GxP-Desk

FIT-CLEAN

CS-TPL-0001 · GXP-DESK DOCUMENTATION

User Requirements Specification.

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

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

- Be the source for every test case and acceptance criterion
- Carry a risk classification (High / Medium / Low) per requirement
- Explicitly name the verification approach (IQ, OQ, PQ)
- Document regulatory citations as referential strings (no FK linking)

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 the 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 a workflow mechanism (approval exists, but without an auto-gate)
- **AI-assisted section generation**: No Composer integration for auto-generating sections

Structure of the URS.

1. System Scope and Intended Use

1.1 System Overview

Description of the system (2–4 paragraphs):

- Vendor and version
- Regulated processes the system supports
- Intended user community
- Scale and geographic coverage

1.2 Intended Use Statement

A concise sentence describing:

- What the system is intended to do (e.g., control the SOP lifecycle)
- For whom (the user community)
- Under which regulations (21 CFR Part 11, EU GMP Annex 11, GAMP 5 Cat 3/4/5)

Example:

> **NOTE**
> The GxP-Desk 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

A two-column table:

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**: A 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 a combination (defined in the 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**: A failure would directly affect product quality, patient safety, or data integrity
- **Medium**: A failure would affect a regulated process but is detectable
- **Low**: A 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 a 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	[Further requirement]	[Citation]	—

Note: The citation column is **free text**. There is no separate citation table or tracking model; the 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**: A 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	[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

- The system runs in the provider's cloud region (GDPR-compliant)
- Users authenticate via platform-native authentication
- The underlying infrastructure is qualified separately
- [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 **Pass** status in the IQ/OQ/PQ test set

02 **Remaining deviations** (documented with respect to risk) must be QA-approved and carried forward as residual risk

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

04 — CODE REFERENCES

Code references.

- **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` (without a citation FK to the URS)
- **URS Item Properties**: `title`, `description`, `riskClass` (High/Medium/Low)

05 — FORMAT TIPS

Format Tips.

- **No linking between documents**: References to URS items are made by ID string, e.g., "URS-F-001"
- **Risk classification** is **per requirement** (not per test)
- **The verification approach** is detailed in the Validation Plan; the URS names only the type (IQ/OQ/PQ)
- **Regulatory citations** are free text; there is 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 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 —