SAN FRANCISCO
EVENTS LIST

# A Risk Based Approach To Data Integrity

**Date :** Feb 22, 2018 - 09:00 AM - Feb 23, 06:00 PM

**Event URL :** http://www.sfbayeventslist.com/events/a-risk-based-approach-to-data-integrity-feb-2018

**Organizer :** GlobalCompliancePanel

**Venue :** Four Points by Sheraton Los Angeles International Airport

**Location :** 9750, Airport Blvd
Los Angeles, CA, USA, ZIP: 90045

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!!

Defined by the Medicines and Healthcare Products Regulatory Agency (MHRA) as "the extent which all data are complete, consistent and accurate throughout the data lifecycle", data integrity is increasingly the focus of regulatory agencies round the world. Companies must now ensure that they are appropriately addressing data integrity and data governance. This includes organizational, procedural and technical controls that must be considered as part of an overarching data governance system. In addition, the effort and resources committed to data integrity must be commensurate with the role it plays in assuring product quality.

To ensure Data Integrity, a GxP regulated company needs to abide by principles, current regulations and industry best practices on the expectations for the management GxP regulated records and data. These principles, regulations and best practices, ensure that data is complete, consistent, accurate, secure and available throughout the record life cycle. This approach is intended to encourage innovation and technological advances while avoiding unacceptable risk to product quality, patient safety and public health.

Key implementation considerations for a corporate data integrity program, include development of a high-level strategy, identifying and gaining executive sponsorship, focusing on management accountability, implementing tools for knowledge sharing and developing and providing the appropriate levels of training. An effective data integrity program includes addressing of behavioral factors and drives a strategy that focuses on prevention, detection, response and

continuous improvement.

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**The Seminar:**

This Seminar addresses the integrity of GxP records and data used within the regulated industries including pharmaceutical, biological, medical devices, cosmetics, food and any other industry where data integrity is important. It provides a method for managing risk to record and data integrity. Learning Objectives for the seminar include:

- Data Integrity Requirements
- Critical Areas of Regulatory Focus and Concern
- Key Concepts
- A Framework for Data Governance and Human Factors
- A Complete Data Life Cycle Approach as Part of a Quality Management System, from Creation to Destruction
- How to Apply Risk Management to Data Integrity

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**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
- Regulators
- Vendors
- Suppliers
- Outsource Service Providers

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**Industries:**

- Pharmaceuticals
- Biotech
- Medical Device
- Radiological Health

- Blood Products
- Companion Animals
- Food
- Cosmetics
- Tobacco
- Academia

**Day 1 Schedule**

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Lecture 1:

**Introduction and Background**

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

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Lecture 2:

**Data Governance Framework**

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

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Lecture 3:

**Quality Risk Management**

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

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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

**Day 2 Schedule**

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Lecture 5:

**Data Integrity Management**

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

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Lecture 6:

**Auditing & Audit Trails**

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

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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

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Lecture 8:

**Data Conversions**

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

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**Quiz: Jeopardy!!!!**

- Data Integrity

**Angela Bazigos**

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Seasoned Executive with 40 years of experience in the Life Sciences & Healthcare Industries. Positions include Chief Compliance Officer http://morflearning.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 to the Boardroom http://blogs.wsj.com/riskandcompliance/2015/07/24/using-training-to-bring-compliance-to-boardrooms/ National Trainer for Society of Quality Assurance. Comments / collaborates with FDA on new guidance documents. Former President of Pacific Regional Chapter of Society of Quality Assurance. Stanford's Who's Who for LifeSciences: http://www.stanfordwhoswho.com/Angela.Bazigos.7144112.html#overview.

Please contact Marilyn Turner: Phone: +1 929 900 1853  Email: marilyn.turner [a] nyeventslist.com for registrations

**Event Categories :**