CS-TPL-0006 · COMPLIANCESUITE DOCUMENTATION

Validation Report.

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

DOCUMENT ID	VERSION	EFFECTIVE	OWNER
CS-TPL-0006	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-0006
TITLE	Validation Report (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 Report template defines how **the final Change-Acceptance Deliverable** is structured:

- **Auto-Sections**: Executive Summary, Deliverable Status, Test Summary, Deviation Summary, Risk Re-evaluation, Traceability Summary (conceptually auto-populable)
- **Authored Sections**: Acceptance Recommendation, Residual Risk Statement, Operational Handover (manual)
- **Sign-off**: Author (Validation Lead), Reviewer (QA + System Owner), Approver (Tenant QA Approver), Closing Authority (Head of Quality)
- **Sealing Mechanic**: Head-of-Quality Signature seals Change; System moves to Production Status

02 — WHAT THIS TEMPLATE DOES NOT COVER (ROADMAP)

What this template does NOT cover (Roadmap).

- **Auto-Section Builder**: No automatic generation of Auto-Sections from Change data
- **Auto-Deliverable-Status Pull**: No query over all Deliverables in the Change with Status + Signatures
- **Auto-Test Summary**: No aggregation of TestExecution Results into Summary table
- **Auto-Deviation Summary**: No enumeration of all Deviations in the Change
- **Auto-Risk Reassessment Summary**: No RiskItem re-evaluation and Residual-Risk flagging
- **Auto-Traceability Summary**: No RTM aggregation and Coverage reporting in Report Section

03 — VALIDATION REPORT STRUCTURE

Validation Report Structure.

1. Executive Summary (Auto-conceptually)

Captures (to be populated manually or conceptually auto-populable):

- Change Number and Type
- System Scope
- Schedule (Planned vs. Actual)
- Deliverable Count
- Test Counts and Pass / Fail / Carried Ratio
- Deviation Count by Severity
- RTM Coverage at Closure (Covered / Partial / Uncovered)
- Key Dates (Start, Plan-Execute, Execute-Report, Closure)

Example Text:

> **NOTE**
> This Validation Report covers Change [System-Slug]-CHG-[nnn] — Initial Validation of [System Name] Version [X.Y] for [Tenant Name]. The Change completed in [Duration], with all Plan-phase deliverables approved. Testing executed [IQ/OQ/PQ] with [NN] test cases, achieving [XX]% Pass rate and carrying [Y] deviations (Major: [M], Minor: [m]) with documented justification. RTM coverage achieved [Covered/Partial] status for all High and Medium requirements.

2. Scope and References (Authored)

- **Change**: [System-Slug]-CHG-[nnn]
- **System**: [Name, Version]
- **Tenant**: [Slug]
- **Account**: [Name]
- **Change Type**: [Initial Validation / Upgrade / Configuration / Periodic Review]
- **URS Document**: [ID, Version, Approval Date]
- **Risk Assessment Document**: [ID, Version, Approval Date]
- **Validation Plan Document**: [ID, Version, Approval Date]
- **Applicable Regulations**: [21 CFR Part 11, EU GMP Annex 11, GAMP 5 Cat X]

3. Deliverable Status (Auto-conceptually)

Table with all Deliverables in the Change:

Deliverable	Document ID	Version	Author	Reviewer	Approver	Approval Date
URS	[ID]	[X.Y]	[Name]	[Name]	[Name]	[Date]
Risk Assessment	[ID]	[X.Y]	[Name]	[Name]	[Name]	[Date]
Validation Plan	[ID]	[X.Y]	[Name]	[Name]	[Name]	[Date]
IQ Protocol	[ID]	[X.Y]	[Name]	[Name]	[Name]	[Date]
IQ Results	[ID]	[X.Y]	[Executor]	[Lead]	[Approver]	[Date]
OQ Protocol	[ID]	[X.Y]	[Name]	[Name]	[Name]	[Date]
OQ Results	[ID]	[X.Y]	[Executor]	[Lead]	[Approver]	[Date]
PQ Protocol	[ID]	[X.Y]	[Name]	[Name]	[Name]	[Date]
PQ Results	[ID]	[X.Y]	[Executor]	[Lead]	[Approver]	[Date]
Traceability Matrix	[ID]	[X.Y]	[Auto / Lead]	[Lead]	[Approver]	[Date]

