GLOBAL GMP DOCUMENTATION | API • INTERMEDIATES • FORMULATIONS • STERILE & NON-STERILE

COMPREHENSIVE SOP MASTER LIST

Pharmaceutical manufacturing facilities — multi-department and dosage-form-specific register

For chemical/API intermediates, active pharmaceutical ingredients, tablets, capsules, ointments/creams/gels, syrups/oral liquids, oral dry powders, liquid injections, sterile powders, vials, ampoules and lyophilized products.

SOP REGISTER	DEPARTMENTS	DOCUMENT TYPE	ISSUE DATE
1224	21	MASTER INDEX	04 NOV 2026

Prepared by ISHA'S GMP CONSULTANCY PRIVATE LIMITED • Ensuring Global GMP Compliance

Chennai, India | +91 86675 89984 | info@ishasgmp.com | www.ishasgmp.com

DOCUMENT STATUS: Illustrative global master index for controlled, site-specific SOP authoring and gap assessment. This is not a set of 1,224 approved full SOP procedures.

01 Document control & scope

Purpose

Establish a risk-based, filterable and department-wise inventory of SOPs expected for an integrated API/intermediates and formulation site. Each title represents a proposed controlled procedure to draft, review, approve, train, implement and periodically review.

Manufacturing scope

Chemical synthetic APIs/intermediates; conditional fermentation/bioprocess API routes; oral solids; topical preparations; oral liquids/dry powders; sterile liquid and dry powder injectables, vials, ampoules and lyophilized injections.

Regulatory intent

Map core QA, production, laboratory, warehousing and utility controls against current US FDA 21 CFR 210/211, EU GMP Volume 4 (Part I/II, appropriate annexes), MHRA UK GMP, TGA/PIC/S GMP, WHO GMP and revised India Schedule M. Map electronic signatures where 21 CFR Part 11 applies.

India clinical rules

Schedule Y is NOT a substitute for revised Schedule M. New Drugs and Clinical Trials Rules 2019 and applicable amendments govern relevant new/investigational/clinical activities; assess Schedule Y references only when still legally applicable.

API starting point

For API/intermediate manufacture determine where GMP begins under ICH Q7 / EU Part II based on the defined starting material and processing stage; do not assume full drug product Part I applies identically to all early intermediates.

Sterile distinction

Apply a specific contamination control strategy and EU GMP Annex 1 for sterile product pathways. Aseptic processing, terminal sterilization, lyophilization and sterile powder filling require distinct procedures and validation.

Implementation

P1 = critical baseline / early implementation; P2 = specialized, conditional or lifecycle procedure. Applicability text is a selection aid and is not by itself a legal determination; final SOP list requires a process/market/site gap assessment.

Forms and records

A procedure normally requires a controlled SOP plus supporting forms, logs, protocols, master records or reports. The Excel workbook provides an evidence field, status and ownership columns to manage execution.

02 Intended usage & approval workflow

01 Approve the scope of facilities, dosage forms, product families, process steps, utilities, testing and target markets.

02 Select all P1 controls applicable to the manufacturing authorization, GMP starting point, process and patient safety risk.

03 Review conditional P2 items for special technologies, high potency, dedicated facilities, biological routes or unique markets.

04 Assign each SOP an author, reviewer, approver, department, training group, record templates, revision and implementation date.

05 Confirm where a common corporate SOP can serve several departments; do not issue duplicated or contradictory local procedures.

06 Issue approved SOPs before first GMP use, qualify staff, link forms/logbooks, and verify performance in internal / readiness audits.

03 Department summary

DEPARTMENT	SOP COUNT	REGISTER PREFIX
Quality Assurance	135	IGC-QA-
Quality Control – Chemistry	114	IGC-QCC-
Quality Control – Microbiology	53	IGC-QCM-
Validation & Qualification	69	IGC-VAL-
API & Intermediate Production	116	IGC-API-
Oral Solid Dosage Production	63	IGC-OSD-
Topical & Semisolid Production	25	IGC-TOP-
Oral Liquid & Dry Powder Production	40	IGC-OLP-
Sterile & Injectable Production	116	IGC-STR-
Packaging Operations	31	IGC-PKG-
Engineering & Maintenance	65	IGC-ENG-
Utilities & HVAC	45	IGC-UTL-
Warehouse & Stores	48	IGC-WH-
Procurement & Vendor Management	25	IGC-PUR-
Human Resources & Administration	39	IGC-HRA-
Research & Development	73	IGC-RND-
Analytical Development Laboratory	50	IGC-ADL-
Regulatory Affairs	26	IGC-RA-
Computerized Systems & IT	35	IGC-IT-
Environment Health & Safety	46	IGC-EHS-
Senior Management & Governance	10	IGC-MGT-

04 Manufacturing applicability guide

Shared PQS, QA, IT, HR, EHS [ALL]: Applies after product-specific tailoring to all enabled site operations.

API chemical synthesis / recovery [API / INTERMEDIATE]: API GMP starting point, intermediates, reagent charging, solvents, process control and finishing.

API fermentation / bioprocess [API / INTERMEDIATE / CONDITIONAL]: Enable only for approved biotechnology / fermentation processing.

API potent / beta-lactam / cytotoxic [API / INTERMEDIATE / CONDITIONAL]: Enable after dedicated risk, containment and facility assessment.

Tablet production [TABLET]: Wet/dry/direct granulation, compression, coating, IPC and packing.

Capsule production [CAPSULE]: Shell conditioning, encapsulation, capsule IPC and packing.

Ointment / cream / gel [TOPICAL]: Semisolid compounding, homogenization, filling and packaging.

Syrup / suspension / oral solution [ORAL-LIQ]: Oral liquid compounding, testing and filling.

Oral dry powder / dry syrup [ORAL-DRY]: Blending, humidity control, filling and reconstitution labeling.

Liquid sterile injection [STERILE / VIAL / AMPOULE]: WFI, component prep, filling, stopper/seal, sterilization / aseptic route.

Sterile dry powder injectable [STERILE-POWDER]: Sterile API, aseptic powder filling and closure controls.

Lyophilized sterile injection [LYO]: Frozen filled vials, lyophilization cycle, SIP and CCI.

Sterile environment, utility and micro [STERILE / MICRO]: CCS, cleanrooms, environmental monitoring, APS and sterility assurance.

Quality control / ADL [LAB / MICRO / ADL]: Apply testing according to established specifications and installed instruments.

Validation / engineering / utilities [ENGINEERING / UTILITIES]: Equipment and systems according to validated facility scope.

Warehouse and purchase [WAREHOUSE / PURCHASE]: Materials, vendors, storage, distribution and supply chain.

Market-specific regulatory activities [RA / ALL]: Depends on product registrations, intended markets and licences.

05 Primary regulatory reference codes

Use this dictionary to interpret primary regulatory map codes in the register. These are framework anchors, not individual clause-by-clause legal conclusions. Always confirm current local adoption, permit conditions, market authorizations and annex applicability.

CODE	FRAMEWORK / DOCUMENT	PRINCIPAL USE
SCH-M	India — revised Schedule M	Pharmaceutical PQS; premises, equipment; products and APIs as applicable
21CFR211	US FDA — 21 CFR Part 211	Finished dosage-form manufacturing, QC and batch release
21CFR210	US FDA — 21 CFR Part 210	Cross-functional GMP framework
21CFR11	US FDA — 21 CFR Part 11	Electronic systems where Part 11 is applicable
ICH-Q7	ICH Q7 / EU GMP Part II	APIs and relevant GMP stages of intermediates
ICH-Q8	ICH Q8(R2)	Formulation R&D and development lifecycle
ICH-Q9	ICH Q9(R1)	Risk-based decision-making and contamination risk
ICH-Q10	ICH Q10	Lifecycle PQS and management responsibilities
ICH-Q11	ICH Q11	API/intermediate process design and control strategy
ICH-Q2	ICH Q2(R2)	QC/ADL method validation
ICH-Q14	ICH Q14	ADL method design and lifecycle

CODE	FRAMEWORK / DOCUMENT	PRINCIPAL USE
EU-I	EU GMP Volume 4 Part I	Finished pharmaceutical products, PQS and supporting departments
EU-I-Ch1	EU GMP Part I Chapter 1	PQS governance
EU-I-Ch2	EU GMP Part I Chapter 2	Personnel, training and hygiene
EU-I-Ch3	EU GMP Part I Chapter 3	Engineering / premises / utilities
EU-I-Ch5	EU GMP Part I Chapter 5	Manufacturing, materials and packaging
EU-I-Ch6	EU GMP Part I Chapter 6	QC testing / laboratory governance
EU-I-Ch7	EU GMP Part I Chapter 7	Suppliers, contract service oversight
EU-A1	EU GMP Annex 1	Sterile processing, CCS, APS, EM, lyophilizer
EU-A9	EU GMP Annex 9	Topical and oral liquid production
EU-A11	EU GMP Annex 11	GxP computerized and electronic systems
EU-A15	EU GMP Annex 15	Facilities, equipment, processes and cleaning
PIC-S	Australia TGA — PIC/S PE009-17	Australian manufacture including APIs and finished medicines
MHRA	UK MHRA — GMP / UK legislation	UK manufacturing / import operations as applicable
WHO	WHO GMP Compendium	Global / non-sterile / sterile / API guidance as applicable
NDCTR	India — NDCTR 2019	Investigational / clinical-trial materials and approvals
SCHEDULE-Y	India — Schedule Y (historical/specific assessment)	Not the general manufacturing GMP standard; verify legal applicability
EHS-LOCAL	EHS — applicable local legislation	Site-specific approvals and statutory obligations

06 SOP MASTER REGISTER — department-by-department

All 1,224 proposed procedures are listed below. Use the accompanying Excel workbook for filtering, regulatory crosswalk, implementation status, owner, evidence and detailed selection.

QUALITY ASSURANCE | 135 SOPs

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-QA-001	Pharmaceutical quality system (PQS) manual control	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-002	Quality policy, objectives and site quality plan	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-003	Organization chart and GMP responsibility matrix	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-004	Quality unit independence and decision authority	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-005	Site Master File preparation and periodic update	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-006	Quality agreements between legal entities and sites	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-007	Quality governance meeting and escalation management	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-008	Quality risk management (QRM) program	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-009	Risk register creation, scoring, review and archival	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-010	Annual GMP compliance review and improvement plan	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-011	Quality culture and employee reporting channels	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-012	GMP document hierarchy and numbering convention	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-013	Standard operating procedure life-cycle management	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-QA-014	Master document register issuance and reconciliation	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-015	Controlled document drafting, verification and approval	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-016	Document effective-date control and deployment	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-017	Document periodic review and obsolescence	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-018	Distribution, retrieval and destruction of obsolete copies	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-019	Good documentation practices / ALCOA+ controls	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-020	Controlled forms, logbooks and registers management	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-021	Blank form issue, reconciliation and destruction	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-022	GMP record retention and secure archival	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-023	GMP record retrieval and authorized access	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-024	Electronic record versus paper record equivalence review	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-025	Data integrity governance and gap assessment	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-026	Electronic data audit-trail review governance	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-027	Planned deviation approval and risk assessment	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-028	Unplanned deviation initiation and classification	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-029	Critical deviation immediate escalation	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-030	Event chronology and evidence preservation	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-031	Deviation impact assessment for affected batches	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-032	Root cause analysis using 5-Why / fishbone	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-033	Human error investigation and system factors review	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-034	CAPA initiation and action assignment	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-035	CAPA risk-based due-date extension	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-036	CAPA implementation evidence verification	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-037	CAPA effectiveness check and closure	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-038	Recurring deviation and CAPA trend analysis	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-039	Non-conforming material identification and disposition	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-040	Manufacturing incident investigation and batch linkage	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-041	Laboratory OOS notification to QA and decision pathway	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-042	OOT trend investigation governance	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-043	Sterility-test failure escalation and investigation	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-044	Environmental monitoring excursion impact assessment	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-045	Microbial contamination investigation governance	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-046	Mix-up / cross-contamination investigation procedure	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-047	Data-integrity event investigation and remediation	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-048	GMP change control request, categorization and approval	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-049	Change impact evaluation for validation and filings	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-050	Temporary change approval and expiry controls	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-051	Emergency GMP change governance	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-QA-052	Change implementation, training and effectiveness	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-053	Post-change review and formal closure	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-054	Master batch production record authorization	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-055	Master packaging record authorization	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-056	Batch record issue, reconciliation and retrieval	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-057	Manufacturing batch record review checklist	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-058	Laboratory raw data review and release recommendation	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-059	Batch disposition: release, reject, reprocess or hold	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-060	Conditional release / exceptional disposition governance	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-061	Batch rejection and destruction authorization	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-062	Product quality review / annual product review	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-063	API product quality review under ICH Q7	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-064	Management review of product quality trends	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-065	Ongoing process verification and statistical review	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-066	GMP batch-to-batch traceability and genealogy	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-067	Retest-date and expiry-date assignment governance	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-068	Shelf-life extension assessment and approval	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-069	Product transfer and technical change governance	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-070	Commercial batch certification market-specific workflow	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-071	Internal GMP audit master schedule	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-072	Process audit conduct and report issue	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-073	Unannounced / for-cause GMP audit procedure	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-074	Audit finding classification and CAPA tracking	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-075	Regulatory inspection preparedness and response room	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-076	Regulatory inspection conduct and evidence provision	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-077	Regulatory observation response and commitment tracking	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-078	Inspection readiness mock-audit program	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-079	Qualified person / authorized person oversight (where applicable)	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-080	Contract manufacturer quality oversight and audit	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-081	Contract laboratory qualification and quality agreement	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-082	Outsourced GMP service provider risk assessment	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-083	Supplier corrective action request (SCAR)	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-084	Quality complaints receipt, triage and classification	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-085	Complaint sample evaluation and investigation	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-086	Product recall initiation, strategy and execution	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-087	Mock recall challenge and reconciliation	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-088	Field alert / expedited quality defect notification by market	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-089	Quality defect risk assessment for patient impact	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-QA-090	Returned goods quality evaluation and disposition	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-091	Suspected falsified / counterfeit medicine escalation	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-092	Product discontinuation and residual stock control	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-093	Adverse event quality complaint interface with pharmacovigilance	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-094	Site contamination control strategy (CCS) governance	STERILE / NON-STERILE	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-095	Sterile manufacturing CCS periodic assessment	STERILE / NON-STERILE	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-096	Cross-contamination control and segregation strategy	STERILE / NON-STERILE	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-097	Health-based exposure limit / PDE governance	STERILE / NON-STERILE	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-098	Cleaning validation limit and worst-case rationale approval	STERILE / NON-STERILE	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-099	Highly potent / sensitizing substance control strategy	STERILE / NON-STERILE	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-100	Dedicated facilities assessment for special risk products	STERILE / NON-STERILE	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-101	Bioburden / endotoxin control strategy	STERILE / NON-STERILE	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-102	Aseptic process deviation risk escalation	STERILE / NON-STERILE	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-103	Environmental monitoring program approval	STERILE / NON-STERILE	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-104	Aseptic simulation design approval and batch impact governance	STERILE / NON-STERILE	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-105	Sterile filtration integrity failure disposition	STERILE / NON-STERILE	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-106	Media fill failure response and batch risk assessment	STERILE / NON-STERILE	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-107	Sterilization cycle failure batch impact assessment	STERILE / NON-STERILE	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-108	Lyophilization process interruption impact assessment	STERILE / NON-STERILE	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-109	Container closure integrity failure escalation	STERILE / NON-STERILE	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-110	Sterility assurance level (SAL) strategy oversight	STERILE / NON-STERILE	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-111	Contamination control effectiveness metrics	STERILE / NON-STERILE	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-112	Microbial identification / objectionable organism risk review	STERILE / NON-STERILE	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-113	Extractables / leachables control strategy (where applicable)	STERILE / NON-STERILE	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-114	Nitrosamine risk assessment and control program	STERILE / NON-STERILE	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-115	Elemental impurities assessment governance	STERILE / NON-STERILE	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-116	Genotoxic / mutagenic impurity risk assessment governance	STERILE / NON-STERILE	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-117	Line clearance verification and independent check	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-118	Area status labeling and visual control verification	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-119	Dispensing / weighing verification by QA	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-120	Yield and reconciliation investigation criteria	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-121	In-process quality inspection and approval	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-122	Rejected / printed packaging component reconciliation	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-123	Batch sampling plan approval and oversight	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-124	Market-specific label and artwork change approval	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-125	Reconciliation of tamper-evidence and serialization records	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-126	QA oversight of outsourced sterilization	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-127	Real-time temperature excursion quality disposition	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-QA-128	Cold chain excursion investigation and release decision	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-129	Customer notification of quality-related changes	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-130	Data integrity oversight of laboratory computerized systems	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-131	Quality oversight of calibration and maintenance overdue equipment	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-132	Equipment breakdown product impact assessment	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-133	Hold-time excursion product impact assessment	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-134	Cleaning validation failure and re-clean authorization	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10
IGC-QA-135	Regulatory commitment tracking and compliance closure	ALL	P1	EU-I;SCH-M;21CFR211;ICH-Q10

