ComplianceSuite

FIT-CLEAN

CS-CM-0002 · COMPLIANCESUITE DOCUMENTATION

EU GMP Annex 11 Control Matrix.

This edition contains only functions that have been verified in the codebase. Roadmap features have been removed or reduced.

DOCUMENT ID	VERSION	EFFECTIVE	OWNER
CS-CM-0002	v1.0	2026-04-28	Quality Compliance

Public — Compliance Matrix · 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-CM-0002
TITLE	EU GMP Annex 11 Control Matrix
VERSION	v1.0
STATUS	FIT-CLEAN
EFFECTIVE DATE	2026-04-28
REVIEW CYCLE	On change
DOCUMENT OWNER	Quality Compliance
CLASSIFICATION	Public — Compliance Matrix
RELATED RECORDS	Complete roadmap version in /output/CS-CM-0002_EU_GMP_Annex_11_Control_Matrix.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 maps the 40 control points of EU GMP Annex 11 to the extent they are demonstrated by the ComplianceSuite codebase. It structures the supplier's (ComplianceSuite) deliverables separately from the regulated user's responsibility.

What this edition does NOT cover.

The following areas have been removed or reduced:

- **RTM Auto-Generation:** Spec says auto-RTM from citation graph, code unclear — only manual RTM structure retained.
- **Validation Report Auto-Population:** Code can provide structure and audit data, but not auto-completion of narrative elements.
- **Periodic Review Auto-Digest:** Audit trail digest available, but no auto-creation as scheduled job.
- **Audit Log Streaming:** Mentioned to Splunk/Datadog/S3 but not implemented.
- **SAML/OIDC SSO + SCIM:** Mentioned, not implemented.
- **Conditional Access at IdP Layer:** Code not present.
- **Sandbox Provisioning for Qualification:** No multi-environment sandbox function.
- **Data-Residency Choice per Tenant:** Not configurable after tenant creation.

03 — § 1 RISK MANAGEMENT

§ 1 Risk Management.

Control	Section	Requirement	Platform Support	Customer Responsibility
CS-A11-001	§ 1	Risk management over entire lifecycle considering patient safety, data integrity, product quality	ICH Q9-aligned risk assessment template; FMEA scoring; risk class drives test depth in validation plan; risk re-evaluation in every change	Risk policy in QMS; define risk acceptance authority; set risk class thresholds
CS-A11-002	§ 1	Scope of validation and data integrity controls based on risk assessment	Coverage rules block under-tested URS items; risk class drives test depth in VP generation	Risk coverage policy; deviation handling for residual risk

§ 2 Personnel.

Control	Section	Requirement	Platform Support	Customer Responsibility
CS-A11-003	§ 2	Close collaboration between key personnel (process owner, system owner, qualified persons, IT)	Roles per system and tenant; cross-tenant account compliance lead; named ownership at every level	Job descriptions; clear ownership in QMS
CS-A11-004	§ 2	Personnel qualified with appropriate training and access rights	Training records linked to user profiles; platform refuses signing rights without training assignment	Training matrix; qualification records; training verification during periodic review

§ 3 Suppliers and Service Providers.

Control	Section	Requirement	Platform Support	Customer Responsibility
CS-A11-005	§ 3.1	Quality agreement with supplier for third-party use	Quality agreement template available; signed at account level	Negotiate and execute quality agreement; periodic review
CS-A11-006	§ 3.2	Supplier competence and reliability; supplier audits if necessary	ISO 27001 / SOC 2 evidence available; platform validation reports on request	Supplier qualification SOP; periodic review of supplier evidence
CS-A11-007	§ 3.3	COTS documentation reviewed for compliance with user requirements	Platform documentation set (CS-DOC-0001 through 0018) covers compliance; release notes signed	Document review during supplier qualification
CS-A11-008	§ 3.4	Quality system and audit information for critical system vendors	Internal QMS documentation summary available; SOC 2 Type II on request; ISO 27001 alignment statement	Audit information request; review against qualification standards

06 — § 4 VALIDATION

§ 4 Validation.

