



# Explore the Crucial Updates in GAMP 5 - Second Edition

The pharmaceutical industry must pay special attention to its level of quality and risk control in its production processes in order to operate and compete in today's globalised, digitised market with an increasingly demanding regulatory framework.

GAMP 5 second edition introduces important new features in terms of the expanded coverage of the guide, the inclusion of emerging technologies such as cloud and AI, and a greater emphasis on risk management and continuous verification. These updates will help the pharmaceutical and medical device industry keep up with emerging technologies and ensure that their systems are effectively validated.

## Benefits of GAMP 5 compliance (Good Automated Manufacturing Practice 5)

### Regulatory compliance

GAMP 5 provides a structured and internationally recognised framework for the validation of IT systems, helping companies to comply with these regulations.

### Quality assurance

IT systems play a crucial role in the manufacturing and quality control of pharmaceutical products. GAMP 5 establishes principles and approaches to ensure that automated systems meet quality and safety requirements, thus contributing to the quality assurance of pharmaceutical products.

### Risk reduction

Validation of IT systems according to GAMP 5 helps to identify and mitigate potential risks associated with the use of technology in the manufacture of pharmaceutical products. This includes reducing risks related to data integrity, patient safety and regulatory compliance.

### Operational efficiency

Implementing GAMP 5 best practices is not only a regulatory necessity but can also lead to greater operational efficiency. Proper validation of IT systems can help avoid unplanned outages, improve productivity and facilitate more efficient management of pharmaceutical processes.

### Data integrity

In the pharmaceutical industry, data integrity is essential to ensure the validity and reliability of results. GAMP 5 provides guidelines to ensure data integrity throughout the life cycle of the computer system, from development to decommissioning. life cycle of the computer system, from development to deactivation.

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**Expansion of the GAMP 5 guide coverage:** The new edition of GAMP 5 expands the coverage of the guide to include systems and devices beyond information and control systems. The guide now covers automation systems, equipment and devices, including robots, vision systems, packaging and labelling equipment, and environmental monitoring systems, among others.



**Inclusion of cloud technology:** The new edition of GAMP 5 includes cloud technology as an area that needs to be validated. The guide provides guidance on how to validate cloud systems and how to manage the risks associated with data security and privacy.



**Focus on risk management:** The new edition of GAMP 5 emphasises risk management as a key component of system validation. The guide provides guidance on how to identify, assess and mitigate risks associated with IT systems and medical devices.



**Incorporation of artificial intelligence (AI) technology:** The new edition of GAMP 5 includes artificial intelligence (AI) technology as an area that needs to be validated. The guidance provides guidance on how to validate AI systems and how to manage the risks associated with data accuracy and confidentiality.



**Focus on continuous verification:** The new edition of GAMP 5 emphasises continuous verification as a key component of system validation. The guide provides guidance on how to implement continuous verification and how to handle system changes and updates over time.

Remember that the implementation of GAMP 5 is a continuous and dynamic process. Periodic reviews and updates should be performed to ensure that IT systems remain compliant over time. Also, consult with industry-specific validation and regulatory experts for additional guidance. Want to know how we can help you? **Contact us.**