GxP-Desk

FIT-CLEAN

CS-TPL-0004 · GXP-DESK DOCUMENTATION

IQ / OQ / PQ Protocol.

FIT-only redaction. Effective 2026-06-04.

DOCUMENT ID	VERSION	EFFECTIVE	OWNER
CS-TPL-0004	v1.0	2026-06-04	Validation Engineering

Public — Documentation · Review cycle: On change

01 — DOCUMENT CONTROL

Control block and metadata anchor.

The control block identifies the document, its current revision, the regulated process it supports, and the people accountable for its lifecycle. Every value below is the source of truth for any downstream record, audit trail entry, or signature block.

DOCUMENT ID	CS-TPL-0004
TITLE	IQ / OQ / PQ Protocol (Format Specification)
VERSION	v1.0
STATUS	FIT-CLEAN
EFFECTIVE DATE	2026-06-04
REVIEW CYCLE	On change
DOCUMENT OWNER	Validation Engineering
CLASSIFICATION	Public — Documentation
RELATED RECORDS	—
SUPERSEDES	— (initial release)

02 — APPROVALS

Sign-off table, ready for ink or e-signature.

The signatures below confirm review and authorisation of this document. Approvals must be recorded in chronological order. If the document is signed electronically, the e-signature record on the GxP-Desk platform supersedes any handwritten entry on this page and carries the same legal weight under 21 CFR Part 11 and EU GMP Annex 11.

Role	Name	Function	Date	Signature
Author		Validation Lead		
Reviewer		Quality Assurance		
Reviewer		Process / System Owner		
Approver		Head of Quality		
Approver		Regulatory Affairs		

03 — CONTENTS

What's in this document.

01 — WHAT THIS TEMPLATE COVERS

What this template covers.

This combined IQ/OQ/PQ template defines how **test protocols** are structured:

- **Header**: Test Type, Change, System, Test Environment, Test Data Class
- **Prerequisites**: documentation, personnel, environmental
- **Test cases**: ID, URS citation (free text), description, pass criterion, evidence required
- **Execution log**: auto-generated platform-side from the Audit Trail
- **Deviations**: severity-based (Critical / Major / Minor / Cosmetic)
- **Signatures**: Protocol Author, Reviewer, Approver (pre-execution); Test Reviewer, Approver (post-execution)
- **Evidence anchoring**: SHA-256 hash of the uploaded files

02 — WHAT THIS TEMPLATE DOES NOT COVER (ROADMAP)

What this template does NOT cover (Roadmap).

- **Auto pre-population of test cases from the URS**: No generation of OQ steps from URS-F items
- **URS citation as FK**: Citations are free text (e.g. "URS-F-001"); there is no foreign-key linkage
- **Living-document inheritance across Changes**: No automatic versioning of protocol templates between Initial and Change
- **Automatic evidence format validation**: Evidence is hashed; format validation is manual
- **Test-case re-use across Changes**: No template library with prebuilt test cases

03 — STRUCTURE OF THE IQ / OQ / PQ PROTOCOL

Structure of the IQ / OQ / PQ Protocol.

1. Header (Protocol Information)

Field	Value
Test Type	[IQ \
Change Number	[System-Slug]-CHG-[nnn]
System Under Test	[System Name and Version]
Test Environment	[Production \
Test Data Classification	[Synthetic \
Test Author	[Name]
Test Reviewer	[Name]
QA Approver	[Name]
Test Executor(s)	[List of Names]
Witness (if applicable)	[Name \

2. Prerequisites

2.1 Documentation Prerequisites

- URS [ID, Version] in **Approved** state
- Risk Assessment [ID, Version] in **Approved** state
- Validation Plan [ID, Version] in **Approved** state with Plan-Execute gate signed
- Test environment configured per Configuration Baseline

2.2 Personnel Prerequisites

- Test Executor(s) trained on this Test Type and on Tenant's evidence-capture SOP
- Test Reviewer assigned and free of Separation of Duties (SoD) conflicts
- QA Approver assigned and free of SoD conflicts

2.3 Environmental Prerequisites

IQ-specific:

- System present at configured version
- Baseline matches Configuration Specification
- Installation location and infrastructure documented

OQ-specific:

- Test data loaded in test environment
- Controlled-vocabulary lookups in place
- Test users configured with required roles

PQ-specific:

- Production-equivalent users and data
- Integration endpoints in test mode if applicable
- Load-generation tools ready (if applicable)

3. Test Cases

3.1 Test Case Structure

Each test case has:

