

A Risk Based Approach To IT Infrastructure Qualification & Compliance

Date : May 24, 2018 - 09:00 AM - May 25, 06:00 PM

Event URL : <http://www.sfbayeventslist.com/events/a-risk-based-approach-to-it-infrastructure-qualification-compliance-may-2018>

Organizer : GlobalCompliancePanel

Venue :

Location : 7901, 34th Ave
Bloomington, MN, USA, ZIP: 55425

GxP Regulated companies are dependent on validated GxP computerized applications to conduct their day to day operations. These applications are, in turn, depended upon a qualified infrastructure that can be relied upon to provide control and regulatory compliance.

The consequences of the IT Infrastructure being out of compliance can result in the failure of an entire site or geographic region being brought to a standstill while the compliance issue is resolved. It can also result in regulatory citations during a regulatory inspection as both the infrastructure be out of compliance and also cause the computerized applications that are dependent on it to be out of compliance.

Effective IT Infrastructure Qualification on the other hand, confers the following benefits.

- Ensures GxP compliance
- Reduces duplication of effort
- Ensures adherence to standards
- Enhances the flow of information throughout an information system
- Promotes adaptability and agility necessary for a changeable environment
- Ensures interoperability among organizational and external entities
- Maintains effective change management policies and practices

Although all business activities depend upon the infrastructure, planning and projects to ensure its effective management are typically undervalued to the detriment of the organization.

According to IDC, a prominent research firm (cited in an article in DM Review), investments in

infrastructure management have the largest single impact on an organization's revenue.

Establishment and maintenance of a controlled infrastructure requires that infrastructure needs to be brought into initial compliance with the company's established standards, through a planned qualification process, based upon domestic and international best practices and standards. The qualification needs to be documented and confirmed by Quality Assurance. Once the IT Infrastructure is qualified, the compliant state needs to be maintained by documented standard processes and quality assurance activities. The effectiveness of maintaining the qualified state needs to be monitored and periodically verified.

The Seminar:

This Seminar provide a risk based approach to meeting current regulatory expectations for compliant IT Infrastructure platforms, including the need to identify, qualify and control those aspects impacted by GxP quality and data integrity. It provides current best practices for the design, qualification and operation of an IT Infrastructure with emphasis on the qualification requirements of the major components. It addresses compliance with international GxP regulations and can be used both for the establishment of new platforms and extensions or existing platforms whether or not they are currently in support of GxP applications. Finally, this seminar covers a range of IT Infrastructures, from those found in companies operating in a global setting to isolated or semi-isolated GxP Infrastructures.

This Seminar focuses on the horizontal approach to IT Infrastructure Qualification which includes the following benefits:

- Higher level of standardization throughout the entire lifecycle
- Minimal overlap in documentation
- Minimal overlap in qualification
- Minimal overlap in audits inspections and assessments

The areas addressed by the seminar include:

- How does IT Infrastructure Qualification fit into GaMP5 lifecycle
 - Quality Management for Infrastructure
 - Risk management for Infrastructure Qualification
 - Installation & Operational Qualification of Infrastructure Componentets
 - Configuration management and change control of infrastructure components and settings in a highly dynamic environment
 - Involvement of service provider in critical infrastructure processes
 - Security management in relation to access controls, availability of services and data integrity
 - Backup, restore and disaster recovery of IT Infrastructure
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Why you should attend:

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- VP of IT
 - Director of IT
 - Quality Managers
 - Project Managers (for CSV / IT)
 - Validation Specialists
 - Database Administrators
 - System Administrators
 - Directors / Senior Directors of Discovery
 - Directors / Senior Directors of Development
 - Directors / Senior Directors of Commercialization
 - Document Managers
 - Training Managers
 - Regulators
 - Vendors
 - Suppliers
 - Outsource Service Providers
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Industries:

- Pharmaceuticals
- Biotech
- Medical Device
- Radiological Health
- Blood Products
- Companion Animals
- Food
- Cosmetics
- Tobacco
- Academia

Day 1 Schedule

Lecture 1:

Introduction and Background

- Introductions / Participants' Understanding / Participants' Objectives for the Course (Please come prepared to discuss)
 - Infrastructure Qualification and the GaMP5 Lifecycle
 - Key Concepts
 - IT Infrastructure Elements
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Lecture 2:

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Quality Management

- Quality Manual
 - Roles Management
 - Records Management
 - Documentation Management
 - Testing Management
 - SOPs
 - Training
 - Audits
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Lecture 3:

Risk Management

- Assessment of Risk Components
 - Implementation of Mitigation and Controls
 - Change Control to Qualified Components
 - Periodic Review
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Lecture 4:

Qualification of Platforms

- IT Infrastructure LifeCycle
- Planning
- Specification & Design
- Exercise

Day 2 Schedule

Lecture 5:

Qualification of Platforms (cont'd)

- Procurement
 - IQ, OQ, PQ
 - Reporting
 - Handover
 - Exercise
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Lecture 6:

Operations

- Security Management

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- Upgrade & Patch Management
 - Server Management
 - Performance Monitoring
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Lecture 7:

Operations (cont'd)

- Client Management
 - Network Management
 - Problem Management
 - Help Desk
 - Outsourcing & Supplier Management
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Lecture 8:

Maintaining the Qualified State

- Change Management
 - Configuration Management
 - Backup, Restore & Archiving
 - Disaster Recovery of IT Infrastructure
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Quiz: Jeopardy!!!!

- IT Infrastructure Qualification & Compliance

Angela Bazigos

CEO, Touchstone Technologies Silicon Valley

Seasoned Executive with 40 years of experience in the Life Sciences & Healthcare Industries. Positions include Chief Compliance Officer <http://morflerning.com/angelabazigos/>. Experience combines Quality Assurance, Regulatory Compliance, Business Administration, Information Technology, Project Management, Clinical Lab Science, Turnarounds and Business Development. Past employers / clients include Roche, Novartis, Genentech & PriceWaterhouseCoopers. Co-authored & prototyped 21 CFR 11 guidance with FDA. Co-authored Computerized Systems in Clinical Research w/ FDA <http://www1.diahome.org/~media/4FA562336EBD46C58CDC43A8B7773095.ashx> Patent on speeding up software compliance <https://www.google.com/patents/US8266578>. Recently quoted in Wall Street Journal for using training to bring regulatory compliance to the Boardroom <http://blogs.wsj.com/riskandcompliance/2015/07/24/using-training-to-bring-compliance-to-boardrooms/> National Trainer for Society of Quality Assurance. Comments / collaborates with FDA on new guidance documents. Former President of Pacific Regional www.sfbayeventslist.com

Chapter of Society of Quality Assurance. Stanford's Who's Who for
LifeSciences: <http://www.stanfordwhoswho.com/Angela.Bazigos.7144112.html#overview>.

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