CS-DOC-0006 · GXP-DESK DOCUMENTATION

Document Templates.

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

DOCUMENT ID	VERSION	EFFECTIVE	OWNER
CS-DOC-0006	v1.0	2026-06-04	Customer Success

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-DOC-0006
TITLE	Document Templates
VERSION	v1.0
STATUS	FIT-CLEAN
EFFECTIVE DATE	2026-06-04
REVIEW CYCLE	On change
DOCUMENT OWNER	Customer Success
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 VERSION COVERS

What this version covers.

This documentation describes the generic template system:

- Template model and basic field-level locking states
- Platform vs. tenant libraries (conceptual)
- TemplateUpload component
- Template parser for DOCX
- PhaseDocumentConfig for phase-to-template mapping
- DocumentSection hierarchy
- DOCX/PDF export
- Signature block structure

02 — WHAT THIS VERSION DOES NOT COVER (ROADMAP TOPICS)

What this version does NOT cover (roadmap topics).

The following concepts from the original specification are not implemented:

- **Pre-built industry-standard templates as shipped defaults** — There is no URS template, no risk template, no IQ/OQ/PQ template that comes out of the box.
- **Mandatory template-major-release republishing** — There is no logic that forces customers to migrate existing deliverables to new platform template versions
- **Template versioning as a semantic version with customer notification** — The template model has no explicit version field. Versioning is a roadmap topic
- **Template marketplace** — Not implemented
- **Auto-generated sections in IQ/OQ from URS** — Not implemented. Sections must be written manually

03 — WHY TEMPLATES MATTER

Why templates matter.

Every regulated deliverable in GxP-Desk is instantiated from a template. The template defines which sections must be present, which fields are mandatory, which fields are field-locked once filled in, which signature blocks are required, and what the platform-rendered PDF looks like. Templates are the platform's contract with the deliverable: every record of class *X* will have at least the structure of the *X* template.

What a template contains

Layer	What it specifies
Schema	Required and optional sections; required and optional fields; data types; controlled vocabularies
Authoring Rules	Field-level locking; conditional sections; AI Composer suitability per section
Approval Routing	Required signers; reviewer/approver order; SoD constraints
Visual Layout	PDF rendering style — typography, callouts, tables, signature blocks, branding overrides
Lifecycle	Versioning, deprecation policy, back-compatibility rules for in-flight deliverables

04 — FIELD-LEVEL LOCKING

Field-level locking.

Field-level locking is the platform's answer to the tension between *"all signed records must be immutable"* and *"in-flight deliverables need fast iteration"*. Locking is per-field, applied automatically at the moments the regulatory framework demands.

Locking states

State	When it is applied	What it means
Open	The field is currently being written	Editable by any user with author rights
Author-locked	The author has marked the field as complete	Editable only by the author until a reviewer round opens
Review-locked	The reviewer has signed; pending QA approval	Editable only via a documented re-open
Approved	The QA approver has signed	Read-only forever; a new revision requires a new deliverable version

Re-opening a review-locked field

Sometimes the reviewer's pass surfaces an issue the author could not see, then iteration produces another pass that uncovers a smaller issue. Re-opening a review-locked field is permitted but controlled: the platform requires a one-line rationale and notifies the reviewer that their previous signature is being invalidated. The audit trail captures both the re-open and the renewed reviewer signature.

Approved is final

There is no way to edit an approved field except by creating a new version of the deliverable. The new version replaces the previous one; both are retained; the audit trail links them. Re-opening an approved field would invert the regulatory model — deliberately, it is not possible.

05 — SIGNATURE BLOCKS

Signature blocks.

Every template ships with a default set of signature blocks: who must sign, in what order, with what meaning. Signatures are e-signatures by default — 21 CFR Part 11 / EU GMP Annex 11 compliant — and can be supplemented (never replaced) with handwritten signatures in jurisdictions that still require them.

