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TEMPLATE PACK

IQ/OQ/PQ protocol templates

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Introduction

This pack provides structured protocol text for the qualification of temperature-controlled equipment and environments in pharmaceuticals, biotech, and logistics. It aligns with expectations from EU GMP Annex 15, FDA current good manufacturing practice, WHO technical supplements, and data integrity requirements for electronic records. It is designed to support teams in preparing audit-ready protocols and reports.

Disclaimer: This material is intended as a general reference. It does not replace your quality management system, SOPs, or regulatory requirements. Each organization is responsible for adapting the content to its specific processes, equipment, and compliance obligations.

Also see: IQ, OQ, PQ in pharmaceuticals: Complete guide to equipment qualification and compliance

How to use the template

This content is written to reduce preparation time and review cycles while staying aligned with GxP expectations. Use the structure to maintain consistency across IQ, OQ, and PQ documentation. Keep acceptance criteria specific, measurable, and traceable to the URS and risk assessment.

- **Audience**: Quality, validation, engineering, and facility teams working with temperature-controlled equipment and environments.
- **Scope**: IQ, OQ, and PQ for units such as laboratory refrigerators and freezers, incubators, cold rooms, and GDP warehouses. It excludes process validation and method validation.
- **Evidence**: Maintain a complete audit trail of raw data, calibration certificates, executed test sheets, and approvals in accordance with your QMS.

1 Document control

- Document title: IQ/OQ/PQ protocol – [Equipment/area name]
- Document ID: [ID]
- Version: [X.Y]
- Effective date: [YYYY-MM-DD]
- Owner: [Role]
- Approvers: [QA reviewer], [System owner], [Validation]
- Supersedes: [ID and version]
- Change history: [Summary of revisions]
- Related documents: [URS ID], [Risk assessment ID], [SOPs], [Calibration policy], [Change control form]

2 Protocol cover page

- Equipment or area: [Name, model, serial/asset ID]
- Location: [Building, room, site]
- Manufacturer and firmware/software: [Details]
- Intended use: [Describe process/use, ranges, loads, criticality]
- Qualification stage(s) covered: [IQ, OQ, PQ]
- Qualification team: [Names and roles]
- References: [Standards, SOPs, guidance]

3 Approvals

- Prepared by: [Name, role, date]
- Reviewed by QA: [Name, role, date]
- Approved by system owner: [Name, role, date]
- Approved by validation: [Name, role, date]
- Training acknowledgment: [List personnel trained to this protocol]

4 User requirements specification (URS) checklist

- [ ] Use this checklist to confirm the URS is complete and testable. Attach the URS as a controlled document.
- [ ] Intended use: Describe product(s), loads, and operating ranges the unit must support.
- [ ] Performance ranges: Define acceptable temperature, humidity, and stability ranges; include recovery expectations.
- [ ] Capacity and configuration: Define usable volume, shelving, door type, ports, and accessories.
- [ ] Utilities and environment: Define electrical power, ventilation, ambient constraints, and installation limits.
- [ ] Monitoring and alarms: Define measurement devices, alarm setpoints, notifications, and response requirements.
- [ ] Data integrity: Define records to retain, retention time, audit trail needs, user roles, and access control.
- [ ] Compliance references: List applicable regulations, standards, and corporate policies.

Also read: How to write a URS for pharmaceutical storage areas and TCUs

5 Risk assessment summary

Summarize the approach and key outcomes of your risk assessment. Link to the full analysis.

- Method: [FMEA/HAZOP/What-if] and rationale for selection.
- Critical risks: Identify failure modes that could impact product quality or data integrity.
- Mitigations: Specify design features, procedural controls, and tests that address each risk.
- Residual risk: Justify that the remaining risk is acceptable for intended use.

6 Traceability matrix

Create a table mapping URS items and risks to protocol tests and acceptance criteria.

- URS reference: [URS-xx]
- Risk reference: [RA-xx]
- Test reference: [IQ/OQ/PQ-T-xx]
- Acceptance criteria: [Specific and measurable]
- Evidence location: [Raw data file, mapping report, calibration certificate]

7 Installation qualification (IQ) protocol

Purpose and scope

Confirms that the equipment or environment has been delivered, installed, and configured as specified. Establishes a baseline for future change control and maintenance.

Responsibilities

- Owner: Ensures readiness, utilities, and access.
- Validation: Prepares protocol, oversees execution, compiles report.
- QA: Reviews and approves protocol and report.

Prerequisites

- Documentation available: User manual, installation guide, drawings.
- Utilities available: Power, ventilation, network, and environmental conditions.
- Calibration certificates: Traceable certificates for all sensors and reference instruments.

IQ tests

- Identification: Verify model, serial/asset ID, firmware/software, and accessories against purchase and design records.
- Location and installation: Verify placement, clearance, leveling, and mounting meet specifications and safety requirements.
- Utilities verification: Verify electrical supply, grounding, network connections, and environmental conditions.
- Components and accessories: Verify presence and condition of shelves, probes, and accessories.
- Calibration verification: Verify that installed sensors and reference instruments meet calibration requirements and intervals.
- Software and configuration: Record software version, alarm setpoints, user roles, and security parameters.
- Documentation set: Confirm availability of manuals, drawings, certificates, and SOP references.

Acceptance criteria

Define objective criteria for each IQ test and link them to the URS and risk assessment.

