A risk based approach to GxP Compliant Laboratory Computerized Systems in the COVID-19 Era and Beyond

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OVERVIEW

Laboratory Computerized Systems and data management operations are increasing in variety, sophistication and complexity in the GxP environment. Widespread reliance on these systems, along with their potential impact on data integrity, and the trend towards cost efficiency within companies, means that companies need achieve GxP compliance of laboratory computerized systems– within a reasonable budget and timeline.

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LEARNINGOBJECTIVES

- Examining the system life cycle and its applicability for most laboratory computerized systems
- Identifying characteristics that distinguish various types of laboratory computerized systems
- Developing a rationale for scaling activities and effort based upon risk, complexity, and novelty
- Defining a strategy for supplier assessments, and the effective leveraging of supplier knowledge, experience, and documentation
- Applying the GAMP® 5 Quality Risk Management (QRM) approach
- Defining necessary operational and maintenance activities
- Recommending an approach to system retirement
- Leveraging deliverables and activities for very similar or identical systems

Faculty Carolyn Troiano

Award winning FDA Compliance Expert for Validation, 21 CFR Part 11 (Electronic Records/Signatures) and Data Integrity.
My experience includes 34+ years in IT/ Business, Marketing & Compliance leadership and management roles at a variety of Fortune 100 companies, across multiple industries.

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AGENDADAY 01

- Lecture 1: Introduction and Background
- Introductions / Participants' Understanding / Participants' Objectives for the Course (Please come prepared to discuss)
- Background
- Industry Context
- Key Concepts
- Lecture 2: Quality Risk Management
- Science Based Quality Risk Management
- Quality Risk Management Process
- Initial Risk Assessment
- Implement & Verify Appropriate Controls
- Review Risks & Monitor Controls
- Lecture 3: Life Cycle Approach
- Computerized Systems Life Cycle
- Specification & Verification
- Computerized System Validation Framework
- Lecture 4: Life Cycle Phases
- Concept
- Project
- Operation
- Retirement

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AGENDADAY 02

- Lecture 5: GxP Compliance
- Data Integrity
- Security
- Defining Electronic Records and Raw Data
- Lecture 6: Risks & Implementation of Systems
- Simple Systems (Analytical Balance,pH Meter, Electronic Pipette)
- Medium Systems (LIMS / ELN)
- Complex Systems (Robotics)
- Lecture 7: Supplier Documentation & Services
- System Development by the Supplier
- Supplier Assessment
- Supplier Good Practices
- Leveraging Supplier Knowledge & Documentation
- Quiz: Jeopardy!!!!
- GxP Compliant Laboratory Computerized Systems

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WHO WILL BENEFIT

- Lab Director
- Lab Scientists
- Computer Validation Professional responsible for defining and managing laboratory computerized systems in regulated life science industries
- Information Technology (IT) personnel
- IT support services
- Management and Laboratory System users
- Software Developers