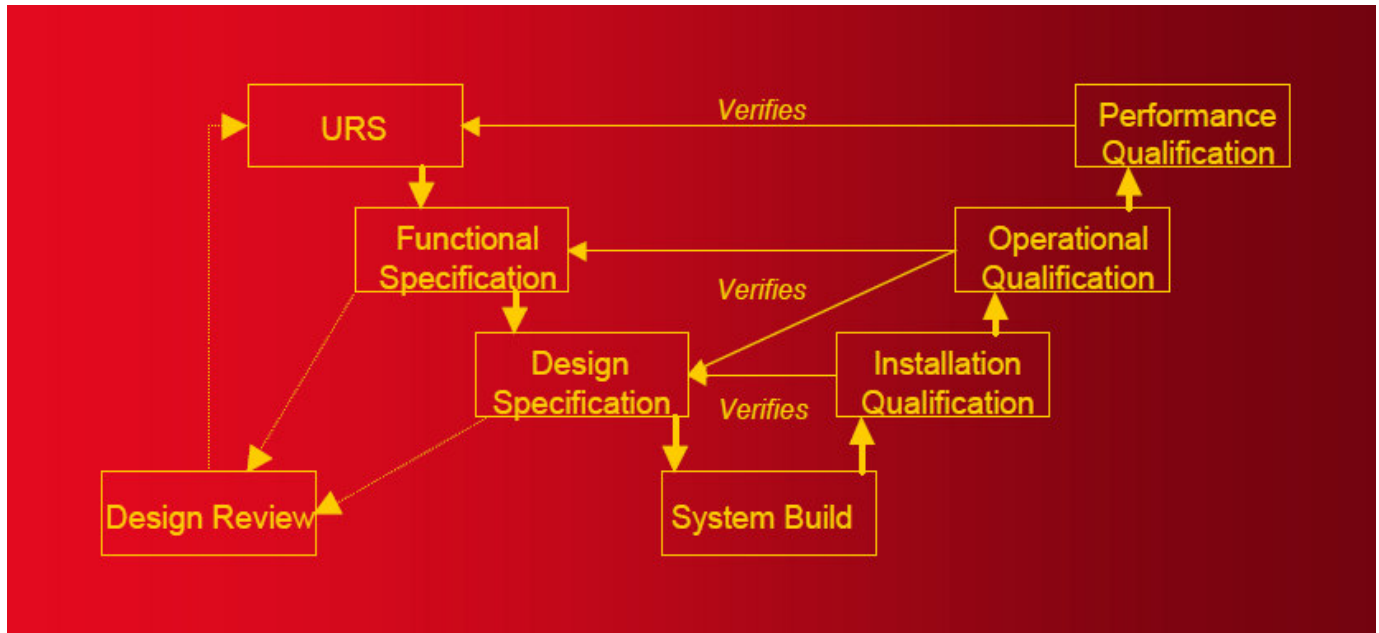


# VALIDATION



GAMP guidance aims to achieve computerized systems that are fit for intended use and meet current regulatory requirements, by building upon existing industry good practice in an efficient and effective manner.

GAMP provides practical guidance that

- ❑ Facilitates the interpretation of regulatory requirements
- ❑ Establishes a common language and terminology
- ❑ Promotes a system life cycle approach based on good practice
- ❑ Clarifies roles and responsibility

It is not a prescriptive method or a standard, but rather provides pragmatic guidance, approaches and tools for the practitioner.

When applied with expertise and good judgment, this Guide offers a robust, cost effective approach. The approach described in this document is designed to be compatible with a wide range of other models, methods, and schemes including

- ❑ Quality systems standards, such as those of the Institute of Electrical and Electronics Engineers (IEEE), and certification schemes, such as the International Organization for Standardization (ISO) 9000 Series
- ❑ Schemes for assessing and improving organization capability and maturity, such as Capability Maturity Model Integration (CMMI)
- ❑ Software process models, such as the various spiral models, or ISO 12207.
- ❑ Software development methods, such as Rapid Application Development (RAD), Agile, Rational Unified Process (RUP), or Extreme Programming (XP).

- ❑ Approaches to IT service management, such as the IT Infrastructure Library (ITIL).

Where possible, terminology is harmonized with standard international sources such as International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and ISO.

This Guide aims to be fully compatible with the approach described in the American Society for Testing and Materials (ASTM) E2500 Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment.

