URS TEMPLATE

Equipment and Utilities

Document No.: Template-VAL-006 | Version: 1.0 | Effective: [DD-MMM-YYYY] | Parent: SOP-VAL-006

THIS GUIDANCE BLOCK IS REMOVED WHEN A URS IS AUTHORED FROM THIS TEMPLATE

Purpose of this Template

This is the corporate template for User Requirements Specifications (URS) for process equipment, utility systems, and manufacturing infrastructure at [Company Name]. The URS is Stage 1 of the qualification lifecycle per [SOP-VAL-006]; it precedes Design Qualification (DQ), Factory Acceptance Test (FAT), Site Acceptance Test (SAT), Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ). Every requirement in this URS becomes a traceable test in subsequent qualification stages.

The architectural decision: the URS captures USER NEED translated into VERIFIABLE REQUIREMENTS. It does not specify the technical solution: the supplier responds to the URS with a Functional Specification (FS) and Design Specification (DS) that propose how the requirements will be met. The URS-FS-DS traceability is the foundation of risk-based qualification per ASTM E2500.

How to Use

- Copy this template; save as draft URS under target document number (URS-[NNN]).
- Replace header text and metadata placeholders ([Company Name], [DD-MMM-YYYY], [X.Y], [Asset ID], etc.).
- Remove this entire 'GUIDANCE BLOCK' section: everything before the §1 Introduction heading.
- Author requirements section by section. Every requirement assigned: unique Req ID (e.g. URS-001, URS-002...); criticality (Critical / High / Medium / Low — see key in §3.1); verification method (DQ / FAT / SAT / IQ / OQ / PQ).
- Requirements must be: ATOMIC (one requirement per Req ID); TESTABLE (acceptance criterion measurable); UNAMBIGUOUS (single interpretation); TRACEABLE (will be referenced in FS / DS and qualification protocols).
- Do NOT prescribe the technical solution where multiple options exist — let the supplier propose. Say WHAT (e.g. 'monitor tank temperature with ±0.5°C accuracy across operating range') not necessarily HOW (e.g. 'use PT100 sensor model X').
- Route for review and approval per [SOP-QA-001] §8.4 and [SOP-VAL-006] §8.2.

Authoring Discipline

- LANGUAGE: SHALL = mandatory requirement. SHOULD = strongly preferred but not mandatory. MAY = optional. Avoid 'will', 'must', 'needs to', use SHALL where mandatory.
- REQUIREMENTS NOT DESIGN: describe operational need, not specific design / brand / model unless brand is the actual requirement (e.g. interoperability with existing system).
- REGULATORY ANCHOR: for every Critical requirement, the regulatory or operational driver is identifiable (EU GMP §X / ICH QX / pharmacopoeial / corporate standard).

- RISK-BASED PRIORITISATION: requirements with direct GMP impact (CCS Tier 1/2, sterility, data integrity, batch certification) classified Critical. Section §3.1 Criticality Key is the corporate standard.
- AVOID DUPLICATION: same requirement stated once. Cross-reference rather than restate.
- AVOID 'TO BE DECIDED': every requirement should be specified at URS approval. Genuine 'TBD' items require explicit acknowledgement in §14 Open Items.

USER REQUIREMENTS SPECIFICATION

[Equipment Name]

Document No.: URS-[XXX] | Version: [X.Y] | Effective Date: [DD-MMM-YYYY]

Identification

URS Document No.	Equipment Name / Description	Equipment / Asset ID	Project Reference
URS-[XXX]	[Equipment description]	[Asset ID / to be assigned]	[Project / Capex code]
GAMP 5 Category	**Criticality Tier (per QRM)**	**Type**	**Process Step / Use**
□ Cat 3 (non-configured COTS) □ Cat 4 (configurable) □ Cat 5 (custom)	□ Direct impact (CCS / sterility) □ Indirect impact □ No impact	□ Process equipment □ Utility system □ Packaging equipment □ Cleaning equipment □ Other	[Manufacturing step / utility role]
URS Author	**Process / User Owner**	**Engineering Owner**	**Date of Authoring**
[Name / Function]	[Name / Function]	[Name / Function]	[DD-MMM-YYYY]

Applicability Assessment

The following assessment shall be completed before authoring the detailed URS requirements. Sections marked “Not Applicable” may be omitted or retained with a clear justification.