- **Test ID**: IQ-001, OQ-001, PQ-001, ... (unique per protocol)
- **Cites URS**: Free-text reference, e.g. "URS-F-001" or "—" (when not directly URS-related)
- **Description**: What is being tested?
- **Pass Criterion**: Quantifiable or qualifiable expectation
- **Evidence Required**: Documentation type(s), e.g. "Screenshot", "Log excerpt", "Performance report"

3.2 Test Case Table

Test ID	Cites URS	Description	Pass Criterion	Evidence Required
IQ-001	—	Confirm System version matches the documented Configuration Baseline.	Reported version equals baseline.	Screenshot of System version display
OQ-014	URS-R-001	Verify audit-trail entry is written for every signature event.	Audit-trail event type `deliverable.qa.approve` exists with correct actor, target, timestamp.	Audit-trail JSONL excerpt
PQ-007	URS-P-001	Round-trip search latency under representative load.	p95 latency ≤ [target from Service Order].	Performance log; load-generator report

Test ID	Cites URS	Description	Pass Criterion	Evidence Required
XX-...	—	[Add test cases.]	[Criterion]	[Evidence type]

3.3 Test Step Format

Each test case contains a sequence of numbered **steps**.

Each step has:

- **Step Number**: 1, 2, 3, ...
- **Action**: What to do
- **Expected Observation**: What should be visible?
- **Result**: Pass / Fail / Not Applicable
- **Evidence Captured**: File reference(s)
- **Executor Initials**: Name of the executor
- **Timestamp**: Server-side UTC

Example step format (in protocol):

```
Test Case: OQ-014
Step 2:
  Action: Log in as QA Approver; approve a document deliverable.
  Expected: System writes audit entry; timestamp reflects server UTC.
  Result: [To be filled at execution]
  Evidence: [Evidence file(s) to upload]
  Executor: ___  Timestamp: ___
```

3.4 Evidence Hashing

> **NOTE**
> On upload, each evidence file is hashed (SHA-256). The hash is part of the test-step audit trail. Tampering after upload is detectable indefinitely.

4. Execution Log

The Execution Log is **generated automatically by the platform** from the Audit Trail and contains:

- Test Case ID
- Step Number
- Executor (authenticated user)
- Timestamp (server-side UTC)

- Result (Pass / Fail / N/A)
- Evidence Reference (Hash + Filename)
- Deviation Reference (if any)
- Comments

Note: The Execution Log is not maintained manually; it is an audit-trail export.

5. Deviations Raised During Test Execution

When a test step does not meet the expected observation:

5.1 Deviation Severity

Severity	Definition	Effect on Change Closure
Critical	Patient safety, product quality, or data integrity is directly affected.	Blocks Change closure absolutely.
Major	Significant operational or regulatory impact; not patient-affecting.	Must be Closed or carried as residual risk with QA approval.
Minor	Limited impact; documented workaround exists.	Should be closed in-Change; can be carried with rationale.
Cosmetic	Documentation, usability, or aesthetic impact.	Tracked; does not block closure.

5.2 Deviation Workflow

01 The Test Executor raises a Deviation directly from the step record

02 The Deviation captures: - Title / Description - Root-cause hypothesis - Investigation steps - Resolution / workaround

03 The QA Approver signs the closure or carry-forward

6. Signatures (Protocol and Results)

6.1 Pre-Execution Signatures (on Protocol)

Block	Signed When	Signature Meaning
Protocol Author	Before execution (Plan-phase gate)	Authored as Validation Lead.
Protocol Reviewer	Before execution (Plan-phase gate)	Reviewed and recommended for approval.
Protocol Approver (QA)	Before execution (Plan-phase gate)	Approved — Protocol fit for execution.

6.2 At-Execution Signatures

Block	Signed When	Signature Meaning
Test Executor	At each step result	Executed step and captured evidence.
Witness (if required)	At applicable step	Witnessed execution.

6.3 Post-Execution Signatures (on Results)

Block	Signed When	Signature Meaning
Test Reviewer	After execution (before Execute-Report gate)	Reviewed test results.
Test Approver (QA)	After execution (Execute-Report gate)	Approved test results — execution complete.

6.4 SoD Enforcement

> **TEST EXECUTOR ≠ TEST APPROVER**
> : The person who executed a test step cannot approve the test results. The platform rejects this approval.

04 — IQ — INSTALLATION QUALIFICATION

IQ — Installation Qualification.

What IQ proves: Is the System installed correctly, with the right version, configuration baseline, and components?

