

CS-TPL-0005 · COMPLIANCESUITE DOCUMENTATION

Requirements Traceability Matrix.

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

DOCUMENT ID	VERSION	EFFECTIVE	OWNER
CS-TPL-0005	v1.0	2026-04-28	Validation Engineering

Public — Documentation · Review cycle: On change

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-0005
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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		

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Glossary & Abbreviations

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What this template covers.

This Traceability Matrix template defines how **each URS Item is linked to its Specifications, Test Cases, Risks, and Verification Status:**

- **Column Semantics:** URS ID, Requirement, Class, Risk Class, FRS/DS Reference, IQ/OQ/PQ Test Case IDs, Test Result, Risk Reference, Mitigation Reference, Coverage Status
- **Coverage Status:** Covered / Partial / Uncovered
- **Document-Relation Model:** TRACES_TO, TESTED_BY, DERIVED_FROM, SUPERSEDES
- **System-level RTM:** Union of all closed Changes against a System

What this template does NOT cover (Roadmap).

- **Auto-Generation from Citation Graph:** No automatic RTM generation from URS→Test Case links
- **Coverage-Gap Detection as Validator:** No Blocking of Acceptance on Uncovered High-Risk Items
- **Coverage Rules with Gate Enforcement:** Coverage Status is documentary; no Workflow enforcement
- **Auto-Regeneration on Changes:** RTM is manually or via API generated; not auto-updated on new Tests

03 — RTM COLUMN SEMANTICS

RTM Column Semantics.

Each column and its population rule:

Column	Source	Population Rule
URS ID	URS deliverable	Every Requirement in the Approved URS, by ID
Requirement Summary	URS deliverable	First sentence of the Requirement, abbreviated
Class	URS deliverable	Functional / Regulatory / Performance / Interface
Risk Class	URS + Risk Assessment	Inherited from URS Classification; can be overridden in Risk Assessment with justification
FRS / DS Reference	FRS / DS deliverable	Citations from URS to FRS or DS Items
IQ Test Case ID	IQ Protocol	Citations from IQ Test Cases to URS (free text, e.g. "IQ-001")
OQ Test Case ID	OQ Protocol	Citations from OQ Test Cases to URS (free text, e.g. "OQ-014")
PQ Test Case ID	PQ Protocol	Citations from PQ Test Cases to URS (free text, e.g. "PQ-007")
Test Result	Test execution records	Latest Result: Pass / Fail-Resolved / Carried as Residual Risk / Pending
Risk Reference	Risk Assessment	Citations from Risks to URS Items (free text, e.g. "RA-001")
Mitigation Reference	Risk Assessment	Mitigation Linkage; resolves to Test Case verifying Mitigation
Coverage Status	Computed	Covered / Partial / Uncovered (see Coverage Rules)

Coverage Rules and Gates.

Coverage Status is **computed** based on Test Results and Risk Classification:

Coverage State	Risk Class	Effect at Gate / Closure
Uncovered	High	Blocks Plan-Execute Gate documentary; blocks Validation Report Acceptance Recommendation
Uncovered	Medium	Blocks Plan-Execute Gate documentary; can be clarified with justification + QA Approval
Uncovered	Low	Warns at Gate; does not block
Partial	High	Warns; Acceptance must include explicit Residual-Risk Statement with Linkage to Partial-Coverage Rows
Partial	Medium / Low	Warns; does not block
Covered	Any	Goal State; no blocking

Note: These Rules are documentary; no Workflow-Engine enforcement.

Sample RTM Row.

An exemplary row (shown vertically for readability):

Field	Value
URS ID	URS-R-001
Requirement	The System shall maintain a tamper-evident, time-stamped audit trail of every regulated record event.
Class	Regulatory
Risk Class	High
FRS / DS Reference	FRS-AUDIT-002; DS-CONFIG-AUDIT-008
IQ Test Case ID	IQ-014
OQ Test Case ID	OQ-014; OQ-015
PQ Test Case ID	PQ-007
Test Result	Pass (latest)
Risk Reference	RA-001
Mitigation Reference	RA-001-M1 → OQ-014
Coverage Status	Covered

RTM Scope: Change-Level vs. System-Level.

Change-Level RTM

- **Scope:** All URS Items in this Change
- **Lifecycle:** Sealed at Change Closure; immutable
- **Update Frequency:** None; is Snapshot
- **Usage:** Within-Change Traceability, Inspection binder basis

System-Level RTM

- **Scope:** Union of all closed Changes against the System
- **Lifecycle:** Generated on demand; current state reflects all closed Changes
- **Update Frequency:** On demand or per API
- **Merge Rule:** Where URS Item appears in multiple Changes, newest Test Result wins; older Results visible in Citation Graph via URS-ID drill-down
- **Supersession:** When a later Change retires a URS Item, RTM marks Row as "Superseded", does not delete it

API Endpoint (conceptually):

```
GET /v1/{accountId}/tenants/{tenantId}/systems/{systemId}/rtm
```

RTM Governance.

Sealed-Record Discipline

URS Items from closed Changes:

- Never disappear from System-Level RTM
- Marked as "Superseded" if later retired
- Retrievable under historical Change-level RTM
- Audit Trail preserves Citation Graph from all Versions

RTM Inspection Use Cases

Use Case 1: Show me a requirement and how you tested it.

- Click URS row in RTM
- Test Cases open in Inspection View
- Test Results and Evidence visible

Use Case 2: Show me a test result and what it proves.

- Click Test Cell in RTM
- Result, Evidence, Parent URS Item open
- Deviation (if any) linked

Use Case 3: Show me what is uncovered.

- Filter RTM: Coverage Status = Uncovered / Partial
- Only these Rows render
- Rationale per row visible

Use Case 4: Show me the cumulative state of this System.

- Switch: Change-Level RTM → System-Level RTM
- Same View shape; broader Scope

Code Reference.

- **DocumentRelation Model:** `prisma/schema.prisma` → `DocumentRelation` (`relationType`: TRACES_TO, TESTED_BY, DERIVED_FROM, SUPERSEDES; `sourceDocId`, `targetDocId`)
- **TraceabilityMatrix Component:** `components/compliance/TraceabilityMatrix.tsx` (Visualization)
- **RTM Data Source:** Aggregation from:
 - URS Items (Approved State)
 - RiskItem (Risk Assessment)
 - TestCase + TestExecution (IQ/OQ/PQ Results)
 - DocumentRelation (Citations)
- **Coverage Status Computation:** Logic in App Layer based on:
 - TestExecution.result (Pass / Fail / Pending)
 - Risk Class (High / Medium / Low)
 - Test-to-URS Citations

RTM Manual Population (Current State).

Since no automatic RTM generation exists:

- 01 **URS Items** are source (from Approved URS)
- 02 **Test Case Citations** are manually maintained in IQ/OQ/PQ Protocols (free text: "URS-F-001")
- 03 **RTM is aggregated** via: - Manual Excel/Spreadsheet (Tenant-specific) - API Query over DocumentRelation (Validation Lead stitches together) - Export from Validation Report (auto sections provide RTM summary)

Format Tips.

- **RTM is primarily a Read Document:** Inspectors read it; Change-Closure Decisions reference it
- **Coverage Classification** is documentary (Covered / Partial / Uncovered); no enforcement
- **Citations are free text:** Test Cases reference URS Items by ID string ("URS-F-001"), not FK
- **System-Level RTM** is on-demand aggregation from all closed Changes; Supersession tracking via DocumentRelation
- **Evidence Drill-down** is possible: RTM cell → Test Result → Evidence Files (hashed)

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 Traceability Matrix 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 —