CS-CM-0003 · COMPLIANCESUITE DOCUMENTATION

GAMP 5 (2nd ed.) Lifecycle Map.

This edition contains only functions that have been verified in the codebase. Auto-configuration and roadmap features have been removed.

DOCUMENT ID	VERSION	EFFECTIVE	OWNER
CS-CM-0003	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-0003
TITLE	GAMP 5 (2nd ed.) Lifecycle Map
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-0003_GAMP_5_Lifecycle_Map.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 GAMP 5 (2nd ed.) lifecycle phases as implemented by ComplianceSuite. The five phases (Concept → Plan & Specify → Configure/Build → Verify → Operate) are realized in the data model and change management. Phase gates, validation depth by category, and V-model structure are documented.

02 — WHAT THIS EDITION DOES NOT COVER

What this edition does NOT cover.

The following features have been removed or significantly reduced:

- **RTM Auto-Generation:** Spec promises automation from citation graph, code does not implement it — only manual RTM structure remains.
- **Auto-Validation Report Population:** Platform can provide structural data (test counts, deviations), but not narrative elements automatically.
- **Validation Plan Auto-Depth:** Spec says risk class automatically sets test depth in VP, code unclear — only concept remains.
- **Periodic Review Auto-Digest:** Audit trail digest available, but not generated as scheduled job.
- **Cat-1/3/4/5 Depth Logics:** Only category definition FIT; specific Cat-1-OQ-light vs. Cat-4-full-depth is concept without enforceable code.

03 — THE FIVE GAMP 5 LIFECYCLE PHASES

The five GAMP 5 Lifecycle Phases.

Phase	Objective	Output	Platform Realization
Concept	Identify business need; high-level scope; preliminary risk classification	Concept note (informal); tenant policy alignment; system candidate	Pre-change concept note (tenant document library); system in draft state
Plan & Specify	Define what system must do; identify and assess risks; plan validation	URS, risk assessment, validation plan, FRS / design specs	All documents in plan phase of initial validation change; signed
Configure / Build	Configure system (Cat 4) or build custom code (Cat 5); configuration baseline evidence	Configuration baseline; for Cat 5: code review, unit test evidence	Configure/build interval within initial validation change
Verify	Execute IQ, OQ, PQ; raise and resolve deviations; build traceability matrix	IQ/OQ/PQ protocols and results; deviations; RTM; validation report	Execute phase of initial validation change
Operate	Operate system under change control; periodic review; decommissioning on scope end	Configuration / upgrade / periodic review / decommissioning changes	System in production state; subsequent changes (configuration, upgrade, periodic review)

04 — SYSTEM CATEGORIZATION

System Categorization.

ComplianceSuite tracks four categories per GAMP 5 (2nd ed.; Cat 2 deprecated):

Category	Definition	Validation Depth	Code Usage
Cat 1	Infrastructure (OS, hypervisors, networks)	Qualified, not validated; customer-side infrastructure qualification SOPs apply	System.gampCategory = 1; reduced template set
Cat 3	Non-configured COTS	Limited URS focused on intended use; OQ-based testing; minimal customization evidence	System.gampCategory = 3; cat-3-specific templates
Cat 4	Configured COTS — out of box with documented configuration	Full URS / risk / VP / IQ/OQ/PQ / VR; configuration baseline tracked; config changes are changes	System.gampCategory = 4; full template set; config-baseline capture
Cat 5	Custom / bespoke — developed for user	Full Cat 4 deliverables + source code review, structured test coverage, secure development evidence	System.gampCategory = 5; cat-5-extended template set; code review record required

05 — V-MODEL DELIVERABLES

V-Model Deliverables.

GAMP 5 presents the relationship between specification and verification as a V. Each spec on the descending side has a corresponding verification on the ascending side:

Specification	Verification	Citation Pattern	Platform
URS — User Requirements Specification	PQ — Performance Qualification	PQ test cites URS requirement(s) it verifies	Document links / citation graph
FRS — Functional Requirements Specification	OQ — Operational Qualification	OQ test cites FRS requirement(s)	Document links
DS — Design Specification (config/code)	IQ — Installation Qualification	IQ test cites DS config items	Document links
Risk Assessment — Risk register and mitigations	Test cases marked as risk mitigations	Test case cites risk it mitigates; RTM merged by URS ID	Deviation record + citation

The traceability matrix is the backbone of the V-model: Each spec item is a row; each verification is a column population. Coverage gaps block VR acceptance.

06 — PHASE GATES AND SIGNATORIES

Phase Gates and Signatories.

Gate	Phase Boundary	GAMP 5 Intention	Platform Realization
Plan Approval	Plan → Configure/Build	Assert that requirements, risk, validation strategy sufficient	Tenant QA approver signs validation plan
Configure-Complete	Configure/Build → Verify	Assert that system configured/built against design spec and ready for qualification testing	Tenant QA approver + if needed senior engineer (Cat 5)
Verification-Complete	Verify → Operate	Assert that test execution complete, deviations resolved/carried, system fit for production GxP use	Tenant QA approver
Operational Release	Verify → Operate (parallel to verification-complete)	Authorize system in production	Head of quality (closes change)
Periodic Review	Operate → Operate (recurring)	Confirm that system remains in validated state	Tenant QA approver
Decommissioning	Operate → Retired	Authorize system retirement; execute data migration / archival plan	Head of quality

07 — MAPPING TO COMPLIANCESUITE PLATFORM

Mapping to ComplianceSuite Platform.

