Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

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

Boston, MA

September 11th & 12th, 2018

8:00 AM to 5:00 PM

Price

Price: **$1,495.00**

(Seminar for One Delegate)

Register for 5 attendees

Price: **$4,485.00** You Save: $2,990.0 (40%)*

~~$7,475.00~~

Register for 10 attendees

Price: **$8,222.00** You Save: $6,728.0 (45%)*

~~$14,950.00~~

ENROLL

***Please note the registration will be closed 2 days (48 Hours) prior to the date of the seminar.*

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.

Overview :

- This highly interactive two-day course uses real life examples and explores proven techniques for reducing costs, usually by two-thirds, associated with implementing, and maintaining computer systems in regulated environments.
- 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.
- It details the requirements for HIPAA Protect Health Information (PHI)
- 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.

Agenda:

Day One

(8am to 5pm; 0.5 registration, 1.0 lunch, 0.5 (2-15min) breaks, 7.0 class = 9.0 total)

8:00am to 8:30am registration

8:30am class starts

Lecture 1: Introduction to the FDA (1:30) {1:30}

- 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 (4:00) {5:30}

- 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, 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: HIPAA Compliance for Electronic Records (0:30) {6:00}

- How Part 11 and HIPAA interrelate
- What are the additional requirements for patient data

Lecture 4: The Five Keys to COTS Computer System Validation (0:30) {6:30}

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

Lecture 5: The Validation Team (0:30) {7:00}

- How to select team members
- How to facilitate a validation project

Day Two

(9am to 3:30pm; 1.0 lunch, 0.5 (2-15min) breaks, 5.00 class = 6.5)

Lecture 6: Ten-Step Process for COTS Risk-Based Computer System Validation (1:00) {1:00}

- 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 7: How to Write Requirements and Specifications (0:30) {1:30}

- Workshop for writing requirements and then expanding them for specifications

Lecture 8: How to Conduct a Hazard Analysis/Risk Assessment-Exercise (0:30) {2:00}

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

Lecture 9: Software Testing (1:00) {3:00}

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

Lecture10: How to write a Data Privacy Statement (0:30) {3:30}

- How to meet the requirements of the EU GDPR

Lecture11: Purchasing COTS Software (0:30) {4:00}

- How to purchase COTS software and evaluate software vendors.

Lecture 12: Cost Reduction Without Increasing Regulatory or Business Risk (1:00) {5:00}

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

Group Participation

10%	2 Attendees to get offer
20%	3 to 6 Attendees to get offer
25%	7 to 10 Attendees to get offer
30%	10+ Attendees to get offer

Payment Option

1. Credit Card: Use the Link to make Payment by Visa/Master/American Express card click on the register now link
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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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