Workshops on:
- Analysis of FDA Warning Letters
- Key Data Integrity Topics / Criteria

Data Integrity

Requirements for a GMP-compliant Data Life Cycle

3-4 November 2015, Barcelona, Spain

SPEAKERS:

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Regierungspräsidium Darmstadt

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LEARNING OBJECTIVES:

- Data Integrity – EU and FDA requirements
- Principles of Data Integrity
- Role of Management in Data Integrity
- Audit Trails and their review
- IT Support for Data Integrity
- Data Integrity and Cloud Computing
- Supplier Chain Data Integrity
- European Inspector's point of view

ECA ACADEMY

This education course is recognised for the ECA GMP Certification Programme „Certified Computer Validation Manager". Please find details at www.gmp-certification.eu

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Objectives

- Understand the current FDA and EU GMP regulations and guidance impacting data integrity from paper records to hybrid and electronic systems
- Understand the FDA requirements for data integrity and MHRA Data Integrity guidance March 2015
- Learn what is required for a data governance system from senior management through to staff in laboratories, manufacturing and quality assurance
- Understand the data life cycle and how it is linked with the business process and where problems can occur for both paper records, hybrid systems and electronic systems

Background

Data Integrity is a global problem and currently a major concern with FDA and European Regulatory Agencies. Multiple FDA warning letters and EU GMP non-compliance reports have highlighted major data integrity failures and falsification in companies globally. The regulatory concern has been responded by the FDA issuing Compliance Program Guide that covers Pre-Approval Inspections. This document became effective in May 2012. The CPG objective 3 covers the laboratory data integrity audit. Furthermore in August 2014, the FDA issued Level 2 guidance on their web site about the sharing of login credentials for computerized systems and the use of test injections for testing into compliance.
In Europe, the UK's MHRA in December 2013 gave notice to regulated users to begin conducting data integrity audits of their own systems and those of their suppliers from the beginning of 2014. In January and March 2015, MHRA issued two versions of a Guidance for Industry on Data Integrity. This document outlines a data integrity governance system and principles for defining quality and data integrity into processes and systems. In addition, the guidance defines 19 terms and provides expectations and examples for many of them and therein is where the document's value lies.
As the regulators are tightening their inspection approaches it is important that managers, supervisors and users in regulated GMP laboratories understand the issues around data integrity and begin programs to ensure that their processes and systems ensure data integrity.

Target Audience

- Managers and staff from Manufacturing, QC/QA and Analytical Development Laboratories of pharmaceutical companies
- Contract Research Organisation and Contract Manufacturing Organisation manufacturing, laboratory and QA personnel
- Auditors (internal and external) responsible for performing self-inspections or external audits and needing to understand and assess data integrity

Programme

Why is Data Integrity Important? – Setting the Scene

- Summary of falsification observed by FDA and EU inspectors 2005 – to date
- FDAISA act 2012 and October 2014 Guidance for Industry and the impact on inspections
- Inspection of computerised systems is changing: from paper to on-line
- MHRA expectation for data governance; data integrity guidance documents 2015
- FDA Level 2 guidance on data integrity: 2010 and 2014 postings

Data Integrity – EU GMP Requirements

- EU GMP Chapter 4 – documentation
- EU GMP Annex 11 computerised systems
- Data integrity definitions
- Difference between paper and electronic systems

MHRA Data Integrity Guidance Key Points

- Data Governance System within the Pharmaceutical Quality System
- Data Life Cycle
- Spectrum of Systems: Paper to Electronic Systems with data integrity audit

Role of Management in Data Integrity

- Role of Senior, Production and Department Management in ensuring data integrity within an organisation and its suppliers
- Data governance within a Quality System
- Failures to address poor data integrity practices and no training

Workshop: Analysis of an FDA Warning Letter

- Working in teams, attendees will analyse one of several FDA warning letters to identify key areas of regulatory concern
- Group discussion of regulatory concerns identified

Principles of Data Integrity

- The ALCOA+ criteria for data integrity
- Data life cycle in the process workflow – managing controls
- Paper versus hybrid versus electronic systems
- Validation of computerised systems for data integrity controls
- Scope: production information versus laboratory data: why are laboratory data higher risk?