URS Area	Applicable?	Justification
Process and operational requirements	☐ Yes ☐ No	[Explain relevance]
Capacity and throughput	☐ Yes ☐ No	[Explain relevance]
Performance requirements	☐ Yes ☐ No	[Explain relevance]
Product-contact materials	☐ Yes ☐ No	[Explain relevance]
Cleaning and sanitization	☐ Yes ☐ No	[Explain relevance]
Sterilisation / SIP / decontamination	☐ Yes ☐ No	[Explain relevance]
Utilities and connections	☐ Yes ☐ No	[Explain relevance]
Cleanroom / environmental requirements	☐ Yes ☐ No	[Explain relevance]
Contamination control strategy integration	☐ Yes ☐ No	[Explain relevance]
Safety and EHS	☐ Yes ☐ No	[Explain relevance]
Controls and automation	☐ Yes ☐ No	[Explain relevance]
Data integrity / electronic records	☐ Yes ☐ No	[Explain relevance]
Recipe / batch reporting	☐ Yes ☐ No	[Explain relevance]
Alarms and interlocks	☐ Yes ☐ No	[Explain relevance]

Calibration and instrumentation	☐ Yes ☐ No	[Explain relevance]
Maintenance and spare parts	☐ Yes ☐ No	[Explain relevance]
Training	☐ Yes ☐ No	[Explain relevance]
Decommissioning	☐ Yes ☐ No	[Explain relevance]

Approval

Role	Name	Signature / e-Signature ID	Date
Author -mEngineering / Manufacturing Science			
Reviewer - Process Owner / User			
Reviewer - Engineering / Automation			
Reviewer – Validation			
Reviewer - Quality Control (if QC sampling / monitoring)			
Reviewer - Microbiology (if sterility-relevant)			
Reviewer - EHS			
Reviewer - IT / CSV (if computerised)			
Reviewer - Maintenance			
Approver - Head of Engineering			
Approver - Head of Manufacturing (Process Owner)			
Approver - Head of Quality Assurance			
Approver - Qualified Person (if Annex 16 / direct impact)			

Revision History

Version	Effective Date	Summary of Change	Change Control / CR No.	Author
1.0	[DD-MMM-YYYY]	Initial issue. New equipment URS.	CR-XXXXX	[Name]

Table of Contents

1. Introduction

1.1 Purpose

[1-2 paragraphs stating what this URS specifies and why. Reference the business / regulatory driver, capacity expansion, replacement of obsolete equipment, new product introduction, regulatory compliance closure, capability gap.]

1.2 Scope

[Define what is included and excluded: e.g. 'This URS covers the [equipment] including [components]. Excluded: site utility connections, building modifications, validation activities (handled per SOP-VAL-006).']

1.3 Definitions and Abbreviations

[Define equipment-specific terms used in this URS: e.g. CIP, SIP, WFI, PW, HVAC, RABS, isolator, OEL, etc.]

2. Regulatory and Quality Framework

[Cite the regulatory framework that drives this URS. Critical equipment URS typically anchors in:]

- EU GMP Volume 4 — Chapter 3 (Premises and Equipment); Annex 15 (Qualification and Validation); Annex 1 (Sterile, if applicable); Annex 11 (Computerised Systems, if applicable).
- US 21 CFR §211.63-211.72 (Equipment); §211.182 (Equipment Cleaning and Use Log).
- ICH Q9 (R1) Quality Risk Management; ICH Q10 PQS.
- ASTM E2500 Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment.
- ISPE Baseline Guides as applicable (Sterile Manufacturing Facilities; Commissioning and Qualification; Engineering Standards).
- PIC/S PE 009.
- [Add product-specific or pharmacopoeial references where applicable.]

[Internal references:]

- [Quality Manual]; [CCS-001] (where contamination control relevant); [VMP-001] Validation Master Plan.
- [SOP-VAL-006] Equipment Qualification (parent SOP); [SOP-VAL-002] Process Validation; [SOP-VAL-003] Cleaning Validation; [SOP-VAL-005] CSV (if computerised); [SOP-VAL-007] Sterilisation / APS (if sterile).
- [SOP-QA-002] Change Control; [SOP-QA-006] QRM.
- [SOP-MFG-020] Cleaning of Premises and Equipment.

3. Approach

3.1 Criticality Key

Every requirement in this URS is classified by criticality. Classification drives verification approach in DQ / IQ / OQ / PQ:

Criticality	Definition	Verification expectation
CRITICAL (C)	Direct impact on product quality, patient safety, sterility, data integrity, or regulatory compliance.	Verification mandatory at IQ/OQ/PQ. Documented test evidence. Deviations require QA approval.
HIGH (H)	Significant impact on process performance, throughput, or operational reliability without direct GMP impact.	Verification at OQ/PQ. Documented test evidence.
MEDIUM (M)	Operational features supporting usability, ergonomics, or efficiency.	Verification at OQ or commissioning. Inspection-based confirmation acceptable.
LOW (L)	Nice-to-have features, aesthetic, or non-functional preferences.	Confirmation at commissioning or FAT only. No formal testing required.

