

Implementing GAMP 5

Factsheet

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An analysis of benefits and challenges for small and medium-sized companies in the life sciences

As any company in the life sciences industries will discover soon enough: Achieving compliance with GAMP 5 is a significant undertaking, especially for small and mid-sized businesses. However, despite these difficulties, it also brings numerous advantages. Let's discuss!

Benefits

- **Improved quality:** GAMP 5 offers guidance on how to guarantee that computerized systems are fit for their intended purpose and function as intended throughout their lifetimes. A proven validation approach enhances the quality of a company's products and procedures.
- **Increased efficiency:** Validated computerized systems increase productivity and decrease costs by being more reliable and efficient.
- **Enhanced reputation:** Compliance with GAMP 5 builds trust in a company's products and processes, and thus raises its reputation among customers and regulatory authorities.
- **Improved competitiveness:** Smart adherence to GAMP 5 enables small and medium-sized businesses to compete more effectively in the highly regulated life sciences industries.



Challenges

- **Limited resources:** Implementing GAMP 5 may be challenging for small and medium-sized businesses due to their limited time, financial, and human resources.
- **Regulatory requirements:** GAMP 5 is just one of many standards that life sciences organizations may need to follow in order to comply with a range of regulatory regulations.
- **Complexity:** GAMP 5 covers a wide range of computerized systems at a deep level of detail, and can therefore be complex to understand and implement in a correct manner.

Implementation approach

If you want to implement GAMP 5 in a smart way, you need a proper baseline.

First of all, you need a Computer System Validation (CSV) Policy or a Validation Master Plan (VMP), outlining the guiding principles, processes, and roles involved in validating your systems. The CSV Policy must be aligned with pertinent laws and regulations, such as US FDA 21 CFR Part 11, EU GMP Annex 11, and ISO 13485. GAMP 5 good practices complete the legal requirements.

Additionally, you need an inventory of all systems in use: hardware, software, and data systems. This will allow you to provide an overview of which systems are GxP-relevant and need to be validated, as well as their current validation status.

To identify the validation need, you need to understand the initial or high-level software risks associated with a business process depending on its criticality regarding patient safety, product quality, data integrity (e.g., is the system used to control data for product release, to support pharmacovigilance or critical parameters in clinicals). This step aims to identify the GxP applicability of a system and its modules (whether or not it is regulated) and to classify its category (e.g., standard, configured, or self-developed). The outcome will subsequently contribute to the planning process. You can also include optional questions in the high-level risk assessment, for example, to cover aspects of data privacy or records management in only one assessment.

Now that you have set up the baseline, let's discuss the steps necessary to validate a system.



To implement GAMP 5 successfully, you need a Validation Plan that outlines your strategy, including the scope, validation strategy, and all activities required for validating the system. We recommend the following steps:

- **Define the system's requirements** and specify its regulatory, functional and performance requirements as well as its expected use.
- **Design and document the system** according to the requirements outlined in the preceding stage.
- **Test the system** based on the risk strategy to make sure it complies with the specifications and operates as intended.
- **Review and approve the validation documentation** by the proper personnel before the validation project is changed to a new stage (e.g., from Specification to Installation).
- **Maintain the validated state of the system** by putting a procedure in place which handles system modifications, thus preserving its validated state across time.

Naturally, the specific tasks involved in the validation process may vary, depending on the complexity and potential impact of the system that is verified.

With our *leading-edge validation* approach, we ensure audit-readiness and cost efficiency.

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