REDUCE COSTS FOR COMPLIANCE WITH DATA INTEGRITY: 21 CFR PART 11, SAAS/CLOUD, EU GDPR

2-Day Virtual Seminar
12 RAC CREDITS

Training Overview

- It details the requirements for Part 11 and Annex 11: SOPs, software product features, infrastructure qualification, and validation.
- 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.
- 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.
- The instructor reviews recent FDA inspection trends and discusses how to streamline document authoring, revision, review, and approval.

Faculty David Nettleton

Computer System Validation's principal, David Nettleton is an industry leader, author, and teacher for 21 CFR Part 11, Annex 11, HIPAA, EU General Data Protection Regulation (GDPR), 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

Learning Objective

- Reduce costs, usually by two-thirds, for compliance with electronic records
- Learn how to use electronic records and electronic signatures to maximize productivity
- Understand what is expected in Part 11 and Annex 11 inspections so you are prepared
- Avoid 483 and Warning Letters
- Understand the responsibilities and specific duties of your staff including IT and QA
- Understand your responsibilities and liabilities when using SaaS/cloud
- Learn how to perform risk-based Computer System Validation using fill-in-the-blank templates
- How to select resources and manage validation projects
- "Right size" change control methods that allows quick and safe system evolution
- Minimize validation documentation to reduce costs without increasing regulatory or business risk

Who Will Benefit

- GMP, GCP, GLP, regulatory professionals
- QA/QC
- IT
- Auditors
- Managers and directors
- Software vendors, SaaS hosting providers

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Agenda Day 01

- Introduction to the FDA (01 :30 hr)
- How the regulations help your company to be successful
- Which data and systems are subject to Part 11.
- 21 CFR Part 11/Annex 11 - Compliance for Electronic Records and Signatures (3:30 hr)
- What Part 11 means to you, not just what it says in the regulations
- Avoid 483 and Warning Letters
- Explore the four primary areas of Part 11 compliance: SOPs, software product features, infrastructure qualification, 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.
- The Five Keys to COTS Computer System Validation (30 Min).....

continued on day 2

Agenda Day 02

- Software demonstrations and discussions (30 Min)
- Ten-Step Process for COTS Risk-Based Computer System Validation (30 Min)
- 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 (30 min)
- Reduce testing by writing test cases that trace to elements of risk management.
- How to write efficient test cases
- How to write a Data Privacy Statement (30 Min).....

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