GxP-Desk

FIT-CLEAN

CS-TPL-0005 · GXP-DESK DOCUMENTATION

Requirements Traceability Matrix.

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

DOCUMENT ID	VERSION	EFFECTIVE	OWNER
CS-TPL-0005	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-0005
TITLE	Requirements Traceability Matrix (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 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

02 — WHAT THIS TEMPLATE DOES NOT COVER (ROADMAP)

What this template does NOT cover (Roadmap).

> **NOTE**
> Updated 2026-06-04: Change-Level auto-generation and gap detection are implemented; the following aspects remain Roadmap:

- **Auto-generation from a Citation-Graph**: The Change-Level RTM is auto-generated, but from DocumentRelation links rather than from a Citation-Graph
- **Coverage-gap detection as a hard validator**: Gaps are detected (`identifyTraceabilityGaps`), but acceptance with uncovered high-risk items is not hard-blocked
- **Coverage rules with gate enforcement**: Coverage Status is documentary; there is no workflow enforcement
- **System-Level union as a sealed PDF + `/rtm` API**: not implemented

03 — RTM COLUMN SEMANTICS

RTM Column Semantics.

Each column and its population rule:

Column	Source	Population rule
URS ID	URS deliverable	Each 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 the URS classification; overridable in the 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 the test case that verifies the mitigation
Coverage Status	Computed	Covered / Partial / Uncovered (see Coverage Rules)

04 — COVERAGE RULES AND GATES

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 the Plan-Execute gate documentarily; blocks the Validation Report Acceptance Recommendation
Uncovered	Medium	Blocks the Plan-Execute gate documentarily; can be resolved with justification + QA approval
Uncovered	Low	Warns at the gate; does not block
Partial	High	Warns; acceptance must include an explicit residual-risk statement with linkage to partial-coverage rows
Partial	Medium / Low	Warns; does not block
Covered	Any	Target state; no blocking

Note: These rules are documentary; there is no workflow-engine enforcement.

05 — SAMPLE RTM ROW

Sample RTM Row.

An example 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; it is a snapshot
- **Use**: Within-Change traceability, inspection-binder basis

System-Level RTM

- **Scope**: Union of all closed Changes against the System
- **Lifecycle**: Generated on demand; the current state reflects all closed Changes
- **Update frequency**: On demand or via API
- **Merge rule**: Where a URS item appears in multiple Changes, the newest test result wins; older results are visible in the Citation-Graph via URS-ID drill-down
- **Supersession**: When a later Change retires a URS item, the RTM marks the row as "Superseded" and does not delete it

API endpoint (conceptual):

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

RTM Governance.

Sealed-Record Discipline

URS items from closed Changes:

- Never disappear from the System-Level RTM
- Are marked as "Superseded" when retired later
- Remain retrievable under the historical Change-level RTM
- The Audit Trail preserves the Citation-Graph of all versions

RTM Inspection Use Cases

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

- Click the URS row in the RTM
- The test cases open in the Inspection View
- Test results and evidence are visible

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

- Click the test cell in the RTM
- The result, evidence, and parent URS item open
- The deviation (if any) is linked

Use Case 3: Show me what is uncovered.

- Filter the RTM: Coverage Status = Uncovered / Partial
- Only these rows render
- The rationale per row is visible

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

- Switch: Change-Level RTM → System-Level RTM
- Same view shape; broader scope

08 — CODE REFERENCES

Code references.

- **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 the app layer based on:
- TestExecution.result (Pass / Fail / Pending)
- Risk Class (High / Medium / Low)
- Test-to-URS citations

09 — RTM POPULATION (CURRENT STATE)

RTM Population (Current State).

The Change-Level RTM is automatically generated (`getTraceabilityMatrix`); in addition:

01 **URS items** are the source (from the Approved URS)

02 **Test-case citations** are maintained manually in the IQ/OQ/PQ Protocols (free text: "URS-F-001")

03 **The RTM is aggregated** via: - Manual Excel/spreadsheet (tenant-specific) - API query over DocumentRelation (the Validation Lead stitches it together) - Export from the Validation Report (auto-sections provide an RTM summary)

10 — FORMATTING TIPS

Formatting tips.

- **The RTM is primarily a read document**: Inspectors read it; Change-closure decisions reference it
- **Coverage classification** is documentary (Covered / Partial / Uncovered); there is no enforcement
- **Citations are free text**: Test cases reference URS items by ID string ("URS-F-001"), not by FK
- **The System-Level RTM** is aggregated on demand 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
1.1	2026-06-04	Documentation Team	Updated against the GAP/FIT re-analysis: Change-Level RTM auto-generation + gap detection marked as FIT.	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 —