How to be efficient and compliant with 21 CFR Part 11, data integrity, and SaaS/Cloud

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Event URL : http://www.BostonEventsList.com/events/how-to-be-efficient-and-compliant-with-21-cfr-part-11-data-integrity-and-saas

Organizer : GlobalCompliancePanel

Venue :

Location : Four Points by Sheraton Boston Logan Airport Revere, MA,
Boston, MA, United States, ZIP: 20001

How to be efficient and compliant with 21 CFR Part 11, data integrity, and SaaS/Cloud

- This interactive two-day course explores proven techniques for reducing costs associated with implementing, using, and maintaining computer systems in regulated environments.
- Many companies are outsourcing IT resources and getting involved with Software as a Service (SaaS) and cloud computing. These vendors are not regulated and therefore regulated companies must ensure compliance for both infrastructure qualification and computer system validation. It is the regulated company that wants to avoid FDA form 483s and warning letters. The seminar is intended for regulated companies, software vendors, and SaaS/Cloud providers.
- The instructor addresses the latest computer system industry standards for data security, data transfer, audit trails, electronic records and signatures, software validation, and computer system validation.
- Today the FDA performs both GxP and Part 11 inspections, the Europeans have released an updated Annex 11 regulation that expands Part 11 requirements and companies must update their systems and processes to maintain compliance.
- This seminar will help you understand the specific requirements associated with local and SaaS/cloud hosting solutions.
- Nearly every computerized system used in laboratory, clinical, manufacturing settings and in the quality process has to be validated.

- Participants learn how to decrease software implementation times and lower costs using a 10-step risk-based approach to computer system validation.
- Finally, the instructor reviews recent FDA inspection trends and discusses how to streamline document authoring, revision, review, and approval.
- This course benefits anyone that uses computer systems to perform their job functions and is ideal for regulatory, clinical, and IT professionals working in the health care, clinical trial, biopharmaceutical, and medical device sectors. It is essential for software vendors, auditors, and quality staff involved in GxP applications.

Course Objectives:

- Understand what is expected in 21 CFR Part 11 and Annex 11 inspections
- Avoid 483 and Warning Letters
- Learn how to buy COTS software and qualify vendors.
- Implement a computer system using risk-based validation to gain maximum productivity and reduce cost by as much as two thirds
- Requirements for local, SaaS, and cloud hosting
- How to select resources and manage validation projects
- "Right size" change control methods that allows quick and safe system evolution
- Minimize the validation documentation to reduce costs without increasing regulatory or business risk
- Write test cases that trace to elements of risk management
- Protect intellectual property and keep electronic records safe

AGENDA

Day 1 Schedule

Overview

Introductions
Regulatory expectations
Quality Systems requirements for medical devices
Quality System structure and writing SOPs
Break
Roles and Responsibilities
Management Responsibility and a Culture of Quality
Management Review

Lunch Break

Key Capabilities for Success
Metrics and performance monitoring
An effective auditing program is a key to self-awareness

Day 2 Schedule

Maturity Modeling
Value proposition for Quality

Break

CAPA, investigation, and root cause analysis - essentials for improvement

Lunch Break

Risk Management for Compliance
Creating a strategy and quality plan

Break

Inspection preparedness and management

SPEAKER

David Nettleton

FDA Compliance Specialist,

Computer System Validation's principal, David Nettleton is an industry leader, author, and teacher for 21 CFR Part 11, Annex 11, HIPAA, software validation, and computer system validation. He is involved with the development, purchase, installation, operation and maintenance of computerized systems used in FDA compliant applications. He has completed more than 270 mission critical laboratory, clinical, and manufacturing software implementation projects. His most popular book is Risk Based *Software Validation - Ten easy Steps,* which provides fill-in-the-blank templates for completing a COTS software validation project.

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Event Categories :