Deviations and nonconformances

Document any departures from expected results with impact assessment and corrective actions.

Attachments

- Equipment list
- Calibration certificates
- As-built drawings and photos

8 Operational qualification (OQ) protocol

Purpose and scope

Challenges functions and controls under defined conditions to demonstrate proper operation against acceptance criteria.

Responsibilities

- Owner: Supports test setup and access.
- Validation: Executes tests and records objective evidence.
- QA: Reviews results and deviations.

Prerequisites

- IQ completed and approved.
- Test equipment calibrated and suitable for range and accuracy.
- Protocol approved and test scripts available.

OQ tests

- Functional checks: Verify controls, displays, door switches, interlocks, and safety features.
- Alarm challenges: Challenge high and low temperature alarms and notification pathways. Record activation thresholds and response times.
- Power interruption/restart: Simulate outages and verify safe restart behavior and data continuity.
- Recovery tests: Open doors or introduce controlled heat loads and measure recovery time and stability.
- Functional mapping: Map temperature (and humidity where applicable) to assess control stability and uniformity with empty or defined test loads.
- Data integrity checks: Verify time synchronization, user access control, audit trail, and completeness of data export.

Also read: Temperature mapping: Tips, frameworks, and pitfalls

Acceptance criteria

Define specific, measurable criteria for each test based on URS and risk assessment.

Deviations and nonconformances

Record the issue, assess impact, determine root cause, and define corrective and preventive actions.

Attachments

- Test data sheets
- Alarm challenge screenshots/records
- Functional mapping report

9 Performance qualification (PQ) protocol

Purpose and scope

Confirms consistent performance in routine use with representative loads, operating patterns, and procedures.

Responsibilities

- Owner: Defines representative use conditions and provides typical loads or simulants.
- Validation: Plans and executes tests, compiles results, and prepares the report.
- QA: Reviews and approves results and CAPA.

Prerequisites

- OQ completed and approved.
- Representative loads and operating procedures available.
- Monitoring devices calibrated and positioned per test plan.

PQ tests

- Representative loading: Qualify with typical product or simulants, including justified worst-case placements.
- Operational mapping: Map the environment under steady-state conditions to verify uniformity and identify hot/cold spots.
- Process capability in use: Monitor excursions, alarms, and responses over a defined period; verify trending and escalation flows.
- Procedural verification: Verify SOP steps for loading, door openings, and alarm response are practical and effective.

Acceptance criteria

Define pass/fail criteria tied to intended use and risk assessment. Explain rationale for test durations and sampling density.

Deviations and nonconformances

Capture issues, assess product impact, and close with root cause and corrective actions.

Attachments

- Mapping plan and report
- Load diagrams and photos
- In-use monitoring data extracts

10 Requalification and periodic review

- Triggers: Define requalification triggers such as significant repairs, relocation, repeated deviations, or trend analysis indicating loss of control.
- Periodic review: Define the frequency and content of reviews, including performance data, deviations, maintenance history, and change control.
- Seasonal considerations: Where relevant, consider seasonal variation when reviewing mapping and performance data.

Also read: Continuous temperature mapping: A framework to eliminate re-mapping

11 Data integrity and electronic records

- Access control: Define user roles, privileges, and authentication requirements.
- Audit trail: Define what events are captured, how they are reviewed, and retention.
- Electronic signatures: Define signing steps and authority levels for approvals.
- Records lifecycle: Define retention time, secure storage, backup, and retrieval testing.
- Supplier assessment: Summarize evaluation of software and service providers supporting the system.

12 Calibration and metrology

- Instruments in scope: List sensors, reference standards, and data loggers with IDs and ranges.
- Calibration requirements: Define standards, intervals, and tolerances; include uncertainty where applicable.
- As-found/as-left: Record conditions and acceptance for each calibration.
- Out-of-tolerance handling: Define impact assessment, product evaluation, and corrective actions.

13 Deviation and CAPA form

- Deviation ID and date: [ID, date]
- Reference: [Protocol section/test ID]
- Description: [Observed condition]
- Immediate action: [Containment]
- Impact assessment: [Product/data integrity]
- Root cause: [Method and outcome]
- Corrective action: [Details and owner]
- Preventive action: [Details and owner]
- Effectiveness check: [Plan and date]
- Approvals: [Signatures]

14 Final report

- Executive summary: State outcome for IQ, OQ, and PQ.
- Scope and deviations: Confirm what was executed and summarize deviations and CAPA.
- Results summary: Summarize key outcomes against acceptance criteria.
- Traceability: Include the completed traceability matrix and references to raw data.
- Statement of fitness: Conclude on suitability for intended use and any conditions or follow-up actions.
- Approvals: QA and system owner sign-off with dates.

15 Appendices

- Example test data sheet: Preformatted table with fields for instrument ID, calibration due date, setpoint, measured values, and pass/fail.
- Alarm challenge worksheet: Steps for safe simulation, expected response, and documentation tips.
- Functional mapping worksheet: Grid layout, sensor IDs, sample frequency, and data integrity checks.
- Representative load diagram: Placeholder diagrams to mark load and probe positions.
- Traceability matrix table: Blank table suitable for direct use.

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- ✓ **Cost- and time-optimized process**
- ✓ **Full GxP compliance confidence**

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