SAN FRANCISCO
EVENTS LIST

21 CFR Part 11 compliance for software validation and SaaS/Cloud

Date : Mar 14, 2018 - 08:30 AM - Mar 15, 05:00 PM

Event URL : http://www.sfbayeventslist.com/events/21-cfr-part-11-compliance-for-software-validation-and-saas-cloud-mar-2018

Organizer : GlobalCompliancePanel

Venue : Hilton Zurich Airport

Location : 1 Main St,
Los Angeles, CA, US, ZIP: 00000

- 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 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

---

Who will benefit:

- QA, IT, management
- all GxP system users

Day 1 Schedule

Lecture 1:

Introduction to the FDA

- How the regulations help your company to be successful
- Which data and systems are subject to Part 11

Lecture 2:

21 CFR Part 11/Annex 11 - Compliance for Electronic Records and Signatures

- What Part 11 means to you, not just what it says in the regulations
- 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

---

Lecture 3:

The Five Keys to COTS Computer System Validation

- The Who, What, Where, When, and Why of CSV

Day 2 Schedule

Lecture 1:

Ten-Step Process for COTS Risk-Based Computer System Validation

- 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).

Lecture 2:

How to Write Requirements and Specifications

- Workshop for writing requirements and then expanding them for specifications

---

Lecture 3:

How to Conduct a Hazard Analysis/Risk Assessment-Exercise

- Step-by-step instructions for performing and documenting a risk assessment, and how to use the results to reduce validation documentation.

Lecture 4:

Software Testing

- Reduce testing by writing test cases that trace to elements of risk management.
- How to write efficient test cases

Lecture 5:

System Change Control

- How to manage a validated system with minimal documentation

---

Lecture 6:

Purchasing COTS Software

- How to purchase COTS software and evaluate software vendors.

Lecture 7:

Cost Reduction Without Increasing Regulatory or Business Risk

- How to save money
- How to increase quality
- How to increase compliance with less documentation

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 260 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.

Services are available to guide companies to create and maintain the systems and procedures required to pass regulatory inspections: product features, vendor audits, software validation, SOPs, training, gap analysis, remediation plans, and project management.

Projects involve: medical devices, blood bank, clinical trial, corrective action, document control, electronic data capture, Excel spreadsheets, laboratory instruments, laboratory information management (LIMS), manufacturing, enterprise resource planning, toxicology systems, and VMWare.

David Nettleton is also the co-author of:

- Managing the Documentation Maze - Answers to Questions You Didn't Even Know to Ask (Wiley - www.wiley.com) 2010
- Electronic Record Keeping; Achieving and Maintaining Compliance with 21 CFR Part 11 and 45 CFR Parts 160, 162, and 164 (Interpharm/CRC - www.crcpress.com, 2004)
- Commercial Off-the-Shelf (COTS) Software Validation for 21 CFR Part 11 Compliance (Davis Horwood International and PDA - www.pda.org, 2003).

Please contact Marilyn Turner: Phone: +1 929 900 1853 Email: marilyn.turner [a] nyeventslist.com for registrations

Event Categories :