End of Quality Assurance · 135 proposed SOPs

QUALITY CONTROL – CHEMISTRY | 114 SOPs

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-QCC-001	QC laboratory organization, access and independent review	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-002	Sample management: receipt, coding and allocation	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-003	QC specification preparation, approval and revision	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-004	Analytical test procedure issuance and change control	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-005	Sampling plan and sample quantity calculation	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-006	Sampling of raw materials and excipients	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-007	Sampling of packaging and printed packaging materials	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-008	Sampling of in-process intermediates	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-009	Sampling of finished pharmaceutical dosage products	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-010	Sampling of APIs and chemical intermediates	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-011	Composite sampling and representativeness assessment	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-012	Retention / reserve sample storage and inventory	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-013	Reference standards qualification and lifecycle	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-014	Working standard preparation, qualification and requalification	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-015	Volumetric solution preparation and standardization	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-016	Reagents and mobile phase preparation and labeling	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-017	Laboratory chemical inventory and expiry checks	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-018	Laboratory glassware cleaning and segregation	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-019	Laboratory safety in chemical testing rooms	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-020	Analytical weighing and balance checks	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-021	pH meter calibration and routine use	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-022	Conductivity meter calibration and routine use	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-023	HPLC system startup, SST, shutdown and maintenance	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-024	UHPLC system operational controls (where installed)	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-025	GC / headspace GC operating and maintenance procedure	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-026	GC-MS/LC-MS instrument usage (where installed)	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-QCC-027	UV-Visible spectrophotometer operation and verification	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-028	FTIR / ATR spectrometer operation and verification	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-029	Karl Fischer water determination procedure	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-030	Loss-on-drying / moisture analyzer operation	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-031	Dissolution tester operation and qualification checks	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-032	Disintegration tester operation and verification	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-033	Friabilator operation and verification	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-034	Hardness / thickness tester operation and verification	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-035	Melting point apparatus operating procedure	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-036	Polarimeter / refractometer operating procedure	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-037	Particle size analysis by sieve and laser diffraction	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-038	API identity testing and acceptance	API / INTERMEDIATE / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-039	API assay and related substances testing	API / INTERMEDIATE / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-040	API process intermediate specification testing	API / INTERMEDIATE / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-041	Starting-material ID and qualification testing	API / INTERMEDIATE / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-042	API residual solvent testing	API / INTERMEDIATE / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-043	API inorganic / elemental impurity evaluation	API / INTERMEDIATE / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-044	API water content determination	API / INTERMEDIATE / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-045	API polymorph / solid-state form identification	API / INTERMEDIATE / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-046	API crystal habit / morphology characterization	API / INTERMEDIATE / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-047	API particle-size distribution analysis	API / INTERMEDIATE / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-048	API optical purity / chiral impurity determination	API / INTERMEDIATE / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-049	API specific rotation and stereochemical testing	API / INTERMEDIATE / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-050	API heavy metals testing under validated methods	API / INTERMEDIATE / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-051	API bulk density / tapped density testing	API / INTERMEDIATE / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-052	API process filtrate / mother-liquor testing	API / INTERMEDIATE / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-053	API distillation fraction testing and acceptance	API / INTERMEDIATE / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-054	Recovered solvent identification and reuse-release testing	API / INTERMEDIATE / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-055	API catalyst / metal residue testing	API / INTERMEDIATE / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-056	API peroxide content testing where relevant	API / INTERMEDIATE / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-057	API nitrosamine analytical control (where applicable)	API / INTERMEDIATE / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-058	Intermediates hold-time and retest testing	API / INTERMEDIATE / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-059	API microbiological quality testing assignment	API / INTERMEDIATE / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-060	API endotoxin testing where intended use requires	API / INTERMEDIATE / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-061	Tablet appearance and physical dimensions testing	FDF-ALL / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-062	Tablet assay and content uniformity testing	FDF-ALL / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-063	Tablet dissolution profile testing	FDF-ALL / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-064	Tablet disintegration and friability testing	FDF-ALL / LAB	P1	EU-I-Ch6;21CFR211;SCH-M

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-QCC-065	Tablet related substances and degradation products testing	FDF-ALL / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-066	Tablet weight variation and dosage uniformity testing	FDF-ALL / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-067	Capsule shell inspection and moisture determination	FDF-ALL / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-068	Capsule fill weight and content uniformity testing	FDF-ALL / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-069	Capsule dissolution / disintegration testing	FDF-ALL / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-070	Oral powder moisture, density and sieve analysis	FDF-ALL / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-071	Oral powder reconstitution and homogeneity testing	FDF-ALL / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-072	Oral solution / syrup assay and preservative content testing	FDF-ALL / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-073	Syrup pH, viscosity, specific gravity and Brix testing	FDF-ALL / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-074	Oral suspension redispersibility / sedimentation testing	FDF-ALL / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-075	Oral suspension particle-size distribution testing	FDF-ALL / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-076	Semisolid assay and uniformity testing	FDF-ALL / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-077	Ointment viscosity, spreadability and rheology testing	FDF-ALL / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-078	Semisolid pH and preservative content determination	FDF-ALL / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-079	Topical in-vitro release testing where applicable	FDF-ALL / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-080	Injectable assay, impurities and pH testing	FDF-ALL / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-081	Injectable visible particles testing	FDF-ALL / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-082	Injectable subvisible particulate matter testing	FDF-ALL / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-083	Injectable osmolality and extractable volume testing	FDF-ALL / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-084	Lyophilized cake appearance and moisture testing	FDF-ALL / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-085	Lyophilized reconstitution time and clarity testing	FDF-ALL / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-086	Sterile injectable container closure integrity analytical support	FDF-ALL / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-087	Drug product extractables/leachables sample handling	FDF-ALL / LAB	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-088	Analytical sequence planning and sample preparation traceability	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-089	Chromatographic integration and manual integration rules	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-090	Audit trail review of chromatographic data systems	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-091	Laboratory test result second-person verification	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-092	Analytical OOS result Phase I assessment	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-093	Analytical OOS full-scale investigation Phase II	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-094	Out-of-trend (OOT) analytical data investigation	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-095	Invalid laboratory result justification and QA approval	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-096	Retest and resampling decision control	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-097	Analytical data repeatability and uncertainty assessment	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-098	Method verification for compendial methods	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-099	Analytical method validation and lifecycle maintenance	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-100	Method transfer from ADL to routine QC	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-101	Test method equivalence and cross-site comparability	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-102	Stability program design and chamber placement	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-QCC-103	Long-term stability study pull, testing and reporting	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-104	Accelerated stability program control	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-105	Intermediate stability and retest-date support	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-106	Photostability testing and exposure records	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-107	In-use stability and reconstitution stability	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-108	Continued stability / ongoing stability program	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-109	Forced degradation investigation support	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-110	Stability trend, excursion and significant-change review	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-111	Stability chamber alarm assessment and sample disposition	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-112	Analytical instrument qualification and periodic requalification	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-113	Laboratory computer software user access and backup	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M
IGC-QCC-114	QC laboratory data archival and retrieval	LAB / ALL	P1	EU-I-Ch6;21CFR211;SCH-M

End of Quality Control – Chemistry · 114 proposed SOPs

QUALITY CONTROL – MICROBIOLOGY | 53 SOPs

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-QCM-001	Microbiology laboratory zoning and aseptic conduct	MICRO / STERILE / NON-STERILE	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-002	Microbiology analyst gowning and qualification	MICRO / STERILE / NON-STERILE	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-003	Aseptic microbiological sampling technique	MICRO / STERILE / NON-STERILE	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-004	Microbiology equipment cleaning and sanitization	MICRO / STERILE / NON-STERILE	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-005	Microbial culture inventory and traceability	MICRO / STERILE / NON-STERILE	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-006	Culture media purchase and receipt control	MICRO / STERILE / NON-STERILE	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-007	Microbiological media preparation, sterilization and labeling	MICRO / STERILE / NON-STERILE	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-008	Growth promotion test for prepared culture media	MICRO / STERILE / NON-STERILE	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-009	Media storage, shelf life and reconciliation	MICRO / STERILE / NON-STERILE	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-010	Reference microorganism receipt and passage control	MICRO / STERILE / NON-STERILE	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-011	Incubators operation, monitoring and mapping	MICRO / STERILE / NON-STERILE	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-012	Autoclave operation for microbiology sterilization	MICRO / STERILE / NON-STERILE	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-013	Biological indicator usage and result interpretation	MICRO / STERILE / NON-STERILE	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-014	Sterility testing isolator / LAF use and checks	MICRO / STERILE / NON-STERILE	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-015	Microbiology laboratory waste decontamination	MICRO / STERILE / NON-STERILE	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-016	Microbiological result data integrity and review	MICRO / STERILE / NON-STERILE	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-017	Environmental monitoring sample chain of custody	MICRO / STERILE / NON-STERILE	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-018	Raw material bioburden / microbial limits testing	MICRO / ALL	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-019	Purified water total microbial count testing	MICRO / ALL	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-020	Water for injection microbial monitoring	MICRO / ALL	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-021	Bacterial endotoxins test (LAL / recombinant reagent where justified)	MICRO / ALL	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-022	Sterility test method suitability and execution	MICRO / ALL	P1	EU-I-Ch6;EU-A1;SCH-M

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-QCM-023	Sterility test invalidation criteria and investigation	MICRO / ALL	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-024	Microbial enumeration test for nonsterile products	MICRO / ALL	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-025	Tests for specified / objectionable microorganisms	MICRO / ALL	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-026	Preservative efficacy / antimicrobial effectiveness testing	MICRO / ALL	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-027	Bioburden testing of pre-sterilization bulk solution	MICRO / ALL	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-028	Bioburden testing of sterile filter feed	MICRO / ALL	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-029	Microbial identification to appropriate taxonomic level	MICRO / ALL	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-030	Gram stain, biochemical and confirmatory ID	MICRO / ALL	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-031	Endotoxin method inhibition/enhancement suitability	MICRO / ALL	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-032	Microbial cleaning verification / swab recovery	MICRO / ALL	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-033	Compressed gas microbiological testing	MICRO / ALL	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-034	Filter / wet component microbiological testing	MICRO / ALL	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-035	API bioburden assessment where product requires	MICRO / ALL	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-036	Packaging component microbiological quality testing	MICRO / ALL	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-037	Environmental monitoring program risk-based locations	STERILE / MICRO	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-038	Settle plate environmental monitoring	STERILE / MICRO	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-039	Active viable air sampling	STERILE / MICRO	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-040	Surface contact plate monitoring	STERILE / MICRO	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-041	Glove and personnel monitoring	STERILE / MICRO	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-042	Non-viable particle monitoring in classified areas	STERILE / MICRO	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-043	Alert/action limits setting and periodic review	STERILE / MICRO	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-044	EM data trending, identification and escalation	STERILE / MICRO	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-045	Environmental excursion investigation support	STERILE / MICRO	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-046	Aseptic process simulation microbiological assessment	STERILE / MICRO	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-047	Media fill growth promotion and incubation controls	STERILE / MICRO	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-048	Media fill unit reconciliation and contamination investigations	STERILE / MICRO	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-049	Disinfectant efficacy and rotation study	STERILE / MICRO	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-050	Disinfectant expiry / in-use hold time	STERILE / MICRO	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-051	Cleanroom microbiological qualification study	STERILE / MICRO	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-052	Isolator / RABS glove integrity microbiological support	STERILE / MICRO	P1	EU-I-Ch6;EU-A1;SCH-M
IGC-QCM-053	Water system biofilm trend / action response	STERILE / MICRO	P1	EU-I-Ch6;EU-A1;SCH-M

End of Quality Control – Microbiology · 53 proposed SOPs

VALIDATION & QUALIFICATION | 69 SOPs

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-VAL-001	Site Validation Master Plan preparation and maintenance	ALL	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-002	User requirement specification (URS) control	ALL	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-003	Design qualification and traceability matrix	ALL	P1	EU-A15;ICH-Q9;SCH-M

