ComplianceOnline
The Largest GRC Advisory Network

2-Day Virtual Seminar

Data Integrity: FDA/EU Requirements and Implementation

By: **Mark Powell,** Director, Mark Powell Scientific Limited

Dates: July 9-10, 2020 (9:00 AM - 5:00 PM EDT)
Location: Virtual Training Through WebEx

Various parts of the country are still battling the Coronavirus (COVID-19), we will conduct the class 100% online.

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SPEAKER

Mark Powell, Director, Mark Powell Scientific Limited

Dr Mark Powell is a Fellow of the Royal Society of Chemistry (RSC) with over thirty years' experience as an analytical chemist. Mark was Honorary Treasurer of the RSC's Analytical Division and led a working group on continuing professional development until July 2016, when his term of office ended. Between 2003 and 2013, he was the Analytical Development Manager, and later Scientific Manager, of a UK-based contract research organization which specialized in early-stage oral drug development. During this time, he was responsible for method validation, verification and transfer activities, as well as the qualification of laboratory instruments and computerized data systems. In 2013, he set up Mark Powell Scientific Limited, which provides training and consultancy services to pharmaceutical companies. Mark has since enjoyed working with companies of all sizes around the world on a variety of training and consultancy assignments, and has recently co-authored a White Paper on Pharmaceutical Data Integrity for the laboratory supply company VWR.

COURSE DESCRIPTION

Data integrity has been a focus for pharmaceutical regulatory inspections for a number of years and look set to remain of concern to regulators and manufacturers for many years to come. Many inspection reports from regulatory agencies around the world cite data integrity as a cause of observations and enforcement action, and actions taken by regulators to restrict the commercial activities of manufacturers on the grounds of data integrity violations have obvious serious consequences for the company concerned.

This 2-day course explains the background to the data integrity regulations and sets out the expectations of pharmaceutical regulators. All the current data integrity guidances emphasise a risk-based approach to compliance, and the course explains how to evaluate and control data integrity risks. A key resource in relation to electronic records is GAMP 5, which deals with controlling risk and managing computerised systems over their life cycle. The practices recommended by GAMP 5 will be dealt with in detail, and practical advice on the appropriate use of Excel spreadsheets given. Data integrity should not be thought of as an exclusively analytical problem, and examples of data integrity violations in production will highlight the risks during manufacturing.

LEARNING OBJECTIVES

Attendees will:

- Understand what data integrity is and why it is so important for patient safety
- Recognise that there are many causes of data integrity breaches
- Know the current regulatory expectations
- Appreciate the difference between static and dynamic records, and be able to apply acceptable strategies for the retention of both types of record
- Be able to categorise and validate GxP computerised systems according to GAMP 5
- Understand the importance of training and quality culture in avoiding regulatory enforcement action
- Learn how to respond to data integrity observations in inspection reports
- Learn how to prevent, detect and remedy data integrity problems

AGENDA

Day 1 (9:00 AM – 5:00 PM EDT)

9:00 AM Session Start

Day 1 – Lectures and Workshop Exercises

Module 1: Historical background and data integrity definitions

- Data integrity and patient safety/product efficacy
- The evolution of GxP regulations – driven by both criminal activity and honest mistakes
- The US FDA's debarment policy
- Evolution of data integrity guidances
- Introduction to GAMP 5
- Early data integrity cases

Module 2: Regulatory expectations

- ALCOA and ALCOA+
- Static and dynamic records
- Essential elements of data governance
- Non-conformance trends
- Data integrity controls
- Data integrity risks in sample analysis and production
- Investigating data integrity problems
- Metadata, audit trails and audit trail review
- Exercise: deliberate falsification

Module 3: Data integrity risk assessment

- Quality risk management: ICH Q9
- Risk management process
- Approaching a data integrity risk assessment
- Controlling risk in computerised systems
- Configuration and life cycle management
- Operating system and application software considerations

Module 4: Computerised systemst

- Audit trails, access controls and user permissions
- Exercise: reviewing records for data integrity violations
- Excel spreadsheets
- Introduction to computerised data system validation

Module 5: Day 1 conclusions

- Extracts from regulatory enforcement letters
- Addressing data integrity problems

Day 2 (9:00 AM – 5:00 PM EDT)

Day 2 - Lectures and Workshop Exercises

Module 6: Managing computerised data systems

- Guidance
  - 21 CFR Part 11
  - EU Annex 11
  - GAMP 5
- Life cycle management and risk assessment
- Supplier assessment

Module 7: Computerised system validation

- Validation planning
  - Policy
  - Plans
  - Documentation
- System description
- Introduction to software testing

Module 8: Conducting a data integrity audit

- Planning the audit
- Conducting the audit
  - Policies, procedures, practices
  - Training
  - Quality culture
- Evaluating quality risk
- Mitigating data integrity risks

Module 9: Managing client audits and regulatory inspections

- The importance of data integrity risk assessments/action plans
- The audit/inspection process
- Client audits
  - Confidentiality
  - Result checking and reporting
- Regulatory inspections
  - Behaviour during inspection
  - Responding to non-conformance observations

WHO WILL BENEFIT

- QA managers and personnel
- Quality control
- Method development
- Analytical chemists
- Validation specialists
- Laboratory managers and supervisors
- Regulatory affairs
- Training departments
- Documentation departments
- Consultants
- Pharmaceutical development and Quality control
- laboratories
- API manufacturers
- Medical device companies
- Contract laboratories

Registration Form

Registration Information:

- **Register Online**. Click Here Use your American Express, Visa or MasterCard.
- Get your group to attend the seminar at a discounted price call +1-201 871 0474.
- Call 201 871 0474 or Fax your PO: 253 663 7224 Pay your check to "PMA Conference
- Management" and Mail the check to: PMA 405 Highview Rd, Englewood NJ 07631. Please fill this form with attendee details and payment details and fax it to 253 663 7224

REGISTER WITH NO WORRIES

Terms & Conditions

Your Registration for the seminar is subject to following terms and conditions. If you need any clarification before registering for this seminar please call us @ 201 871 0474 or email us @ register@pmaconference.com

Note: In view of Coronavirus situation and travel advisory issued, ComplianceOnline will waive off all cancellation charges for the registrations till May 30, 2020

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Seminar Topic: Data Integrity: FDA/EU Requirements and Implementation

Date & Location: July 9-10, 2020 (9:00 AM - 5:00 PM EDT)

Attendee Details:

	Name	Title	Email
Attendee 1			
Attendee 2			
Attendee 3			
Attendee 4			

Email address (so you can receive order acknowledgements, updated news, product information and special offers)

Company Information

Organization .....

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Address .....

.....

City .....

State ..... Zip.....

Country .....

Phone ..... Fax .....

Payment Options

☐ Check enclosed

☐ Charge to: ☐ Visa ☐ MasterCard ☐ American Express

Credit card no. .....

Expiration date .....

Total amount $ .....

Signature .....
(Signature required on credit card and bill-me orders.)

Print name.....

☐ Bill me/my company $ .....

Purchase order # .....