




2-day In-person Seminar:

A Risk Based Approach To Data Integrity

-  Los Angeles, CA
-  February 22nd & 23rd, 2018
-  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://morflarning.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. Co-authored & prototyped 21 CFR 11 guidance with FDA. Co-authored Computerized Systems in Clinical Research w/ FDA <http://www1.diahome.org/~media/4FA562336EBD46C58CDC43A8B7773095.ashx> Patent on speeding up software compliance <https://www.google.com/patents/US8266578>. Recently quoted in Wall Street Journal for using training to bring regulatory compliance

Overview :

The impact of Data Integrity issues on a regulated company can be significant: it can result in recalls of products, warning or untitled letters, import alerts, injunctions, seizures, legal action, etc. These regulatory actions can have significant financial impact to the company. However, and most importantly, data integrity issues can lead to potential patient harm!!

Price

Price: **\$1,495.00**

(Seminar for One Delegate)

Register for 5 attendees

Price: **\$4,485.00** You Save: \$2,990.0 (40%)*
~~\$7,475.00~~

Register for 10 attendees

Price: **\$8,222.00** You Save: \$6,728.0 (45%)*
~~\$14,950.00~~

ENROLL

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



Data Integrity

Agenda:

Day One

Lecture 1: Introduction and Background

- Introductions / Participants' Understanding / Participants' Objectives for the Course (Please come prepared to discuss)
- Regulatory Focus
- Data Integrity Requirements

Lecture 2: Data Governance Framework

- Elements of the Data Governance Framework
- Human Factors in Data Integrity
- Data Integrity Maturity Model

Lecture 3: Quality Risk Management

- Process Risk Management
- Quality Risk Management
- Product and Process Context

Lecture 4: Data Life Cycle

- Data Creation
- Data Processing
- Data Review, Reporting and Use
- Data Retention & Retrieval
- Data Destruction
- Integrating Data Integrity into Existing Records Management Process

Why you should attend:

- VP of IT
- Director of IT
- Quality Managers
- Project Managers (for CSV / 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

Day Two

Lecture 5: Data Integrity Management

- Corporate Data Integrity Program
- Data Integrity Maturity Model
- Human Factors
- Inspection Readiness

Lecture 6: Auditing & Audit Trails

- Data Audit Trail
- Audit Trail Review
- Data Auditing
- Periodic Review

Lecture 7: Data Integrity for Electronic Records / Electronic Signatures (ERES)

- User Requirements
- Process Mapping & Interfaces
- Controls for Electronic Records / Electronic Signatures
- Data Integrity for Spreadsheets & End-User Applications
- Data Integrity for IT Infrastructure

Lecture 8: Data Conversions

- Retention, Archiving & Migration
- Paper Records & Hybrid Situations
- Converting Electronic to Alternative Format or Alternative Format Hybrids

Quiz: Jeopardy!!!!

- Data Integrity



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
- 4 Wire Transfer: Please drop an email to support@globalcompliancepanel.com or call our toll free +1-800-447-9407 for the wire transfer information

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