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-VAL-004	Risk assessment for validation and qualification	ALL	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-005	Factory acceptance test (FAT) execution	ALL	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-006	Site acceptance test (SAT) execution	ALL	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-007	Commissioning-to-qualification turnover	ALL	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-008	Installation qualification (IQ) protocol execution	ALL	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-009	Operational qualification (OQ) protocol execution	ALL	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-010	Performance qualification (PQ) protocol execution	ALL	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-011	Validation protocol preparation, review and approval	ALL	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-012	Validation execution incident and deviation management	ALL	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-013	Validation summary report generation and closure	ALL	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-014	Periodic review of validated state	ALL	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-015	Requalification / revalidation trigger assessment	ALL	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-016	Validation change and lifecycle documentation	ALL	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-017	Critical manufacturing equipment qualification	ALL / API / FDF	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-018	Manufacturing process validation lifecycle management	ALL / API / FDF	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-019	Process design / PPQ / continued process verification	ALL / API / FDF	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-020	API process validation and critical step verification	ALL / API / FDF	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-021	Reaction and crystallization process validation	ALL / API / FDF	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-022	API isolation and drying process validation	ALL / API / FDF	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-023	Tablet granulation process validation	ALL / API / FDF	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-024	Tablet compression and coating PPQ	ALL / API / FDF	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-025	Capsule encapsulation process validation	ALL / API / FDF	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-026	Oral liquid compounding and filling PPQ	ALL / API / FDF	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-027	Topical bulk mixing and filling process validation	ALL / API / FDF	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-028	Dry powder blending and filling PPQ	ALL / API / FDF	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-029	Sterile compounding and filling process validation	ALL / API / FDF	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-030	Sterilization process validation / lethality studies	ALL / API / FDF	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-031	Depyrogenation cycle validation	ALL / API / FDF	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-032	Sterilizing-grade filtration validation	ALL / API / FDF	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-033	Sterile filter integrity method validation	ALL / API / FDF	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-034	Aseptic process simulation (APS/media fill) validation	ALL / API / FDF	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-035	Lyophilizer equipment qualification	ALL / API / FDF	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-036	Lyophilization cycle development, PPQ and verification	ALL / API / FDF	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-037	Automatic inspection machine qualification	ALL / API / FDF	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-038	Computerized vision inspection challenge testing	ALL / API / FDF	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-039	Critical cleaning process validation	ALL / API / FDF	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-040	Cleaning validation swab/rinse recovery studies	ALL / API / FDF	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-041	Cleaning validation PDE / HBEL limits establishment	ALL / API / FDF	P1	EU-A15;ICH-Q9;SCH-M

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-VAL-042	Equipment dirty/clean hold time validation	ALL / API / FDF	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-043	Bulk intermediate and formulated product hold-time study	ALL / API / FDF	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-044	Blend uniformity and mixing validation	ALL / API / FDF	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-045	Container closure integrity method validation	ALL / API / FDF	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-046	Primary packaging seal integrity validation	ALL / API / FDF	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-047	Transportation / cold chain qualification	ALL / API / FDF	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-048	Cleanroom classification and qualification	ENGINEERING / STERILE / NON-STERILE	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-049	Cleanroom airflow visualization / smoke studies	ENGINEERING / STERILE / NON-STERILE	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-050	HVAC system IQ/OQ/PQ	ENGINEERING / STERILE / NON-STERILE	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-051	Airflow, differential pressure and recovery-time studies	ENGINEERING / STERILE / NON-STERILE	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-052	HEPA filter integrity testing and certification	ENGINEERING / STERILE / NON-STERILE	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-053	Air change rate and recovery study	ENGINEERING / STERILE / NON-STERILE	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-054	Temperature and relative humidity mapping	ENGINEERING / STERILE / NON-STERILE	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-055	Warehouse / cold-room temperature mapping	ENGINEERING / STERILE / NON-STERILE	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-056	Purified water system validation	ENGINEERING / STERILE / NON-STERILE	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-057	Water-for-injection system qualification	ENGINEERING / STERILE / NON-STERILE	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-058	Clean steam system qualification	ENGINEERING / STERILE / NON-STERILE	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-059	Compressed air and process gas validation	ENGINEERING / STERILE / NON-STERILE	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-060	Sterile gas filtration qualification	ENGINEERING / STERILE / NON-STERILE	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-061	Clean-in-place (CIP) cycle validation	ENGINEERING / STERILE / NON-STERILE	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-062	Steam-in-place (SIP) cycle validation	ENGINEERING / STERILE / NON-STERILE	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-063	Autoclave thermal mapping and load pattern qualification	ENGINEERING / STERILE / NON-STERILE	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-064	Dry-heat oven / tunnel depyrogenation validation	ENGINEERING / STERILE / NON-STERILE	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-065	Wash equipment cleaning-cycle validation	ENGINEERING / STERILE / NON-STERILE	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-066	Aseptic isolator / RABS decontamination validation	ENGINEERING / STERILE / NON-STERILE	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-067	VHP cycle development and biological challenge	ENGINEERING / STERILE / NON-STERILE	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-068	Lyophilizer sterilization / SIP qualification	ENGINEERING / STERILE / NON-STERILE	P1	EU-A15;ICH-Q9;SCH-M
IGC-VAL-069	BMS/EMS system qualification and alarm challenge	ENGINEERING / STERILE / NON-STERILE	P1	EU-A15;ICH-Q9;SCH-M

End of Validation & Qualification · 69 proposed SOPs

API & INTERMEDIATE PRODUCTION | 116 SOPs

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-API-001	API GMP starting point and intermediate classification	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-002	API and intermediate manufacturing flow chart approval	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-003	API master production instruction preparation	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-004	Intermediate master manufacturing record approval	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-005	API batch manufacturing record issue and control	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-006	Campaign production planning and product sequencing	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-API-007	API critical process parameter (CPP) monitoring	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-008	API critical quality attribute (CQA) control	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-009	API process risk assessment and control strategy	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-010	Route of synthesis / raw material specification control	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-011	API material traceability and genealogy management	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-012	API scale-up / tech transfer readiness checklist	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-013	Reprocessing, reworking and recovery authorization	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-014	API retest date and expiry assignment process	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-015	API process yield and theoretical yield reconciliation	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-016	API intermediate hold-time and storage management	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-017	API contract manufacturing process oversight	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-018	API dedicated / multi-product equipment changeover	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-019	API critical manufacturing equipment status labeling	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-020	API production area clearance and housekeeping	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-021	API reaction vessel pre-use inspection	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-022	Reactor charging sequence verification	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-023	Dispensing and charging of liquid raw materials	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-024	Dispensing and charging of solids / powders	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-025	Charging of hazardous / pyrophoric materials where approved	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-026	Closed transfer / vacuum conveying of chemicals	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-027	Reactor inerting and nitrogen blanketing	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-028	Reaction temperature ramp and hold control	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-029	Reaction pressure / vacuum control	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-030	Agitation speed and mixing time control	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-031	Reaction pH control and adjustment	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-032	Reaction progress / in-process testing coordination	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-033	Controlled addition / metered reagent dosing	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-034	Quenching process and reaction termination	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-035	Exothermic reaction hazard and upset response	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-036	Gas evolution / vent scrubber operation	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-037	Hydrogenation process and catalyst charging (where applicable)	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-038	Catalyst removal and filtration control	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-039	Oxidation / reduction reaction monitoring (where applicable)	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-040	Halogenation / hazardous reagent management (where applicable)	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-041	Enzyme-assisted process handling (where applicable)	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-042	Process sampling of reaction mass	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-043	Inert gas purity and oxygen limit verification	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-044	Reactor drain, heel and residue management	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-API-045	Liquid-liquid extraction and phase separation	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-046	Aqueous and organic layer identification / labeling	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-047	API washing and neutralization operation	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-048	Crystallization seeding and supersaturation control	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-049	Crystallization cooling profile execution	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-050	Anti-solvent addition and solvent switch	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-051	Solvent distillation and concentration	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-052	Vacuum distillation and distillation cut control	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-053	Fractional distillation of intermediate mixtures	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-054	Centrifuge loading, spinning and unloading	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-055	Nutsche filtration / ANFD operation	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-056	Filter press operation and cake handling	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-057	Centrifuge / filter cloth integrity and change	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-058	API filter cake washing and endpoint control	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-059	Mother liquor handling and segregation	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-060	API precipitation and pH shift recovery	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-061	Carbon treatment and decolorization filtration	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-062	Chromatographic purification / resin handling where used	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-063	Membrane filtration / ultrafiltration of intermediates	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-064	API extraction from natural materials where used	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-065	API salt formation and conversion control	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-066	API drying end-point and moisture testing	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-067	Vacuum tray dryer loading and operation	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-068	Rotary vacuum dryer / RVD operation	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-069	Agitated filter dryer / ANFD drying operation	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-070	Fluid-bed dryer operation for APIs where used	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-071	Spray drying of APIs / intermediates where used	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-072	Freeze drying of API bulk material where used	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-073	Drying temperature / vacuum / time records	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-074	Residual solvent drying endpoint assessment	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-075	API milling and particle size reduction	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-076	Micronization / jet milling controls	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-077	Delumping and sieving of dried API	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-078	API blending / homogenization operation	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-079	API physical form and polymorph protection	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-080	API powder transfer and closed containment	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-081	API final bulk packing into approved liners	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-082	API drums / containers labeling and sealing	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-API-083	API sampling and bulk release to warehouse	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-084	API packing area clearance and yield reconciliation	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-085	Fresh solvent tank receipt and identification	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-086	Solvent storage tank transfer and identification	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-087	Recovered solvent distillation and collection	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-088	Recovered solvent quarantine and testing request	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-089	Recovered solvent reuse qualification and release	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-090	Mixed solvent / contaminated solvent segregation	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-091	Solvent inventory, mass balance and reconciliation	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-092	Solvent transfer pipeline flushing and status	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-093	Nitrogen system use for flammable solvent transfers	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-094	Solvent recovery plant cleaning / campaign changeover	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-095	Spent catalyst handling and authorized disposal	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-096	Hazardous mother liquor collection and disposal	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-097	Reaction byproduct separation and quality disposition	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-098	Solvent vapour emissions capture and scrubber checks	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-099	Intermediate recovery from mother liquor (where justified)	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-100	API waste / reject material destruction and reconciliation	API / INTERMEDIATE	P1	ICH-Q7;EU-II;SCH-M
IGC-API-101	High potency API containment and closed handling (if applicable)	API / INTERMEDIATE / CONDITIONAL	P2	ICH-Q7;EU-II;SCH-M
IGC-API-102	Potent API equipment decontamination verification (if applicable)	API / INTERMEDIATE / CONDITIONAL	P2	ICH-Q7;EU-II;SCH-M
IGC-API-103	Beta-lactam / sensitizer dedicated-area control (if applicable)	API / INTERMEDIATE / CONDITIONAL	P2	ICH-Q7;EU-II;SCH-M
IGC-API-104	Cytotoxic / hormonal API process segregation (if applicable)	API / INTERMEDIATE / CONDITIONAL	P2	ICH-Q7;EU-II;SCH-M
IGC-API-105	API biocatalysis process handling (if applicable)	API / INTERMEDIATE / CONDITIONAL	P2	ICH-Q7;EU-II;SCH-M
IGC-API-106	Cell bank receipt, storage and traceability (fermentation route)	API / INTERMEDIATE / CONDITIONAL	P2	ICH-Q7;EU-II;SCH-M
IGC-API-107	Seed inoculum preparation (fermentation route)	API / INTERMEDIATE / CONDITIONAL	P2	ICH-Q7;EU-II;SCH-M
IGC-API-108	Fermenter cleaning and sterilization (fermentation route)	API / INTERMEDIATE / CONDITIONAL	P2	ICH-Q7;EU-II;SCH-M
IGC-API-109	Fermentation media preparation and sterilization (fermentation route)	API / INTERMEDIATE / CONDITIONAL	P2	ICH-Q7;EU-II;SCH-M
IGC-API-110	Fermentation inoculation and process control (fermentation route)	API / INTERMEDIATE / CONDITIONAL	P2	ICH-Q7;EU-II;SCH-M
IGC-API-111	Fermentation harvest and cell separation (fermentation route)	API / INTERMEDIATE / CONDITIONAL	P2	ICH-Q7;EU-II;SCH-M
IGC-API-112	Downstream purification / chromatography (bioprocess route)	API / INTERMEDIATE / CONDITIONAL	P2	ICH-Q7;EU-II;SCH-M
IGC-API-113	Bioburden / endotoxin controls for bioprocess API (as applicable)	API / INTERMEDIATE / CONDITIONAL	P2	ICH-Q7;EU-II;SCH-M
IGC-API-114	Recombinant API viral safety strategy (biological route)	API / INTERMEDIATE / CONDITIONAL	P2	ICH-Q7;EU-II;SCH-M
IGC-API-115	API process impurity carryover and purge verification	API / INTERMEDIATE / CONDITIONAL	P2	ICH-Q7;EU-II;SCH-M
IGC-API-116	API nitrosamine control in route of synthesis	API / INTERMEDIATE / CONDITIONAL	P2	ICH-Q7;EU-II;SCH-M

End of API & Intermediate Production · 116 proposed SOPs

ORAL SOLID DOSAGE PRODUCTION | 63 SOPs

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-OSD-001	Oral solid dosage area entry and gowning	OSD / TABLET / CAPSULE	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-002	Oral solid manufacturing campaign planning	OSD / TABLET / CAPSULE	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-003	OSD area / equipment line clearance	OSD / TABLET / CAPSULE	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-004	OSD raw material dispensing and segregation	OSD / TABLET / CAPSULE	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-005	OSD dispensing booth verification and use	OSD / TABLET / CAPSULE	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-006	OSD API and excipient weighing verification	OSD / TABLET / CAPSULE	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-007	OSD material sieving and mesh integrity	OSD / TABLET / CAPSULE	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-008	OSD pre-blend preparation and charge sequence	OSD / TABLET / CAPSULE	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-009	OSD intermediate container identification and traceability	OSD / TABLET / CAPSULE	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-010	OSD in-process sampling and QC dispatch	OSD / TABLET / CAPSULE	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-011	OSD blend and granule storage / hold time	OSD / TABLET / CAPSULE	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-012	OSD process yield and reconciliation	OSD / TABLET / CAPSULE	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-013	OSD airborne dust and containment controls	OSD / TABLET / CAPSULE	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-014	OSD product changeover and cleaning verification	OSD / TABLET / CAPSULE	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-015	OSD manufacturing equipment logbook recording	OSD / TABLET / CAPSULE	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-016	Rapid mixer granulator pre-use inspection	TABLET	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-017	High shear wet granulation operation	TABLET	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-018	Binder solution preparation and filtration	TABLET	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-019	Granulation endpoint determination	TABLET	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-020	Fluid bed granulation and drying operation	TABLET	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-021	Tray drying of wet granules	TABLET	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-022	Loss-on-drying monitoring of granules	TABLET	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-023	Dry granulation by roller compaction	TABLET	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-024	Slugging and dry granule milling (where used)	TABLET	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-025	Wet granule sizing / oscillating granulation	TABLET	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-026	Prelubrication blending operation	TABLET	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-027	Final lubrication blending operation	TABLET	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-028	Blend uniformity sampling and acceptance	TABLET	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-029	Tablet compression machine setup	TABLET	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-030	Tablet tooling / punch / die identification and inspection	TABLET	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-031	Tablet compression startup and first-off approval	TABLET	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-032	Tablet IPC: average weight and weight variation	TABLET	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-033	Tablet IPC: thickness, hardness and friability	TABLET	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-034	Tablet IPC: disintegration and appearance	TABLET	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-035	Tablet defect handling during compression	TABLET	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-036	Tablet metal detection and challenge testing	TABLET	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-037	Deduster operation and monitoring	TABLET	P1	EU-I-Ch5;21CFR211;SCH-M