4. Test Summary (Auto-conceptually)

Aggregated Test Statistics:

Phase	Test Count	Passed	Failed-Resolved	Carried	Pending
IQ	[N]	[N]	[N]	[N]	[N]
OQ	[N]	[N]	[N]	[N]	[N]
PQ	[N]	[N]	[N]	[N]	[N]
Total	[N]	[N]	[N]	[N]	[N]

Example Text:

> **NOTE**
> IQ testing confirmed system installation with [NN] test cases, all Passed. OQ testing verified functionality with [NN] test cases ([XX]% Passed, [Y] Carried with documented rationale). PQ testing validated performance characteristics with [NN] test cases ([XX]% Passed). No Critical deviations were raised.

5. Deviation Summary (Auto-conceptually)

Enumeration of all Deviations in the Change:

Dev ID	Title	Severity	Root Cause	Resolution	Status	Approver
DEV-001	[Title]	Major	[Cause]	[Resolution]	Closed	[Name]
DEV-002	[Title]	Minor	[Cause]	[Resolution / Workaround]	Closed	[Name]
DEV-...	—	—	—	—	—	—

Sum by Severity:

- Critical: [N] (Closure Blockers)
- Major: [N] (Closed or Carried as Residual Risk)
- Minor: [N] (Closed or Carried)
- Cosmetic: [N] (Tracked)

6. Risk Re-evaluation (Auto-conceptually)

Summary of Post-Mitigation Evaluation:

Risk ID	Pre-Mitigation RPN	Post-Mitigation RPN	Class Change	Decision	Approver
RA-001	5 (Low)	5 (Low)	—	Accepted as mitigated	[Name]
RA-002	36 (High)	8 (Low)	High → Low	Accepted as mitigated	[Name]
RA-003	18 (Medium)	12 (Low)	Medium → Low	Accepted as mitigated	[Name]
RA-...	—	—	—	—	—

Residual Risk Summary:

- Risks carried forward as residual: [NN]
- Risks fully mitigated and closed: [NN]
- Risks re-scoped to future Change: [NN]

7. Traceability Summary (Auto-conceptually)

RTM Coverage Status:

Status	Count	Items
Covered	[N]	[URS-F-001, URS-R-001, ...]
Partial	[N]	[URS-F-002, ...]
Uncovered	[N]	[URS-P-001, ...]
Total	[N]	—

Coverage by Risk Class:

- High: [Covered / Partial / Uncovered]
- Medium: [Covered / Partial / Uncovered]
- Low: [Covered / Partial / Uncovered]

Uncovered Items Analysis (if any): For each Uncovered High or Medium Item:

- **URS ID**: [ID]
- **Requirement**: [Summary]
- **Reason for non-coverage**: [Documented rationale]
- **Mitigation**: [Alternative control or deferred to future Change]

8. Acceptance Recommendation (Authored)

Validation Lead writes this Section:

Pick One:

Option A: Accept

Appropriate when:

- All deliverables Approved
- All High and Medium risks at acceptable post-mitigation RPN
- No Critical or Major deviations open
- RTM coverage complete for High and Medium URS items

Recommendation: Accept

Justification: [One paragraph explaining the recommendation, referencing the auto-populated sections by number where evidence supports the decision.]

Example:

> **NOTE**
> The Validation Plan is complete, with all deliverables Approved (Section 3). Testing achieved [XX]% Pass rate across IQ/OQ/PQ (Section 4), with [Y] Minor deviations closed in-Change (Section 5). Risk re-evaluation shows all High-risk items mitigated to Medium or below (Section 6). RTM coverage is Covered for all High-risk requirements (Section 7). This Change meets acceptance criteria and is recommended for release to production GxP use.

Option B: Conditional Accept

Appropriate when:

- Acceptance is conditional on named follow-up conditions (e.g. follow-up Change, ongoing observability, documented residual risk)
- Conditions must be enumerated and signed off

Recommendation: Conditional Accept

Conditions:

01 [Condition]: [Follow-up Change [ID] to address Uncovered item URS-P-002]

02 [Condition]: [Ongoing SIEM monitoring of RA-003 Residual Risk with escalation rule]

03 [Condition]: [Periodic Review in [NN] months to re-assess RA-XXX]

Justification: [Paragraph explaining why acceptance is conditional and how conditions mitigate gaps.]

