

2-day In-person Seminar:

Data Integrity, 21 CFR 11 & Annex 11 Implementation



SFO, CA



December 7th & 8th, 2017



9:00 AM to 6:00 PM



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Seasoned Executive with 40 years of experience in the Life Sciences & Healthcare Industries. Positions include Chief Compliance Officer <http://morfllearning.com/angelabazigos/>. Experience combines Quality Assurance, Regulatory Compliance, Business Administration, Information Technology, Project Management, Clinical Lab Science, Turnarounds and Business Development. Past employers / clients include Roche, Novartis, Genentech & PriceWaterhouseCoopers.

Overview :

The Problem:

We have all heard of Data Integrity but do you really understand what it is? Do you understand how 21 CFR 11 and Annex 11 fit into this picture? Specifically, can you answer questions on the following:

- Evolution of 21 CFR Part 11 and Annex 11 and Why they are Back in the News
- Overview and Key Requirements of Part 11 & Annex 11
- How to use a Risk Based Assessment to reduce work while still achieving Data Integrity and Compliance?
- How FDA & other Regulatory Authorities Inspect Computerized Systems for Data Integrity?

I often refer to 21 CFR 11 and Annex 11 as Good Software Engineering with the Documentation on Steroids! However, unless one knows how to implement Data Integrity

Price

Price: **\$1,495.00**

(Seminar for One Delegate)

Register for 5 attendees

Price: **\$4,485.00** You Save: \$2,990.00 (40%)*
~~\$7,475.00~~

Register for 10 attendees

Price: **\$8,222.00** You Save: \$6,728.00 (45%)*
~~\$14,950.00~~

ENROLL

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



Agenda:

Day One

Lecture 1: Introduction / Background

- Introductions / Participants' Understanding
- Participants' Objectives for the Course (Please come prepared to discuss)

Lecture 2: Data Integrity

- What is Data Integrity
- How is it implemented
- Data Integrity Frequently Asked Questions

Lecture 3: 21 CFR 11 & Annex 11

- 21 CFR 11
- Annex 11
- 21 CFR 11.10(a) - Computer Systems Validation

Lecture 4: Risk Assessment & Requirements

- Risk Assessment for Requirements
- Gathering Requirements
- Entity Relationship Diagram
- Process Decomposition
- Exercise on how to create Requirements



Day Two

Lecture 1: Design

- Design Specifications
- Software Configuration and Build
- Exercise on how to create Design Specifications

Lecture 2: Verification & Testing

- Traceability Matrix
- Verification and Testing
- Other Documents

Lecture 3: Special Topics

- Test Tools for DATA INTEGRITY
- Infrastructure Requirements

Lecture 4: Change Control & SOPs

- Change Control
- SOPs

The Seminar:

This Hands-On course will provide the attendees with more detailed experience on validation / 21 CFR 11 compliance of a computer system, as well as details for activities associated with computer systems validation as follows:

- 1.What is Data Integrity and how is it implemented
- 2.How to use Risk Based Assessments to reduce work while still achieving Data Integrity and Compliance?
- 3.Data Integrity Frequently Asked Questions
- 4.Validation Master Plan
- 5.Risk Based Assessment
- 6.Complete Validation for a System (software development lifecycle)
- 7.Automated Test Tools
- 8.Infrastructure Requirements
- 9.Change Control
- 10.SOPs

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
- 2 Check: Kindly make the check payable to NetZealous DBA GlobalCompliancePanel and mailed to 161 Mission Falls Lane, Suite 216, Fremont, CA 94539, USA
- 3 PO: Please drop an email to support@globalcompliancepanel.com or call the our toll free +1-800-447-9407 for the invoice and you may fax the PO to 302 288 6884
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What You will get

- 1 Learning Objectives
- 2 Participation certificates
- 3 Interactive sessions with the US expert
- 4 Post event email assistance to your queries.
- 5 Special price on future purchase of web based trainings.
- 6 Special price on future consulting or expertise services.
- 7 Special price on future seminars by GlobalCompliancePanel.
- 8 Seminar Kit – includes presentation handout, ID card, brochure, trainings catalog, notepad and pen.
- 9 Networking with industry's top notch professionals

Contact Information: Event Coordinator

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Kindly get in touch with us for any help or information.

Look forward to meeting you at the seminar

GlobalCompliancePanel