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-OSD-038	In-process tablet bulk storage and transfer	TABLET	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-039	Film coating solution preparation	TABLET	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-040	Film coating pan / perforated coater operation	TABLET	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-041	Coating spray parameters and process controls	TABLET	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-042	Enteric coating / modified-release coating control	TABLET	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-043	Sugar coating procedure where applicable	TABLET	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-044	Tablet printing / embossing inspection	TABLET	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-045	Tablet coating endpoint and final appearance	TABLET	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-046	Tablet count and bulk container transfer	TABLET	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-047	Empty capsule shell receipt and conditioning	CAPSULE	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-048	Empty capsule shell inspection and segregation	CAPSULE	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-049	Capsule shell storage humidity monitoring	CAPSULE	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-050	Capsule filling machine setup and line clearance	CAPSULE	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-051	Capsule powder / granule filling sequence	CAPSULE	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-052	Capsule pellet / mini-tablet filling control where applicable	CAPSULE	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-053	Capsule fill weight IPC and adjustment	CAPSULE	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-054	Capsule locking / banding / sealing check	CAPSULE	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-055	Capsule separation and rejection handling	CAPSULE	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-056	Capsule polishing and dedusting	CAPSULE	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-057	Capsule metal detector challenge test	CAPSULE	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-058	Capsule appearance and defect inspection	CAPSULE	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-059	Capsule counting and bulk packing	CAPSULE	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-060	Capsule printing quality checks where applicable	CAPSULE	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-061	Capsule split / leakage defect investigation	CAPSULE	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-062	Capsule hopper refill and material identity checks	CAPSULE	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-OSD-063	Capsule filling line yield reconciliation	CAPSULE	P1	EU-I-Ch5;21CFR211;SCH-M

End of Oral Solid Dosage Production · 63 proposed SOPs

TOPICAL & SEMISOLID PRODUCTION | 25 SOPs

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-TOP-001	Topical production area clearance and hygiene	TOPICAL	P1	EU-A9;21CFR211;SCH-M
IGC-TOP-002	Topical active and excipient dispensing	TOPICAL	P1	EU-A9;21CFR211;SCH-M
IGC-TOP-003	Water and oil phase preparation for creams	TOPICAL	P1	EU-A9;21CFR211;SCH-M
IGC-TOP-004	Waxes / fats melting and thermal control	TOPICAL	P1	EU-A9;21CFR211;SCH-M
IGC-TOP-005	Ointment base preparation and filtration	TOPICAL	P1	EU-A9;21CFR211;SCH-M
IGC-TOP-006	Ointment API levigation and incorporation	TOPICAL	P1	EU-A9;21CFR211;SCH-M
IGC-TOP-007	Cream emulsification and homogenization	TOPICAL	P1	EU-A9;21CFR211;SCH-M
IGC-TOP-008	High shear mixer / homogenizer operation	TOPICAL	P1	EU-A9;21CFR211;SCH-M

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-TOP-009	Cooling phase and temperature control	TOPICAL	P1	EU-A9;21CFR211;SCH-M
IGC-TOP-010	Vacuum deaeration / bubble removal	TOPICAL	P1	EU-A9;21CFR211;SCH-M
IGC-TOP-011	Topical gel polymer hydration procedure	TOPICAL	P1	EU-A9;21CFR211;SCH-M
IGC-TOP-012	Gel neutralization and pH adjustment	TOPICAL	P1	EU-A9;21CFR211;SCH-M
IGC-TOP-013	Topical suspension / particle dispersion	TOPICAL	P1	EU-A9;21CFR211;SCH-M
IGC-TOP-014	Topical viscosity and rheology IPC	TOPICAL	P1	EU-A9;21CFR211;SCH-M
IGC-TOP-015	Topical microbial and preservative control	TOPICAL	P1	EU-A9;21CFR211;SCH-M
IGC-TOP-016	Topical bulk product recirculation and transfer	TOPICAL	P1	EU-A9;21CFR211;SCH-M
IGC-TOP-017	Topical homogeneity sampling and evaluation	TOPICAL	P1	EU-A9;21CFR211;SCH-M
IGC-TOP-018	Topical fill weight / net content IPC	TOPICAL	P1	EU-A9;21CFR211;SCH-M
IGC-TOP-019	Tube filling and crimping / sealing operation	TOPICAL	P1	EU-A9;21CFR211;SCH-M
IGC-TOP-020	Laminated tube heat sealing and integrity checks	TOPICAL	P1	EU-A9;21CFR211;SCH-M
IGC-TOP-021	Jar / bottle filling and closure torque checks	TOPICAL	P1	EU-A9;21CFR211;SCH-M
IGC-TOP-022	Topical filling line clearance and reconciliation	TOPICAL	P1	EU-A9;21CFR211;SCH-M
IGC-TOP-023	Topical cleaning for highly viscous materials	TOPICAL	P1	EU-A9;21CFR211;SCH-M
IGC-TOP-024	Topical hold-time / in-use tank management	TOPICAL	P1	EU-A9;21CFR211;SCH-M
IGC-TOP-025	Topical bulk transfer hoses and pumps cleaning	TOPICAL	P1	EU-A9;21CFR211;SCH-M

End of Topical & Semisolid Production · 25 proposed SOPs

ORAL LIQUID & DRY POWDER PRODUCTION | 40 SOPs

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-OLP-001	Oral liquid production room and vessel release	ORAL-LIQ	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-002	Syrup preparation using validated purified water	ORAL-LIQ	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-003	Sugar / sweetener dissolution and syrup filtration	ORAL-LIQ	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-004	Oral solution API dissolution and mixing	ORAL-LIQ	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-005	Preservative solution preparation and addition	ORAL-LIQ	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-006	Flavor / color addition and mixing verification	ORAL-LIQ	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-007	Liquid dosage pH adjustment	ORAL-LIQ	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-008	Liquid bulk filtration and transfer	ORAL-LIQ	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-009	Liquid manufacturing vessel recirculation control	ORAL-LIQ	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-010	Liquid mixing speed, time and temperature IPC	ORAL-LIQ	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-011	Suspension wetting and dispersant preparation	ORAL-LIQ	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-012	Suspension homogenization and particle control	ORAL-LIQ	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-013	Emulsion preparation for oral liquids where applicable	ORAL-LIQ	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-014	Oral liquid viscosity and specific gravity IPC	ORAL-LIQ	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-015	Oral liquid density / Brix controls	ORAL-LIQ	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-016	Oral liquid microbial risk and time-at-temperature control	ORAL-LIQ	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-017	Oral liquid hold time, transfer and tank status	ORAL-LIQ	P1	EU-A9;EU-I-Ch5;SCH-M

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-OLP-018	Oral liquid bottle rinsing and drying	ORAL-LIQ	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-019	Oral liquid bottle filling operation	ORAL-LIQ	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-020	Oral liquid fill volume and net content checks	ORAL-LIQ	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-021	Cap application / torque / tamper seal checks	ORAL-LIQ	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-022	Induction sealing and leak test	ORAL-LIQ	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-023	Oral liquid line cleaning, drying and changeover	ORAL-LIQ	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-024	Syrup / suspension batch yield reconciliation	ORAL-LIQ	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-025	DEG / EG-risk excipient receipt, identity and testing interface	ORAL-LIQ	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-026	Oral dry powder area clearance and dust controls	ORAL-DRY	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-027	Dry powder raw material sieving and charging	ORAL-DRY	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-028	Powder blending sequence and blend uniformity	ORAL-DRY	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-029	Hygroscopic powder humidity exposure control	ORAL-DRY	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-030	Dry powder particle size adjustment and screening	ORAL-DRY	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-031	Dry syrup granulation and drying where required	ORAL-DRY	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-032	Dry syrup powder filling machine operation	ORAL-DRY	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-033	Dry syrup fill weight and container check	ORAL-DRY	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-034	Reconstitution water volume / instruction verification	ORAL-DRY	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-035	Desiccant insertion and reconciliation where applicable	ORAL-DRY	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-036	Powder sachet / stick pack fill-seal operation	ORAL-DRY	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-037	Dry powder bulk hold-time and packaging transfer	ORAL-DRY	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-038	Dry powder machine cleaning and changeover	ORAL-DRY	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-039	Dry powder line metal detector check	ORAL-DRY	P1	EU-A9;EU-I-Ch5;SCH-M
IGC-OLP-040	Powder segregation / caking deviation management	ORAL-DRY	P1	EU-A9;EU-I-Ch5;SCH-M

End of Oral Liquid & Dry Powder Production · 40 proposed SOPs

STERILE & INJECTABLE PRODUCTION | 116 SOPs

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-STR-001	Sterile manufacturing contamination control strategy implementation	STERILE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-002	Sterile area personnel entry, gowning and qualification	STERILE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-003	Aseptic operator initial and periodic qualification	STERILE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-004	Sterile cleanroom Grade A/B/C/D personnel flow	STERILE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-005	Sterile material transfer / airlock and passbox control	STERILE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-006	Cleanroom interventions classification and authorization	STERILE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-007	Aseptic line setup and sterile component handling	STERILE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-008	Unidirectional airflow protection during critical operations	STERILE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-009	Aseptic assembly of sterile filling path	STERILE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-010	Sterile batch campaigning and line clearance	STERILE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-011	Open versus closed processing risk assessment	STERILE	P1	EU-A1;21CFR211;SCH-M

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-STR-012	Aseptic process control of personnel movements	STERILE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-013	Sterile process monitoring and intervention recording	STERILE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-014	Sterile equipment hold time and storage	STERILE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-015	Sterile production daily pre-startup checklist	STERILE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-016	Sterile batch reconciliation and sterile-specific review	STERILE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-017	Sterile vial receipt / defect screening	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-018	Vial washing machine startup and operating controls	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-019	Vial cleaning / final rinse quality monitoring	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-020	Vial depyrogenation tunnel operation	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-021	Vial tunnel heat distribution and cycle monitoring	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-022	Ampoule washing machine operating controls	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-023	Ampoule drying / depyrogenation procedure	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-024	Rubber stopper washing and preparation	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-025	Rubber stopper sterilization load preparation	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-026	Aluminium seal washing / sterilization where indicated	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-027	Sterilizable filling parts preparation and wrapping	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-028	Autoclave load configuration and sterilization	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-029	Steam sterilization cycle monitoring and release	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-030	Dry-heat sterilization cycle monitoring	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-031	SIP of product contact vessels and pipelines	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-032	Sterilizing gas / vent filter integrity check	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-033	Sterile component transfer through classified areas	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-034	Sterile filter receipt, integrity and traceability	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-035	Water for injection point-of-use precheck	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-036	Aseptic solution compounding vessel inspection	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-037	Sterile injectable API dispensing and transfer	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-038	Injectable solution mixing and pH adjustment	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-039	Injectable solution osmolarity / tonicity adjustment	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-040	Nitrogen sparging / inertization of injectable solution	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-041	Pre-filtration of injectable bulk solution	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-042	Sterilizing-grade filter selection and installation	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-043	Sterile filtration pre-use post-sterilization integrity test (PUPSIT) assessment	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-044	Pre-use sterilized filter integrity verification where applicable	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-045	Aseptic sterile filtration through validated system	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-046	Sterile bulk solution bioburden sampling	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-047	Sterile filtration pressure / flow / time monitoring	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-048	Post-use sterile filter integrity test	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-049	Sterile bulk solution hold-time management	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-STR-050	Sterile closed transfer to filling manifold	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-051	Bulk solution temperature / oxidation protection	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-052	Sterile process sampling and IPC	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-053	Liquid vial filling machine setup and challenge	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-054	Vial filling volume / weight IPC	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-055	Aseptic vial filling and stoppering sequence	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-056	Stopper placement and closure defect check	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-057	Aseptic vial capping / crimping controls	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-058	Ampoule filling equipment setup and operation	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-059	Ampoule filling volume / weight IPC	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-060	Ampoule neck sealing / flame sealing parameters	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-061	Ampoule leaker testing and rejection	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-062	Ampoule tip / stem defect inspection	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-063	Vial vacuum / headspace / nitrogen controls where relevant	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-064	Sterile line stoppage and restart controls	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-065	Aseptic interventions during filling and closure	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-066	Fill needle / tubing replacement procedure	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-067	Sterile reject container identification / reconciliation	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-068	Terminal sterilization loading and batch segregation	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-069	Post-terminal sterilization cooling and unload checks	STERILE / VIAL / AMPOULE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-070	Lyophilizer startup and pre-use status check	LYO	P1	EU-A1;21CFR211;SCH-M
IGC-STR-071	Lyophilizer chamber cleaning and sanitization	LYO	P1	EU-A1;21CFR211;SCH-M
IGC-STR-072	Lyophilizer SIP and sterilization readiness	LYO	P1	EU-A1;21CFR211;SCH-M
IGC-STR-073	Lyophilizer vacuum leak testing	LYO	P1	EU-A1;21CFR211;SCH-M
IGC-STR-074	Lyophilizer shelf temperature sensor checks	LYO	P1	EU-A1;21CFR211;SCH-M
IGC-STR-075	Aseptic partial stoppering of filled vials	LYO	P1	EU-A1;21CFR211;SCH-M
IGC-STR-076	Aseptic vial loading into lyophilizer	LYO	P1	EU-A1;21CFR211;SCH-M
IGC-STR-077	Protected loading and unloading interface operation	LYO	P1	EU-A1;21CFR211;SCH-M
IGC-STR-078	Lyophilization recipe / cycle authorization	LYO	P1	EU-A1;21CFR211;SCH-M
IGC-STR-079	Product freezing profile and nucleation control	LYO	P1	EU-A1;21CFR211;SCH-M
IGC-STR-080	Primary drying shelf temperature and chamber pressure	LYO	P1	EU-A1;21CFR211;SCH-M
IGC-STR-081	Secondary drying endpoint and residual moisture controls	LYO	P1	EU-A1;21CFR211;SCH-M
IGC-STR-082	Condenser operation and ice load monitoring	LYO	P1	EU-A1;21CFR211;SCH-M
IGC-STR-083	Chamber pressure control and vacuum pump monitoring	LYO	P1	EU-A1;21CFR211;SCH-M
IGC-STR-084	Lyophilization cycle trend review and intervention	LYO	P1	EU-A1;21CFR211;SCH-M
IGC-STR-085	Lyophilizer stoppering under vacuum / inert gas	LYO	P1	EU-A1;21CFR211;SCH-M
IGC-STR-086	Lyophilized vial unloading and transfer	LYO	P1	EU-A1;21CFR211;SCH-M
IGC-STR-087	Lyophilization process interruption / power failure response	LYO	P1	EU-A1;21CFR211;SCH-M

