ComplianceSuite

FIT-CLEAN

CS-DOC-0012 · COMPLIANCESUITE DOCUMENTATION

EU GMP Annex 11 Alignment.

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

DOCUMENT ID	VERSION	EFFECTIVE	OWNER
CS-DOC-0012	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.

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RELATED RECORDS	/output/CS-DOC-0012_EU_GMP_Annex_11_Alignment.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 edition documents the EU GMP Annex 11-relevant Features of ComplianceSuite that have been verified as FIT in the codebase:

- **Sections 1–3:** Risk Management (RiskAssessment + RiskItem), Personnel (TrainingCurriculum), Suppliers (Supplier + SupplierAssessment + QualityAgreement)
- **Section 4:** Validation Lifecycle (Change Model, Phase Gates, V-Model with Document Types)
- **Sections 7–14:** Data Storage, Audit Trail, Change Management, Periodic Review, Security, Electronic Signature
- **Sections 15–17:** Batch Release (Scope Definition), Business Continuity (Infra Statement), Archiving (archivedAt, Archive Path)
- **Responsibility Split:** Platform vs. Customer as explicit concept per Section

What this edition does NOT cover.

- **Section 4.5:** RTM Auto-Generation
- **Section 5:** Automatic Data Validation and Reconciliation
- **Section 6:** Automatic Accuracy Checks
- **Section 11:** Audit Trail Digest for Periodic Review
- **Section 13:** Incident Management (no Module)
- **Section 15:** Batch Release System Integration (too specific)
- **Section 16:** Business Continuity with Disaster Recovery Playbook (Infrastructure Statement without Code)

03 — OVERVIEW: RESPONSIBILITY SPLIT

Overview: Responsibility Split.

EU GMP Annex 11 explicitly divides responsibility between:

- **Regulated User** (Manufacturer or Applicant): Operates GMP and QMS
- **Service Provider** (ComplianceSuite): Delivers Platform Infrastructure

This edition makes the split transparent section-by-section.

Sections 1–3: Risk, Personnel, Suppliers.

Section	Topic	Platform	Customer
1	Risk Management	RiskAssessment Model with RiskItem (S/P/D/RPN per ICH Q9); FMEA Scoring; Risk-based Test Strategy in Validation Plan	Risk Acceptance; Risk Policy; Risk Classification Thresholds in QMS
2	Personnel	Roles per System and Tenant; Training Record Linkage; SoD Enforcement	Job Descriptions; Training Matrix; Qualification of Validation Team
3	Suppliers & Service Providers	ComplianceSuite's ISO 27001 / SOC 2 Evidence; Quality Agreement Template; Platform Validation Summary on Request	Supplier Qualification of ComplianceSuite; Quality Agreement in Force; Supplier Review Cycle

05 — SECTION 4: VALIDATED LIFECYCLE

Section 4: Validated Lifecycle.

The core spine of Annex 11. ComplianceSuite implements it as standard Change Pattern.

Sub-Clause	Platform	Customer
4.1 Documented validation lifecycle	Phase-gated Change: URS → Risk → VP → IQ/OQ/PQ → VR → Closure; Phase Locks; Signature Gates	Validation Master Plan in QMS; Lifecycle Policy; Closure Approver
4.2 Risk-based scope	Risk Class steers Test Depth; Coverage Rules block under-tested URS Items	Risk Policy; Risk Acceptance Authority
4.3 Specifications	URS, Risk, FRS Templates; Field Level Locking; Author/Reviewer/Approver Chain	Authoring SOP; Subject Matter Experts
4.4 Configuration management	System Metadata as Configuration Baseline; Configuration Change Pattern; Baseline captured at Change Closure	Configuration Management Policy; Baseline Ownership
4.5 Traceability	Manual RTM Editor (Auto-Generation not implemented)	Sign-off on RTM at Change Closure
4.6 Documentation	Templates; Inspection View; PDF Exports with embedded Signatures	Document Management Policy; Retention Policy
4.7 Source code review (Cat 5 only)	Custom Code Review Record; Static Analysis Evidence Attachment; Reviewer Signature	Source Code Review SOP; Secure Development Training
4.8 Test deviations	Deviation Records in Change; Platform blocks Closure with open Critical Deviations	Deviation Policy; CAPA Process

Sections 7–14: Operational Controls.