IQ Test Cases (Examples)

Test ID	Description	Pass Criterion	Evidence
IQ-001	System version matches baseline.	Version display equals documented baseline.	Screenshot
IQ-002	Required components are present (e.g. database, web server, identity provider).	Component list matches Bill of Materials.	Component verification report
IQ-003	Configuration file checksums match baseline.	SHA-256 of config file equals documented baseline.	Checksum verification report

05 — OQ — OPERATIONAL QUALIFICATION

OQ — Operational Qualification.

What OQ proves: Does the System operate correctly under controlled conditions? Does each requirement function as specified?

OQ Test Cases (Examples)

Test ID	Cites URS	Description	Pass Criterion	Evidence
OQ-001	URS-F-001	Authorized author can create document from approved template.	Document created; template source confirmed.	Screenshot of created document
OQ-014	URS-R-001	Audit-trail event written for every signature event.	Audit-trail contains entry with correct actor, action, timestamp.	Audit-trail JSONL excerpt
OQ-015	URS-R-003	Password-based authentication enforced before signature.	User must authenticate; signature proceeds only after successful auth.	Screenshot sequence

06 — PQ — PERFORMANCE QUALIFICATION

PQ — Performance Qualification.

What PQ proves: Does the System perform in the intended use environment with intended users and data?

PQ Test Cases (Examples)

Test ID	Cites URS	Description	Pass Criterion	Evidence
PQ-001	URS-P-001	Round-trip search latency under target load.	p95 latency ≤ [Service Order target].	Performance log; load-generator report
PQ-002	URS-P-002	System supports concurrent-user capacity.	System remains responsive with [target] simultaneous users.	Load test report; response-time percentiles
PQ-007	URS-F-002	Document workflow (Author → Reviewer → Approver) executes end-to-end with production-equivalent data.	All workflow steps complete; document transitions to Approved.	Workflow execution screenshot; timestamp log

07 — CODE REFERENCES

Code references.

- **TestCase model**: `prisma/schema.prisma` → `TestCase` (testId, description, passCriterion, evidenceRequired, testExecutionId)
- **TestExecution model**: `TestExecution` (executorId, startTime, endTime, result, deviationId)
- **Evidence upload**: Hash-anchored via SHA-256 in the Audit Trail
- **Deviation model**: `Deviation` (title, severity, rootCause, resolution, status)
- **Test Step execution**: Logged per step in the Audit Trail with executor, result, evidence hash
- **Signature workflow**: Document approval chain on Protocol/Results documents
- **SoD Enforcement**: `requireChangePermission` with role checks (Executor ≠ Approver)

08 — FORMATTING TIPS

Formatting tips.

- **Test cases are not automatically pre-populated**: Manual authoring based on the URS and the VP risk-based strategy
- **Evidence is hashed**: Tampering detection via SHA-256 comparison is possible indefinitely
- **The Execution Log is auto-generated**: It is not maintained manually
- **Deviations are step-level**: They are detected and documented directly upon failure
- **Prerequisites must be true**: The platform does not validate them; a manual checkpoint is required
- **Test Data Classification** is important for regulatory acceptance (Synthetic vs. Production-equivalent)

REVISION HISTORY

Every change, tracked and signed.

Add one row for every controlled revision. Minor changes (typos, formatting) increment the patch version; substantive edits trigger a fresh review cycle and a new approver round.

Version	Date	Author	Summary of Change	Approver
1.0	2026-04-28	Documentation Team	Initial release of the IQ/OQ/PQ template.	Head of Documentation
—	—	—	Reserved for next revision. Do not delete this row.	—

GLOSSARY

Shared language, no ambiguity.

Definitions used throughout this document. Where a term has a specific meaning inside GxP-Desk, the platform-specific definition takes precedence over the generic regulatory term.

CSV	Computerized Systems Validation
GAMP 5	Good Automated Manufacturing Practice, Edition 5 (2nd edition, 2022)
GxP	Good 'x' Practice — covers GMP, GLP, GCP, GDP, GVP
IQ / OQ / PQ	Installation / Operational / Performance Qualification
Part 11	21 CFR Part 11 — US FDA rule on electronic records and electronic signatures
Annex 11	EU GMP Annex 11 — EU rule on computerised systems
URS	User Requirements Specification
FRS	Functional Requirements Specification
RTM	Requirements Traceability Matrix
SOP	Standard Operating Procedure
ALCOA+	Attributable, Legible, Contemporaneous, Original, Accurate (+ Complete, Consistent, Enduring, Available)
ICH Q9	International Council for Harmonisation Quality Risk Management guideline

— End of document —