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

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

Location 1: Scottsdale, AZ | May 1-2, 2019  
Location 2: Philadelphia, PA | June 13-14, 2019

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).

AGENDA

DAY ONE: 8.00AM – 5.00PM

Registration Process: 8:00 AM – 8:30 AM
Session Start Time: 8:30 AM

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 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 documentation.
   - Ensure data integrity, security, and protect intellectual property.
   - Understand the current computer system industry standards for data 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)

5. The Validation Team (30 min)
   - How to select team members
   - How to facilitate a validation project

DAY TWO: 8.30AM – 3.30PM

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. How to write a Data Privacy Statement (30 Min)
    - How to meet the requirements of the EU GDPR

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

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

- Lead Auditor

"This 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 participants 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 makes 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

"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 participants was beneficial.

- Director - Global IT Governance

"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.

- Sr. Validation Engineer

"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.

- Sr. Validation Engineer

"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.

- Lead Auditor/Sr. Laboratory Compliance Specialist
Registration Form

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

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