ComplianceSuite

FIT-CLEAN

CS-TPL-0003 · COMPLIANCESUITE DOCUMENTATION

Validation Plan.

FIT-only redaction. Effective 2026-04-28.

DOCUMENT ID	VERSION	EFFECTIVE	OWNER
CS-TPL-0003	v1.0	2026-04-28	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-0003
TITLE	Validation Plan (Format Specification)
VERSION	v1.0
STATUS	FIT-CLEAN
EFFECTIVE DATE	2026-04-28
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 ComplianceSuite 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 Validation Plan template defines how **validation strategy, roles, deliverables, phase gates, and acceptance criteria** are documented for a Change:

- **Scope and References**: System, Change, Regulations
- **Roles and Responsibilities**: Change Author, Reviewer, QA Approver, Validation Lead, Test Executors, Head of Quality, System Owner
- **Deliverable Matrix**: Document Type, Author, Reviewer, Approver, Phase
- **Risk-Based Test Strategy**: IQ/OQ/PQ depth based on URS Risk classification
- **Phase Gates and Exit Criteria**: Plan-Execute, Execute-Report, Closure
- **Deviation and CAPA Handling**: Severity-based (Minor / Major / Critical)

02 — WHAT THIS TEMPLATE DOES NOT COVER (ROADMAP)

What this template does NOT cover (Roadmap).

- **Auto-Population of Scope/Deliverables**: No automatic population from Change Metadata
- **Enforced Phase-Gate Locks**: Phase Gates are documentary; no Workflow-Engine enforcement that Plan is locked before Execute
- **Two-Person QA-Approval Configuration**: No mandatory Dual-Approval per Gate
- **Inspection-Tag-Based Gate Criteria**: Inspection Tag is Metadata, but no Gate-Validation Trigger
- **Auto-Generation of Deliverable Matrix**: Manually maintained, not auto-populated

Validation Plan Structure.

1. Scope and References

1.1 Scope

This Validation Plan applies to:

- **Change Number**: [System-Slug]-CHG-[nnn]
- **Change Type**: Initial Validation / Upgrade / Configuration / Periodic Review
- **System**: [System Name and Slug]
- **Tenant**: [Tenant Slug]
- **Account**: [Account Name]

1.2 References

- **URS**: [Doc-ID, Version]
- **Risk Assessment**: [Doc-ID, Version]
- **Tenant SOPs**: [List of SOP IDs]
- **Applicable Regulations**: 21 CFR Part 11; EU GMP Annex 11; GAMP 5 (2nd ed.) Cat [3 / 4 / 5]

2. Roles and Responsibilities

Role	Responsibility	Named Individual
Change Author	Authors deliverables; submits for review.	[Name]
Change Reviewer	Reviews deliverables; recommends approval.	[Name]
Tenant QA Approver	Approves deliverables; signs phase gates.	[Name]
Tenant Validation Lead	Owns the Plan; arbitrates scoping questions.	[Name]
Test Executor(s)	Executes IQ/OQ/PQ steps; captures evidence.	[List]
Head of Quality	Closes the Change at Validation Report approval.	[Name]

Role	Responsibility	Named Individual
System Owner	Operational accountability for the System post-release.	[Name]

3. Deliverable Matrix

All Deliverables per Phase with Author, Reviewer, Approver:

Deliverable	Author	Reviewer	Approver	Phase
URS	Validation Lead	QA / SME	Tenant QA Approver	Plan
Risk Assessment	Validation Lead	QA / SME	Tenant QA Approver + Compliance Lead (high-risk)	Plan
Validation Plan	Validation Lead	QA	Tenant QA Approver	Plan
IQ Protocol	Validation Lead	QA / SME	Tenant QA Approver	Plan
IQ Results	Test Executor	Validation Lead	Tenant QA Approver	Execute
OQ Protocol	Validation Lead	QA / SME	Tenant QA Approver	Plan
OQ Results	Test Executor	Validation Lead	Tenant QA Approver	Execute
PQ Protocol	Validation Lead	QA / SME	Tenant QA Approver	Plan
PQ Results	Test Executor	Validation Lead	Tenant QA Approver	Execute
Traceability Matrix	[Manual or Auto-generated]	Validation Lead	Tenant QA Approver	Throughout
Validation Report	Validation Lead	QA + System Owner	Tenant QA Approver + Head of Quality	Report

Note: Traceability Matrix is not automatically generated in current code; maintained manually or via DocumentRelation API aggregation.

