

# Data Integrity

## Requirements for a GMP-compliant Data Life Cycle

All participants get a free copy of the current version of the ECA „Data Governance and Data Integrity for GMP Regulated Facilities“ Guidance

### SPEAKERS:



**Bob McDowall**  
*R.D. McDowall Ltd.*



**Karl-Heinz Menges**  
*Regierungspräsidium  
Darmstadt*



**Yves Samson**  
*Kereon AG*

### Workshops on:

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

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29 – 31 August 2017, Copenhagen, Denmark

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### LEARNING OBJECTIVES:

- FDA Draft Guidance for Industry ‘Data Integrity and Compliance with cGMP’
- The new MHRA draft Guidance GxP Data Integrity
- Data Integrity – EU requirements
- 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



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

29 – 31 August 2017, Copenhagen, Denmark

## 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 July 2016 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 issued two versions of a Guidance for Industry on Data Integrity in January and March 2015. 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. A new draft version of the Guidance was published in July 2016. 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
- CRO and CMO 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 2016
- 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

### FDA Draft Guidance for Industry ‘Data Integrity and Compliance with cGMP’

- Background
- Questions and Answers regarding Data Integrity

### 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

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**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 30 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. He recently published the second edition of his book on Validation of Chromatography Data Systems: Ensuring Data Integrity, Meeting Business and Regulatory Requirements.



**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*

Automation and system engineer with over 25 years experience, including 11 years as regulated user, Yves is the founder of Kereon AG, Basel. He supports his customers as consultant, trainer, and e-compliance auditor.


He is member of GAMP Europe Steering Committees, chairman and co-founder of GAMP Franco-phone. He 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**  
P.O. Box 10 17 64  
69007 Heidelberg  
Germany

 **Reservation Form:**  
+ 49 6221 84 44 34

 **e-mail:**  
info@concept-heidelberg.de

 **Internet:**  
www.gmp-compliance.org

### Date

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Tuesday, 29 August 2017, 09.00 h – 17.30 h  
(Registration and coffee 08.30 h – 09.00 h)  
Wednesday, 30 August 2017, 08.30 h – 17.30 h  
Thursday, 31 August 2017, 08.30 – 13.15 h

### Venue

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Radisson Blu Scandinavia Hotel  
Amager Boulevard 70  
2300 Copenhagen S, Denmark  
Phone +45 33 96 50 00  
Fax +45 33 96 55 00

### Fees (per delegate plus VAT)

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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, dinner on the first day, lunch on day 1 and day 2. VAT is reclaimable.

### Accommodation

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CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. 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

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The official conference language will be English.

### Organisation and Contact

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

CONCEPT HEIDELBERG  
P.O. Box 10 17 64  
69007 Heidelberg, Germany  
Phone +49(0) 62 21/84 44-0  
Fax +49(0) 62 21/84 44 84  
info@concept-heidelberg.de  
www.concept-heidelberg.de

### For questions regarding content:

Dr Andreas Mangel (Operations Director)  
at +49(0) 62 21 / 84 44 41 or at  
mangel@concept-heidelberg.de.

### For questions regarding reservation, hotel, organisation etc.:

Mr Rouwen Schopka (Organisation Manager)  
at +49(0) 62 21 / 84 44 13 or per e-mail at  
schopka@concept-heidelberg.de.

### Social Event

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In the evening of the first course day, 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.



### GMP/GDP In-house Training Courses

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Are you interested in a GMP/GDP training course at your facility for a larger group of people? We offer practice-oriented GMP/GDP training courses on:

- Basic GMP
  - APIs (ICH Q7)
  - Medicinal Products
  - Biopharmaceuticals
- Quality Assurance
- Quality Control
- Validation/Qualification
- Regulatory Affairs
- Sterile Manufacturing
- IT / Computer Validation
- Good Distribution Practice (GDP)
- Data Integrity

You will find a time schedule for each training course at [www.gmp-compliance.com](http://www.gmp-compliance.com), button "Inhouse Training"

We also offer in-house training courses for Qualified Persons. Please contact us for more information: [info@gmp-compliance.org](mailto:info@gmp-compliance.org)

We will be happy to design further GMP training courses for you on request.

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

Reservation Form (Please complete in full)

**Data Integrity – Requirements for a GMP-compliant Data Life Cycle**  
29 - 31 August 2017, Copenhagen, Denmark

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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If you cannot attend the conference, you have two options:

1. We are happy to welcome a substitute colleague at any time.

2. If you have to cancel entirely, we must charge the fol-

lowing processing fees: Cancellation

- until 2 weeks prior to the conference 10 %

- within 1 week prior to the conference 50 %

- within 1 week prior to the conference 100 %

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tors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.

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ing to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of January 2012)

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ing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my

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