CS-DOC-0006 · COMPLIANCESUITE DOCUMENTATION

Document Templates.

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

DOCUMENT ID	VERSION	EFFECTIVE	OWNER
CS-DOC-0006	v1.0	2026-04-28	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	2026-04-28
REVIEW CYCLE	On change
DOCUMENT OWNER	Customer Success
CLASSIFICATION	Public — Documentation
RELATED RECORDS	/output/CS-DOC-0006_Document_Templates.pdf
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 EDITION COVERS

What this edition covers.

This documentation covers 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

What this edition does NOT cover (Roadmap topics).

The following concepts from the original spec are not implemented:

- **Pre-built industry-standard templates as shipped defaults** — There are no URS Template, no Risk Template, no IQ/OQ/PQ Template that come out of the box.
- **Template Major Release Republishing obligation** — No logic that enforces customers to migrate existing Deliverables to new Platform Template versions
- **Template Versioning as 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 ComplianceSuite is instantiated from a Template. The Template defines which Sections must be present, which Fields are mandatory, which Fields are Field-locked once filled, which Signature Blocks are required, and how the Platform-rendered PDF looks. 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 sequence; 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

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 rapid iteration"*. Locking is per-Field, automatically applied at the moments the Regulatory Framework demands.

Locking States

State	When applied	What it means
Open	Field is being written	Editable by any User with Author rights
Author-locked	Author has marked the Field as complete	Editable by Author only until Reviewer round opens
Review-locked	Reviewer has signed; pending QA Approval	Editable only via documented Re-open
Approved	QA Approver has signed	Read-Only forever; new revision requires new Deliverable version

Re-opening a Review-locked Field

Sometimes a Reviewer's pass surfaces a problem the Author could not see, then iteration produces another pass that uncovers a smaller problem. Re-opening a Review-locked Field is allowed but controlled: the Platform requires a One-Line justification and notifies the Reviewer that their previous Signature is 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; both are retained; the Audit Trail links them. Re-opening an Approved Field would invert the Regulatory model — intentionally, it is not possible.

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>." Captures the person responsible for the Deliverable's content
Reviewer	"Reviewed and recommended for approval as <role>." Captures peer or technical review
Approver	"Approved as <role>." Captures 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

Account Compliance Lead manages the Account-level **Signature Meaning Library**. Each Tenant can extend the Library (additively only — Account-level meanings are always available) and choose which meanings appear on each Tenant-Templates Signature Block.

Why we hardwire Signature Meanings:

FDA Warning Letters frequently cite *"the meaning of the Signature was not clear"*. Hardwired 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. Each version is QA-approved; each assignment to a Deliverable is logged; each retirement preserves the history of every Deliverable written against the retired version.

Operation	Who can perform it	Audit Trail entry
Author new version	Tenant Validation Lead	Template Version Drafted
Approve new version	Tenant QA Approver	Template Version Approved (signed)
Activate new version	Tenant QA Approver	Template Version Activated
Retire Version	Tenant QA Approver (with Rationale)	Template Version Retired
Migrate in-flight Deliverables to 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 offers a default ComplianceSuite-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. 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 color, used for Callouts and Accent Rules
- **Footer Left Text** — Tagline or Classification Label

What CANNOT be customized

- **Document Control Block Layout** — The KV Table structure is Regulatory; reordering 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

Code Reference.

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 Phase to 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	2026-04-28	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 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 —