Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

How to be Efficient and Compliant with Part 11, Validation, and SaaS/Cloud

Boston, MA

February 4th & 5th, 2019

8:00 AM to 5:00 PM

Price

Price: **$1,295.00**

(Seminar for One Delegate)

Register for 5 attendees

Price: **$3,885.00** You Save: $2,590.0 (40%)*

~~$6,475.00~~

Register for 10 attendees

Price: **$7,122.00** You Save: $5,828.0 (45%)*

~~$12,950.00~~

ENROLL

Register now and save $200. (Early Bird)

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

Carolyn Troiano

Consultant, BrainStorm Central Consulting

Carolyn (McKillop) Troiano has more than 35 years of experience in the tobacco, pharmaceutical, medical device and other FDA-regulated industries. She has worked directly, or on a consulting basis, for many of the larger pharmaceutical and tobacco companies in the US and Europe, developing and executing compliance strategies and programs. Carolyn is currently active in the Association of Information Technology Professionals (AITP), and Project Management Institute (PMI) chapters in the Richmond, VA area.

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.
- 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.
- 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.
- This seminar will help you understand the specific requirements associated with local and SaaS/cloud hosting solutions.

Agenda:

Day One

Day 1 (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: The Five Keys to COTS Computer System Validation (0:30) {6:30}

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

Lecture 4: The Validation Team (0:30) {7:00}

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

Day Two

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

Lecture 5: 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 6: How to Write Requirements and Specifications (0:30) {1:30}

- Workshop for writing requirements and then expanding them for specifications

Lecture 7: 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 8: 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

Lecture 9: System Change Control (0:30) {3:30}

- How to manage a validated system with minimal documentation

Lecture10: Purchasing COTS Software (0:30) {4:00}

- How to purchase COTS software and evaluate software vendors.

Lecture 11: 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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