ComplianceOnline
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2-Day Virtual Seminar

Reduce costs for compliance with data integrity: 21 CFR Part 11, SaaS/Cloud, EU GDPR

By: **David Nettleton**, FDA Compliance Specialist, Computer System Validation

Dates: September 23-24, 2020 (9:00 AM - 3:00 PM PDT)

Location: Virtual Training Through WebEx

Various parts of the country are still battling the Coronavirus (COVID-19), we will conduct the class 100% online.

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.

LEARNING OBJECTIVE

- 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

COURSE DESCRIPTION

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.
- Participants will learn how to write a Data Privacy Statement to comply with the EU General Data Protection Regulation (GDPR).
- This course benefits anyone that uses computer systems to perform their job functions and is ideal for 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.

AGENDA

Day One (9:00 AM – 3:00 PM PDT)

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 (3:30 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.

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 Two (9:00 AM – 3:00 PM PDT)

Ten-Step Process for COTS Risk-Based Computer System Validation (1:30 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-blanktemplates.
- 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

How to write a Data Privacy Statement (30 Min)

- How to meet the requirements of the EU GDPR

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

WHO WILL BENEFIT

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





TESTIMONIALS

"Really good location with good lunch. This seminar was full of valuable topics."

System Admin, IT

"This is my first experience with ComplianceOnline and I would definitely attend other seminars."

- Director Technical Services

"Thanks for finding me and giving me the opportunity to take this session. I like all the topics, especially 21 CFR Part II Compliance. David Nettleton is a phenomenal instructor. The amount of interaction between the participants and presenters is ideal which help us to explore more. I would strongly recommend this seminar."

- Technical Writer

"I really enjoyed the class. I thought the information that David Nettleton gave us was real world examples of the way Computer System Validation should be done. I have suggested to a few of my colleagues to review the information that we were given at the Computer System Validation Reduce Costs and Avoid 483."

- Lisa Wyeth

"This was one of, if not the best, most informative, enjoyable trainings I've attended in my 11 year GMP career and I have been to many. David was simply an outstanding presenter. In this class, there was much participation and people learn from other's questions. Overall I had a very positive experience and brought back value to my company."

- Lead Auditor

"The training was excellent and I encountered no difficulties either with the registration process or during the event. This was one of the best trainings that I have attended over the years."

- Sr. QA Engineer

"I enjoyed the seminar very much. I am hoping to be able to implement some of the things I learned in my own work efforts. I thought David was an excellent facilitator and he kept the pace moving along properly to cover all of the material in time. If I had one criticism, it would be not understanding how I am going to change the culture of mine and other companies that spend so many dollars on validation projects that drag on and on. In David's world, he can complete a project in a week of planning and implementation; in my world, people spend the first week just letting the concept of a project sink in, and then maybe get started within a month or so. I'd like to be able to expedite projects in the way he has laid out; we'll see how it goes."

- Sr. Validation Engineer

"Electronic Signature topic was very valuable for me because we are implementing a document management system. The presenter is very knowledgeable; the amount of interaction between the participants and presenters was good."

- Information Technology Specialist

"I really enjoyed the class. I thought the information that David Nettleton gave us was real world examples of the way Computer System Validation should be done. I have suggested to a few of my colleagues to review the information that we were given at the Computer System Validation Reduce Costs and Avoid 483.
The registration was an easy process. I forwarded the information to our Human Resources and they were able to handle it from the beginning."

- GCP Manager

"I really appreciate the presentation given on topic "The 10 step approach". Overall program was well organized and coordinated. Experience with speaker was good, it was an engaging presentation. Informal conversation with other participant was beneficial."

- Assistant Manager of Technical Development

"This was a very well seminar. The location, the food, the training material were all very much appreciated. David was a very charismatic, knows his stuff and presents the info in a way that making it entertaining."

- Software Quality Manager

"Great dynamics between instructor and participants. The program was well organized and coordinated. Large amount of data was delivered in short time period."

- Engineering Electrical Controls Manager

"Seminar was very good, informative and a lovely speaker making a tedious topic interesting. Overall the subjects are well chosen and the program was well organized and coordinated."

- Director - Global IT Governance

"This was one of, if not the best, most informative, enjoyable trainings I've attended in my 11 year GMP career and I have been to many. David was simply an outstanding presenter. I think the thing that sets him apart from others, in addition to his obvious expertise and knowledge in computer validation, is that he is what today I feel is rare: a good teacher.
David as a teacher is very engaging. The normal nervousness of attendees has little chance of survival in David's class. He breaks through the ice, gets people comfortable and maintains a high level of professionalism. This creates an open atmosphere where people are free to think and ask questions. I generally am not afraid to ask questions and many times I feel alone in that. But in this class, there was much participation and people learn from other's questions. I attribute this to David's personality and approach to getting attendees involved.
In terms of improvements, the only thing I would change would be to have the lunch in a room where people could network (i.e. round tables) vs. coming back into the training room where you sat next to one person. The venue itself was great and the food was fantastic. The Ritz Carlton is a great location. Their service was also excellent.
Overall I had a very positive experience and brought back value to my company. I just wish I had more of a chance to network with the other attendees, although I did connect with a few."

- Lead Auditor/Sr. Laboratory Compliance Specialist



Registration Form

Registration Information:

- **Register Online**. Use your American Express, Visa or MasterCard.
- Get your group to attend the seminar at a discounted price call +1-888-717-2436.
- Call Toll Free: +1-888-717-2436 (USA) or Fax your PO: 650-362-2367
- Pay your check to (payee name) "MetricStream Inc" our parent company and Mail the check to: ComplianceOnline (MetricStream, Inc), 2479 East Bayshore Road, Suite 260, Palo Alto, CA 94303.
- Please fill this form with attendee details and payment details and fax it to +1-650-362-2367

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Note: In view of Coronavirus situation and travel advisory issued, ComplianceOnline will waive off all cancellation charges for the registrations till August 15, 2020

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Written cancellations through fax or email (from the person who has registered for this conference) received at least 10 calendar days prior to the start date of the event will receive a refund — less a $300 administration fee. No cancellations will be accepted — nor refunds issued — within 10 calendar days from the start date of the event. On request by email or fax (before the seminar) a credit for the amount paid minus administration fees ($300) will be transferred to any future ComplianceOnline event and a credit note will be issued. Substitutions may be made at any time. No-shows will be charged the full amount. We discourage onsite registrations, however if you wish to register onsite payment to happen through credit card immediately or check to be submitted onsite. Conference material will be given on the spot if it is available after distributing to other attendees. In case it is not available we will send the material after the conference is over. In the event ComplianceOnline cancels the seminar, ComplianceOnline is not responsible for any airfare, hotel, other costs or losses incurred by registrants. Some topics and speakers may be subject to change without notice.

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Seminar Topic: Reduce costs for compliance with data integrity: 21 CFR Part 11, SaaS/Cloud, EU GDPR

Date & Location: September 23-24, 2020 (9:00 AM - 3:00 PM PDT)

Attendee Details:

	Name	Title	Email
Attendee 1			
Attendee 2			
Attendee 3			
Attendee 4			

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