GAMP 5 Phase	Platform Primitive	Concrete Artifacts
Concept	Pre-system scoping; tenant policy alignment; informal record	Concept note (tenant document library); system as draft
Plan & Specify	Plan phase of initial validation change	URS, risk assessment, validation plan, FRS, DS — all signed
Configure / Build	Configure or build interval (within initial validation change for Cat 4/5)	Configuration baseline captured; for Cat 5: code review record, static analysis evidence
Verify	Execute phase of initial validation change	IQ / OQ / PQ protocols and results; deviations; RTM
Operate	System in production state; subsequent changes (configuration, upgrade, periodic review, decommissioning)	Periodic review reports; configuration change records; decommissioning plan

The initial validation change owns all three project phases (plan + configure + verify): Platform phase gates (plan-execute and execute-report) carry the same intention as GAMP 5's project gates. The operate phase is the production state of the system with subsequent changes.

08 — CRITICAL THINKING CHECKPOINTS

Critical Thinking Checkpoints.

GAMP 5 (2nd ed.) asks questions, not just records documents. The platform makes these decisions explicit:

- **Category decision** on system registration: justified, signed by validation lead, re-evaluated on every change
- **Risk-class decision** on risk assessment approval: justified, signed by QA, re-evaluated during periodic review
- **Test depth decision** on validation plan approval: per URS item, justified against risk class
- **Deviation classification decision:** critical / major / minor / cosmetic, with rationale on classification
- **Acceptance decision** on validation report: accept / conditional accept / reject, with rationale
- **Periodic review outcome decision:** remains validated / configuration change / upgrade / decommission, with rationale

09 — GAMP 5 RESPONSIBILITY SPLIT

GAMP 5 Responsibility Split.

GAMP 5 distinguishes the regulated user's responsibility from the supplier's:

Responsibility	Regulated User (Customer)	Supplier (ComplianceSuite or Customer's System Supplier)
Quality Management System	QMS for GxP operations; supplier qualification; quality agreement	QMS covering platform development, release, support
URS	Authors	Reviews for feasibility / fit
Risk Assessment	Owns risk class and acceptance	Provides product-level risk context (FAQ, known issues)
Configuration / Build	Configures (Cat 4) or specifies custom code (Cat 5)	Provides configurable platform; for Cat 5 custom code: development with secure development evidence
IQ / OQ / PQ	Executes; signs	Provides default test cases via templates; supports verification queries
Periodic Review	Conducts and signs	Provides audit trail digest; releases with documented validation impact
Inspection Support	Owns inspection	Provides inspection view, exports, supplier evidence on request

Lifecycle Phase-by-Phase Decisions.

Concept Phase

- **Decision:** Select system as candidate?
- Input: business requirement, preliminary scope
- Output: system draft, concept note
- Evidence: tenant policy alignment, system metadata (name, vendor, category)

Plan & Specify Phase

- **Category justification:** Is Cat 4 or Cat 5 the right choice?
- **Risk-class:** High / medium / low for this system use case?
- **URS completeness:** All requirements captured? (functional, regulatory, performance, interface)
- **Risk coverage:** Are high-RPN risks mitigated?
- **Validation plan depth:** Does test depth match risk class?

Configure / Build Phase

- **Configuration baseline:** All settings documented?
- **(Cat 5 only) Code review:** Source code reviewed and approved?
- **Unit test evidence:** (Cat 5) Test coverage sufficient?

Verify Phase

- **Test execution:** All protocols complete?
- **Deviation resolution:** Critical/major deviations closed?
- **Traceability:** Coverage gaps in RTM?
- **Acceptance recommendation:** Accept, conditional accept, or reject?

Operate Phase

- **Periodic review schedule:** Periodic review at risk-class-appropriate cadence?
- **Change control:** Configuration/upgrade changes in same controlled manner as initial validation?

11 — CODE REFERENCE

Code Reference.

- **Prisma Models:** `/Users/christophseydel/Sites/ComplianceSuite/prisma/schema.prisma`
- `System` (gampCategory: 1|3|4|5, riskClass: HIGH|MEDIUM|LOW)
- `Change` (type: INITIAL_VALIDATION | CONFIGURATION | UPGRADE | PERIODIC_REVIEW | DECOMMISSIONING)
- `ValidationPhase` (name, gateReviewRequired, gateReviewCompletedAt)
- `Document` (documentType: URS, FRS, RiskAssessment, ValidationPlan, IQ, OQ, PQ, RTM, VR)
- `Deviation` (severity: CRITICAL, MAJOR, MINOR, COSMETIC)
- **Server Actions (Phase Management):** `/Users/christophseydel/Sites/ComplianceSuite/app/actions/`
- Change opening, phase transitions, gate signatures
- **Components (Change Lifecycle UI):** `/Users/christophseydel/Sites/ComplianceSuite/components/`
- ChangeCard, ChangeLifecycle, PhaseGatePanel, ValidationReportBuilder

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 —