



## GAMP 5: A Quality Risk Management Approach to Computer System Validation

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### ABSTRACT

The GAMP Guide is a voluntary set of guidelines created by industry leaders to help companies understand and meet cGMP regulations for automated systems. Produced by the GAMP Forum, a technical subcommittee of ISPE, the GAMP Guide has been revised several times to accommodate changes to regulatory policies, best industrial practice requirements and in computer system validation. Present guide is GAMP – 5. As part of its recent initiative cGMPs for the twenty-first century “A Risk-Based Approach”, FDA has begun applying risk and impact assessment, including validation of Electronic Data Management System (EDMS), categorization of system components and supplier assessment as a validation strategy. FDA has recommended to use risk analysis techniques to allow manufacturers to put their time and effort in electronic data management and testing. GAMP 5 states that automated computer system validation (CSV) testing tools can be used to improve test execution efficiency and effectiveness. Automated CSV tools provide the most benefit for larger enterprise applications such as enterprise resource planning, Document management systems, Laboratory information management systems, Corrective action and Preventive action, etc. Organizations should consider a formalized validation plan for each tool or set of tools to describe the risk, use, and validation or qualification requirements to maximize the benefits. These initiatives can realize significant value by the adoption and integration with the computer system compliance process and EDMS.

**Keywords:** Computer system validation, EDMS, GAMP, Risk Management.

### INTRODUCTION

**G**AMP 5, addresses automated testing, states, “Automated test execution tools can be used to improve test execution efficiency and effectiveness”. Any use of automated test execution tools should be defined in test strategy. Tools should be used in accordance with defined instructions, manuals as appropriate, and tool should be held under Configuration Management.

#### GAMP comes in to force

For the better of understanding of healthcare automated manufacturing started in the late 80's and early 90's, when greater validation of the pharmaceutical industries was becoming necessary as automated systems played a greater role in healthcare production. The first GAMP guidelines were put into action in March 1994. January 2008 being the latest releases of the GAMP 5 guidelines<sup>1-2</sup>.

#### GAMP 4 to GAMP 5 Evolution<sup>3</sup>.

The GAMP guide has been updated to keep up with concepts and regulatory & industry developments.

- To avoid duplication of activities fully integrate engineering and computer system activities so that they are only performed once.
- Leverage supplier activities to the maximum possible extent, while still ensuring fitness for intended use.
- Scale all life cycle activities and associated documentation according to risk, complexity, and

novelty e.g. If the system uses non-configured off the shelf software, complexity, novelty and risk is therefore low. If the system uses programmed software designed specifically for the application, the novelty, complexity and risk is high.

#### GAMP applies to:

Healthcare industries that produce pharmaceutical, biotechnology & medical devices fall under the embrace of the GAMP guidelines. The ISPE is an international organization, the GAMP documents are a guide to progress good manufacturing practices worldwide. Because the GAMP guidelines are not a standard a company cannot be Certified, Compliant or Approved<sup>3</sup>.

#### Objective:

GAMP 5 discusses topics and issues associated with computer validation in order to provide useful resources for daily work applications. It brings information regarding regulatory requirements for the validation, qualification and risk assessment of computerized systems.

#### GAMP 5 Drivers

- The need to develop a Guidance that will satisfy the regulatory requirements for CSV
- Scalable approach to GxP Compliance through the complete life cycle
- Drive towards Risk Based Approach
- Effective Supplier Relationships



- Use of Existing Documentation and Knowledge
- Continuous Improvement within QMS
- Quality by Design
- Effective Governance to Achieve and Maintain GxP Compliance.

**DISCUSSION**

**Industry Guidance to Risk-based approach in Computer System Validation**

The ICH guidance for industry, (Q9) Quality Risk Management, offers a systematic approach to quality risk management and suggests a methodical process for the assessment, control, communication, and review of risks. International Society of Pharmaceutical Engineers (ISPE) GAMP 5 has also issued guidance on how to adopt a risk-based approach to validation based on the various categories of software in consideration. We will focus on the GAMP 5 guidance on the risk-based approach and its implementation. The ISPE GAMP5 guidance is aligned to the ICH Q9 guidance and both suggest the use of risk assessment as the key input to deciding the extent and effort for validation. GAMP 5 has classified software's under various categories based on its complexity, reliability based on its extended use in the industry, and the likelihood of failure. GAMP 5 has stressed to rely on the maturity of the suppliers Quality Management System (QMS). It suggests that an evaluation should be performed of the suppliers QMS and accordingly the suppliers documentation be relied upon and thereby reduce the effort of validating the product.

**The software categories in GAMP 5**

Category 1: Infrastructure Software (includes operating systems, database managers, middleware, and any other tools for network monitoring, batch job scheduling tools etc.)