## **RATIONALE FOR GAMP 5**

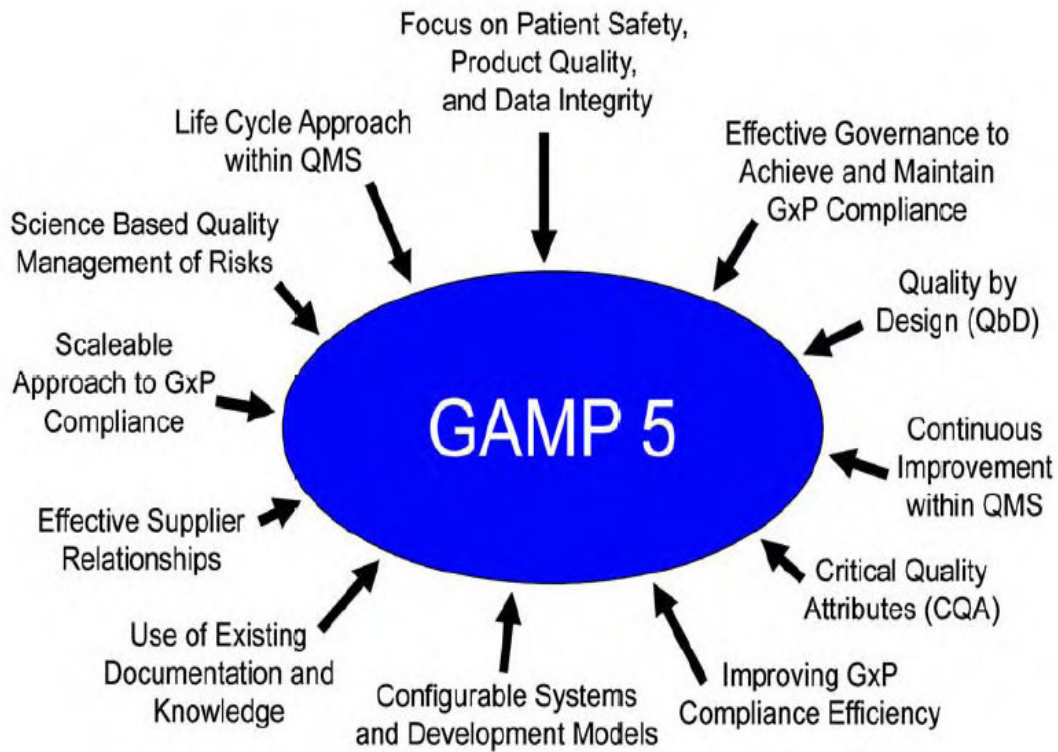
This revision of GAMP has been significantly updated to align with the concepts and terminology of recent regulatory and industry developments including

- ❑ ICH Guidance Q8, Q9, and the forthcoming setting out expectations for the application of science- and risk-based approaches to drug development and manufacture supported by pharmaceutical quality systems
- ❑ Product Quality Lifecycle Implementation (POLI) an initiative launched by ISPE to help industry to implement ICH guidance
- ❑ US Food and Drug Administration (FDA) current Good Manufacturing Practices (cGMPs) for the 21st Century Initiative and associated guidance promoting science based risk management
- ❑ Pharmaceutical Inspection Cooperation Scheme (PIC/S) Guidance on Good Practices for Computerized Systems in Regulated GxP Environments clarifying regulatory expectations
- ❑ Emerging industry standards such as those produced by the ASTM E55 Committee<sup>1</sup> promoting process understanding, control, and capability for drug development and manufacture.

These regulatory and industry developments focus attention on patient safety product quality, and data integrity.

In addition to this, there is the need to

- ❑ Avoid duplication of activities (e.g., by fully integrating 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
- ❑ Recognize that most computerized systems are now based on configurable packages, many of them networked
- ❑ Acknowledge that traditional linear or waterfall development models are not the most appropriate in all cases. These regulatory and industry developments and expectations lead to the drivers



The purpose of this Guide is to provide a cost effective framework of good practice to ensure that computerized systems are fit for intended use and compliant with applicable regulations. The framework aims to safeguard patient safety, product quality, and data integrity, while also delivering business benefit. This Guide also provides suppliers to the life science industry with guidance on the development and maintenance of systems by following good practice.

Patient safety is affected by the integrity of critical records, data, and decisions, as well as those aspects affecting physical attributes of the product. The phrase ‘patient safety, product quality, and data integrity’ is used throughout this document to underline this point.

This Guide is intended for use by **regulated companies, suppliers, and regulators**. Suppliers include providers of software, hardware; equipment, system integration services, and IT support services, both internal and external to the regulated company.

This Guide has been designed for use by a wide range of disciplines and responsibilities, including:

- ❑ Management
- ❑ Quality unit
- ❑ Research
- ❑ Development

- ❑ Manufacture
- ❑ Laboratory
- ❑ Engineering
- ❑ IT
- ❑ Support staff
- ❑ All associated suppliers

GAMP documents are guides and not standards. It is the responsibility of regulated companies to establish policies and procedures to meet applicable regulatory requirements. Consequently, it is inappropriate for suppliers or products to claim that they are GAMP certified, approved, or compliant.

## SCOPE

This Guide applies to computerized systems used in regulated activities covered by:

- ❑ Good Manufacturing Practice (GMP) (pharmaceutical, including Active Pharmaceutical Ingredient (API), veterinary, and blood)
- ❑ Good Clinical Practice (GCP)
- ❑ Good Laboratory Practice (GLP)
- ❑ Good Distribution Practice (GDP)
- ❑ Medical Device Regulations (with the exception of software embedded within medical devices)

This provides an approach that is suitable for all types of computerized systems, focusing on those based on standard and configurable products, but equally applicable to custom (bespoke) applications.

The principles described can be applied to a wide range of computerized systems. Detailed application of these principles to specific system types (e.g., IT, infrastructure, process control systems, and analytical laboratory systems) is described in supporting GAMP Good Practice Guides

Not all the activities defined in this Guide will apply to every system. The scaleable approach enables regulated companies to select the appropriate system life cycle activities.

This Guide is also consistent with other regulatory demands such as Sarbanes-Oxley (SOX).<sup>2</sup> However, the use of this Guide does **not** guarantee compliance with, or replace, these regulatory demands.

It is recognized that there are acceptable methods other than those described in this Guide. The Guide is not intended to place any constraints on innovation and development of new concepts and technologies.

### More Information

For more information on Pharma IT Solutions, contact your  
POLMON account manager  
Mr.N.V.Sagar  
Asst Manager – Automation  
Mob No.: +91-9959999092  
E-Mail Id: vidyasagar@polmon.com

**POLMON Instruments Pvt. Ltd.,**  
‘POLMON HOUSE’, Nizampet Road  
Kukatpally, Hyderabad – 500072  
Tel : 040-23053046, 23055970, 23057642  
Website: www.polmon.com