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-STR-088	Lyophilized cake appearance in-process assessment	LYO	P1	EU-A1;21CFR211;SCH-M
IGC-STR-089	Lyophilizer defrost / condensate removal	LYO	P1	EU-A1;21CFR211;SCH-M
IGC-STR-090	Lyophilizer batch and cycle data archival	LYO	P1	EU-A1;21CFR211;SCH-M
IGC-STR-091	Sterile dry powder API transfer and receiving	STERILE-POWDER	P1	EU-A1;21CFR211;SCH-M
IGC-STR-092	Sterile powder isolator / aseptic booth prechecks	STERILE-POWDER	P1	EU-A1;21CFR211;SCH-M
IGC-STR-093	Sterile powder container opening in critical area	STERILE-POWDER	P1	EU-A1;21CFR211;SCH-M
IGC-STR-094	Sterile powder dispensing and aliquot verification	STERILE-POWDER	P1	EU-A1;21CFR211;SCH-M
IGC-STR-095	Sterile powder filling machine setup and challenge	STERILE-POWDER	P1	EU-A1;21CFR211;SCH-M
IGC-STR-096	Sterile powder fill weight IPC and tolerance control	STERILE-POWDER	P1	EU-A1;21CFR211;SCH-M
IGC-STR-097	Sterile powder vibration / dosing uniformity checks	STERILE-POWDER	P1	EU-A1;21CFR211;SCH-M
IGC-STR-098	Sterile powder stoppering and capping controls	STERILE-POWDER	P1	EU-A1;21CFR211;SCH-M
IGC-STR-099	Sterile powder particulate / visible foreign matter prevention	STERILE-POWDER	P1	EU-A1;21CFR211;SCH-M
IGC-STR-100	Sterile powder powder-path cleaning and sterilization	STERILE-POWDER	P1	EU-A1;21CFR211;SCH-M
IGC-STR-101	Sterile powder environmental monitoring during fill	STERILE-POWDER	P1	EU-A1;21CFR211;SCH-M
IGC-STR-102	Sterile powder container integrity check	STERILE-POWDER	P1	EU-A1;21CFR211;SCH-M
IGC-STR-103	Sterile powder reject handling and reconciliation	STERILE-POWDER	P1	EU-A1;21CFR211;SCH-M
IGC-STR-104	100 percent visual inspection of injectable containers	STERILE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-105	Manual visual inspector training and qualification	STERILE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-106	Manual visual inspection room and light verification	STERILE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-107	Automated visual inspection equipment line startup	STERILE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-108	Automatic inspection reject challenge and performance checks	STERILE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-109	Defect library / defect severity classification	STERILE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-110	Vial / ampoule visible particle rejection criteria	STERILE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-111	Container closure integrity test execution	STERILE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-112	Vial crimp / seal integrity assessment	STERILE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-113	Ampoule seal integrity / leak detection test	STERILE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-114	Sterile unit reconciliation and reject disposition	STERILE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-115	Sterile product particulate trend investigation	STERILE	P1	EU-A1;21CFR211;SCH-M
IGC-STR-116	Sterile product pre-release inspection review	STERILE	P1	EU-A1;21CFR211;SCH-M

End of Sterile & Injectable Production · 116 proposed SOPs

PACKAGING OPERATIONS | 31 SOPs

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-PKG-001	Packaging material receipt-to-line issuance traceability	FDF-ALL / API	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-PKG-002	Packaging master record issue and approval	FDF-ALL / API	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-PKG-003	Primary packaging line clearance	FDF-ALL / API	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-PKG-004	Secondary packaging line clearance	FDF-ALL / API	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-PKG-005	Printed material identity check before line start	FDF-ALL / API	P1	EU-I-Ch5;21CFR211;SCH-M

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-PKG-006	Foil / PVC / PVDC roll issuance and reconciliation	FDF-ALL / API	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-PKG-007	Blister packaging machine setup and operation	FDF-ALL / API	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-PKG-008	Blister seal temperature / pressure / dwell controls	FDF-ALL / API	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-PKG-009	Blister leak testing and online IPC	FDF-ALL / API	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-PKG-010	Strip packaging machine setup and operation	FDF-ALL / API	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-PKG-011	Bottle counting / filling for tablets and capsules	FDF-ALL / API	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-PKG-012	Tablet / capsule desiccant and cotton insertion controls	FDF-ALL / API	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-PKG-013	Bottle cap application and induction seal checks	FDF-ALL / API	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-PKG-014	Bottle labeling and label inspection	FDF-ALL / API	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-PKG-015	Sachet / stick pack line setup and operation	FDF-ALL / API	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-PKG-016	Topical tube / carton packaging linkage	FDF-ALL / API	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-PKG-017	Parenteral vial / ampoule label verification	FDF-ALL / API	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-PKG-018	Sterile serialization / aggregation label reconciliation	FDF-ALL / API	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-PKG-019	Batch coding / expiry printing verification	FDF-ALL / API	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-PKG-020	Packaging vision system / barcode challenge check	FDF-ALL / API	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-PKG-021	Cartoner operation and leaflet insertion verification	FDF-ALL / API	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-PKG-022	Tamper-evident packaging inspection	FDF-ALL / API	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-PKG-023	Line rejects, reworks and scrap segregation	FDF-ALL / API	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-PKG-024	Printed component reconciliation and controlled destruction	FDF-ALL / API	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-PKG-025	Finished pack shipper packing and sealing	FDF-ALL / API	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-PKG-026	Online checkweigher challenge and IPC	FDF-ALL / API	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-PKG-027	Packaging final yield and reconciliation	FDF-ALL / API	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-PKG-028	Artwork proof control and regulatory labeling check	FDF-ALL / API	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-PKG-029	Market-specific leaflet / caution label verification	FDF-ALL / API	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-PKG-030	API / intermediate bulk bagging and drum closure	FDF-ALL / API	P1	EU-I-Ch5;21CFR211;SCH-M
IGC-PKG-031	API container label / seal / tamper evidence check	FDF-ALL / API	P1	EU-I-Ch5;21CFR211;SCH-M

End of Packaging Operations · 31 proposed SOPs

ENGINEERING & MAINTENANCE | 65 SOPs

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-ENG-001	Engineering organization, work request and responsibilities	ENGINEERING / ALL	P1	EU-I-Ch3;SCH-M
IGC-ENG-002	Asset numbering, equipment identification and history files	ENGINEERING / ALL	P1	EU-I-Ch3;SCH-M
IGC-ENG-003	Equipment user requirement specification (URS) preparation	ENGINEERING / ALL	P1	EU-I-Ch3;SCH-M
IGC-ENG-004	Engineering drawing control: P&ID, GA and as-built files	ENGINEERING / ALL	P1	EU-I-Ch3;SCH-M
IGC-ENG-005	Plant equipment installation and commissioning handover	ENGINEERING / ALL	P1	EU-I-Ch3;SCH-M
IGC-ENG-006	Equipment preventive maintenance master plan	ENGINEERING / ALL	P1	EU-I-Ch3;SCH-M
IGC-ENG-007	Maintenance job card issuance and closure	ENGINEERING / ALL	P1	EU-I-Ch3;SCH-M
IGC-ENG-008	Breakdown maintenance response and restoration	ENGINEERING / ALL	P1	EU-I-Ch3;SCH-M

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-ENG-009	Maintenance deviation / quality impact escalation	ENGINEERING / ALL	P1	EU-I-Ch3;SCH-M
IGC-ENG-010	Risk-based maintenance of product contact equipment	ENGINEERING / ALL	P1	EU-I-Ch3;SCH-M
IGC-ENG-011	Maintenance after-hours and emergency callout	ENGINEERING / ALL	P1	EU-I-Ch3;SCH-M
IGC-ENG-012	Equipment lubrication plan and food/pharma grade lubricant control	ENGINEERING / ALL	P1	EU-I-Ch3;SCH-M
IGC-ENG-013	GMP workshop and tools segregation	ENGINEERING / ALL	P1	EU-I-Ch3;SCH-M
IGC-ENG-014	Engineering spare part identification and inventory	ENGINEERING / ALL	P1	EU-I-Ch3;SCH-M
IGC-ENG-015	Critical spare parts min/max controls	ENGINEERING / ALL	P1	EU-I-Ch3;SCH-M
IGC-ENG-016	Engineering contractor entry, permit and GMP oversight	ENGINEERING / ALL	P1	EU-I-Ch3;SCH-M
IGC-ENG-017	Technical change / modification assessment	ENGINEERING / ALL	P1	EU-I-Ch3;SCH-M
IGC-ENG-018	Equipment obsolescence and replacement planning	ENGINEERING / ALL	P1	EU-I-Ch3;SCH-M
IGC-ENG-019	Equipment history card and breakdown trend review	ENGINEERING / ALL	P1	EU-I-Ch3;SCH-M
IGC-ENG-020	Maintenance effectiveness and MTBF/MTTR trend review	ENGINEERING / ALL	P1	EU-I-Ch3;SCH-M
IGC-ENG-021	Pest-proofing and facility fabric maintenance	ENGINEERING / ALL	P1	EU-I-Ch3;SCH-M
IGC-ENG-022	Equipment decommissioning and asset disposal	ENGINEERING / ALL	P1	EU-I-Ch3;SCH-M
IGC-ENG-023	Reactors and pressure vessel inspection maintenance	API / FDF / STERILE	P1	EU-I-Ch3;SCH-M
IGC-ENG-024	Mechanical seals and agitator maintenance	API / FDF / STERILE	P1	EU-I-Ch3;SCH-M
IGC-ENG-025	Centrifuge / ANFD preventive maintenance	API / FDF / STERILE	P1	EU-I-Ch3;SCH-M
IGC-ENG-026	Vacuum dryer preventive maintenance	API / FDF / STERILE	P1	EU-I-Ch3;SCH-M
IGC-ENG-027	Solvent transfer pumps and mechanical seal checks	API / FDF / STERILE	P1	EU-I-Ch3;SCH-M
IGC-ENG-028	Fluid bed processor and granulator maintenance	API / FDF / STERILE	P1	EU-I-Ch3;SCH-M
IGC-ENG-029	Compression machine preventive maintenance	API / FDF / STERILE	P1	EU-I-Ch3;SCH-M
IGC-ENG-030	Punch / die tooling wear and punch cup inspection	API / FDF / STERILE	P1	EU-I-Ch3;SCH-M
IGC-ENG-031	Capsule filling equipment maintenance	API / FDF / STERILE	P1	EU-I-Ch3;SCH-M
IGC-ENG-032	Tablet coating machine preventive maintenance	API / FDF / STERILE	P1	EU-I-Ch3;SCH-M
IGC-ENG-033	Oral liquid tank and transfer pump maintenance	API / FDF / STERILE	P1	EU-I-Ch3;SCH-M
IGC-ENG-034	Topical homogenizer and filling machine maintenance	API / FDF / STERILE	P1	EU-I-Ch3;SCH-M
IGC-ENG-035	Vial / ampoule washing machine preventive maintenance	API / FDF / STERILE	P1	EU-I-Ch3;SCH-M
IGC-ENG-036	Vial depyrogenation tunnel maintenance	API / FDF / STERILE	P1	EU-I-Ch3;SCH-M
IGC-ENG-037	Autoclave preventive maintenance and safety interlocks	API / FDF / STERILE	P1	EU-I-Ch3;SCH-M
IGC-ENG-038	Sterile filling machine preventive maintenance	API / FDF / STERILE	P1	EU-I-Ch3;SCH-M
IGC-ENG-039	Lyophilizer condenser, vacuum and shelf maintenance	API / FDF / STERILE	P1	EU-I-Ch3;SCH-M
IGC-ENG-040	Lyo chamber stopper mechanism maintenance	API / FDF / STERILE	P1	EU-I-Ch3;SCH-M
IGC-ENG-041	Aseptic isolator / RABS maintenance access control	API / FDF / STERILE	P1	EU-I-Ch3;SCH-M
IGC-ENG-042	Sterile filter housing inspection and gasket control	API / FDF / STERILE	P1	EU-I-Ch3;SCH-M
IGC-ENG-043	Labeling / packing machine preventive maintenance	API / FDF / STERILE	P1	EU-I-Ch3;SCH-M
IGC-ENG-044	Metal detector preventive maintenance and challenge support	API / FDF / STERILE	P1	EU-I-Ch3;SCH-M
IGC-ENG-045	Equipment guard, interlock and emergency-stop verification	API / FDF / STERILE	P1	EU-I-Ch3;SCH-M
IGC-ENG-046	Calibration master list and classification	ENGINEERING / LAB	P1	EU-I-Ch3;SCH-M

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-ENG-047	Critical measurement system calibration frequency	ENGINEERING / LAB	P1	EU-I-Ch3;SCH-M
IGC-ENG-048	Calibration traceability to recognized standards	ENGINEERING / LAB	P1	EU-I-Ch3;SCH-M
IGC-ENG-049	Calibration contract laboratory qualification	ENGINEERING / LAB	P1	EU-I-Ch3;SCH-M
IGC-ENG-050	Calibration standard certificate review	ENGINEERING / LAB	P1	EU-I-Ch3;SCH-M
IGC-ENG-051	Balance and load cell calibration support	ENGINEERING / LAB	P1	EU-I-Ch3;SCH-M
IGC-ENG-052	Temperature sensor / RTD / thermocouple calibration	ENGINEERING / LAB	P1	EU-I-Ch3;SCH-M
IGC-ENG-053	Differential pressure transmitter calibration	ENGINEERING / LAB	P1	EU-I-Ch3;SCH-M
IGC-ENG-054	Pressure gauge / vacuum gauge calibration	ENGINEERING / LAB	P1	EU-I-Ch3;SCH-M
IGC-ENG-055	Flow meter and totalizer calibration	ENGINEERING / LAB	P1	EU-I-Ch3;SCH-M
IGC-ENG-056	pH / conductivity online probe calibration	ENGINEERING / LAB	P1	EU-I-Ch3;SCH-M
IGC-ENG-057	Humidity sensor calibration	ENGINEERING / LAB	P1	EU-I-Ch3;SCH-M
IGC-ENG-058	PLC / SCADA data point verification	ENGINEERING / LAB	P1	EU-I-Ch3;SCH-M
IGC-ENG-059	Calibration sticker issuance and tamper controls	ENGINEERING / LAB	P1	EU-I-Ch3;SCH-M
IGC-ENG-060	Out-of-calibration investigation and product impact	ENGINEERING / LAB	P1	EU-I-Ch3;SCH-M
IGC-ENG-061	Calibration overdue equipment lockout	ENGINEERING / LAB	P1	EU-I-Ch3;SCH-M
IGC-ENG-062	Measuring instrument storage and handling	ENGINEERING / LAB	P1	EU-I-Ch3;SCH-M
IGC-ENG-063	Environmental data logger calibration	ENGINEERING / LAB	P1	EU-I-Ch3;SCH-M
IGC-ENG-064	Sterilizer temperature mapping instrument calibration	ENGINEERING / LAB	P1	EU-I-Ch3;SCH-M
IGC-ENG-065	Lyophilizer pressure and temperature sensor calibration	ENGINEERING / LAB	P1	EU-I-Ch3;SCH-M