4. Risk-Based Test Strategy

Test depth based on URS Risk classification:

URS Risk Class	IQ	OQ	PQ
High	Required where applicable	Required, with focused negative tests	Required end-to-end with realistic data
Medium	Required where applicable	Required, positive-path	Required, sampled
Low	As applicable	Required, positive-path	Optional

Tests are linked with URS items via **ID-based references** (e.g. Test cites "URS-F-001"), not automatic FK.

Uncovered High-Risk Items block the Plan-Execute Gate **documentary** (i.e. Validation Lead must explicit waive or solve Coverage).

5. Phase Gates and Exit Criteria

5.1 Plan-Execute Gate

Exit Criteria:

- URS, Risk, Validation Plan, IQ/OQ/PQ Protocols all Approved
- Risk Register covers all High and Medium URS Items
- [Further Criteria]

Signatory: Tenant QA Approver

5.2 Execute-Report Gate

Exit Criteria:

- All Test Cases reach Terminal Status
- No Critical Deviations open
- All Major Deviations closed or with QA Approval carried as Residual Risk
- Test Results all Approved

Signatory: Tenant QA Approver

5.3 Closure Gate

Exit Criteria:

- Validation Report Approved
- Acceptance Recommendation placed (Accept / Conditional Accept / Reject)
- Closure Checklist green
- Head of Quality Release Authorization

Signatory: Head of Quality (seals the Change and marks System as Production)

6. Schedule

Phase milestones, target dates, dependencies:

Milestone	Target Date	Dependencies
Plan-phase start	[Date]	Change registered, Validation Lead assigned
Plan-Execute gate signed	[Date]	URS, Risk, Protocols Approved
Execute-phase start	[Date]	Test environment ready

Milestone	Target Date	Dependencies
Execute-Report gate signed	[Date]	All tests terminal; deviations resolved or carried
Closure	[Date]	Validation Report Approved, Head of Quality available

Note: Platform tracks actual vs. planned; material deviations are documented as Audit Trail entry.

7. Deviation and CAPA Handling

7.1 Deviation Severity

Severity	Definition	Effect on 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.

7.2 Deviation Workflow

- Deviations are **raised during Test Execution** by Test Executors
- Severity classification occurs immediately
- Investigation, Root Cause, Resolution are documented
- QA Approver signs Closure or Carry-Forward Decision
- Carry-Forward requires documented justification

7.3 CAPA Tracking

CAPAs initiated in this Change:

- Are tracked in the Tenant CAPA system
- Their Closure is referenced in the Validation Report
- CAPAs not closed in this Change are **Closure Blockers** (Major Deviation equivalent)

8. Out-of-Scope Statements

- [Function or scope explicitly out of this Change]
- [Risk class or test type explicitly deferred]

- [Documented exclusions inherited from URS]

9. Acceptance Criteria

This Plan is successfully fulfilled when:

01 **Plan phase:** - All Plan Deliverables (URS, Risk, Protocols) are Approved - Plan-Execute gate is signed

01 **Execute phase:** - All Test Cases are terminal (Passed, Failed-Resolved, or Carried) - All deviations are resolved or carried with QA approval - Execute-Report gate is signed

01 **Closure:** - Validation Report is Approved - Acceptance Recommendation is placed - Head of Quality releases System for GxP use - Change is sealed (immutable)

Code Reference.

- **Change Model**: `prisma/schema.prisma` → `Change` (changeId, type, status, systemId, tenantId)
- **Phase Status**: `Plan` / `Execute` / `Report` (enum ChangePhase, but not workflow-enforced)
- **Document Sections**: `DocumentSection` model for Editorial Content
- **Document Status**: APPROVED, REJECTED, IN_REVIEW, DRAFT (but no automatic Phase Lock)
- **PhaseDocumentConfig**: `TenantSetting` with Phase-to-Template mapping
- **Deliverable Matrix**: Manually maintained as Document Sections or as separate table
- **Deviation Model**: `Deviation` with severity, status, resolution

05 — FORMAT TIPS

Format Tips.

- **Validation Plan is signed once** after Plan phase; Material Changes require Re-open, Re-review, Re-approval
- **Phase Gates are documentary**, not procedurally enforced (i.e. no blocking of UI)
- **Risk-Based Test Strategy** is defined in Validation Plan; concrete Test Cases are detailed in IQ/OQ/PQ Protocols
- **Traceability Matrix** is manually or via API generated; not auto-updated on Test Changes
- **Schedule** should be realistic; Platform tracks Actual vs. Planned

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 Validation Plan 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 ComplianceSuite, 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 —