3.2 Verification Approach

[Identify how requirements will be verified: typical mapping: design review at DQ; FAT before shipment; SAT after installation; IQ for installation correctness; OQ for operational performance; PQ for process performance in routine use. Critical requirements verified at multiple stages where applicable.]

3.3 GAMP 5 Category

[State the GAMP 5 category: Cat 3 (COTS, non-configured); Cat 4 (configurable); Cat 5 (custom). Drives the rigour of CSV per [SOP-VAL-005] if computerised.]

4. Process and Operational Requirements

4.1 Process Context

[Describe the process step / role this equipment supports: what it does in the manufacturing flow; upstream / downstream connections; product types handled; campaign vs dedicated.]

4.2 Process Requirements

Requirements relating to the process operations the equipment must perform:

Req ID	Requirement	Criticality	Verification
URS-001	[e.g. The equipment shall handle [product type / volume / batch size range].]	C	DQ / OQ / PQ
URS-002	[e.g. The equipment shall operate at [temperature range] with control to ±[X]°C.]	C	OQ / PQ

URS-003	[e.g. The equipment shall achieve [process outcome: e.g. mixing homogeneity, dissolution rate, granulation moisture].]	C	PQ
URS-004	[Add as needed]		

4.3 Capacity and Throughput

Req ID	Requirement	Criticality	Verification
URS-010	[e.g. The equipment shall process [X] batches per shift.]	H	PQ
URS-011	[e.g. Changeover time between products shall not exceed [Y] hours.]	H	OQ / PQ
URS-012	[Add as needed]		

4.4 Operational Modes

[Manual / semi-auto / fully-auto modes; emergency stop; safety interlocks; recovery from power loss; restart logic.]

Req ID	Requirement	Criticality	Verification
URS-020	[e.g. The equipment shall provide MANUAL, AUTO and CIP/SIP operating modes.]	C	OQ
URS-021	[e.g. Emergency stop shall halt all motion within [X] seconds and require manual reset.]	C	OQ
URS-022	[Add as needed]		

5. Performance Requirements

Quantitative performance requirements: accuracy, precision, repeatability, control range, response time.

Req ID	Requirement	Criticality	Verification
URS-030	[e.g. Temperature control accuracy ±[X]°C across operating range.]	C	OQ
URS-031	[e.g. Pressure control accuracy ±[X] bar.]	C	OQ
URS-032	[e.g. Speed control accuracy ±[X]% of setpoint.]	H	OQ
URS-033	[e.g. Yield / efficiency target ≥ [X]%.]	H	PQ
URS-034	[e.g. Repeatability across [N] cycles within [X]% of mean.]	C	OQ / PQ
URS-035	[Add as needed]		

6. Materials of Construction

[Materials in product contact must be compatible with product chemistry. Materials in cleaning fluid contact must be compatible with cleaning agents per [SOP-VAL-003]. Where applicable, USP <87>/<88> biocompatibility; EU regulation on food-contact materials; pharmacopoeial compendia.]

Req ID	Requirement	Criticality	Verification
URS-040	[e.g. All product-contact surfaces shall be 316L stainless steel with Ra ≤ 0.5 µm (electropolished).]	C	DQ / IQ
URS-041	[e.g. Gaskets and seals shall be EPDM / PTFE / silicone compliant with USP <87>/<88> Class VI.]	C	DQ / IQ
URS-042	[e.g. Materials shall be resistant to the cleaning agents per [SOP-VAL-003] including [list].]	C	DQ
URS-043	[e.g. No leachables or extractables exceeding [acceptance criteria].]	C	DQ / PQ
URS-044	[Add as needed]		

7. Cleaning and Sanitisation

7.1 Cleanability Design

Equipment must be designed for cleaning per [SOP-MFG-020] and validated per [SOP-VAL-003]:

Req ID	Requirement	Criticality	Verification
URS-050	[e.g. The equipment shall be designed for CIP using [cleaning regime].]	C	DQ / PQ (cleaning validation)
URS-051	[e.g. All product-contact surfaces shall be accessible for swab sampling.]	C	DQ
URS-052	[e.g. No dead legs > [3D] anywhere in product-contact piping (ASME BPE).]	C	DQ / IQ
URS-053	[e.g. Drainage shall be complete with no residual hold-up volume > [X] mL.]	C	DQ / IQ
URS-054	[Add as needed]		