End of Engineering & Maintenance · 65 proposed SOPs

UTILITIES & HVAC | 45 SOPs

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-UTL-001	Utility system operation and shift logbook	UTILITIES / ALL	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-002	Purified water system operation and distribution	UTILITIES / ALL	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-003	Purified water pretreatment filtration maintenance	UTILITIES / ALL	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-004	Reverse osmosis / EDI operation and sanitization	UTILITIES / ALL	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-005	Purified water loop sanitization and monitoring	UTILITIES / ALL	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-006	Water sampling point disinfection and flushing	UTILITIES / ALL	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-007	Purified water online conductivity and TOC monitoring	UTILITIES / ALL	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-008	Purified water microbial alert / action response	UTILITIES / ALL	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-009	Water system change and requalification impact assessment	UTILITIES / ALL	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-010	Water for injection generation and distribution	UTILITIES / ALL	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-011	WFI storage and hot loop temperature control	UTILITIES / ALL	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-012	WFI sanitization and endotoxin control	UTILITIES / ALL	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-013	Clean steam generator operation and quality control	UTILITIES / ALL	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-014	Plant steam boiler operation and safety checks	UTILITIES / ALL	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-015	Compressed air generation, drying and filtration	UTILITIES / ALL	P1	EU-I-Ch3;EU-A1;SCH-M

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-UTL-016	Compressed air dew point / oil / particle monitoring	UTILITIES / ALL	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-017	Nitrogen generator / supply operation and quality monitoring	UTILITIES / ALL	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-018	Process gas point-of-use filtration and filter checks	UTILITIES / ALL	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-019	Vacuum plant operation and vacuum quality monitoring	UTILITIES / ALL	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-020	CIP skids operation, chemical dosing and documentation	UTILITIES / ALL	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-021	SIP plant operation and cycle control	UTILITIES / ALL	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-022	Heat exchanger inspection and utility cross-leak controls	UTILITIES / ALL	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-023	HVAC air handling unit operation and monitoring	UTILITIES / STERILE / NON-STERILE	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-024	AHU differential pressure / airflow alarm response	UTILITIES / STERILE / NON-STERILE	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-025	HEPA / pre-filter change and certification	UTILITIES / STERILE / NON-STERILE	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-026	AHU filter differential pressure monitoring	UTILITIES / STERILE / NON-STERILE	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-027	Room differential pressure cascade monitoring	UTILITIES / STERILE / NON-STERILE	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-028	Cleanroom temperature and RH monitoring	UTILITIES / STERILE / NON-STERILE	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-029	Cleanroom recovery after power / HVAC failure	UTILITIES / STERILE / NON-STERILE	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-030	HVAC planned shutdown and restart authorization	UTILITIES / STERILE / NON-STERILE	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-031	Unidirectional airflow unit / LAF operation	UTILITIES / STERILE / NON-STERILE	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-032	Airlock / interlock operation and alarm management	UTILITIES / STERILE / NON-STERILE	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-033	Dust extraction / dedusting system operation	UTILITIES / STERILE / NON-STERILE	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-034	API solvent ventilation and local exhaust controls	UTILITIES / STERILE / NON-STERILE	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-035	HVAC requalification and trending schedule	UTILITIES / STERILE / NON-STERILE	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-036	Building management system (BMS) alarm review	UTILITIES / STERILE / NON-STERILE	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-037	Environmental monitoring system (EMS) trending and alarm review	UTILITIES / STERILE / NON-STERILE	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-038	Chilled water plant operation and monitoring	UTILITIES / STERILE / NON-STERILE	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-039	Cooling tower operation and biocide control	UTILITIES / STERILE / NON-STERILE	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-040	Heating hot water and process heat utility monitoring	UTILITIES / STERILE / NON-STERILE	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-041	Diesel generator operation and changeover	UTILITIES / STERILE / NON-STERILE	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-042	UPS system operation, battery maintenance and alarm	UTILITIES / STERILE / NON-STERILE	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-043	Emergency power for aseptic and cold-chain processes	UTILITIES / STERILE / NON-STERILE	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-044	Electrical preventive maintenance / thermography	UTILITIES / STERILE / NON-STERILE	P1	EU-I-Ch3;EU-A1;SCH-M
IGC-UTL-045	Energy management / utility consumption trend	UTILITIES / STERILE / NON-STERILE	P1	EU-I-Ch3;EU-A1;SCH-M

End of Utilities & HVAC · 45 proposed SOPs

WAREHOUSE & STORES | 48 SOPs

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-WH-001	Material receiving and delivery document verification	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-002	Incoming vehicle inspection and unloading control	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-003	Goods inward note / goods receipt entry	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-004	API starting materials and intermediates receipt	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-WH-005	API bulk product receipt and controlled storage	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-006	Excipient receipt and contamination prevention	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-007	Primary packaging materials receipt and quarantine	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-008	Printed packaging materials secured receipt	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-009	Temperature-sensitive material acceptance and logging	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-010	Cold-chain receipt temperature excursion handling	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-011	Materials sampling booth issue and status control	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-012	Raw material quarantine identification	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-013	QC sampling request and sampling logistics	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-014	Material status: quarantine / released / rejected	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-015	Controlled material location / bin address allocation	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-016	Material identification and label traceability	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-017	Warehouse temperature and humidity recording	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-018	Cold-room / freezer monitoring and alarm escalation	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-019	Controlled substances / narcotic security (where applicable)	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-020	Flammable chemicals and solvents warehouse control	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-021	Hazardous substances storage compatibility segregation	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-022	Highly potent / allergenic material storage segregation	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-023	Returned / recalled product segregated storage	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-024	Rejected material cage and locked access	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-025	Stock rotation FEFO / FIFO and expiry surveillance	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-026	Material retest date monitoring and requalification	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-027	Raw material dispensing and issue authorization	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-028	Independent weight verification and dispensing reconciliation	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-029	Weighing balance pre-use check and cleaning	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-030	Dispensing booth line clearance and containment	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-031	Sampling tool cleaning and traceable storage	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-032	Staging of materials to production	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-033	Intra-site and inter-site material movement	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-034	Bulk API / intermediate container seal reconciliation	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-035	Inventory cycle counts and stock adjustments	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-036	Inventory discrepancies and investigation	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-037	Finished goods receipt from packaging	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-038	Finished goods quarantine before QA release	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-039	Finished goods pick, pack and dispatch	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-040	Temperature-controlled finished product dispatch	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-041	Shipment vehicle qualification / inspection	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-042	Transport lane qualification / route risk assessment	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-WH-043	Dispatch batch traceability to consignee	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-044	API/finished goods export and shipment documentation	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-045	Material shortage / damaged package investigation	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-046	Obsolete / scrap material disposition and destruction	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-047	Inventory data system access and transaction review	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M
IGC-WH-048	Customer returned goods receiving and isolation	WAREHOUSE / ALL	P1	EU-I-Ch5;ICH-Q7;SCH-M

End of Warehouse & Stores · 48 proposed SOPs

PROCUREMENT & VENDOR MANAGEMENT | 25 SOPs

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-PUR-001	Procurement request approval and specification verification	PURCHASE / ALL	P1	EU-I-Ch7;ICH-Q7;SCH-M
IGC-PUR-002	Approved vendor list management	PURCHASE / ALL	P1	EU-I-Ch7;ICH-Q7;SCH-M
IGC-PUR-003	Vendor prequalification questionnaire review	PURCHASE / ALL	P1	EU-I-Ch7;ICH-Q7;SCH-M
IGC-PUR-004	Critical raw material supplier audit coordination	PURCHASE / ALL	P1	EU-I-Ch7;ICH-Q7;SCH-M
IGC-PUR-005	Supplier criticality and quality risk ranking	PURCHASE / ALL	P1	EU-I-Ch7;ICH-Q7;SCH-M
IGC-PUR-006	API starting material source change evaluation	PURCHASE / ALL	P1	EU-I-Ch7;ICH-Q7;SCH-M
IGC-PUR-007	Excipient vendor qualification and supply chain risk	PURCHASE / ALL	P1	EU-I-Ch7;ICH-Q7;SCH-M
IGC-PUR-008	Primary packaging supplier qualification	PURCHASE / ALL	P1	EU-I-Ch7;ICH-Q7;SCH-M
IGC-PUR-009	Sterile component supplier qualification	PURCHASE / ALL	P1	EU-I-Ch7;ICH-Q7;SCH-M
IGC-PUR-010	Single-source critical supplier continuity planning	PURCHASE / ALL	P1	EU-I-Ch7;ICH-Q7;SCH-M
IGC-PUR-011	Procurement purchase order technical review	PURCHASE / ALL	P1	EU-I-Ch7;ICH-Q7;SCH-M
IGC-PUR-012	Quality agreement requirements for critical suppliers	PURCHASE / ALL	P1	EU-I-Ch7;ICH-Q7;SCH-M
IGC-PUR-013	Contract manufacturing organization selection support	PURCHASE / ALL	P1	EU-I-Ch7;ICH-Q7;SCH-M
IGC-PUR-014	Contract laboratory due-diligence evaluation	PURCHASE / ALL	P1	EU-I-Ch7;ICH-Q7;SCH-M
IGC-PUR-015	Third-party calibration service qualification	PURCHASE / ALL	P1	EU-I-Ch7;ICH-Q7;SCH-M
IGC-PUR-016	Third-party sterilization service qualification	PURCHASE / ALL	P1	EU-I-Ch7;ICH-Q7;SCH-M
IGC-PUR-017	Incoming supplier COA reliability and periodic verification	PURCHASE / ALL	P1	EU-I-Ch7;ICH-Q7;SCH-M
IGC-PUR-018	Supplier performance scorecard and on-time quality	PURCHASE / ALL	P1	EU-I-Ch7;ICH-Q7;SCH-M
IGC-PUR-019	Supplier nonconformance / rejection escalation	PURCHASE / ALL	P1	EU-I-Ch7;ICH-Q7;SCH-M
IGC-PUR-020	Supplier change notification tracking	PURCHASE / ALL	P1	EU-I-Ch7;ICH-Q7;SCH-M
IGC-PUR-021	Supply chain authenticity / anti-counterfeit verification	PURCHASE / ALL	P1	EU-I-Ch7;ICH-Q7;SCH-M
IGC-PUR-022	Broker / distributor traceability due diligence	PURCHASE / ALL	P1	EU-I-Ch7;ICH-Q7;SCH-M
IGC-PUR-023	Purchased equipment FAT/qualification deliverable control	PURCHASE / ALL	P1	EU-I-Ch7;ICH-Q7;SCH-M
IGC-PUR-024	Maintenance services / spare parts procurement control	PURCHASE / ALL	P1	EU-I-Ch7;ICH-Q7;SCH-M
IGC-PUR-025	Outsourced IT/cloud service vendor qualification	PURCHASE / ALL	P1	EU-I-Ch7;ICH-Q7;SCH-M

End of Procurement & Vendor Management · 25 proposed SOPs

HUMAN RESOURCES & ADMINISTRATION | 39 SOPs

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-HRA-001	GMP organization structure and job description control	HR / ALL	P1	EU-I-Ch2;SCH-M
IGC-HRA-002	Recruitment and qualification of GMP personnel	HR / ALL	P1	EU-I-Ch2;SCH-M
IGC-HRA-003	New employee joining and initial GMP induction	HR / ALL	P1	EU-I-Ch2;SCH-M
IGC-HRA-004	GMP annual training needs assessment	HR / ALL	P1	EU-I-Ch2;SCH-M
IGC-HRA-005	Training matrix and role-based curriculum creation	HR / ALL	P1	EU-I-Ch2;SCH-M
IGC-HRA-006	GMP SOP training assignment and effectiveness	HR / ALL	P1	EU-I-Ch2;SCH-M
IGC-HRA-007	Training records, attendance and qualification tracking	HR / ALL	P1	EU-I-Ch2;SCH-M
IGC-HRA-008	Periodic refresher training and training overdue escalation	HR / ALL	P1	EU-I-Ch2;SCH-M
IGC-HRA-009	Qualified trainer assessment and authorization	HR / ALL	P1	EU-I-Ch2;SCH-M
IGC-HRA-010	Department-specific on-the-job training (OJT)	HR / ALL	P1	EU-I-Ch2;SCH-M
IGC-HRA-011	Operator competency qualification and requalification	HR / ALL	P1	EU-I-Ch2;SCH-M
IGC-HRA-012	Aseptic personnel qualification tracking	HR / ALL	P1	EU-I-Ch2;SCH-M
IGC-HRA-013	Employee hygiene and sickness reporting	HR / ALL	P1	EU-I-Ch2;SCH-M
IGC-HRA-014	Personnel entry / access and gowning orientation	HR / ALL	P1	EU-I-Ch2;SCH-M
IGC-HRA-015	Medical fitness assessment as permitted by law	HR / ALL	P1	EU-I-Ch2;SCH-M
IGC-HRA-016	Contractual worker GMP induction and supervision	HR / ALL	P1	EU-I-Ch2;SCH-M
IGC-HRA-017	Visitor GMP induction and escort rules	HR / ALL	P1	EU-I-Ch2;SCH-M
IGC-HRA-018	External auditor / regulator access and escort	HR / ALL	P1	EU-I-Ch2;SCH-M
IGC-HRA-019	Personnel transfer / role change retraining	HR / ALL	P1	EU-I-Ch2;SCH-M
IGC-HRA-020	GMP disciplinary and conduct escalation	HR / ALL	P1	EU-I-Ch2;SCH-M
IGC-HRA-021	Personnel exit, document recovery and access removal	HR / ALL	P1	EU-I-Ch2;SCH-M
IGC-HRA-022	Occupational exposure surveillance referral process	HR / ALL	P1	EU-I-Ch2;SCH-M
IGC-HRA-023	Employee shift rostering and fatigue risk controls	HR / ALL	P1	EU-I-Ch2;SCH-M
IGC-HRA-024	Staff / visitor access badge administration	ADMIN / ALL	P2	EU-I-Ch2;SCH-M
IGC-HRA-025	Security gate material movement and gate pass	ADMIN / ALL	P2	EU-I-Ch2;SCH-M
IGC-HRA-026	Site housekeeping and waste segregation oversight	ADMIN / ALL	P2	EU-I-Ch2;SCH-M
IGC-HRA-027	GMP gown / uniform issuance and laundering	ADMIN / ALL	P2	EU-I-Ch2;SCH-M
IGC-HRA-028	Cafeteria and personnel welfare area hygiene	ADMIN / ALL	P2	EU-I-Ch2;SCH-M
IGC-HRA-029	Pest management contract and monitoring review	ADMIN / ALL	P2	EU-I-Ch2;SCH-M
IGC-HRA-030	Facility maintenance work permit coordination	ADMIN / ALL	P2	EU-I-Ch2;SCH-M
IGC-HRA-031	Security incident reporting and escalation	ADMIN / ALL	P2	EU-I-Ch2;SCH-M
IGC-HRA-032	Emergency communication and evacuation coordination	ADMIN / ALL	P2	EU-I-Ch2;SCH-M
IGC-HRA-033	Contractor attendance and site movement register	ADMIN / ALL	P2	EU-I-Ch2;SCH-M
IGC-HRA-034	Vehicle parking / loading dock administrative control	ADMIN / ALL	P2	EU-I-Ch2;SCH-M
IGC-HRA-035	Documented business continuity contact tree	ADMIN / ALL	P2	EU-I-Ch2;SCH-M
IGC-HRA-036	IT asset allocation and return at exit	ADMIN / ALL	P2	EU-I-Ch2;SCH-M
IGC-HRA-037	GMP training venue and assessment logistics	ADMIN / ALL	P2	EU-I-Ch2;SCH-M

