User Requirements Specification (URS)

IQ/OQ/PQ Protocol Pack · Template 01 of 09

URS No. _____ **Version** _____

Equipment / area name _____ **Equipment ID / asset No.** _____

Location (building, room) _____ **Department** _____

Manufacturer _____ **Model** _____

Serial No. _____ **URS ref.** _____

Equipment type ☐ Stability chamber ☐ Cold room ☐ Refrigerator ☐ Freezer ☐ Ultra-low freezer ☐ Warehouse ☐ Other: _____

1 Approval and change history

This urs must be approved before any part of it is executed. The approval date must be earlier than the date on the first executed data sheet.

Prepared by (User department)	Reviewed by (Engineering)	Approved by (QA)
Name _____	Name _____	Name _____
Designation _____	Designation _____	Designation _____
Signature _____	Signature _____	Signature _____
Date _____	Date _____	Date _____

Change history

Version	Date	Description of change	Author

2 Purpose and scope

State what the equipment or area must do and what it will store. Every requirement must be specific and testable: write a number, not a word. Each line is later traced to at least one DQ, IQ, OQ or PQ test.

Intended use _____

_____

_____

Products / materials to be stored and their labelled storage conditions _____

_____

_____

Capacity (volume, pallet positions or shelves) _____

3 Requirements

Performance

Req. ID	Requirement	Value / limit	Critical?	Verified in
PER-01	Temperature setpoint and acceptance range at every point where product is stored		☐ Y ☐ N	☐ DQ ☐ IQ ☐ OQ ☐ PQ
PER-02	RH setpoint and acceptance range (if controlled)		☐ Y ☐ N	☐ DQ ☐ IQ ☐ OQ ☐ PQ
PER-03	Uniformity across the chamber or room, empty and loaded		☐ Y ☐ N	☐ DQ ☐ IQ ☐ OQ ☐ PQ
PER-04	Recovery time after the longest routine door opening		☐ Y ☐ N	☐ DQ ☐ IQ ☐ OQ ☐ PQ
PER-05	Performance in the hottest and coldest seasons (areas affected by ambient)		☐ Y ☐ N	☐ DQ ☐ IQ ☐ OQ ☐ PQ
PER-06	Holdover time after power failure		☐ Y ☐ N	☐ DQ ☐ IQ ☐ OQ ☐ PQ

Alarms and notifications

Req. ID	Requirement	Value / limit	Critical?	Verified in
ALM-01	High and low temperature alarm limits and delay		☐ Y ☐ N	☐ DQ ☐ IQ ☐ OQ ☐ PQ
ALM-02	High and low RH alarm limits (if controlled)		☐ Y ☐ N	☐ DQ ☐ IQ ☐ OQ ☐ PQ

Req. ID	Requirement	Value / limit	Critical?	Verified in
ALM-03	Door-open alarm		☐ Y ☐ N	☐ DQ ☐ IQ ☐ OQ ☐ PQ
ALM-04	Power failure alarm		☐ Y ☐ N	☐ DQ ☐ IQ ☐ OQ ☐ PQ
ALM-05	Notification channels (sounder, SMS, email, call) and escalation contacts		☐ Y ☐ N	☐ DQ ☐ IQ ☐ OQ ☐ PQ

Monitoring, data and computerised system

Req. ID	Requirement	Value / limit	Critical?	Verified in
DAT-01	Independent monitoring sensor(s), separate from the controller		☐ Y ☐ N	☐ DQ ☐ IQ ☐ OQ ☐ PQ
DAT-02	Logging interval and data retention period		☐ Y ☐ N	☐ DQ ☐ IQ ☐ OQ ☐ PQ
DAT-03	Audit trail of setpoint and limit changes		☐ Y ☐ N	☐ DQ ☐ IQ ☐ OQ ☐ PQ
DAT-04	Role-based access control and unique user IDs		☐ Y ☐ N	☐ DQ ☐ IQ ☐ OQ ☐ PQ
DAT-05	Electronic records and signatures (21 CFR Part 11 / Annex 11, if applicable)		☐ Y ☐ N	☐ DQ ☐ IQ ☐ OQ ☐ PQ
DAT-06	Data backup and restore		☐ Y ☐ N	☐ DQ ☐ IQ ☐ OQ ☐ PQ
DAT-07	Reports: format and content		☐ Y ☐ N	☐ DQ ☐ IQ ☐ OQ ☐ PQ

Utilities and installation

Req. ID	Requirement	Value / limit	Critical?	Verified in
UTL-01	Electrical supply (voltage, phase, frequency, circuit rating, earthing)		☐ Y ☐ N	☐ DQ ☐ IQ ☐ OQ ☐ PQ
UTL-02	Emergency power (generator / UPS) and changeover		☐ Y ☐ N	☐ DQ ☐ IQ ☐ OQ ☐ PQ
UTL-03	Ambient conditions at the installation site		☐ Y ☐ N	☐ DQ ☐ IQ ☐ OQ ☐ PQ
UTL-04	Space, access and clearances		☐ Y ☐ N	☐ DQ ☐ IQ ☐ OQ ☐ PQ

Req. ID	Requirement	Value / limit	Critical?	Verified in

Documentation, calibration and support

Req. ID	Requirement	Value / limit	Critical?	Verified in
DOC-01	Drawings, as-built drawings, wiring diagrams and manuals		☐ Y ☐ N	☐ DQ ☐ IQ ☐ OQ ☐ PQ
DOC-02	Calibration certificates for every critical sensor, traceable to national standards		☐ Y ☐ N	☐ DQ ☐ IQ ☐ OQ ☐ PQ
DOC-03	Spare parts list		☐ Y ☐ N	☐ DQ ☐ IQ ☐ OQ ☐ PQ
DOC-04	Vendor IQ/OQ documentation (if supplied)		☐ Y ☐ N	☐ DQ ☐ IQ ☐ OQ ☐ PQ
DOC-05	Training for operators and maintenance staff		☐ Y ☐ N	☐ DQ ☐ IQ ☐ OQ ☐ PQ
DOC-06	Service response and preventive maintenance		☐ Y ☐ N	☐ DQ ☐ IQ ☐ OQ ☐ PQ