7.2 Sanitisation / Sterilisation (if applicable)

Req ID	Requirement	Criticality	Verification
URS-060	[e.g. The equipment shall support SIP at [X]°C for [Y] minutes (F0 ≥ [Z]).]	C	OQ / PQ
URS-061	[e.g. Product-contact surfaces shall withstand repeated steam exposure without degradation.]	C	DQ
URS-062	[Add as needed]		

8. Utilities and Connections

[Specify utility requirements: water (PW / WFI / utility); steam (plant / pure / clean); compressed air (instrument / process); gases (N2 / CO2 / etc.); electrical power; drainage; HVAC integration.]

Req ID	Requirement	Criticality	Verification
URS-070	[e.g. Electrical: 400V 3-phase + N + PE; [X] kW connected load; supplied via [protection class].]	H	IQ
URS-071	[e.g. Compressed air: ISO 8573-1 Class [X.Y.Z]; [N] L/min at [P] bar.]	C	IQ
URS-072	[e.g. Pure steam: per EU GMP Annex 1; supply pressure [X] bar.]	C	IQ
URS-073	[e.g. WFI / PW per current Ph.Eur. monograph; supply temperature [X]°C.]	C	IQ
URS-074	[e.g. HVAC: equipment shall not compromise area classification (Grade [X]) at design conditions.]	C	IQ / OQ
URS-075	[Add as needed]		

9. Environmental Requirements

9.1 Operating Environment

Req ID	Requirement	Criticality	Verification
URS-080	[e.g. The equipment shall operate within ambient T = [range]°C, RH = [range]%.]	M	OQ
URS-081	[e.g. Equipment shall maintain Grade [X] cleanroom classification per [CCS-001] when installed.]	C	IQ / OQ
URS-082	[e.g. Noise emission < [X] dB(A) at operator position.]	M	FAT / SAT
URS-083	[Add as needed]		

9.2 Contamination Control Integration

[How the equipment integrates with the site CCS: pressure cascade, gowning interfaces, RABS / isolator integration, material airlocks. Cross-reference [CCS-001].]

10. Safety and EHS

[Safety requirements per applicable regulations: Machinery Directive 2006/42/EC; ATEX where applicable; Pressure Equipment Directive; chemical / biological / mechanical / electrical hazards; OEL containment per product handled.]

Req ID	Requirement	Criticality	Verification

URS-090	[e.g. The equipment shall comply with Machinery Directive 2006/42/EC; CE-marked.]	C	DQ / IQ
URS-091	[e.g. Emergency stop function per ISO 13850; safety category per EN ISO 13849-1 ≥ [PLd].]	C	DQ / OQ
URS-092	[e.g. Containment performance to OEL [X] µg/m³ where applicable.]	C	OQ / PQ
URS-093	[e.g. ATEX certification Zone [X] where applicable.]	C	DQ
URS-094	[e.g. Operator interface designed for ergonomic use; minimum reach / force per EN standards.]	M	FAT
URS-095	[Add as needed]		

11. Controls, Automation and Data

11.1 Control System

[PLC / DCS / SCADA / HMI requirements where applicable. GAMP 5 category drives CSV approach per [SOP-VAL-005].]

Req ID	Requirement	Criticality	Verification
URS-100	[e.g. The equipment shall have a PLC-based control system with HMI.]	C	DQ / OQ
URS-101	[e.g. The control system shall comply with EU GMP Annex 11 and 21 CFR Part 11.]	C	DQ / OQ
URS-102	[e.g. Named-user access with role-based privileges per [SOP-QA-012] §8.6.]	C	OQ
URS-103	[e.g. Audit trail capture of all GxP-relevant actions per [SOP-QA-012] §8.4.]	C	OQ
URS-104	[Add as needed]		

11.2 Data Integrity

Data integrity requirements per [SOP-QA-012]: ALCOA++ operationalised at the equipment level:

Req ID	Requirement	Criticality	Verification
URS-110	[e.g. The system shall capture all critical process parameters with timestamp and operator attribution.]	C	OQ
URS-111	[e.g. The system shall prevent data deletion and require electronic signatures per 21 CFR Part 11.]	C	OQ
URS-112	[e.g. The system shall support backup / restore per [SOP-QA-012] §8.8.]	C	OQ

URS-113	[e.g. Critical alarms shall be configured for [parameters]; alarm history retrievable.]	C	OQ
URS-114	[Add as needed]		

11.3 Connectivity and Integration

[Integration with site MES / SCADA / Historian / LIMS / batch record system where applicable. Specify protocols (OPC-UA, etc.), data interface points.]

