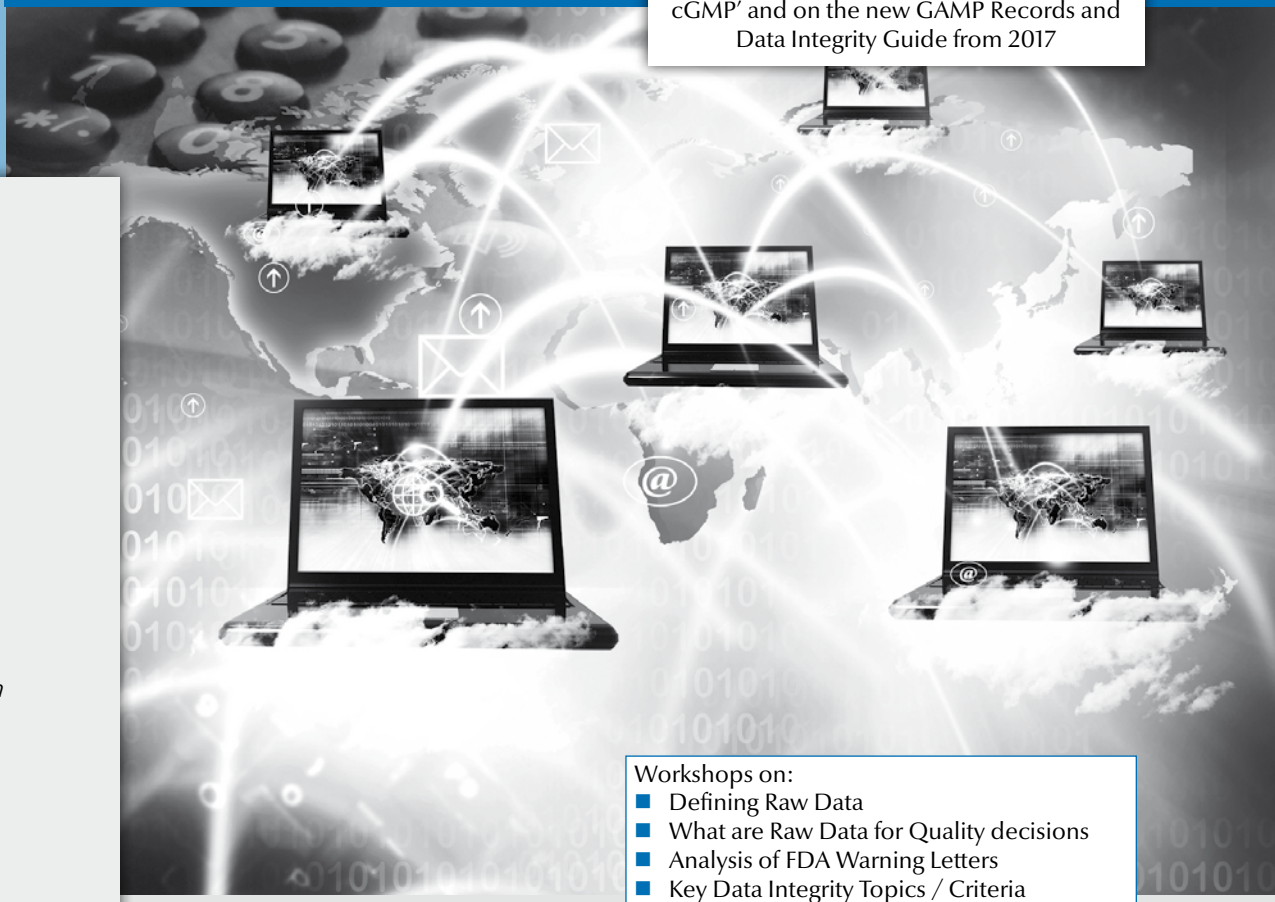
ECA Academy
Your GMP/GDP Information Source

Raw Data
Understanding, Defining and Managing

Data Integrity
Requirements for a GMP-compliant Data Life Cycle

Comments on the FDA Draft Guidance for Industry 'Data Integrity and Compliance with cGMP' and on the new GAMP Records and Data Integrity Guide from 2017



Workshops on:
- Defining Raw Data
- What are Raw Data for Quality decisions
- Analysis of FDA Warning Letters
- Key Data Integrity Topics / Criteria
- Assessing a System for Data Integrity

SPEAKERS:

Bob McDowall
R.D. McDowall Ltd.

Karl-Heinz Menges
Regierungspräsidium Darmstadt

Yves Samson
Kereon AG

12 and 13 – 15 December 2017, Berlin, Germany

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- FDA Draft Guidance for Industry 'Data Integrity and Compliance with cGMP'
- The new MHRA draft Guidance GxP Data Integrity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
- Interpretation of Raw Data

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

Raw Data - Understanding, Defining and Managing

12 December 2017, Berlin, Germany

Objectives

The aim of this one day course is to understand what can be defined as raw data and explore the meaning of the term for manufacturing, laboratory and quality records. Is there harmonisation of US and EU GMP regulations? For example,

- What is a "quality decision" and what is the impact of having to define raw data for the process or system?
- Can raw data be equivalent to complete information and complete data?
- Should we treat manufacturing "information" and laboratory "data" as the same?

