GAMP® Good Practice Guide

GxP Compliant Laboratory Computerized Systems (2nd edition)

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GAMP® 5
GAMP Good Practice Guides

Figure: GAMP Documentation Structure (ISPE)
Why GPG 2nd Edition?
Why GPG 2nd Edition?

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Why GPG 2nd Edition?
Why GPG 2nd Edition?
Why GPG 2nd Edition?

SUMMARY

• The automation of laboratory testing and data management operations is increasing in sophistication and complexity.

• Due to the wide diversity of systems, a single prescriptive approach would be neither practical nor cost-effective.

• The aim is to achieve compliance, efficiency, and effectiveness – within a reasonable budget and timeline – for a wide variety of systems.
What is NEW?
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1. Describes a flexible approach consistent with GAMP® 5, based on risks associated with the use of the system to support the relevant business process (scalable Life Cycle approach)

2. Applies the GAMP® 5 specification, verification and implementation approach to laboratory computerized systems

3. Emphasizes the importance of leveraging supplier documentation and knowledge to avoid unnecessary duplication of efforts
1. GAMP® 5
Scalable Life Cycle Approach

• A flexible approach consistent with GAMP® 5

  – Product and process understanding (business impact)
  – System impact on patient safety, product quality, and data integrity (risk assessment)
  – System complexity and novelty (architecture and system components)
  – Outcome of supplier assessment (supplier capability)
  – Calibration of laboratory systems (instrument impact)

see also: GPG – A risk-based approach to Calibration Management (ISPE, 2010)
Business Process System Overview Diagram

Figure: Example of Process and Data flow of GC/MS (ISPE, GPG)
## Categorization of Laboratory Computerized Systems

<table>
<thead>
<tr>
<th><strong>GAMP GPG (1st Edition)</strong></th>
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<tr>
<td>GAMP GPG – Subcategory A</td>
<td>GAMP5 – Category 3 Non-Configured Products</td>
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<td>GAMP GPG – Subcategory B</td>
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<td>GAMP5 – Category 5 Customized Products</td>
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<td>GAMP GPG – Subcategory G</td>
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Figure: Comparison of Categories in First and Second Editions of the Guide (GAMP GPG)
2. GAMP® 5 - System Life Cycle

Figure: A General Approach for Achieving Compliance and Fitness for Intended Use (ISPE, GAMP® 5)
GAMP® 5 - “Specification” stage

- Define the laboratory computerized systems functions and the intended limits of operation for the equipment as used in the laboratory.

- **User Requirements Specifications (URS)** should be produced for ALL laboratory computerized systems, but e.g.
  - Systems with greater technical complexity will have greater available functionality, the requirements documents will reflect this complexity.
  - For simple systems or for multiple installations of the same type of system, generic requirements documentation can be created.
  - Functions to be used need to be tested, functions not intended to be used are not typically documented and tested.
GAMP® 5 - “Verification” stage

- Demonstrates compliance and fitness for intended use
- Verification of a laboratory computerized system should provide documented evidence.
- Consider ‘risk based approach’
  - Calibration, routine system suitability checks
  - Installation verification and/or configuration
  - Functional testing
  - Equipment qualification versus software validation
  - Requirements testing (performance, security, data integrity, ...)
  - Re-execution of functional testing for additional installations
3. GAMP® 5

Leveraging supplier work

- Most laboratory computerized systems are configured systems (GAMP cat. 4).

- **Leveraging supplier documentation and knowledge** is acceptable, based on the outcome of your **Supplier Assessment**.
  - Supplier Involvement
  - Supplier Qualification
Good Practice Guide
Laboratory Computerized Systems

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• Table of Content: Good Practice Guide (Annexes)
  – Categories of Software (e.g. GAMP cat. 3, cat. 4)
  – System Description
  – Data Integrity
  – Categories of Laboratory Systems (“simple”, “medium”, “complex” systems)
  – System Interfacing Considerations (LIMS, ELN, ...)
  – Robotics systems
  – Electronic Records and Raw Data
  – Security Management for Laboratory Computerized Systems
  – Supplier Documentation and Services