Req ID	Requirement	Criticality	Verification
URS-120	[e.g. The equipment shall interface with site MES via OPC-UA for batch record data acquisition.]	H	OQ
URS-121	[e.g. Process data shall be available for export in standard formats (CSV, XML).]	M	OQ
URS-122	[Add as needed]		

12. Documentation and Qualification Deliverables

Supplier-provided documentation expected as part of equipment supply per [SOP-VAL-006]:

- Functional Specification (FS): supplier's response to this URS describing how requirements will be met.
- Design Specification (DS): detailed design including drawings, P&IDs, electrical schematics, software architecture.
- Bill of Materials with material certificates (especially product-contact).
- Welding documentation per ASME BPE / EN 287 (where applicable).
- Calibration certificates for instrumentation.
- FAT protocol and report: supplier-led, [Company Name] witnessed.
- SAT protocol and report: site-led.
- Operating manual; Maintenance manual; Cleaning procedure draft.
- Spare parts list with criticality.
- Training materials for operators and maintenance.
- Software source code / configuration documentation (Cat 5 only).
- Certificate of Conformance / CE Declaration.
- Traceability matrix URS ↔ FS ↔ DS ↔ tests.

13. Maintenance and Lifecycle

[Maintenance access, spare parts availability, supplier support, expected service life. Reference [SOP-VAL-006] §8.7 ongoing qualification / [SOP-QA-013] continuous improvement.]

Req ID	Requirement	Criticality	Verification
URS-130	[e.g. The equipment shall be designed for minimum [Y] years operational life.]	M	DQ

URS-131	[e.g. Preventive maintenance plan with frequencies; tools list; spare parts inventory recommendation.]	H	Documentation
URS-132	[e.g. Supplier shall provide spare parts availability commitment for [X] years post-installation.]	M	Contract
URS-133	[e.g. Access to all maintenance points without major dismantling.]	M	DQ
URS-134	[Add as needed]		

14. Training

[Training requirements per [SOP-HR-001]. Tier 2 specialised competence typically required for operators of critical equipment.]

Req ID	Requirement	Criticality	Verification
URS-140	[e.g. Supplier shall provide [N] days of on-site training for operators.]	H	Contract
URS-141	[e.g. Supplier shall provide [N] days of maintenance training.]	H	Contract
URS-142	[e.g. Train-the-trainer material allowing internal cascade training.]	M	Contract
URS-143	[Add as needed]		

15. Decommissioning

[Decommissioning considerations: clean-out, decontamination, dismantling, disposal of materials, archive of records per [SOP-QA-005].]

Req ID	Requirement	Criticality	Verification
URS-150	[e.g. Equipment shall be designed for safe decontamination and dismantling at end of life.]	L	Documentation
URS-151	[Add as needed]		

16. Acceptance Criteria Summary

Critical and High requirements above constitute the binding acceptance criteria. Equipment supply will be deemed acceptable when:

- All Critical requirements verified at applicable qualification stage (FAT / SAT / IQ / OQ / PQ).
- All High requirements verified at applicable stage or justified deviation accepted via [SOP-QA-002] Change Control.
- Medium and Low requirements confirmed at commissioning.
- Traceability matrix URS ↔ FS ↔ DS ↔ tests complete and approved.
- All supplier documentation per §12 delivered and accepted.

17. Open Items

[Items genuinely undecided at URS approval — must be closed before next stage (FS / DS / FAT). Each TBD has an owner and target date.]

TBD Ref.	Item	Owner	Target close
TBD-01			
TBD-02			

18. Cross-References and Traceability

- [VMP-001] Validation Master Plan — programme-level context.
- [SOP-VAL-006] Equipment Qualification — parent SOP; defines DQ / IQ / OQ / PQ.
- [SOP-VAL-002] Process Validation — PQ approach where process-relevant.
- [SOP-VAL-003] Cleaning Validation — cleaning approach for this equipment.
- [SOP-VAL-005] CSV — applies if computerised (most equipment now is).
- [SOP-VAL-007] Sterilisation / APS — applies if sterile-related.
- [SOP-QA-002] Change Control — for URS revisions during the project.
- [SOP-QA-006] QRM — criticality assessment underpinning §3.1.
- [SOP-QA-012] Data Integrity — ALCOA++ requirements operationalised in §11.
- [CCS-001] — contamination control integration.
- Project documentation: FS / DS / FAT / SAT / IQ / OQ / PQ — traceability matrix maintained per [SOP-VAL-006].

— END OF URS —