Background

FDA GMP in 21 CFR 211 requires "complete information" for manufacturing records and "complete data" for laboratory records. In contrast, Chapter 4 of EU GMP on documentation contains in the Principle three sentences that are in apparent contradiction to the United States regulations:

- Records include the raw data which is used to generate other records
- For electronic records regulated users should define which data are to be used as raw data
- At least, all data on which quality decisions are based should be defined as raw data

In the days of harmonisation of regulations how can we reconcile these differences? This situation is compounded by the failure of EU GMP to define the term "raw data" in the regulations to help industry plan their approach to meeting these regulatory requirements

Target Audience for both courses

- 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

Data, Information and Knowledge

An overview presentation covering for production, laboratories and QA. Link to regulations e.g,

- Data, information and knowledge
- US GMP regulations: 211.68(b), 211.180(d), 211.188 and 211.194(a-e): complete data and complete information
- EU GMP Chapter 4 regulations – raw data principles outlined from a GMP perspective

Cutting Through the Confusion and Fog of Regulatory Terms

Currently there are many terms used in GMP regulations and data integrity guidance documents. What do they mean? How are they relevant to debate? Definition and interpretation of

- Original record / record
- Raw data – MHRA GMP and US GLP definitions
- Data and metadata
- True copy
- Complete data
- Initial data
- Translating raw data for a GMP environment: should we treat manufacturing and laboratory the same when it comes to raw data?

Interpretation of Raw Data for Production Systems

Using a manufacturing process that is automated by standalone PLCs, PLCs linked to a SCADA system and an automated Manufacturing Execution System, what constitutes raw data will be outlined.

- Raw Data for PLCs
- PLCs linked to a SCADA system
- SCADA linked to a Manufacturing Execution System

Interpretation of Raw Data for Laboratory Systems

Using a process involving a chromatography data system and a LIMS, what constitutes raw data will be outlined in two scenarios

- Hybrid CDS and manual input to the LIMS
- Electronic CDS with automatic transfer to the LIMS
- Managing sample management and preparation records

Workshop: Defining Raw Data for Production, QA and Laboratory Systems

This workshop is intended to reinforce the two previous presentations. Attendees will be given laboratory, quality assurance and production scenarios to define raw data. Outputs will be discussed with the course

Can a True Copy be Raw Data?

This brief presentation will start from the definitions of raw data and true copy and explore if and how a true copy can be considered raw data.

Workshop: What are Raw Data for quality decisions

- Identifying GMP quality decisions?
- For each quality decision – define the raw data

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

13 – 15 December 2017, Berlin, Germany

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.

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, MHRA and GAMP 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
- The GAMP Records and Data Integrity Guide

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 dos 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

Conference Language

The official conference language will be English.

Organisation and Contact

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

On 13 December 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.

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 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, Meetings 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 Francophone. 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

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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

☐ **Raw Data – Understanding, Defining and Managing,** 12 December 2017, Berlin, Germany
☐ **Data Integrity – Requirements for a GMP-compliant Data Life Cycle,** 13 – 15 December 2017, Berlin, Germany

☐ Mr ☐ Ms

Title, first name, surname

Company Department

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

Street/P.O. Box

City Zip Code Country

Phone/Fax

E-Mail (please fill in)

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

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1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees: Cancellation
- until 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

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Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according 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)
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing 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 personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html).
I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date

Raw Data:
Tuesday, 12 December 2017, 09.00 h – 17.15 h
(Registration and coffee 08.30 h - 09.00 h)

Data Integrity:
Wednesday, 13 December 2017, 09.00 h – 17.30 h
(Registration and coffee 08.30 h - 09.00 h)
Thursday, 14 December 2017, 08.30 h – 17.30 h
Friday, 15 December 2017, 08.30 – 13.15 h

Venue of both events

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin
Phone +49 (0)30 212 7 - 0
Fax +49 (0)30 212 7-799
berlin@steigenberger.de

Fees Raw Data (per delegate plus VAT)

ECA Members € 790
APIC Members € 840
Non-ECA Members € 890
EU GMP Inspectorates € 445
The conference fee is payable in advance after receipt of invoice and includes conference documentation, lunch and all refreshments. VAT is reclaimable.

Fees Data Integrity (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, dinner on the first day, lunch on day 1 and day 2. VAT is reclaimable.

Would you like to save money?

If you book both courses simultaneously, the fees reduce as folllows:

Fees Raw Data + Data Integrity (per delegate plus VAT)

ECA Members € 2,390
APIC Members € 2,490
Non-ECA Members € 2,590
EU GMP Inspectorates € 1,440
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on 13 December, lunch on 12 / 13 / 14 December and all refreshments. VAT is reclaimable.

Accommodation

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.