ineffective device
VAL-028	Periodic requalification	changes, wear and process trend	validated state decays unnoticed
VAL-029	Validation deviations closure	scientific impact and retest	unresolved major variation accepted
VAL-030	Traceability matrix for validation	URS to controls to tests	critical control unverified

Suggested methods: Process FMEA / validation risk

Potential device stream(s): ALL

34 | WAREHOUSE, TRANSPORT & DISTRIBUTION

24 distinct assessment topics • 72 proposed scenario prompts in companion workbook

Purpose: Evaluate each listed equipment/activity for the applicable device model, intended use, patient hazard, preventive controls and objective evidence. Mark nonapplicable topics with rationale.

Topic ID	Equipment / process / activity	Critical parameter / control point	Possible patient / safety effect
WH-001	Goods receipt and lot identity	approved supplier, PO and material code	incorrect part enters product
WH-002	Quarantine segregation	status labels and ERP controls	unreleased component used
WH-003	Controlled device component storage	temperature, RH and shelf-life	polymer/adhesive deterioration
WH-004	Cold-chain reagent storage	continuous monitoring and alarm	IVD reagent loses potency
WH-005	Sterile pack storage	sharp edges, stacking and crushing	microbial barrier damaged
WH-006	Device/implant clean components storage	sealed containers and handling	particle contamination prior to assembly
WH-007	FEFO and expiry control	system lot selection and hold	expired consumable shipped
WH-008	Incoming material sampling	representative plan and cross-contamination	substandard component accepted
WH-009	Warehouse bin accuracy	location and part/variant code	product mix-up in picking
WH-010	Kitting and issue reconciliation	lot control and route to production	device traceability gap
WH-011	Returns and field recall segregation	secure holding and disposition	returned unsafe device re-sold
WH-012	Damaged goods classification	inspection and documented disposition	hidden damage after impact
WH-013	Pallet quality and hygiene	broken wood/fiber contamination	device package contaminated
WH-014	Temperature excursion investigation	device-specific evidence and requalification	latent deterioration ignored
WH-015	Data logger qualification	accuracy and measurement positions	unrecognized shipping condition
WH-016	International shipping packaging	vibration, humidity, altitude and stacking	performance/sterile barrier failure
WH-017	Hazardous material storage	flammable adhesives, EO and cylinders	fire/toxic incident
WH-018	Clean/dirty path in logistics	supplier packaging removal and secondary handling	bioburden brought into cleanroom
WH-019	Dispatch serial/UDI record	lot/serial and destination completeness	field safety action traceability failure
WH-020	Distribution agent quality agreement	customer complaints and storage conditions	unsafe handling outsourced
WH-021	Customs and transit holding	environment and delays	short-shelf-life IVD degradation
WH-022	Chain-of-custody for sterile implants	security and authenticity	tampered device accepted
WH-023	Recall simulation lot/serial trace	trace to hospitals and kits	delayed retrieval of unsafe device
WH-024	Inventory cycle counts	reconciliation and false availability	traceability / supply interruption

Suggested methods: Distribution FMEA

Potential device stream(s): ALL

35 | WOUND CARE, DRESSINGS & TEXTILE DEVICES

20 distinct assessment topics • 60 proposed scenario prompts in companion workbook

Purpose: Evaluate each listed equipment/activity for the applicable device model, intended use, patient hazard, preventive controls and objective evidence. Mark nonapplicable topics with rationale.

Topic ID	Equipment / process / activity	Critical parameter / control point	Possible patient / safety effect
TX-001	Cotton/gauze incoming identity	fiber purity and contaminant control	foreign matter or allergy
TX-002	Nonwoven fabric gsm	weight uniformity and absorbency	inadequate barrier or exudate management
TX-003	Nonwoven thermal bonding	bond strength and fiber shedding	barrier failure or particles in wound
TX-004	Surgical drape liquid barrier	fluid penetration and hydrostatic pressure	infection barrier ineffective
TX-005	Gown seam welding	seam continuity and strength	fluid ingress to staff/patient
TX-006	Dressing adhesive coating	coat weight and adhesion	skin trauma or dressing detachment
TX-007	Dressing hydrogel loading	hydration and preservative stability	tissue maceration or ineffective healing
TX-008	Foam dressing pore structure	absorption and retention capacity	exudate leakage and wound deterioration
TX-009	Alginate dressing fiber distribution	material identity and absorption	tissue irritation or poor absorption
TX-010	Antimicrobial dressing active loading	concentration uniformity and leachables	local toxicity or weak antimicrobial effect
TX-011	Absorbable suture tensile retention	strength vs implantation time	wound dehiscence
TX-012	Suture needle swage pull	needle-suture attachment force	needle retention in patient
TX-013	Suture packaging cut length	size/length/needle matching	wrong clinical performance
TX-014	Bandage tensile/elastic behavior	stretch and recovery consistency	excess compression or poor support
TX-015	Surgical cotton linting	particle/fiber release	wound foreign body
TX-016	Dressing sterilization penetration	pack configuration and bioburden	wound contamination
TX-017	Barrier peel performance	controlled opening without shedding	aseptic presentation breach
TX-018	Textile laundering / reusable barrier life	number of validated cycles	loss of fluid barrier effectiveness
TX-019	Dressing shelf-life adhesive performance	aging and storage humidity	skin injury or detachment
TX-020	Wound contact biocompatibility	prolonged tissue contact effects	local inflammation

Suggested methods: Process FMEA / bioburden risk

Potential device stream(s): WOUND;DISPOSABLE;SURGICAL

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EUROPEAN MEDICAL DEVICE SERVICES

ISO 13485 quality management system implementation; ISO 14971 device risk-management files; EU MDR / IVDR technical documentation and regulatory strategy; clinical/performance evaluation support; sterile and nonsterile manufacturing facility design; cleanrooms, assembly, process and sterilization validation; equipment qualification; global QMS, audits, CAPA and turnkey implementation consultancy.

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Important notice: This is a reference inventory for site/device risk screening. No claim of conformity, approval or endorsement by FDA, EU authorities, CDSCO, MHRA, TGA or ISO is intended. Device manufacturers remain responsible for applicability determinations, risk acceptance and regulatory compliance.