21 CFR Part 11 Compliance for SaaS/Cloud Applications

Date : Apr 25, 2018 - 08:00 AM

Event URL : http://www.BostonEventsList.com/events/21-cfr-part-11-compliance-for-saas-cloud-applications-apr-2018

Organizer : NYMT

Venue :

Location : Courtyard by Marriott Boston Cambridge777 Memorial DriveCambridge, MA 02139United States,
Boston, MA, US, ZIP: 02139

21 CFR Part 11 Compliance for SaaS/Cloud Applications

***** LIMITED TIME OFFER: FREE $100 AMAZON GIFT CARD! *****
REGISTER TODAY!

This interactive two-day course will explore proven techniques for reducing costs associated with implementing, using, and maintaining computer systems in regulated environments. 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.

Many companies outsource IT resources and are involved in 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 to avoid FDA form 483s and Warning Letters.

This course is intended for these regulated companies, software vendors, and SaaS/cloud providers. The seminar instructor will:

- Address the latest computer system industry standards for data security,data transfer, audit trails, electronic records and signatures, software validation, and computer system validation.
- Help participants understand the specific requirements associated with local and SaaS/cloud hosting solutions.
- Illustrate the importance of validating the quality process and every computerized system used in laboratory, clinical, and manufacturing settings.
- Demonstrate how to decrease software implementation times and lower costs using a 10-step risk-based approach to computer system validation.
- Review recent FDA inspection trends and discuss how to streamline document authoring, revision, review, and approval.

Seminar Fee Includes:

Lunch
AM-PM Tea/Coffee
Seminar Material
USB with seminar presentation
Hard copy of presentation
Attendance Certificate
$100 Gift Cert for next seminar

Learning Objectives:

- Understand what is expected in Part 11 and Annex 11 inspections
- Avoid 483s 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

Interview with

David Nettleton, FDA Compliance Specialist

Who will Benefit:

This course will benefit all who use 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.

- Regulatory Affairs
- QA/ QC
- IT/IS

- Software Managers
- Project Managers
- Software vendors and suppliers

AGENDA

DAY 01(8:00 AM - 5:00 PM)

- 08.00 AM - 08.30 AM: Registration
- 08.30 AM: Session Start
- Introduction to the FDA (1 hr)
    - How the regulations help your company to be successful
    - Which data and systems are subject to Part 11.
- 21 CFR Part 11 - Compliance for Electronic Records and Signatures (4 hr)
    - What Part 11 means to you, not just what it says in the regulation.
    - Avoid 483 and Warning Letters.
    - Explore the three primary areas of Part 11 compliance: SOPs, software product features, and validation documentation.
    - How SaaS/cloud computing changes qualification and validation
    - Ensure data integrity, security, and protect intellectual property.
    - Understand the current computer system industry standards for security, data transfer, and audit trails.
    - Electronic signatures, digital pens, and biometric signatures.
    - SOPs required for the IT infrastructure.
    - Product features to look for when purchasing COTS software.
    - Reduce validation resources by using easy to understand fill-in-the-blank validation documents.
- HIPAA Compliance for Electronic Records (30 Min)
    - How Part 11 and HIPAA interrelate
    - What are the additional requirements for patient data
- The Five Keys to COTS Computer System Validation (30 Min)
    - The Who, What, Where, When, and Why of CSV
- The Validation Team (30 Min)
    - How to select team members
    - How to facilitate a validation project

DAY 02(8:30 AM - 3:30 PM)

- Ten-Step Process for COTS Risk-Based Computer System Validation (1 hr)
  - Learn which documents the FDA expects to audit.
  - How to use the risk-based validation approach to lower costs.
  - How to link requirements, specifications, risk management, and testing.
  - Document a computer system validation project using easy to understand fill-in-the-blank templates.
  - Based on: "Risk-Based Software Validation - Ten Easy Steps" (Davis Horwood International and PDA - www.pda.org, 2006).
- How to Write Requirements and Specifications (30 Min)
  - Workshop for writing requirements and then expanding them for specifications
- How to Conduct a Hazard Analysis/Risk Assessment-Exercise (30 Min)
  - Step-by-step instructions for performing and documenting a risk assessment, and how to use the results to reduce validation documentation.
- Software Testing (1 hr)
  - Reduce testing by writing test cases that trace to elements of risk management.
  - How to write efficient test cases
- System Change Control (30 Min)
  - How to manage a validated system with minimal documentation
- Purchasing COTS Software (30 Min)
  - How to purchase COTS software and evaluate software vendors
- Cost Reduction Without Increasing Regulatory or Business Risk (1 hr)
  - How to save money
  - How to increase quality
  - How to increase compliance with less documentation

SPEAKER

David Nettleton
FDA Compliance Specialist, Computer System Validation

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 230 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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