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-HRA-038	Records room restricted access coordination	ADMIN / ALL	P2	EU-I-Ch2;SCH-M
IGC-HRA-039	GMP signage and room identification maintenance	ADMIN / ALL	P2	EU-I-Ch2;SCH-M

End of Human Resources & Administration · 39 proposed SOPs

RESEARCH & DEVELOPMENT | 73 SOPs

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-RND-001	R&D project initiation and development plan	RND / API / INTERMEDIATE	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-002	API target product profile and route selection	RND / API / INTERMEDIATE	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-003	API starting material selection justification	RND / API / INTERMEDIATE	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-004	API route scouting and alternative route comparison	RND / API / INTERMEDIATE	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-005	API synthetic route process safety assessment	RND / API / INTERMEDIATE	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-006	API reaction optimization and DOE studies	RND / API / INTERMEDIATE	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-007	API impurity formation and fate/purge evaluation	RND / API / INTERMEDIATE	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-008	API genotoxic impurity assessment during development	RND / API / INTERMEDIATE	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-009	API nitrosamine formation potential evaluation	RND / API / INTERMEDIATE	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-010	API residual solvent selection and purge design	RND / API / INTERMEDIATE	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-011	API crystallization, seeding and polymorph studies	RND / API / INTERMEDIATE	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-012	API salt screening / solid form selection	RND / API / INTERMEDIATE	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-013	API particle size / morphology development	RND / API / INTERMEDIATE	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-014	API process intermediate acceptance criteria definition	RND / API / INTERMEDIATE	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-015	API pilot plant batch manufacturing and traceability	RND / API / INTERMEDIATE	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-016	API kilo-lab material handling and safe scale-up	RND / API / INTERMEDIATE	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-017	API reaction calorimetry and thermal hazard studies	RND / API / INTERMEDIATE	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-018	API pilot-to-commercial scale-up report	RND / API / INTERMEDIATE	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-019	API technology transfer protocol and process package	RND / API / INTERMEDIATE	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-020	API hold time and intermediate stability development	RND / API / INTERMEDIATE	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-021	API stability-indicating specification development	RND / API / INTERMEDIATE	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-022	Biocatalytic API route development (where applicable)	RND / API / INTERMEDIATE	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-023	Fermentation / cell culture process development (where applicable)	RND / API / INTERMEDIATE	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-024	API extractable impurity / leachable risk where applicable	RND / API / INTERMEDIATE	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-025	API critical process parameters and proven acceptable ranges	RND / API / INTERMEDIATE	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-026	API process validation readiness review	RND / API / INTERMEDIATE	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-027	Product development target profile / QTPP	RND / FDF	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-028	Drug substance-excipient compatibility screening	RND / FDF	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-029	Excipient selection and functionality evaluation	RND / FDF	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-030	Tablet formulation prototype design	RND / FDF	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-031	Tablet direct compression feasibility	RND / FDF	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-032	Wet granulation formulation trials	RND / FDF	P1	ICH-Q8;ICH-Q11;ICH-Q7

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-RND-033	Dry granulation formulation trials	RND / FDF	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-034	Tablet coating formulation and process development	RND / FDF	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-035	Modified-release dissolution profile development	RND / FDF	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-036	Capsule fill formulation and powder flow development	RND / FDF	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-037	Capsule shell compatibility and stability screening	RND / FDF	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-038	Oral liquid preservative and sweetener selection	RND / FDF	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-039	Syrup solubility and taste-masking assessment	RND / FDF	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-040	Oral suspension wetting and sedimentation optimization	RND / FDF	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-041	Dry powder / dry syrup reconstitution development	RND / FDF	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-042	Topical cream emulsion type and stability study	RND / FDF	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-043	Topical ointment base selection and compatibility	RND / FDF	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-044	Topical gel rheology and viscosity development	RND / FDF	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-045	Sterile injectable formulation compatibility studies	RND / FDF	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-046	Injectable isotonicity / pH buffer development	RND / FDF	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-047	Sterile injectable sterilization approach selection	RND / FDF	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-048	Lyophilization formulation and cryoprotectant screening	RND / FDF	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-049	Lyophilization critical product temperature determination	RND / FDF	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-050	Lyophilization freezing / primary / secondary drying cycle design	RND / FDF	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-051	Sterile powder injectable formulation development (where applicable)	RND / FDF	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-052	Container-closure system selection and compatibility	RND / FDF	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-053	Primary packaging extractables/leachables risk assessment	RND / FDF	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-054	In-use and reconstitution stability plan	RND / FDF	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-055	Photostability and accelerated degradation study plan	RND / FDF	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-056	Pilot batch manufacture and evaluation	RND / FDF	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-057	Scale-up / site technology transfer for formulation	RND / FDF	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-058	Product lifecycle change and comparability assessment	RND / FDF	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-059	R&D lab notebook preparation, review and archival	RND / ALL	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-060	R&D sample labeling, coding and genealogy	RND / ALL	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-061	Development experiment deviation and learning log	RND / ALL	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-062	R&D instrument use and calibration oversight	RND / ALL	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-063	Development chemical inventory and small-quantity handling	RND / ALL	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-064	Prototype / pilot scale equipment qualification approach	RND / ALL	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-065	R&D area hygiene and contamination prevention	RND / ALL	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-066	R&D data integrity and electronic notebook access	RND / ALL	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-067	Design-of-experiments data review and statistical analysis	RND / ALL	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-068	Risk assessment and criticality evaluation during development	RND / ALL	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-069	Technical development report approval	RND / ALL	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-070	Development-to-GMP handover checklist	RND / ALL	P1	ICH-Q8;ICH-Q11;ICH-Q7

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-RND-071	R&D material and batch record traceability	RND / ALL	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-072	R&D retain sample management and disposal	RND / ALL	P1	ICH-Q8;ICH-Q11;ICH-Q7
IGC-RND-073	Product development change log maintenance	RND / ALL	P1	ICH-Q8;ICH-Q11;ICH-Q7

End of Research & Development · 73 proposed SOPs

ANALYTICAL DEVELOPMENT LABORATORY | 50 SOPs

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-ADL-001	ADL project/sample receipt and coding	ADL / API / FDF	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-002	ADL notebook, chromatogram and data governance	ADL / API / FDF	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-003	Analytical method development plan and protocol	ADL / API / FDF	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-004	HPLC assay method development	ADL / API / FDF	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-005	HPLC impurity profiling / related substances development	ADL / API / FDF	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-006	GC / headspace residual solvent method development	ADL / API / FDF	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-007	Chiral assay and enantiomeric impurity method development	ADL / API / FDF	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-008	LC-MS / GC-MS trace impurity analytical development	ADL / API / FDF	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-009	Nitrosamine analytical method development	ADL / API / FDF	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-010	Elemental impurity analytical method development	ADL / API / FDF	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-011	Dissolution method development and discrimination studies	ADL / API / FDF	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-012	Dissolution profile comparison and f2 evaluation	ADL / API / FDF	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-013	Content uniformity / dosage uniformity method development	ADL / API / FDF	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-014	Tablet / capsule stability-indicating method development	ADL / API / FDF	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-015	Topical in vitro release analytical method development	ADL / API / FDF	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-016	Injectable particulate / extractable volume method development	ADL / API / FDF	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-017	Lyophilized residual moisture / reconstitution method development	ADL / API / FDF	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-018	Sterile product endotoxin method suitability collaboration	ADL / API / FDF	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-019	Photostability / forced degradation method assessment	ADL / API / FDF	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-020	Analytical specificity / selectivity verification	ADL / API / FDF	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-021	Analytical accuracy and recovery study	ADL / API / FDF	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-022	Analytical precision / intermediate precision study	ADL / API / FDF	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-023	Linearity and range validation study	ADL / API / FDF	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-024	LOD / LOQ determination and verification	ADL / API / FDF	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-025	Robustness / ruggedness and system suitability study	ADL / API / FDF	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-026	Filter compatibility / adsorption study	ADL / API / FDF	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-027	Solution stability and mobile phase stability study	ADL / API / FDF	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-028	Method sample preparation reproducibility study	ADL / API / FDF	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-029	Analytical method verification / validation summary report	ADL / API / FDF	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-030	Stability-indicating method validation	ADL / API / FDF	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-031	Process impurity isolation and identification	ADL / ALL	P1	ICH-Q2;ICH-Q14;21CFR211

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-ADL-032	Process / degradation impurity reference standard qualification	ADL / ALL	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-033	Primary and working reference standard handling	ADL / ALL	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-034	Analytical method transfer protocol preparation	ADL / ALL	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-035	Analytical method transfer execution and acceptance	ADL / ALL	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-036	Method transfer discrepancy assessment and remediation	ADL / ALL	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-037	Cross-site laboratory method comparability study	ADL / ALL	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-038	Development sample storage and stability log	ADL / ALL	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-039	Forced degradation study planning and data assessment	ADL / ALL	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-040	HPLC column selection / column life management	ADL / ALL	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-041	ADL chromatographic integration criteria and audit trail	ADL / ALL	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-042	ADL instrument calibration / qualification checks	ADL / ALL	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-043	ADL data integrity / electronic systems access	ADL / ALL	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-044	Analytical method change management and lifecycle review	ADL / ALL	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-045	ADL investigation of atypical test results	ADL / ALL	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-046	Genotoxic impurity structure alert and analytical limits assessment	ADL / ALL	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-047	Extractables and leachables screening analytical support	ADL / ALL	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-048	API solid-state polymorph XRPD/DSC analysis where available	ADL / ALL	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-049	Particle size method development and validation	ADL / ALL	P1	ICH-Q2;ICH-Q14;21CFR211
IGC-ADL-050	ADL method qualification for process development samples	ADL / ALL	P1	ICH-Q2;ICH-Q14;21CFR211

End of Analytical Development Laboratory · 50 proposed SOPs

REGULATORY AFFAIRS | 26 SOPs

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-RA-001	Indian manufacturing license application / amendment control	RA / ALL	P1	EU-I;21CFR211;SCH-M;NDCTR
IGC-RA-002	State licensing authority inspection follow-up tracking	RA / ALL	P1	EU-I;21CFR211;SCH-M;NDCTR
IGC-RA-003	CDSCO product approval / permission regulatory interface	RA / ALL	P1	EU-I;21CFR211;SCH-M;NDCTR
IGC-RA-004	Site-specific manufacturing activity and product license matrix	RA / ALL	P1	EU-I;21CFR211;SCH-M;NDCTR
IGC-RA-005	Formulation registration dossier / CTD compilation controls	RA / ALL	P1	EU-I;21CFR211;SCH-M;NDCTR
IGC-RA-006	API / drug substance dossier / DMF preparation controls	RA / ALL	P1	EU-I;21CFR211;SCH-M;NDCTR
IGC-RA-007	European ASMF / CEP supporting regulatory coordination	RA / ALL	P1	EU-I;21CFR211;SCH-M;NDCTR
IGC-RA-008	US DMF submission and annual update (where applicable)	RA / ALL	P1	EU-I;21CFR211;SCH-M;NDCTR
IGC-RA-009	Australia TGA GMP clearance / sponsor coordination	RA / ALL	P1	EU-I;21CFR211;SCH-M;NDCTR
IGC-RA-010	UK MHRA manufacturer / importer authorization coordination	RA / ALL	P1	EU-I;21CFR211;SCH-M;NDCTR
IGC-RA-011	EU GMP / QP certification dossier interface (where applicable)	RA / ALL	P1	EU-I;21CFR211;SCH-M;NDCTR
IGC-RA-012	Market authorization compliance and commitment log	RA / ALL	P1	EU-I;21CFR211;SCH-M;NDCTR
IGC-RA-013	Manufacturing process change regulatory assessment	RA / ALL	P1	EU-I;21CFR211;SCH-M;NDCTR
IGC-RA-014	Regulatory variations notification and filing requirements	RA / ALL	P1	EU-I;21CFR211;SCH-M;NDCTR
IGC-RA-015	New product introduction registration / approval checklist	RA / ALL	P1	EU-I;21CFR211;SCH-M;NDCTR

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-RA-016	Regulatory authority correspondence and deficiency response	RA / ALL	P1	EU-I;21CFR211;SCH-M;NDCTR
IGC-RA-017	Regulatory inspection product dossier readiness	RA / ALL	P1	EU-I;21CFR211;SCH-M;NDCTR
IGC-RA-018	Regulatory artwork / labeling compliance approval	RA / ALL	P1	EU-I;21CFR211;SCH-M;NDCTR
IGC-RA-019	Serialization / track and trace market compliance monitoring	RA / ALL	P1	EU-I;21CFR211;SCH-M;NDCTR
IGC-RA-020	API QR code / pack traceability market requirements	RA / ALL	P1	EU-I;21CFR211;SCH-M;NDCTR
IGC-RA-021	Product import/export regulatory documentation	RA / ALL	P1	EU-I;21CFR211;SCH-M;NDCTR
IGC-RA-022	Change of manufacturing site / tech transfer notification	RA / ALL	P1	EU-I;21CFR211;SCH-M;NDCTR
IGC-RA-023	Product recall regulatory reporting requirements	RA / ALL	P1	EU-I;21CFR211;SCH-M;NDCTR
IGC-RA-024	Stability commitments and post-approval requirements	RA / ALL	P1	EU-I;21CFR211;SCH-M;NDCTR
IGC-RA-025	Clinical trial / investigational material NDCTR assessment	RA / ALL	P1	EU-I;21CFR211;SCH-M;NDCTR
IGC-RA-026	Schedule Y legacy citation and applicability review	RA / ALL	P1	EU-I;21CFR211;SCH-M;NDCTR

