CS-CM-0003 · GXP-DESK DOCUMENTATION

GAMP 5 (2nd ed.) Lifecycle Map.

This version contains exclusively 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	2026-06-04	Quality Compliance

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-CM-0003
TITLE	GAMP 5 (2nd ed.) Lifecycle Map
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EFFECTIVE DATE	2026-06-04
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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 maps the GAMP 5 (2nd ed.) lifecycle phases as GxP-Desk implements them. The five phases (Concept → Plan & Specify → Configure/Build → Verify → Operate) are realized in the data model and in Change Management. Phase gates, validation depth by category, and the V-Model structure are documented.

02 — WHAT THIS VERSION DOES NOT COVER

What this version does NOT cover.

The following functions have been removed or substantially reduced:

- **RTM from Citation-Graph / System-Level union:** The Change-Level RTM including gap detection is now FIT (2026-06-04); the auto-generation from a Citation-Graph and the system-wide union remain open.
- **Auto Validation-Report population:** The platform can supply structural data (test counts, deviations), but cannot automatically populate narrative elements.
- **Validation Plan auto-depth:** The spec states that the Risk Class automatically sets the test depth in the VP; the code is unclear — only the concept remains.
- **Periodic Review auto-digest:** An Audit-Trail digest is available, but it is not generated as a scheduled job.
- **Cat-1/3/4/5 depth logics:** Only the category definition is FIT; the specific Cat-1 OQ-light vs. Cat-4 full-depth distinction is a concept without enforceable code.

03 — THE FIVE GAMP 5 LIFECYCLE PHASES

The Five GAMP 5 Lifecycle Phases.

Phase	Goal	Output	Platform realization
Concept	Identify the 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 the System must do; identify and assess risks; plan validation	URS, Risk Assessment, Validation Plan, FRS / Design Specs	All docs in the Plan phase of the Initial Validation Change; signed
Configure / Build	Configure the 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 the Initial Validation Change
Verify	Execute IQ, OQ, PQ; raise and resolve deviations; build the Traceability Matrix	IQ/OQ/PQ Protocols and Results; deviations; RTM; Validation Report	Execute phase of the Initial Validation Change
Operate	Operate the System under change control; Periodic Review; decommissioning at end of scope	Configuration / Upgrade / Periodic Review / Decommissioning Changes	System in Production state; subsequent Changes (Configuration, Upgrade, Periodic Review)

04 — SYSTEM CATEGORIZATION

System Categorization.

GxP-Desk 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 the box with documented config	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 the user	Full Cat 4 deliverables + source-code review, structured test coverage, secure-dev evidence	System.gampCategory = 5; Cat-5-extended template set; code-review record required

05 — V-MODEL DELIVERABLES

V-Model Deliverables.

GAMP 5 represents 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 the URS requirement(s) it verifies	Document Links / Citation Graph
FRS — Functional Requirements Specification	OQ — Operational Qualification	OQ test cites the FRS requirement(s)	Document Links
DS — Design Specification (config/code)	IQ — Installation Qualification	IQ test cites the DS config items	Document Links
Risk Assessment — Risk Register and mitigations	Test Cases marked as Risk Mitigations	Test case cites the 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. The Change-Level RTM is auto-generated and detects coverage gaps; the gate blockage for uncovered high-risk items is currently documentary (no hard workflow stop).

06 — PHASE GATES AND SIGNATORIES

Phase Gates and Signatories.

Gate	Phase boundary	GAMP 5 intent	Platform realization
Plan-Approval	Plan → Configure/Build	Affirmation that requirements, risk, and validation strategy are sufficient	Tenant QA Approver signs the Validation Plan
Configure-Complete	Configure/Build → Verify	Affirmation that the System is built/configured against the design spec and ready for qualification testing	Tenant QA Approver + Senior Engineer if applicable (Cat 5)
Verification-Complete	Verify → Operate	Affirmation that test execution is complete, deviations resolved/carried, the System fit for production GxP use	Tenant QA Approver
Operational Release	Verify → Operate (parallel with Verification-Complete)	Authorization to release the System into production	Head of Quality (closes the Change)
Periodic-Review	Operate → Operate (recurring)	Confirmation that the System remains in the validated state	Tenant QA Approver
Decommissioning	Operate → Retired	Authorization to retire the System; execute data-migration / archival plan	Head of Quality

07 — MAPPING TO THE GXP-DESK PLATFORM

Mapping to the GxP-Desk 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 the Initial Validation Change	URS, Risk Assessment, Validation Plan, FRS, DS — all signed
Configure / Build	Configure or Build interval (within the Initial Validation Change for Cat 4/5)	Configuration Baseline captured; for Cat 5: code-review record, static-analysis evidence
Verify	Execute phase of the 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 holds all three project phases (Plan + Configure + Verify): The platform phase gates (Plan-Execute and Execute-Report) carry the same intent 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, it does not just file documents. The platform makes these decisions explicit:

- **Category Decision** at System registration: Justified, signed by the Validation Lead, re-evaluated at every Change
- **Risk-Class Decision** at Risk Assessment approval: Justified, signed by QA, re-evaluated at Periodic Review
- **Test Depth Decision** at Validation Plan approval: Per URS item, justified against the Risk Class
- **Deviation Classification Decision:** Critical / Major / Minor / Cosmetic, with rationale at classification
- **Acceptance Decision** at the 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 responsibility of the regulated user from that of the supplier:

Responsibility	Regulated User (Customer)	Supplier (GxP-Desk or the 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 the Risk Class and acceptance	Provides product-level risk context (FAQ, known issues)
Configuration / Build	Configures (Cat 4) or specifies custom code (Cat 5)	Provides the configurable platform; for Cat 5 custom code: development with secure-dev evidence
IQ / OQ / PQ	Executes; signs	Provides default test cases via templates; supports verification queries
Periodic Review	Conducts and signs	Provides the Audit-Trail digest; releases with documented validation impact
Inspection Support	Owns the inspection	Provides Inspection View, exports, supplier evidence on request

Lifecycle Phase-by-Phase Decisions.

Concept Phase

- **Decision:** Select the System as a 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:** Are all requirements captured? (Functional, Regulatory, Performance, Interface)
- **Risk coverage:** Are high-RPN risks mitigated?
- **Validation Plan depth:** Does the test depth match the Risk Class?

Configure / Build Phase

- **Configuration baseline:** Are all settings documented?
- **(Cat 5 only) Code review:** Is the source code reviewed and approved?
- **Unit test evidence:** (Cat 5) Is test coverage sufficient?

Verify Phase

- **Test execution:** Are all protocols complete?
- **Deviation resolution:** Are Critical/Major deviations closed?
- **Traceability:** Coverage gaps in the RTM?
- **Acceptance recommendation:** Accept, Conditional Accept, or Reject?

Operate Phase

- **Periodic Review schedule:** Periodic Review at a Risk-Class-appropriate cadence?

- **Change control:** Are Configuration/Upgrade Changes handled in the same controlled manner as the Initial Validation?

11 — CODE REFERENCES

Code references.

- **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

As of: 2026-06-04 | **Version:** 1.0 | **Classification:** Public — Compliance Matrix

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 —