ComplianceSuite

FIT-CLEAN

CS-TPL-0001 · COMPLIANCESUITE DOCUMENTATION

User Requirements Specification.

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

DOCUMENT ID	VERSION	EFFECTIVE	OWNER
CS-TPL-0001	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-0001
TITLE	User Requirements Specification (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 URS template defines how **functional, regulatory, performance, and interface-related requirements** are structured to:

- Be the source for every Test Case and Acceptance Criterion
- Carry risk classification (High / Medium / Low) per requirement
- Explicitly name verification approach (IQ, OQ, PQ)
- Document regulatory citations as reference strings (no FK linkage)

02 — WHAT THIS TEMPLATE DOES NOT COVER (ROADMAP)

What this template does NOT cover (Roadmap).

- **Auto-Linking to Test Cases**: No automatic bidirectional FK to TestCase model
- **Citation Management**: No Citation table or Citation-Tracking; Regulatory citations are free text per URS item
- **Living-Document Inheritance**: No automatic versioning across Changes
- **Mandatory-Acceptance Workflow**: No enforced QA signature on URS Approval as Workflow mechanic (Approval exists, but without Auto-Gate)
- **AI-Driven Section Generation**: No Composer integration for Auto-Generating Sections

URS Structure.

1. System Scope and Intended Use

1.1 System Overview

Description of the System (2–4 paragraphs):

- Vendor and Version
- Regulated processes that the System supports
- Intended user community
- Scaling and geographic coverage

1.2 Intended Use Statement

A concise sentence that describes:

- What the System shall accomplish (e.g. control SOP lifecycle)
- For whom (User Community)
- Under which Regulations (21 CFR Part 11, EU GMP Annex 11, GAMP 5 Cat 3/4/5)

Example:

> **NOTE**
> The ComplianceSuite System is intended to control the lifecycle of regulated documents and validation packages for QA teams operating under 21 CFR Part 11 and EU GMP Annex 11.

1.3 Inclusion / Exclusion Summary

Table with two columns:

In Scope	Out of Scope
Document lifecycle (draft → approval → release)	Mobile-App usage
Audit trail for all signature events	Third-party integration UI
SCIM-based User Provisioning	Report generation (separate requirement)

2. Functional Requirements

Each functional requirement has:

- **ID**: URS-F-001, URS-F-002, ...
- **Requirement**: Concise statement, e.g. "The System shall allow authorised authors to create controlled documents from approved templates only."
- **Risk**: High / Medium / Low (defined in this document)
- **Verification**: IQ, OQ, PQ, or combination (defined in Validation Plan)

Table: Functional Requirements

ID	Requirement	Risk	Verification
URS-F-001	The System shall allow authorised authors to create controlled documents from approved templates only.	Medium	OQ
URS-F-002	The System shall route every controlled document through Author → Reviewer → Approver, enforcing Separation of Duties.	High	OQ + PQ
URS-F-003	[Add further requirement]	—	—

Risk Classification Rule

Risk classification **per requirement**:

- **High**: Failure would directly impact product quality, patient safety, or data integrity
- **Medium**: Failure would impact regulated process, but is detectable
- **Low**: Failure affects only usability or convenience

3. Regulatory Requirements

Each regulatory requirement has:

- **ID**: URS-R-001, URS-R-002, ...
- **Requirement**: Statement
- **Citation**: Regulatory reference (free text: e.g. "21 CFR § 11.10(e); EU Annex 11 § 9")
- **Verification**: IQ, OQ, PQ, or combination

Table: Regulatory Requirements

ID	Requirement	Citation	Verification
URS-R-001	The System shall maintain a tamper-evident, time-stamped audit trail of every regulated record event.	21 CFR § 11.10(e); EU Annex 11 § 9	OQ
URS-R-002	Electronic signatures shall include the printed name, date, and meaning of the signature.	21 CFR § 11.50	OQ
URS-R-003	[Add further requirement]	[Citation]	—

Note: The Citation column is **free text**. There is no separate Citation table or Tracking model; Regulatory references are documented as strings.

4. Performance Requirements

Each performance requirement has:

- **ID**: URS-P-001, URS-P-002, ...
- **Requirement**: e.g. "Round-trip search latency across the controlled-document repository"
- **Acceptance Criterion**: Measurable value (e.g. "p95 latency ≤ 200ms")
- **Verification**: IQ, OQ, PQ

Table: Performance Requirements

ID	Requirement	Acceptance Criterion	Verification
URS-P-001	Round-trip search latency across the controlled-document repository.	p95 latency ≤ [Service Order value]	PQ
URS-P-002	Concurrent-user capacity.	[Service Order value] simultaneous users	PQ
URS-P-003	[Add further requirement]	[Criterion]	—

5. Interface Requirements

Each interface requirement has:

- **ID**: URS-I-001, URS-I-002, ...
- **Interface**: e.g. "Identity Provider", "Audit-log Destination"
- **Requirement**: Protocol, Format, Authentication
- **Verification**: IQ, OQ, PQ

Table: Interface Requirements

ID	Interface	Requirement	Verification
URS-I-001	Authentication	Platform-native JWT authentication with strong password policy	IQ + OQ
URS-I-002	Audit-log Destination	Append-only audit trail with export capability	IQ + OQ
URS-I-003	[Interface]	[Requirement]	—

6. Constraints and Assumptions

- System runs in Cloud Region of Provider (GDPR-compliant)
- Users authenticate via Platform-native Authentication
- Underlying infrastructure is separately qualified
- [Further Assumptions]

7. Out of Scope

- Mobile-App usage of the System
- Third-party UI for Integration Setup
- [Further Out-of-Scope Items]

8. Acceptance Approach

Acceptance of this URS requires:

01 **All Functional and Regulatory requirements** with Risk ≥ Medium must be in the IQ/OQ/PQ Test Set with status **Pass**

02 **Remaining Deviations** (risk-documented) must be QA-approved as residual Risk

03 **Validation Report** must: - Provide acceptance recommendation (Accept / Conditional Accept / Reject) - Be signed by Head of Quality

Code Reference.

- **Template System**: `lib/template-parser.ts` (DOCX→JSON Parser)
- **Template Upload**: `components/templates/TemplateUpload.tsx`
- **Document Sections**: `prisma/schema.prisma` → `DocumentSection` model
- **Phase Configuration**: `PhaseDocumentConfig` in TenantSetting
- **Test Case Model**: `TestCase` (no Citation-FK to URS)
- **URS Item Properties**: `title`, `description`, `riskClass` (High/Medium/Low)

05 — FORMAT TIPS

Format Tips.

- **No linkage between documents**: References to URS items are by ID string, e.g. "URS-F-001"
- **Risk classification** is **per requirement** (not per test)
- **Verification approach** is detailed in Validation Plan; URS only names the type (IQ/OQ/PQ)
- **Regulatory Citations** are free text; no tracking model behind them
- **Revision history** with Version, Date, Author, Approver

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 URS 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 —