End of Regulatory Affairs · 26 proposed SOPs

COMPUTERIZED SYSTEMS & IT | 35 SOPs

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-IT-001	GxP computerized system inventory and risk ranking	IT / ALL	P1	EU-A11;21CFR11;SCH-M
IGC-IT-002	Computer system validation master plan	IT / ALL	P1	EU-A11;21CFR11;SCH-M
IGC-IT-003	Computerized system URS and supplier assessment	IT / ALL	P1	EU-A11;21CFR11;SCH-M
IGC-IT-004	Computerized system functional / design specification	IT / ALL	P1	EU-A11;21CFR11;SCH-M
IGC-IT-005	Computer system configuration baseline control	IT / ALL	P1	EU-A11;21CFR11;SCH-M
IGC-IT-006	Computerized system IQ / OQ / PQ	IT / ALL	P1	EU-A11;21CFR11;SCH-M
IGC-IT-007	Computer software validation and acceptance testing	IT / ALL	P1	EU-A11;21CFR11;SCH-M
IGC-IT-008	Risk-based GxP system periodic review	IT / ALL	P1	EU-A11;21CFR11;SCH-M
IGC-IT-009	User access provisioning / role approval	IT / ALL	P1	EU-A11;21CFR11;SCH-M
IGC-IT-010	Privileged administrator access control	IT / ALL	P1	EU-A11;21CFR11;SCH-M
IGC-IT-011	User deactivation and periodic access review	IT / ALL	P1	EU-A11;21CFR11;SCH-M
IGC-IT-012	Password, lockout and authentication controls	IT / ALL	P1	EU-A11;21CFR11;SCH-M
IGC-IT-013	Electronic records / signature compliance assessment	IT / ALL	P1	EU-A11;21CFR11;SCH-M
IGC-IT-014	Electronic signature accountability and linking	IT / ALL	P1	EU-A11;21CFR11;SCH-M
IGC-IT-015	Time synchronization and electronic timestamps	IT / ALL	P1	EU-A11;21CFR11;SCH-M
IGC-IT-016	Audit trail activation / configuration and review	IT / ALL	P1	EU-A11;21CFR11;SCH-M
IGC-IT-017	GMP data backup, restoration and recovery test	IT / ALL	P1	EU-A11;21CFR11;SCH-M
IGC-IT-018	Disaster recovery and business continuity tests	IT / ALL	P1	EU-A11;21CFR11;SCH-M
IGC-IT-019	Cybersecurity patch / antivirus risk assessment	IT / ALL	P1	EU-A11;21CFR11;SCH-M
IGC-IT-020	GxP change control for software and configuration	IT / ALL	P1	EU-A11;21CFR11;SCH-M
IGC-IT-021	Infrastructure / network qualification boundary	IT / ALL	P1	EU-A11;21CFR11;SCH-M
IGC-IT-022	ERP / warehouse system GxP validation	IT / ALL	P1	EU-A11;21CFR11;SCH-M
IGC-IT-023	LIMS system validation and sample traceability	IT / ALL	P1	EU-A11;21CFR11;SCH-M

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-IT-024	CDS / HPLC chromatography system validation	IT / ALL	P1	EU-A11;21CFR11;SCH-M
IGC-IT-025	BMS / EMS / SCADA validation and audit trails	IT / ALL	P1	EU-A11;21CFR11;SCH-M
IGC-IT-026	Manufacturing execution system (MES) validation	IT / ALL	P1	EU-A11;21CFR11;SCH-M
IGC-IT-027	Electronic batch record (EBR) validation and review	IT / ALL	P1	EU-A11;21CFR11;SCH-M
IGC-IT-028	Electronic document management system (eDMS) validation	IT / ALL	P1	EU-A11;21CFR11;SCH-M
IGC-IT-029	Data migration and legacy data verification	IT / ALL	P1	EU-A11;21CFR11;SCH-M
IGC-IT-030	Cloud-hosted GxP system supplier oversight	IT / ALL	P1	EU-A11;21CFR11;SCH-M
IGC-IT-031	Electronic data archiving and retention	IT / ALL	P1	EU-A11;21CFR11;SCH-M
IGC-IT-032	Incident / downtime management and paper fallback	IT / ALL	P1	EU-A11;21CFR11;SCH-M
IGC-IT-033	Spreadsheet validation / controlled calculations	IT / ALL	P1	EU-A11;21CFR11;SCH-M
IGC-IT-034	Printer, label software and serialization system controls	IT / ALL	P1	EU-A11;21CFR11;SCH-M
IGC-IT-035	Electronic instrument interfaces and data transfer verification	IT / ALL	P1	EU-A11;21CFR11;SCH-M

End of Computerized Systems & IT · 35 proposed SOPs

ENVIRONMENT HEALTH & SAFETY | 46 SOPs

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-EHS-001	Environmental, health and safety management program	EHS / API / FDF	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-002	Legal register for EHS permits and statutory consents	EHS / API / FDF	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-003	Job safety analysis (JSA) and risk assessment	EHS / API / FDF	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-004	Process safety management / HAZOP program	EHS / API / FDF	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-005	Chemical risk assessment and SDS control	EHS / API / FDF	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-006	Chemical compatibility and storage segregation	EHS / API / FDF	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-007	Flammable solvent dispensing and explosion prevention	EHS / API / FDF	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-008	Static electricity / bonding / grounding controls	EHS / API / FDF	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-009	ATEX / hazardous area equipment selection interface	EHS / API / FDF	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-010	Reactor thermal runaway and pressure relief response	EHS / API / FDF	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-011	Confined space entry permit and gas testing	EHS / API / FDF	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-012	Hot work permit and fire watch	EHS / API / FDF	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-013	Work at height permit and fall protection	EHS / API / FDF	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-014	Electrical isolation / lock-out tag-out (LOTO)	EHS / API / FDF	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-015	Pressure vessel / boiler inspection and certification	EHS / API / FDF	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-016	Forklift / material handling equipment safety	EHS / API / FDF	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-017	Compressed gas cylinder storage and handling	EHS / API / FDF	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-018	Cryogenic liquid / liquid nitrogen handling where applicable	EHS / API / FDF	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-019	Potent API exposure risk and occupational exposure banding	EHS / API / FDF	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-020	Respiratory protective equipment selection and fit testing	EHS / API / FDF	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-021	Chemical PPE selection, issue and maintenance	EHS / API / FDF	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-022	Personnel exposure incident / spill first aid	EHS / API / FDF	P1	EHS-LOCAL;ICH-Q7;SCH-M

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-EHS-023	Solvent spill containment and emergency cleanup	EHS / API / FDF	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-024	Hydrogenation / pyrophoric chemical risk controls (where applicable)	EHS / API / FDF	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-025	Hazardous waste segregation, labeling and manifest	EHS / ALL	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-026	Solvent waste storage, transporter and disposal review	EHS / ALL	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-027	Effluent treatment plant operation and monitoring	EHS / ALL	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-028	ETP sampling, analysis and compliance review	EHS / ALL	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-029	Air emission / scrubber monitoring and maintenance	EHS / ALL	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-030	Wastewater / drain contamination prevention	EHS / ALL	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-031	Fire alarm, extinguisher and hydrant inspection	EHS / ALL	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-032	Emergency response plan and incident command	EHS / ALL	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-033	Mock fire / evacuation drill and effectiveness	EHS / ALL	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-034	Chemical release / toxic gas emergency response	EHS / ALL	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-035	Medical emergency / occupational injury reporting	EHS / ALL	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-036	Environmental incident notification and root cause analysis	EHS / ALL	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-037	Accident / near-miss reporting and CAPA	EHS / ALL	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-038	Safety training and contractor safety induction	EHS / ALL	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-039	Energy isolation and equipment maintenance coordination	EHS / ALL	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-040	Noise, heat stress and ergonomics monitoring	EHS / ALL	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-041	EHS preventive inspection and safety walkdown	EHS / ALL	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-042	Emergency shower / eyewash inspection	EHS / ALL	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-043	Sustainability and solvent reduction initiative review	EHS / ALL	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-044	Waste minimization / API discharge control (where applicable)	EHS / ALL	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-045	Biological waste decontamination and disposal (where applicable)	EHS / ALL	P1	EHS-LOCAL;ICH-Q7;SCH-M
IGC-EHS-046	Radiation source and laser safety (if installed)	EHS / ALL	P1	EHS-LOCAL;ICH-Q7;SCH-M

End of Environment Health & Safety · 46 proposed SOPs

SENIOR MANAGEMENT & GOVERNANCE | 10 SOPs

SOP ID	PROCEDURE / SOP TITLE	APPLICABILITY	P	PRIMARY MAP
IGC-MGT-001	Senior management annual PQS review and resource commitment	ALL	P1	ICH-Q10;EU-I-Ch1;SCH-M
IGC-MGT-002	GMP management review agenda and action tracking	ALL	P1	ICH-Q10;EU-I-Ch1;SCH-M
IGC-MGT-003	Quality metric KPI definition, ownership and escalation	ALL	P1	ICH-Q10;EU-I-Ch1;SCH-M
IGC-MGT-004	Quality performance scorecard and critical trend review	ALL	P1	ICH-Q10;EU-I-Ch1;SCH-M
IGC-MGT-005	Site capacity and GMP resource adequacy assessment	ALL	P1	ICH-Q10;EU-I-Ch1;SCH-M
IGC-MGT-006	Regulatory inspection escalation to corporate leadership	ALL	P1	ICH-Q10;EU-I-Ch1;SCH-M
IGC-MGT-007	Management of material product shortages and quality impact	ALL	P1	ICH-Q10;EU-I-Ch1;SCH-M
IGC-MGT-008	Supplier and outsourced activity governance escalation	ALL	P1	ICH-Q10;EU-I-Ch1;SCH-M
IGC-MGT-009	Capital investment and critical remediation prioritization	ALL	P1	ICH-Q10;EU-I-Ch1;SCH-M
IGC-MGT-010	Business continuity and supply interruption risk review	ALL	P1	ICH-Q10;EU-I-Ch1;SCH-M

End of Senior Management & Governance · 10 proposed SOPs

07 Regulatory source links and implementation caveats

SCH-M India — revised Schedule M: https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadGazette_NotificationsFiles/2023.12.28_DR_Final%20G.S.R.%20922%28E%29_Notification%20of%20Schedule%20M%20of.pdf

21CFR211 US FDA — 21 CFR Part 211: https://www.ecfr.gov/current/title-21/part-211

21CFR210 US FDA — 21 CFR Part 210: https://www.ecfr.gov/current/title-21/part-210

21CFR11 US FDA — 21 CFR Part 11: https://www.ecfr.gov/current/title-21/part-11

ICH-Q7 ICH Q7 / EU GMP Part II: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q7a-good-manufacturing-practice-guidance-active-pharmaceutical-ingredients

ICH-Q8 ICH Q8(R2): https://www.ich.org/page/quality-guidelines

ICH-Q9 ICH Q9(R1): https://www.ich.org/page/quality-guidelines

ICH-Q10 ICH Q10: https://www.ich.org/page/quality-guidelines

ICH-Q11 ICH Q11: https://www.ich.org/page/quality-guidelines

ICH-Q2 ICH Q2(R2): https://www.ich.org/page/quality-guidelines

ICH-Q14 ICH Q14: https://www.ich.org/page/quality-guidelines

EU-I EU GMP Volume 4 Part I: https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en

EU-I-Ch1 EU GMP Part I Chapter 1: https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en

EU-I-Ch2 EU GMP Part I Chapter 2: https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en

EU-I-Ch3 EU GMP Part I Chapter 3: https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en

EU-I-Ch5 EU GMP Part I Chapter 5: https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en

EU-I-Ch6 EU GMP Part I Chapter 6: https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en

EU-I-Ch7 EU GMP Part I Chapter 7: https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en

EU-A1 EU GMP Annex 1: https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en

EU-A9 EU GMP Annex 9: https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en

EU-A11 EU GMP Annex 11: https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en

EU-A15 EU GMP Annex 15: https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en

PIC-S Australia TGA — PIC/S PE009-17: https://www.tga.gov.au/products/medicines/manufacturing/manufacture-medicine/good-manufacturing-practice-gmp/complying-pics-guide-good-manufacturing-practice-medicinal-products

MHRA UK MHRA — GMP / UK legislation: https://www.gov.uk/guidance/good-manufacturing-practice-and-good-distribution-practice

WHO WHO GMP Compendium: https://www.who.int/publications/i/item/9789240086081

NDCTR India — NDCTR 2019: https://www.cdsco.gov.in/opencms/opencms/en/Acts-and-rules/New-Drugs/

SCHEDULE-Y India — Schedule Y (historical/specific assessment): https://www.cdsco.gov.in/opencms/opencms/en/Acts-and-rules/New-Drugs/

EHS-LOCAL EHS — applicable local legislation: https://www.cpcb.nic.in/

Scope and legal review notes

A site must validate this index against its manufacturing licences, product portfolio, API GMP starting materials, licensed premises, classified areas, installed equipment, markets, critical utilities, applicable pharmacopoeias, registered process descriptions and contract-manufacturing responsibilities. No generic index can certify regulatory completeness without a documented site-specific gap assessment.

Examples of conditional families: fermentation / cell culture, beta-lactam and potent API controls, terminal sterilization, sterilizing filtration, nitrogen blanketing, biologicals, cold chain, serialization, API QR tracking, extractables/leachables and market-specific QP/importation obligations. Refer to the current legislation and authority interpretations.

GLOBAL GMP & TURNKEY CONSULTANCY

OUR EUROPEAN OFFICE

ISHA'S GMP & TURNKEY CONSULTANCY EUROPE LTD

Ireland Office

3 Graydon Green
Newcastle, Dublin, D22 Y9V9
Ireland

PHONE

+353 89 989 1842

EMAIL

info@ishasgmpeu.ie

WEBSITE

www.ishasgmpeu.ie

European cGMP • Regulatory Affairs • API and Formulation Plants • Sterile & Non-Sterile Facilities • Turnkey Engineering

INDIA HEAD OFFICE | ISHA'S GMP CONSULTANCY PRIVATE LIMITED

55/66, 1st Cross Street, CRR Puram, Manapakkam, Chennai – 600125, India
+91 86675 89984 | info@ishasgmp.com | www.ishasgmp.com