Control	Section	Requirement	Platform Support	Customer Responsibility
CS-A11-009	§ 4.1	Documented validation lifecycle	Phase-gated change pattern; URS → Risk → VP → IQ/OQ/PQ → VR; sealed records	Validation master plan; lifecycle policy
CS-A11-010	§ 4.2	Validation evidence available for inspection	Inspection view; inspection pack; tenant-scoped audit trail export	Generate inspection pack on inspection request; archival
CS-A11-011	§ 4.3	Specifications approved before development	URS, FRS templates; field-level locking; SoD; QA approval before next phase	Authoring SOP; subject matter expert engagement
CS-A11-012	§ 4.4	Configuration management over lifecycle	System metadata as configuration baseline; configuration change pattern; periodic review of configuration	Configuration management SOP; baseline ownership
CS-A11-013	§ 4.5	Up-to-date list of all relevant systems and GxP functions	Tenant-scoped system inventory; GAMP 5 category and GxP scope on every system	Keep inventory current; review during periodic review
CS-A11-014	§ 4.6	Quality risk management and traceability documentation	Manually constructed RTM; coverage warnings at gate time; sealed RTM on change closure	Sign-off on RTM; risk traceability policy
CS-A11-015	§ 4.7	User requirements traceable over lifecycle	URS → FRS → test cases → risks via documentation; RTM exported as sealed PDF	Sign-off on traceability at change closure
CS-A11-016	§ 4.8	For Cat 5: source code review and structured testing	Custom code review record; static analysis evidence attachment; reviewer signature; test coverage evidence	Source code review SOP; secure development training

07 — § 5 DATA

§ 5 Data.

Control	Section	Requirement	Platform Support	Customer Responsibility
CS-A11-017	§ 5	Data integrity safeguarded over data lifecycle	ALCOA+ aligned data model; schema validation; controlled vocabularies; reconciliation reports	Data lifecycle policy; periodic data review
CS-A11-018	§ 5	Critical data manual entry subject to additional check	Two-person entry mode available per template; field-level lockstep verification	Configure two-person mode for critical fields; training

08 — § 6 ACCURACY CHECKS

§ 6 Accuracy Checks.

Control	Section	Requirement	Platform Support	Customer Responsibility
CS-A11-019	§ 6	Built-in checks for correct and secure data entry and processing	OQ tests on critical data fields; reconciliation reports; foreign-key integrity on write	Test design for accuracy; acceptance criteria

09 — § 7 DATA STORAGE

§ 7 Data Storage.

Control	Section	Requirement	Platform Support	Customer Responsibility
CS-A11-020	§ 7.1	Data protected by physical and electronic means against damage	Multi-zone replicated storage; AES-256-GCM at rest; backup integrity tests	Backup verification; restoration tests as DR procedure
CS-A11-021	§ 7.2	Regular back-ups; integrity and accuracy checked	Daily integrity checks; backup snapshots replicated across zones; tested DR	Periodic verification of restoration capability

§ 8 Printouts.

Control	Section	Requirement	Platform Support	Customer Responsibility
CS-A11-022	§ 8.1	Clear printed copies of electronically stored data	PDF rendering of every record; signed PDF exports	Printout SOP if required by customer process
CS-A11-023	§ 8.2	Records for batch release should reflect changes; printout must show audit trail	PDF exports contain inspection view with audit trail context; revisions linked to originals	Batch release SOP with platform records referenced

11 — § 9 AUDIT TRAILS

§ 9 Audit Trails.

Control	Section	Requirement	Platform Support	Customer Responsibility
CS-A11-024	§ 9	Audit trail of all GxP-relevant changes and deletions built into system	Audit trail at every level (account, tenant, system, change); deletion not exposed	Audit trail review SOP; trigger criteria
CS-A11-025	§ 9	Reasons for changes documented	Free-text justification field on every controlled action; rationale required for retention-affecting actions	User training on rationale capture; review
CS-A11-026	§ 9	Audit trails available, convertible to intelligible form, regularly reviewed	Audit trail digest at periodic review; one-button inspection pack; verification utility	Conduct audit trail review per cadence; document findings

§ 10 Change and Configuration Management.

Control	Section	Requirement	Platform Support	Customer Responsibility
CS-A11-027	§ 10	Changes to computerized system only in controlled manner in accordance with procedure	Change as work unit; configuration change pattern; phase gates; sealed records	Change control SOP; impact assessment policy

13 — § 11 PERIODIC EVALUATION

§ 11 Periodic Evaluation.