Section	Topic	Platform	Customer
7	Data storage	Replicated Storage; Daily Integrity Checks; Retention Baseline at Account/Tenant level	Retention Policy; Legal Hold Overrides
8	Printouts & Exports	Inspection-ready PDF Rendering; Machine-Readable JSON Exports	Printout SOP; Archive Policy
9	Audit trail	Append-only Audit Trail at each level; Tamper Evidence via Hash Fields; Scope Filter (Account/Tenant/System/Change)	Audit Trail Review SOP; Trigger Criteria
10	Change & configuration management	Change as Unit of Work with Lifecycle DRAFT→SUBMITTED→APPROVED→IN_PROGRESS→COMPLETED→CLOSED; ChangeImpactAssessment Model; Configuration Change Pattern	Change Control SOP; Change Impact Assessment Policy
11	Periodic evaluation	Periodic Review Change Pattern; Review Phase with Audit Context	Periodic Review SOP; Cadence Policy
12	Security	JWT Authentication; RBAC; Permission Guards; Encryption at Rest (AES-256) and in Transit (TLS 1.3)	Information Security SOP; Access Review Cadence
14	Electronic signature	ElectronicSignature Model with signerName/signerEmail/meaning/signedAt/contentHash/signatureHash; Manifestations visible in Inspection View; SoD Enforcement in Sign Flow	E-Signature Policy; Customer SOP for Signature Meaning Application

07 — SECTIONS 15–17: FINAL SECTIONS

Sections 15–17: Final Sections.

Section	Topic	Platform	Customer
15	Batch release	Out of Scope. Customers' Batch Release System is registered as separate System; ComplianceSuite holds Validation Evidence.	Batch Release SOP; QP Responsibilities; Interface Validation (if relevant)
16	Business continuity	Standard Postgres Snapshot Backups at Hosting Provider; Customer can extract data via DOCX/PDF Export anytime	Business Continuity Policy; Tested Fallback Procedures; Communication Chain
17	Archiving	Tenant Archival Path; Read-Only Frozen Tenants; Complete Audit Trail Export at Archival	Archiving SOP; Retention Horizon consistent with Regulatory Floor; Scheduled Archive Review

08 — VALIDATION MODEL DEEP-DIVE

Validation Model Deep-Dive.

Phase-Gated Changes

ComplianceSuite implements Validation as **Phase-gated Change** with the following Model:

01 **Requirements & Planning:** - URS (User Requirements Specification) — author, review, approve - Risk Assessment — RiskItems with S (Severity), P (Probability), D (Detectability), RPN (Risk Priority Number) - Validation Plan — Test Strategy, Phase Gates, Coverage Rules

01 **Qualification:** - IQ (Installation Qualification) — System Environment validated - OQ (Operational Qualification) — Critical Functions tested - PQ (Performance Qualification) — Business Processes validated against URS

01 **Closure:** - Validation Report — Summary of all Test Results - Approval Gate — Signer (Author, QA, Approver) must confirm

SoD (Separation of Duties)

- **Author, Reviewer, Approver are separated** (Roles and User level)
- **Signing blocks if SoD violated** — Platform evaluates SoD constraints at each Signature Attempt
- **Role Narrowing allowed, Role Widening not** — Role Model prevents Privilege Escalation via Role Assignment

Document Types

Documents have a Type: URS, Risk Assessment, Validation Plan, IQ/OQ/PQ Record, Validation Report, etc. Type steers:

- Template offer
- Signature Meanings (what a Signer confirms with this Signature)
- Phase Gates (in which Phases Signing is possible)
- Lock Behavior (after Final Approval locked)

Data Scope & Filtering.

Account Scope

- Users and Roles
- Tenant Lifecycle
- Account-level Configuration

Tenant Scope

- Systems (registered Computerized Systems)
- Changes (Validation Changes, Configuration Changes)
- Documents
- Training Records

System Scope

- GAMP Category (Cat 4 or Cat 5)
- Periodic Review Cycle
- Supplier Qualification (if System is Integration)

Change Scope

- Phase and Status (URS authored, Risk reviewed, VP approved, IQ running, OQ complete, VR approved, Closed)
- Deliverables and their Signatures
- Deviations and CAPAs

10 — CUSTOMER RESPONSIBILITIES — ANNEX 11 VIEW

Customer Responsibilities — Annex 11 View.

From Annex 11 perspective, the Customer is responsible for:

01 **Quality Management System:** Documentation and implementation of GMP-compliant QMS

02 **Risk Management:** Definition of Risk Categories; Acceptance Thresholds

03 **Personnel:** Training; Competency Evidence; Job Descriptions

04 **Supplier Qualification:** Evaluation of ComplianceSuite via ISO 27001, SOC 2, Security Whitepaper

05 **Validation Strategy:** Definition of Test Depth, Scope, Gate Criteria per System

06 **Change Control:** SOP for Approval, Impact Assessment, CAPA Integration

07 **Periodic Review:** Execution, Documentation, Closure via Periodic Review Change

Effective: 2026-04-28 **Source:** Codebase Snapshot with FIT Verification **Contact:** Compliance Office, ComplianceSuite

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 —