

GAMP 5 (Second Edition)

GAMP 5 provides a risk-based framework to validate and control computerized systems to ensure data integrity and regulatory compliance.



What it is

GxP / GAMP 5 — Good Automated Manufacturing Practice is a quality management framework that supports organizations in ensuring the integrity, reliability, and compliance of automated systems used in regulated industries such as pharmaceuticals, biotechnology, and life sciences.

Developed and published by the International Society for Pharmaceutical Engineering (ISPE), GAMP 5 is widely adopted by organizations and regulators to guide the validation, operation, and control of computerized systems in facilities subject to GxP (Good Practice) regulations. The framework covers areas including risk management, internal controls, data integrity, cybersecurity, and regulatory compliance in automated manufacturing environments.

At a glance

PUBLISHER

International Society for
Pharmaceutical Engineering (ISPE)

TYPE

Guidance

VERSION

GAMP 5 Second Edition

EFFECTIVE

2008

DOMAIN

Quality & Safety

FAMILY

Other

REGION

United States

INDUSTRY

Healthcare & Life Sciences

ADOPTION MODEL

Regulatory Compliance

IMPLEMENTATION COMPLEXITY

High

Source: <https://ispe.org/publications/guidance-documents/gamp-5>

Why it matters

- **Increase audit readiness** Enable organizations to maintain thorough documentation and controls that facilitate smooth regulatory inspections and third-party audits.
- **Strengthen data integrity** Support reliable data handling and storage practices that safeguard critical manufacturing and quality records from errors or manipulation.
- **Enhance regulatory alignment** Align internal systems with global regulatory expectations, reducing compliance gaps and supporting ongoing adherence to industry requirements.
- **Promote operational resilience** Establish risk-based processes and change management, minimizing system downtime and ensuring business continuity in regulated settings.

How SmartSuite supports GAMP 5

Intended Use and Validation Strategy Document intended use, risk classification, and validation approach for each system.	Validation Deliverables and Traceability Manage URS, risk assessment, test evidence, and traceability in one place.	Testing, Deviations, and CAPA Track test execution, deviations, corrective actions, and closure verification.
Change Control to Maintain Validated State Run change impact assessments, approvals, and retesting workflows.	SOPs, Training, and Compliance Evidence Centralize SOPs, training records, and acknowledgements tied to validation.	Inspection Readiness Reporting Report validation status, open actions, and evidence coverage across systems.

Common framework mappings

- 21 CFR Part 11
- ISO 13485:2016

Official resources

GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems Provides guidelines for validation and compliance of automated systems in regulated industries. ispe.org/publications/guidance-documents/gamp-5	ISPE GAMP 5 Guide: Compliant GxP Computerized Systems Outlines principles for ensuring data integrity and operational compliance in life sciences manufacturing. ispe.org/publications/guidance-documents/gamp-5-guide-2nd-edition
GAMP 5 Knowledge Center Offers resources and tools supporting implementation of GAMP 5 principles in manufacturing settings. ispe.org/publications/guidance-documents/gamp-5-guide-2nd-edition	ISPE GAMP Community of Practice Explains ongoing development and community resources related to GAMP 5 framework. ispe.org/Communities-Practice

Frequently asked questions

What is GAMP 5 used for?

GAMP 5 is a guidance framework for ensuring the integrity, reliability, and compliance of automated and computerized systems in regulated industries such as pharmaceuticals, life sciences, and biotechnology. It supports organizations in validating their systems to meet GxP requirements and regulatory expectations.

Is compliance with GAMP 5 mandatory or certifiable?

GAMP 5 itself is not a certifiable standard and is not required by law, but it is widely recognized by regulators as best practice for validating computerized systems subject to GxP regulations. Organizations often adopt GAMP 5 to demonstrate due diligence and compliance with regulatory requirements.

What systems or processes are covered by GAMP 5?

GAMP 5 applies to all automated or computerized systems involved in the manufacturing, control, and management of products within regulated sectors. This includes process control systems, laboratory information management, manufacturing execution systems, and electronic records.

What are the key concepts and documentation requirements in GAMP 5?

GAMP 5 emphasizes a risk-based approach to validation, robust documentation, clear requirements definition, system categorization, and lifecycle management. Essential artifacts include user requirement specifications, functional specifications, validation plans and reports, risk assessments, and audit trails.

How is a risk-based approach implemented under GAMP 5?

A risk-based approach in GAMP 5 involves assessing the impact and likelihood of risks associated with system functionality, data integrity, and product quality. Controls are implemented and documented based on risk priority, focusing validation resources on critical system aspects.

How does GAMP 5 align with other regulatory frameworks or standards?

GAMP 5 is designed to complement existing regulatory frameworks such as FDA 21 CFR Part 11, EU Annex 11, and ISO 9001. It provides practical implementation guidance for fulfilling computerized system requirements specified within these and other GxP regulations.

What are the ongoing requirements for maintaining GAMP 5 compliance?

Maintaining GAMP 5 compliance requires ongoing change management, periodic review of system performance, regular risk assessments, detailed documentation, and traceable audit trails. Continuous training, monitoring, and revalidation activities are critical to ensure continued system compliance and data integrity.

How would SmartSuite support GAMP 5?

SmartSuite supports GAMP 5 by enabling organizations to track validation activities, manage risk assessments, implement and monitor controls, collect compliance evidence, and maintain comprehensive audit trails. The platform facilitates real-time reporting, centralized documentation, and audit readiness, helping streamline ongoing regulatory compliance efforts.

License included / downloadable: No GAMP 5 guidance is published by the International Society for Pharmaceutical Engineering (ISPE). Access to the full framework documentation typically requires purchasing official publications. License not included with platform

Full framework page and mappings: smartsuite.com/frameworks/gxp-gamp-5-good-automated-manufacturing-practice