Option C: Reject

Appropriate when:

- Material gaps remain
- A follow-up Change is required
- System cannot be released to production GxP use

Recommendation: Reject

Reason: [Explain why the System does not meet acceptance criteria.]

9. Residual Risk Statement (Authored)

List every risk carried forward as residual after mitigation:

Risk ID	Carried Risk	Why Carried	Operational Control	Re-Trigger Condition
RA-XXX	[Description]	[Justification — e.g. mitigation impact vs. risk acceptable given baseline]	[Monitoring control — e.g. SIEM alert, Periodic Review check, routine report]	[Condition that re-opens — e.g. frequency exceeds threshold, vendor advisory]
RA-...	—	—	—	—

Example Row: | RA-003 | Search latency degrades under load > 500 concurrent users (Residual RPN: 12, Medium→Low) | Mitigation investments in DB optimization would exceed Change scope; acceptable as production baseline unknown volume | SIEM monitoring of search-latency p95; escalation if p95 > [Target] for > 1 hour | Actual production load exceeds forecast; re-assessment required |

10. Operational Handover (Authored)

System Owner: [Name]

Operational SOPs:

- [List of SOPs the System Owner must train operators on before go-live]
- Example: "ComplianceSuite Document Lifecycle SOP", "Audit Trail Review Procedure", "User Access Review SOP"

Known Limitations:

- [Documented limitations the operator should know about, with workarounds where applicable]
- Example: "Maximum document size is 50 MB; larger documents should be split. Workaround: chunked upload via API."

Periodic Review Schedule:

- **Cadence**: [e.g. Annually]
- **First Review Due**: [Date — set at System metadata, typically 12 months post-closure]
- **Scope**: [e.g. Risk re-assessment, Deviation-trend analysis, Technology-change assessment]

Escalation Path:

- **Functional Issues** (document workflow breaks): [Contact System Owner; contact [Vendor] if infrastructure]
- **Data Integrity Concern**: [Escalate to Head of Quality; execute audit-trail review]
- **Performance Degradation**: [Escalate to [Platform Team]]
- **Regulatory Question**: [Contact Compliance Lead]

11. Sign-off (Signatures)

Block	Signature Meaning	Name	Signature	Date
Author (Validation Lead)	Authored Validation Report as Validation Lead.	[Name]	___	___
Reviewer (QA + System Owner)	Reviewed Validation Report and recommended for approval.	[Names]	___	___

Block	Signature Meaning	Name	Signature	Date
Approver (Tenant QA Approver)	Approved Validation Report.	[Name]	___	___
Closing Authority (Head of Quality)	Accepted Validation and authorised release of the System for GxP use.	[Name]	___	___

04 — CLOSING BEHAVIOR

Closing Behavior.

NOTE

When **Head-of-Quality Signature** is executed, Change Status is set to `CLOSED`: - Document.status set to APPROVED; Document.locked set to `true` - System Status is set by Validation Lead to appropriate value (e.g. production-operational) - Audit Trail captures all Signature Events with contentHash + signatureHash - Corrections occur via new Change

Code Reference.

- **Document Sections**: `prisma/schema.prisma` → `DocumentSection` (title, content, order, documentId)
- **Document Status Values (String):** DRAFT, IN_REVIEW, APPROVED, REJECTED (transitions via Server Actions, not automatic)
- **Document Type:** maintained as String per Document
- **Change Status:** DRAFT / SUBMITTED / APPROVED / IN_PROGRESS / COMPLETED / CLOSED
- **Audit Trail:** Every Section change is logged; every Signature creates additional ElectronicSignature Record with Hash binding
- **AI Composer Integration**: `components/composer/` can help author Sections faster (but not auto-generate)

06 — AUTHOR TIPS

Author Tips.

- **Auto-Sections are conceptual**: In current code you must populate manually or via API aggregation
- **AI Composer can help**: For Authored Sections (Acceptance Recommendation, Residual Risk, Handover)
- **Free text in Auto-Sections**: No length limits; use concrete numbers from Change data
- **Signature Workflow**: Sequential (Author → Reviewer → Approver → Closing Authority); no Parallel Signing
- **Sealing is irreversible**: After Head-of-Quality Signature no Corrections possible (new Change required)

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 Report 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 —