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2-day In-person Seminar

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

Instructor: David Nettleton

30th & 31th October, 2018

9:00 AM to 6:00 PM

Mumbai India

The Leela Mumbai

Seminar Price Details

Seminar Fee for One Delegate

Price : **Rs.14,000.00**

Register for 5 attendees

Price : **Rs.42,000.00**

Save: Rs.28,000.00 (40%)

Register for 10 attendees

Price : **Rs.77,000.00**

Save: Rs.63,000.00 (45%)

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Instructor:

David Nettleton

Director & FDA Compliance Specialist, Computer System Validation and FDA Compliance consultant

David Nettleton, is an FDA Compliance Specialist for 21 CFR Part 11, HIPAA, and Computer System Validation. His latest book is "Risk Based Software Validation - Ten easy Steps" that relates to the development, purchase, installation, operation and maintenance of computerized systems used in regulated applications. He specializes in performing gap analysis, remediation plans, SOP development, vendor audits, training, and project management. He has completed more than 185 mission critical software validation projects.

Overview:

- 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.

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Agenda:

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

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Group Registrations

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Benefit Get y our team up to speed!

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Kindly get in touch with us for any help or information.
Look forward to meeting you at the seminar
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