SmartSuite

Framework / Quality & Safety / Other

GAMP 5 (Second Edition)

ISPE GAMP 5 Second Edition (July 2022) is guidance for risk-based validation of GxP computerized systems: life cycle, software categories, critical thinking and supplier roles.



What it is

ISPE GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems, Second Edition, is guidance from the International Society for Pharmaceutical Engineering (ISPE) on validating and operating computerized systems in GxP-regulated life sciences. It was published in July 2022 as the update of the 2008 first edition, and regulated companies, suppliers and regulators use it to show that systems are fit for intended use and protect patient safety, product quality and data integrity.

GAMP is guidance, not a law or a certifiable standard. ISPE says it does not define a prescriptive method.

At a glance

PUBLISHER International Society for Pharmaceutical Engineering (ISPE)	TYPE Guidance	VERSION ISPE GAMP 5 Guide, Second Edition (2022)
EFFECTIVE July 2022 (Second Edition; first edition 2008)	DOMAIN Quality & Safety	FAMILY Other
REGION International	INDUSTRY Healthcare & Life Sciences	ADOPTION MODEL Voluntary
IMPLEMENTATION COMPLEXITY High		

Source: ispe.org/publications/guidance-documents/gamp-5-guide-2nd-edition

Why it matters

- **Effort scaled to risk** Life cycle activities are added, removed and scaled by the GxP impact, complexity and novelty of a system, not by software category alone (Appendix M4).
- **Supplier knowledge put to use** Chapter 7 and Appendix M2 describe supplier activities and assessment, and the Second Edition encourages regulated companies to use supplier knowledge and documentation where possible.
- **Support for Agile and iterative work** The specification and verification approach is not inherently linear and fully supports iterative and incremental methods (section 3.2 and Appendix D8).
- **Critical thinking built in** Section 3.4 and Appendix M12 show how subject matter experts apply critical thinking, including planning test effort in proportion to risk and using exploratory testing.

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How SmartSuite supports GAMP 5

System Inventory with Intended Use

Record each system's intended use, GxP impact, components and Appendix M4 category, with a business owner and a quality owner.

Risk Assessment Register

Record risks to patient safety, product quality and data integrity by function, with severity, probability, detectability and mitigations (chapter 5).

Supplier and Service Provider Records

Track supplier assessments, quality agreements, service levels and contract exit terms for each system's suppliers (chapter 7 and Appendix M2).

Specification, Test and Traceability

Link requirements, specifications and test results, and keep exploratory test notes beside scripted results (Appendices D1, D5 and M5).

Change, Incident and CAPA Workflow

Run operational change, incident, problem management and corrective and preventive action records with approvals (Appendices O4, O5 and O6).

Periodic Review and Retirement

Schedule periodic reviews, backup and restore checks, retirement and archiving tasks, and report open actions to quality (Appendices O8, O9, M10 and O13).

Common framework mappings

21 CFR Part 11 | ISO 13485:2016 | ISO 9001:2026

Official resources

ISPE GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems (Second Edition)

ISPE's page for the Second Edition (July 2022) of the GAMP 5 guide, with table of contents and purchase options.

ispe.org/publications/guidance-documents/gamp-5-guide-2nd-edition

ISPE GAMP Community of Practice

The ISPE technical community that maintains the GAMP guides and good practice guides.

cop.ispe.org/communities/community-home?CommunityKey=ed72d220-cd9e-4ba9-87c2-a4b3623e5ca5

What is GAMP?

ISPE's overview of GAMP guidance: its aims, the guidance documents and training.

ispe.org/initiatives/regulatory/what-gamp

GAMP 5 Second Edition table of contents (PDF)

ISPE's table of contents for the Second Edition: chapters 1 to 8 and Appendices M, D, O, S and G.

ispewebassets.org/files/publications/guidance-documents/2022-TOC/ISPE-GAMP5-Ed2_TOC.pdf

Frequently asked questions

Is GAMP 5 mandatory or certifiable?

No. GAMP 5 is ISPE guidance, not a law or a certifiable standard, and ISPE says it does not define a prescriptive method. Regulations such as 21 CFR Part 11 and EU GMP Annex 11 are what bind regulated companies, and GAMP shows one widely used way to meet them.

What changed in the Second Edition?

ISPE published the Second Edition in July 2022. It keeps the first edition's framework and key concepts and adds critical thinking, a bigger role for service providers, support for iterative and Agile development, more use of tools and automation, and appendices on blockchain, AI/ML, cloud computing and open-source software.

What are the GAMP software categories?

Appendix M4 groups components as infrastructure software, tools and IT services; standard system components; configured components; and custom applications and components. The guide treats them as a continuum and says categorization is not a checklist for validation. Life cycle activities are scaled by GxP impact, complexity and novelty.

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How does GAMP 5 relate to 21 CFR Part 11 and EU GMP Annex 11?

Those texts set requirements, and GAMP helps interpret them. For example, 21 CFR 11.10(a) calls for validation of systems to ensure accuracy, reliability and consistent intended performance. GAMP's life cycle, risk management and supplier chapters describe how a regulated company can do that in proportion to risk.

How do I get the GAMP 5 guide?

ISPE sells the Second Edition, with member and non-member pricing, and its guidance license limits use to the individual purchaser for personal, non-commercial purposes. ISPE also publishes a free table of contents and an overview page called What is GAMP.

License included / downloadable: No The guide is a paid ISPE publication. ISPE's guidance license allows personal, non-commercial use by the individual purchaser, and the text is not included with the platform.

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

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