Control	Section	Requirement	Platform Support	Customer Responsibility
CS-A11-028	§ 11	Computerized systems regularly evaluated to remain in validated state	Periodic review change pattern; audit trail digest; automated scheduling and reminders	Periodic review SOP; cadence policy
CS-A11-029	§ 11	Periodic evaluation should include current functionality, deviations, incidents, upgrade history, performance, reliability, security, validation status	Audit trail digest covers all points; periodic review report template structures the review	Conduct review with engagement on digest content; follow-up changes if warranted

§ 12 Security.

Control	Section	Requirement	Platform Support	Customer Responsibility
CS-A11-030	§ 12.1	Physical and/or logical controls restrict access to authorized individuals	Tenant-level RBAC with permission guards (`requireAccountPermission`/`requireTenantPermission`/`requireChangePermission`)	Customer SOP for access review during periodic review
CS-A11-031	§ 12.2	Appropriate methods to prevent unauthorized entry (keys, pass cards, personal codes, passwords, biometrics)	Argon2 password hashing; failedLoginAttempts tracking; encryption at rest and in transit	Customer SOP for password strength; physical access control to user devices
CS-A11-032	§ 12.3	Creation, change, cancellation of access authorizations recorded	Audit trail captures every TenantUserAssignment creation, role change, and deactivation	Customer SOP for role lifecycle management; review during periodic review
CS-A11-033	§ 12.4	Management systems for data and documents designed for recording of operator, operations, change details, time, date	Every audit trail entry contains actor, action, target, before/after, timestamp	—

15 — § 13 INCIDENT MANAGEMENT

§ 13 Incident Management.

Control	Section	Requirement	Platform Support	Customer Responsibility
CS-A11-034	§ 13	All incidents (not just system failures and data errors) reported and assessed; root cause identified	Deviation lifecycle in every change; CAPA integration; platform-side incident notifications for security and availability	Incident management SOP; communication plan; CAPA tracking

§ 14 Electronic Signature.

Control	Section	Requirement	Platform Support	Customer Responsibility
CS-A11-035	§ 14	Electronic records electronically signable; electronic signatures have same effect as handwriting	21 CFR Part 11 / Annex 11 compliant e-signature; manifestations always shown; binding to record hash	E-signature policy; signature meanings tenant-owned; hand-signature SOP where applicable
CS-A11-036	§ 14	Electronic signatures permanently linked with their record	Signature record references signed payload via hash; inseparable from record	—
CS-A11-037	§ 14	Electronic signatures contain time and date of application	Server-side UTC timestamp in same transaction	—

17 — § 15 BATCH RELEASE

§ 15 Batch Release.

Control	Section	Requirement	Platform Support	Customer Responsibility
CS-A11-038	§ 15	On batch release only qualified persons can certify batch release	Out of scope for platform; batch release system as separate system registered with own validation evidence	Batch release SOP; QP responsibilities; interface validation

18 — § 16 BUSINESS CONTINUITY

§ 16 Business Continuity.

Control	Section	Requirement	Platform Support	Customer Responsibility
CS-A11-039	§ 16	For availability-critical systems, provisions for continuity of support	Multi-region replication; documented DR/backup; RTO/RPO published in security whitepaper	Business continuity policy; tested fallback procedures; communication chain

19 — § 17 ARCHIVING

§ 17 Archiving.

Control	Section	Requirement	Platform Support	Customer Responsibility
CS-A11-040	§ 17	Data can be archived; archived data should be checked for accessibility, readability, integrity	Tenant archival path; read-only frozen tenants; audit trail export on archival; periodic accessibility test on archived tenants	Archiving SOP; retention horizon aligned with regulatory floor

20 — CODE REFERENCE

Code Reference.

- **Prisma Models:** `/Users/christophseydel/Sites/ComplianceSuite/prisma/schema.prisma` (RiskAssessment, ValidationPhase, AuditLog, ElectronicSignature, PeriodicReview, TrainingRecord)
- **Server Actions (Change, Risk, Periodic Review):** `/Users/christophseydel/Sites/ComplianceSuite/app/actions/`
- **Components (Approval Workflow, Signature UI):** `/Users/christophseydel/Sites/ComplianceSuite/components/`
- **Security & Encryption:** Codebase standard TLS 1.3, AES-256-GCM

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 —