Default signature meanings

Block	Recorded meaning
Author	"Authored as <role>." Records the person responsible for the content of the deliverable
Reviewer	"Reviewed and recommended for approval as <role>." Records peer or technical review
Approver	"Approved as <role>." Records regulatory and quality approval
Witness (optional)	"Witnessed execution as <role>." Used in IQ/OQ/PQ test execution where a second pair of eyes is required
Closing Authority	"Authorised release of the System for GxP use as <role>." Used at change closure

Customizing signature meanings

The Account Compliance Lead manages the account-level **Signature Meaning Library**. Each tenant can extend the library (additive only — account-level meanings are always available) and choose which meanings appear on each tenant template's signature block.

Why we hard-wire signature meanings:

FDA warning letters frequently cite *"the meaning of the signature was not clear"*. Hard-wired meanings, drawn from a controlled library, make this deviation category practically impossible. The cost — a small library to manage — is trivial compared to the benefit at inspection.

06 — TEMPLATE GOVERNANCE

Template governance.

Tenant templates are themselves regulated records. Every version is QA-approved; every assignment to a deliverable is logged; every retirement preserves the history of each deliverable that was written against the retired version.

Operation	Who can perform it	Audit-trail entry
Author a new version	Tenant Validation Lead	Template Version Drafted
Approve a new version	Tenant QA Approver	Template Version Approved (signed)
Activate a new version	Tenant QA Approver	Template Version Activated
Retire a version	Tenant QA Approver (with rationale)	Template Version Retired
Migrate in-flight deliverables to a new version	Tenant Validation Lead, with QA approval	Per-deliverable migration record

07 — BRANDING AND PDF RENDERING

Branding and PDF rendering.

Templates are rendered to PDF for export, inspection and long-term archival. The platform provides a default GxP-Desk-branded layout; customers can override the visual layer within a controlled policy.

What can be customized

- **Cover page logo and wordmark** — Replace with your corporate logo. The PDF cover headline retains the two-tone treatment
- **Header / footer wordmark** — Custom text (typically *"Customer name — Validation Library"*)
- **Brand colour** — Replace the platform brand blue with a corporate colour, used for callouts and accent rules
- **Footer left text** — Tagline or classification label

What cannot be customized

- **Document control block layout** — The key-value table structure is regulatory; reordering it breaks the readout pattern inspectors expect
- **Signature block layout** — Roles, meanings, table structure, signed-on-platform notice — all fixed
- **Audit-trail visibility** — The audit-trail footer entry (Doc ID · Version · Classification · Page) is always present
- **End-of-document marker** — The *"— End of document —"* trailer is always present; inspectors look for it

08 — CODE REFERENCES

Code references.

Prisma models

- `Template` — `name`, `description`, `documentType`, `fileType` ("docx"|"pdf"), `content` (Bytes), `customerId`/`tenantId`, timestamps
- `Document` — `title`, `type`, `status` (Draft, Review, Approval, Approved), `version`, `locked`, `templateId`, `changeId`/`systemId`, timestamps
- `DocumentSection` — `title`, `order`, `level`, `userNotes`, `aiDraft`, `content`, `isLocked`, `documentId`, timestamps
- `PhaseDocumentConfig` — maps a phase to a template; `tenantId`, `phaseId`, `templateId`
- `ElectronicSignature` — signature records with `signatureType` (Author, Reviewer, Approver, Witness, ClosingAuthority), `documentId`, `userId`

Components

- `components/templates/TemplateUpload.tsx` — DOCX upload and parsing
- `components/editor/TipTapEditor.tsx` — rich-text editor with sections and locking UI

Libraries

- `lib/template-parser.ts` — DOCX to JSON parsing
- `lib/pdf-export.ts` — document to PDF rendering with branding overrides

Server actions

- `app/actions/document/*` — document creation, section authoring, lock management
- `app/actions/template/*` — template upload, governance, versioning (partial)

End of documentation

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	2026-06-04	Documentation Team	FIT-only redaction limited to codebase-verified functionality.	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 —