CS-DOC-0012 · GXP-DESK DOCUMENTATION

EU GMP Annex 11 Alignment.

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

DOCUMENT ID	VERSION	EFFECTIVE	OWNER
CS-DOC-0012	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-0012
TITLE	EU GMP Annex 11 Alignment
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 version documents the EU GMP Annex 11-relevant features of GxP-Desk 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 (infrastructure statement), archiving (archivedAt, archive path)
- **Responsibility split:** Platform vs. customer as an explicit concept per section

02 — WHAT THIS VERSION DOES NOT COVER

What this version does NOT cover.

- **Section 4.5:** RTM auto-generation from a citation graph (change-level RTM including gap detection is FIT; system-level union/citation graph still open)
- **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 a 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 marketing authorization holder): Operates GMP and the QMS
- **Service Provider** (GxP-Desk): Provides the platform infrastructure

This version 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 the Validation Plan	Risk acceptance; risk policy; risk classification thresholds in the QMS
2	Personnel	Roles per system and tenant; training record linkage; SoD enforcement	Job descriptions; training matrix; qualification of the validation team
3	Suppliers & Service Providers	GxP-Desk's ISO 27001 / SOC 2 evidence; quality agreement template; platform validation summary on request	Supplier qualification of GxP-Desk; quality agreement in force; supplier review cycle

05 — SECTION 4: VALIDATED LIFECYCLE

Section 4: Validated Lifecycle.

The core spine of Annex 11. GxP-Desk implements it as a 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 the QMS; lifecycle policy; closure approver
4.2 Risk-based scope	Risk class drives 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 a configuration baseline; configuration change pattern; baseline captured at change closure	Configuration management policy; baseline ownership
4.5 Traceability	Auto-generated change-level RTM (`getTraceabilityMatrix`) including gap detection; system-level union/citation graph: Roadmap	Sign-off on the RTM at change closure
4.6 Documentation	Templates; Inspection View; PDF exports (integrity via the audit hash chain + verification JSON, no X.509 PDF signature)	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 the change; the 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 the 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 every level; tamper-evident hash chain v2 (immutability trigger, Verify-Report); scope filters (account/tenant /system/change)	Audit trail review SOP; trigger criteria
10	Change & configuration management	Change as a unit of work with the 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; SSO (SAML/OIDC) with enforcement; MFA (WebAuthn/TOTP/recovery); RBAC; permission guards; encryption at rest (AES-256, optional BYOK) and in transit (TLS 1.3)	Information-security SOP; access-review cadence

Section	Topic	Platform	Customer
14	Electronic signature	ElectronicSignature model with signerName/signerEmail/meaning/signedAt/contentHash/signatureHash; manifestations visible in the Inspection View; SoD enforcement in the sign flow	E-signature policy; customer SOP for applying signature meanings

07 — SECTIONS 15–17: FINAL SECTIONS

Sections 15–17: Final Sections.

Section	Topic	Platform	Customer
15	Batch release	Out of scope. The customer's batch-release system is registered as a separate system; GxP-Desk holds the validation evidence.	Batch-release SOP; QP responsibilities; interface validation (where relevant)
16	Business continuity	Standard Postgres snapshot backups at the hosting provider; the customer can export data via DOCX/PDF at any time	Business-continuity policy; tested fallback procedures; communication chain
17	Archiving	Tenant archival path; read-only frozen tenants; full audit trail export at archival	Archiving SOP; retention horizon consistent with the regulatory floor; scheduled archive review

08 — VALIDATION MODEL DEEP-DIVE

Validation Model Deep-Dive.

Phase-Gated Changes

GxP-Desk implements validation as a **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 the URS

01 **Closure:** - Validation Report — summary of all test results - Approval Gate — signers (author, QA, approver) must confirm

SoD (Separation of Duties)

- **Author, reviewer and approver are kept separate** (at the role and user level)
- **Signing is blocked if SoD is violated** — the platform evaluates SoD constraints on every signature attempt
- **Role narrowing is allowed, role widening is not** — the role model prevents privilege escalation through role assignment

Document Types

Documents have a type: URS, Risk Assessment, Validation Plan, IQ/OQ/PQ Record, Validation Report, etc. The type controls:

- The templates offered
- The signature meanings (what a signer confirms with that signature)
- The phase gates (in which phases signing is possible)
- The lock behavior (locked after final approval)

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 the system is an 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 an Annex 11 perspective, the customer is responsible for:

01 **Quality management system:** Documenting and implementing a GMP-conformant QMS

02 **Risk management:** Defining risk categorizations; acceptance thresholds

03 **Personnel:** Training; competency evidence; job descriptions

04 **Supplier qualification:** Assessing GxP-Desk via ISO 27001, SOC 2, the security whitepaper

05 **Validation strategy:** Defining test depth, scope and gate criteria per system

06 **Change control:** SOP for approval, impact assessment and CAPA integration

07 **Periodic review:** Execution, documentation and closure via the periodic-review change

As of: 2026-06-04 **Source:** Codebase snapshot with FIT verification **Contact:** Compliance Office, GxP-Desk

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 —