Category 3: Non-Configured Software (includes all COTS software that comes with a default configuration)

Category 4: Configured Software (includes COTS systems that can be configured as per business processes as well as customized)

Category 5: Custom Software

Note: "Firmware" was earlier classified as "Category 2" under GAMP 4. This classification was removed under GAMP 5.

GAMP suggests the identification and evaluation of risks throughout the life cycle of the software. Key risk areas must be identified and efforts focused only on the point of risk.

**Risk Management Goals**

Systematic process for identifying, assessing, mitigating, controlling, and communicating risk, based on

- Good science

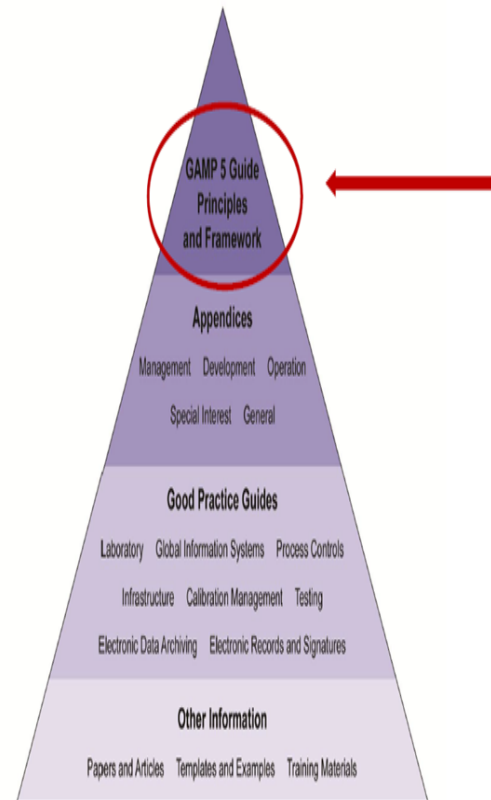
- Process and product understanding

Recognize that zero risk is impractical and unattainable

Aim is for **acceptable risk**

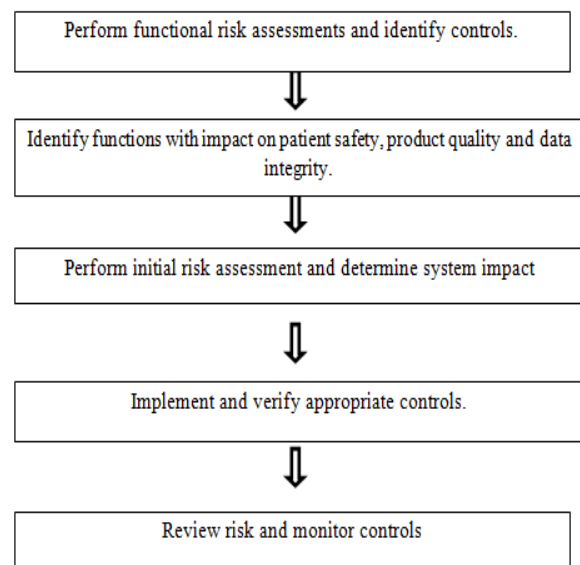
Consistent with risk-based approach based on ISO14971 (and ERES GPG) as well as other contemporary risk based tools.

**Structure of GAMP5**



**Figure 1:** GAMP 5 A risk based approach to compliant GxP computerized system

**Quality Risk Management Process<sup>1</sup>**



**Figure 2:** Quality Risk Management process

**The Main Components of an EDMS that need to be managed**

- Platform Hardware (Servers and clients)
- Server Software (Platform and Application)
- Client Software
- EDMS Processes (Process Owner)
- EDMS Community (People, SME, System Owner- may also be Process Owner)

**Key Concepts**

- Lifecycle Approach within QMS
- Scalable Lifecycle Activities
- Process and Product Understanding
- Science Based Quality Risk Management
- Leveraging Supplier Involvement

**Life Cycle Approach within a QMS**

- Life cycle approach: defining activities in a systematic way from understanding the requirements to system retirement.
- It enables management control and a consistent approach across systems.
- The life cycle should form an intrinsic part of the company's Quality Management System (QMS).
- The QMS should enable continuous process and system improvements based on periodic reviews and evaluation, operational and performance data, and root-cause analysis of failures.
- Identified improvements and corrective actions should follow change management.

**Product and Process Understanding**

- An understanding of the supported process is fundamental
- Focus on risk associated with Patient Safety, Product Quality, and Data Integrity
- Need to understand risks associated with a business process before the risks associated with specific functions of computerized systems can be assessed
- Specification of requirements should be focused on critical aspects
- The extent and detail of requirement of specification should be based on the associated risk, complexity, and novelty of the system.

