Workshops on:
- Analysis of FDA Warning Letters
- Key Data Integrity Topics / Criteria
- Assessing a System for Data Integrity

Data Integrity

Requirements for a GMP-compliant Data Life Cycle

17-19 May 2016, Berlin, Germany

SPEAKERS:

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LEARNING OBJECTIVES:

- Data Integrity – EU and FDA requirements
- Principles of Data Integrity
- Data Governance
- Role of Management in Data Integrity
- Audit Trails and their review
- IT Support for Data Integrity
- Implementing Data Integrity Training
- Data Integrity and Cloud Computing
- Supplier Chain Data Integrity
- European Inspector's point of view
- Case study: Data Integrity questions as part of an inspection

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

Data Integrity - Requirements for a GMP-compliant Data Life Cycle

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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, MHRA Data Integrity guidance March 2015 and WHO guidance from September 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.

The WHO guidance is complimentary to the MHRA guidance in that it provides guidance for data governance and also expectations for records in both paper and electronic form.
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
- Impact of WHO guidance for data integrity

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

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?

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

WHO and MHRA Data Integrity Guidances - 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

Development and Scope of a Data Governance System
- Within a PQS, what is the scope of a data governance system?
- Who are involved?
- What are their roles?

Implementing Data Integrity Training
- Scope of data integrity training
- What cover in the training?
- Checking training effectiveness
- Integrating data integrity training with GMP 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

US 21 CFR 211 and EU GMP Chapter 4: Complete data vs raw data vs 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

Case study: Data Integrity questions as part of an inspection
- Lab System
- QA System
- Manufacturing System

Ensuring Data Integrity in a Chromatography System
- Configuration of CDS software
- SOP for integration
- Using samples for testing the System

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 v 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

Workshop: Assessing a System for Data Integrity
- Using a checklist based on the data integrity criteria, attendees will assess a system for data integrity

Case study: Can Spreadsheets meet Data Integrity requirements?
- Problems with spreadsheets
- Good Practice for using spreadsheets in a regulated environment
- Building data integrity features into a spreadsheet

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 IT Infrastructure control & compliance and Lab System Validation 2nd edition Good Practice Guides. He is a core member of the GAMP Data Integrity SIG.

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:
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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

Date

Tuesday, 17 May 2016, 13.00 h – 18.00 h
(Registration and coffee 12.00 h - 13.00 h)
Wednesday, 18 May 2016, 08.30 h – 17.30 h
Thursday, 19 May 2016,08.30 – 16.30 h

Venue

InterCityHotel Berlin Hauptbahnhof
Katharina-Paulus-Straße 5
10557 Berlin, Germany
Tel +49 (0)30 288 755 0
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Fees (per delegate plus VAT)

ECA Members € 1,790
APIC Members € 1,890
Non-ECA Members € 1,990
EU GMP Inspectorates € 995
The conference fee is payable in advance after receipt of invoice and includes conference documentation, welcome snack and dinner on the first day, lunch on the second and third day day and all refreshments. VAT is reclaimable.

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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Mr Rouwen Schopka (Organisation Manager)
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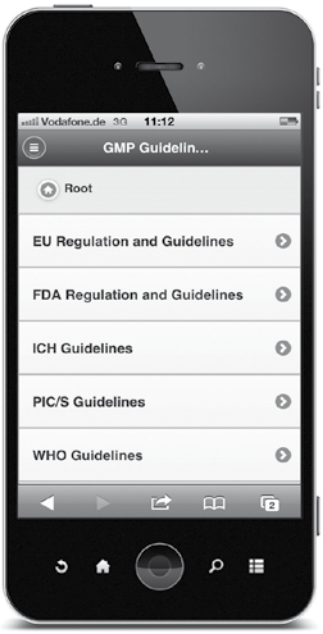
schopka@concept-heidelberg.de.

Social Event

On 17 May, 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.

Use the GMP App at no costs!

The ECA Foundation has developed a GMP App which offers a comprehensive GMP Guideline database with more than 1,400 GMP Guidelines and ten thousands of pages. Check relevant Guidelines (full text versions) during internal audits, regulatory inspections or GMP compliance meetings – simply on your smartphone or tablet PC. In addition to this wealth of guideline information the GMP App also comprises features like GMP News, a comprehensive GMP Search Engine. To open the app just enter app.gmp-compliance.org in your browser and the WebApp opens immediately.



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Title, first name, surname

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

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- until 2 weeks prior to the conference 10 %,
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