MHRA Data Integrity Definitions - A German Inspector's View

- Data / Raw data / Source data / Original data
- Inspection versus investigation

US 21 CFR 211 and EU GMP Chapter 4: Complete data versus raw data versus primary record

- Why complete data and raw data are important for understanding data integrity
- EU GMP Chapter 4 requirements for raw data
- 21 CFR 211 requirements for laboratory records: complete data
- FDA Level 2 guidance: paper versus e-records
- Complete data / raw data / primary record example

Audit Trails and Their Review

- Understanding Annex 11 requirements for audit trails
- Differences between Part 11 and Annex 11 requirements for audit trail
- Default comments versus free text as reasons for change
- Review of audit trail entries: how to comply with Annex 11
- Reality versus regulation: are audit trails in commercial products ready for Annex 11?

User Account Management and Application Configuration

- Separation of roles and responsibilities between IT and the business
- Documentation of the configuration of an application e.g. audit trail, user types and access privileges
- User account management: the do's and don'ts
- User identities must be unique
- Regular review of each system users and privileges

IT Support for Data Integrity

- IT facilities, environmental controls and physical security
- Qualified IT infrastructure and validated IT systems
- Backup and recovery / Change control
- IT support including database administration
- Impact of IT infrastructure on data integrity

GMP Meets the Cloud

- Regulatory compliance requirements to consider before going to the cloud
- Are ISO 27001 or SSAE 16 adequate to meet GMP regulations?
- Whose responsibility is data integrity when using the cloud?
- Cloud suppliers: are you dealing with a single entity?
- How to select a cloud supplier

Ten Compliance Commandments for Laboratory Systems

- Outline of the 10 key areas for data integrity when using computerised systems in a regulated environment

Facilitated Discussion / Workshop on Key Data Integrity Topics

- Recording results on paper
- Configuration of software applications
- Unique user identities for all users
- Unauthorised access
- Appropriate access privileges for each user role
- Is my chromatographic system ready? Role of "test" injections
- Audit trails – options for older systems
- Manual chromatographic integration
- Standalone versus network systems
- Protecting electronic records of standalone systems

Supply Chain Data Integrity

- Approaches to ensuring data integrity of your suppliers
- Role of technical agreements and audits

Key Learning Points and Final Discussion

- Summary of Data Integrity Requirements and Key Learning Points
- Final Discussions and close of the course

Speakers

Dr Bob McDowall, R.D. McDowall Limited, UK
Analytical chemist with over 40 years experience including 15 years working in the pharmaceutical industry and afterwards working for the industry as a consultant. Bob is an ISO 17025 assessor and he has been involved with the validation of computerised systems for over 25 years and is the author of a book on the validation of chromatography data systems. He was also a contributor to the GAMP GPG IT Infrastructure control & compliance.

Karl-Heinz Menges, Regierungspräsidium Darmstadt, Germany
He is Inspector at the Regierungspraesidium Darmstadt in Germany. Mr Menges has been an Inspector for over 25 years and he is currently Head of the German Inspectors Working Group. He is also a member of GAMP D-A-CH steering committee and the German delegate of the PIC/S Expert Circle for computerised systems. Mr Menges has also contributed to Annex 11, PIC/S document PI 011 Recommendations on Computerised Systems and several GAMP CPGs.

Yves Samson, Kereon AG, Switzerland
Yves is founder of Kereon AG, Basel. He is member of GAMP Europe Steering Committees, chairman and co-founder of GAMP Francophone and edited the French version of GAMP 4 and GAMP 5. Within ISPE he was an active member of the working group "IT Infrastructure Compliance and Control".

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
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69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

If the bill-to-address deviates from the specifications on the right, please fill out here:

Reservation Form (Please complete in full)

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☐ Mr ☐ Ms

Title, first name, surname

Company | Department

Important: Please indicate your company's VAT ID Number | **P.O. Number (if applicable)**

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Date

Tuesday, 3 November 2015, 09.00 h – 18.00 h
(Registration and coffee 08.30 h - 09.00 h)
Wednesday, 4 November 2015, 08.30 h – 16.30 h

Venue

Barceló Sants
Placa dels Paisos Catalans, s/n
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08014 Barcelona, Spain
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Fees (per delegate plus VAT)

ECA Members € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

Social Event
On 3 November, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotels. You will receive a room reservation form when you have registered for the event. Reservation should be made directly with the hotel. Early reservation is recommended.

Conference Language

The official conference language will be English.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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