

2-day In-person Seminar:

# 21 CFR Part 11 Compliance for SaaS/Cloud Applications

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

**Location 1:** Philadelphia, PA | October 18-19, 2018

**Location 2:** San Francisco, CA | November 6-7, 2018



## 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.

## 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

# COURSE DESCRIPTION

This Computer System Validation Training course will explore proven techniques for reducing costs associated with implementing, using, and maintaining computer systems in regulated environments. 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.

Many companies outsource IT resources and are involved in 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 to avoid FDA form 483s and Warning Letters.

This Computer System Validation Training course is intended for these regulated companies, software vendors, and SaaS/cloud providers. The seminar instructor will:

- ✓ Address the latest computer system industry standards for data security, data transfer, audit trails, electronic records and signatures, software validation, and computer system validation.
- ✓ Help participants understand the specific requirements associated with local and SaaS/cloud hosting solutions.
- ✓ Illustrate the importance of validating the quality process and every computerized system used in laboratory, clinical, and manufacturing settings.
- ✓ Demonstrate how to decrease software implementation times and lower costs using a 10-step risk-based approach to computer system validation.
- ✓ Review recent FDA inspection trends and discuss how to streamline document authoring, revision, review, and approval.

# AGENDA

## Day One (8:30 AM – 5:00 PM)

**08.00 AM - 08.30 AM: Registration**

**08.30 AM: Session Start**

1. Introduction to the FDA (1 hr)
  - ✓ How the regulations help your company to be successful
  - ✓ Which data and systems are subject to Part 11.
2. 21 CFR Part 11 - Compliance for Electronic Records and Signatures (4 hr)
  - ✓ 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
3. HIPAA Compliance for Electronic Records (30 Min)
  - ✓ How Part 11 and HIPAA interrelate
  - ✓ What are the additional requirements for patient data
4. The Five Keys to COTS Computer System Validation (30 Min)
  - ✓ The Who, What, Where, When, and Why of CSV
5. The Validation Team (30 Min)
  - ✓ How to select team members
  - ✓ How to facilitate a validation project

## Day Two (8:30 AM – 3:30 PM)

6. Ten-Step Process for COTS Risk-Based Computer System Validation (1 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-blank templates.
  - ✓ Based on: "Risk-Based Software Validation - Ten Easy Steps" (Davis Horwood International and PDA - www.pda.org, 2006).
7. How to Write Requirements and Specifications (30 Min)
  - ✓ Workshop for writing requirements and then expanding them for specifications
8. 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.
9. Software Testing (1 hr)
  - ✓ Reduce testing by writing test cases that trace to elements of risk management.
  - ✓ How to write efficient test cases
10. System Change Control (30 Min)
  - ✓ How to manage a validated system with minimal documentation
11. Purchasing COTS Software (30 Min)
  - ✓ How to purchase COTS software and evaluate software vendors
12. 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

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.

- ▶ Regulatory Affairs
- ▶ QA/ QC
- ▶ IT/IS
- ▶ Software Managers
- ▶ Project Managers
- ▶ Software vendors and suppliers





# TESTIMONIALS



“All topics were informative and interesting. Database validation was the most valuable topic for me as I was hired for this job function. David is excellent and personable speaker; his knowledge and experience provide credibility and exceptional insight. Overall it was a wonderful event. Excellent choice of venue, materials and food was arranged by ComplianceOnline!!!”

- Software and Training Support Specialist

“Thanks ComplianceOnline. Your website is very accessible and communicates well. It covers many compliance topics. For this seminar venue was convenient for west coast. Sometimes I cannot travel so attend those trainings online.”

- Director, Validation

“It was a great seminar. I like the topic Hazard/Risk Assessment. I do all other validation activities as David presented but didn't evaluate my specs for Risk but I can really see how this will benefit the whole validation process and am definitely adding it.”

- Business System Analyst, Documentation

“I am more confident about ability to carry out Computer System Validation. David provides Comprehensive information in a way that makes sense. He's patient, passionate about what he does, and provides great examples! Thank You, David!”

- 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

“The course was well prepared. I like the "10 steps of validation" topic. I will apply this to all of my programs. It was great to make new connections, informal conversations with other participants during the networking hours was very beneficial. Speaker was very interactive. I will recommend this course and ComplianceOnline.com to others.”

- IT Director

“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

