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Essentials of GAMP-5: A quality risk-based approach to compliant GxP computerized systems

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The new GAMP-5 guidelines were released February 2008 at the ISPE Manufacturing Excellence Conference in Tampa, Florida. These guidelines are the latest, up-to-date thinking in the approach to validation of GxP computerized systems. The purpose of the guidelines is to "provide a cost effective framework of good practice to ensure that computerized systems are fit for use and compliant with regulation."

There are five key concepts to GAMP 5:

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

Why GAMP 5 Now?

Since the release of GAMP 4 in 2001 the regulatory bodies had made significant updates in their thinking and approach to regulatory compliance. These changes include;

- FDA cGMPs for the 21st Century initiative and associated guidance promoting science-based risk management
- ICH Guidance Q8, Q9, and soon to be released Q10, which is expected to promote science based risk management
- PIC/S Guidance Practice for Computerized Systems in Regulated GxP Environments which clarify regulatory expectations

GAMP also designed GAMP 5 to be compatible with IEEE standards, ISO 9000 and 12207, IT Infrastructure Library (ITIL), and other international standards.

GAMP also wanted to:

- Focus attention on computerized systems that most impact patient safety, product quality, and data integrity
- Leverage supplier activities to the maximum possible extent while ensuring fitness for intended use
- Recognize that most computerized systems are now based on configurable packages

Biography

P.Lalasa is a student of JSS College of Pharmacy, JSS University, Mysore, Karnataka, India. She has completed her B.Pharm from JSS College of Pharmacy under RGUHS, Bangalore, Karnataka, India during 2007-2011. Presently she is pursuing M.Pharm in Pharmaceutical Quality Assurance in the same college. Her areas of interest are Quality Management System, GMP etc.

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