




2-day In-person Seminar:

Data Integrity Workshop: FDA Requirements and Implementation

-  Zurich, Switzerland
-  April 19th & 20th, 2017
-  9:00 AM to 6:00 PM



Angela Bazigos

CEO, Touchstone Technologies Silicon Valley

Angela Bazigos, is the CEO of Touchstone Technologies Silicon Valley, Inc. "Your Passport to Compliance". She has 30 years of experience in the Lifesciences industry spanning Project Management, Quality Assurance and Regulatory Affairs and has a patent aimed at speeding up Software Compliance.

Ms Bazigos is a member of the SQA CVIC (Society of Quality Assurance Computer Validation Initiative Committee), ASQ, DIA and RAPS and consults to investment groups on Lifesciences investments as well as Pharma / Biotech / Medical Device companies on compliance matters, including strategy, submissions, quality assurance and remediations following action by the FDA.

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?

Price

Price: **\$1,895.00**

(Seminar for One Delegate)

Register for 5 attendees

Price: **\$5,685.00** You Save: \$3,790.0 (40%)*
~~\$9,475.00~~

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

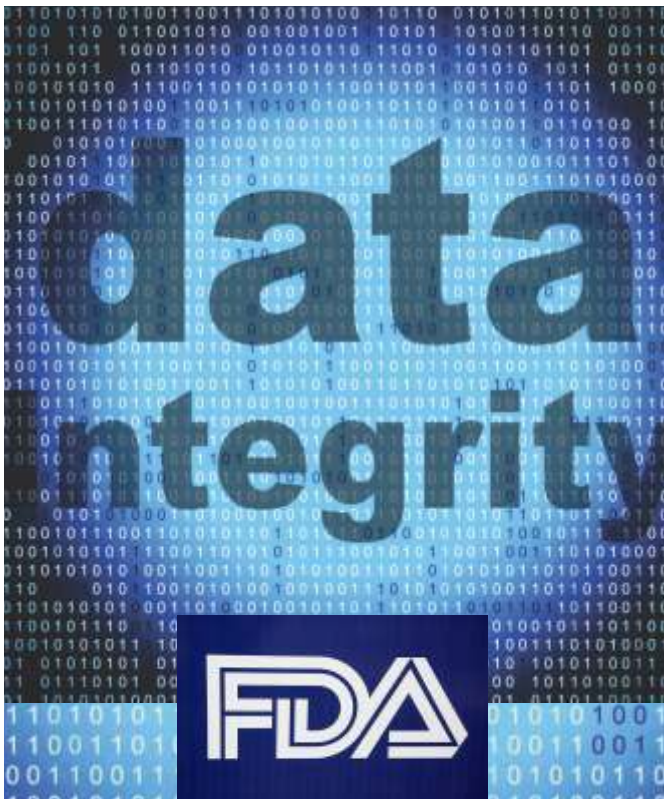
- Traceability Matrix
- Verification and Testing
- Other Documents

Lecture 3: Special Topics

- Test Tools for DATA INTEGRITY
- Infrastructure Requirements

Lecture 4: Change Control & SOPs

- Change Control
- SOPs



Who Should Attend:

- VP of IT
- Director of IT
- Quality Managers
- Project Managers (for DATA INTEGRITY / IT)
- Validation Specialists
- Database Administrators
- System Administrators
- Directors / Senior Directors of Discovery
- Directors / Senior Directors of Development
- Directors / Senior Directors of Commercialization
- Document Managers
- Training Managers
- Consultants
- Data Managers
- Safety Managers

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

NetZealous LLC, DBA GlobalCompliancePanel
161 Mission Falls Lane, Suite 216,
Fremont, CA 94539, USA
Toll free: +1-800-447-9407
Fax: 302 288 6884
Email: support@globalcompliancepanel.com

www.globalcompliancepanel.com

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

Look forward to meeting you at the seminar

GlobalCompliancePanel