**Leveraging Supplier Involvement**

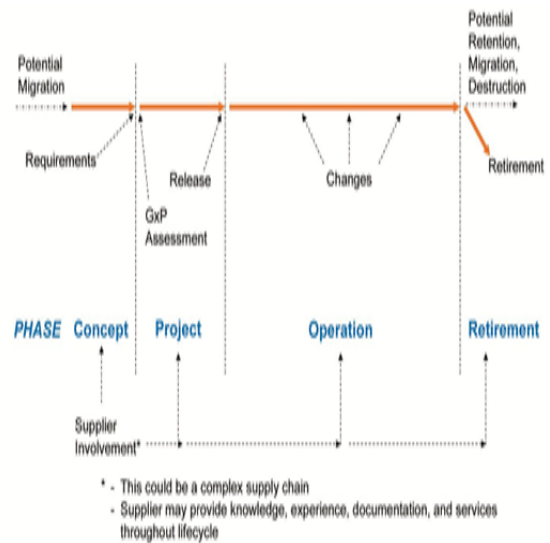
Involvement could be:

- Requirements gathering
- Risk assessments

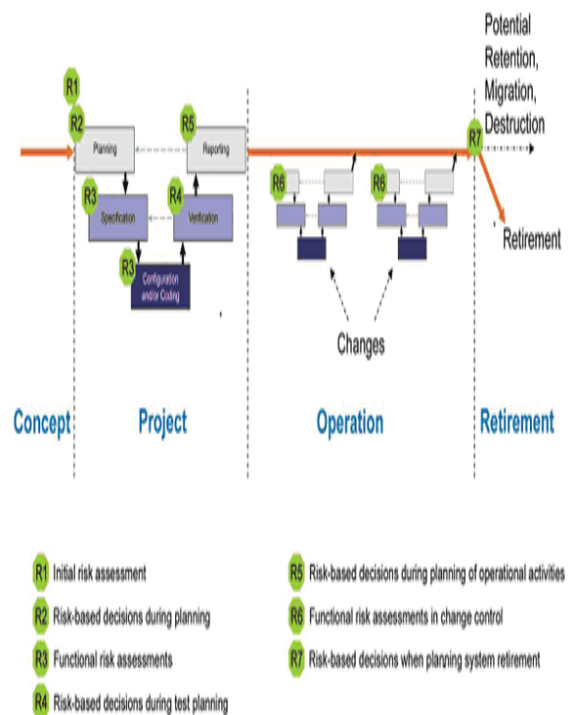
- Creation of functional and other specifications
- System configuration
- Testing and other verification
- Support and maintenance.
- Documentation should be assessed for suitability, accuracy and completeness.

**Computer System Life Cycle**

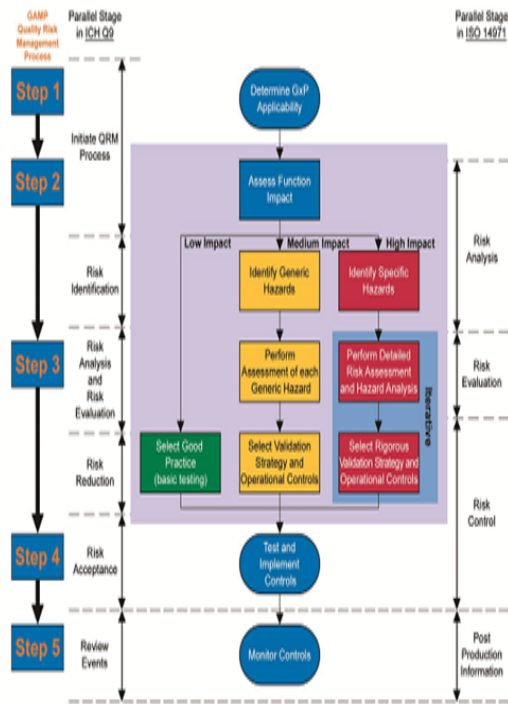
The computerized system life cycle encompasses all activities from initial concept to retirement and data migration or destruction.



**Figure 3:** GAMP 5 - A risk based approach to compliant GxP computerized system



**Figure 4:** GAMP 5 - A risk based approach to compliant GxP computerized system



**Figure 5:** GAMP 5 - A risk based approach to compliant GxP computerized system

**CONCLUSION**

GAMP 5 goes on to explain that if an automated testing tool is used on a GXP regulated system, becomes subject to specification and verification based on risk. While GAMP 5 doesn't focus on all types of automated tools, these principles should apply when considering automated tools for GXP systems.

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