Data Integrity Master Class

With an optional full-day pre-course session on

Raw Data - Understanding, Defining and Managing

20 YEARS | ECA Academy
Your GMP/GDP Information Source

SPEAKERS:

Ib Alstrup
Danish Medicines Agency

Bob McDowall
R.D. McDowall Ltd.

Yves Samson
Kereon AG

Dr Wolfgang Schumacher
formerly F. Hoffmann-La Roche Ltd

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4 and 5-7 June 2019, Copenhagen, Denmark

LEARNING OBJECTIVES:

- What are Raw Data
- Interpretation of Raw Data
- True Copy vs. Raw Data
- Data Integrity in the Pharmaceutical Quality System / Data Governance
- Data Flow Analysis
- Metrics for Data Integrity
- Preparing your company for a Data Integrity inspection
- Second Persons review
- Control of Master templates
- Vulnerability of Records
- Data Migration
- QA Oversight for Data Integrity
- Data Integrity Audit results
- Data Integrity investigations

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

4 June 2019, Copenhagen, Denmark

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:

- Record 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.

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 Master Class

5-7 June 2019, Copenhagen, Denmark

Objectives

- You will get familiar with the current regulatory requirements on data integrity and how regulators refine these requirements
- You will get a deeper understanding what FDA and European inspectors expects from pharmaceutical companies in regard to Data Integrity
- You will learn how to implement the (new) regulatory requirements on Data Integrity into your Pharmaceutical Quality System
- You will learn how to prepare your company for an successful inspection in regard to Data Integrity
- You will understand how to establish an effective Data Governance system
- You will learn how to investigate Data Integrity issues in your company

Background

Even Data Integrity is one of the basic GMP principles since years multiple Data Integrity citations were reported by FDA und European inspectors during the last 3 years. Many US Warning Letters and EU Non-Compliance Reports deal with serious Data Integrity violations. Data Integrity questions have been and will continue be the focus of many GMP inspections.

As a consequence international authorities – FDA, EMA, PIC/S, WHO, MHRA - published draft documents to describe the regulatory expectations of Data Integrity. Although all guidelines are not intended to impose additional regulatory burden to the regulated companies, a lot of uncertainty predominates the pharmaceutical industry how to implement these requirements into the daily business.

Target Audience for both Courses

The courses are directed at

- 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

Especially the Data Integrity Master Class course is directed to participants who have first experiences in Data Integrity, e.g. the ECA course "Data Integrity – Requirements for a GMP-compliant Data Life Cycle.

Programme

Regulatory Update
- EU GMP Requirements
  - Chapter 4
  - Annex 11
- Guidance Documents Overview (state of the art)
  - GMDP Inspectors WG, Data Integrity Q&A
  - (PIC/S Good Practices for Data Management and Integrity in regulated GMP/GDP Environments)
  - WHO, Annex 5 Guidance on Good Data and Record Management Practices
  - MHRA GxP Data Integrity Definitions and Guidance for Industry
  - FDA, Data Integrity and Compliance with cGMP
- "These Guides are not intended to impose additional regulatory burden upon regulated entities" Is This correct?
  - Data Governance
  - Dynamic Data

Data Integrity in the pharmaceutical quality system / Data Governance
- Which PQS elements need to be added or updated?
- The Data Integrity Program
  - Priorities (immediate/short/mid-term)
  - Capacity
  - Timing
- Governance responsibilities
- Data governance vs. IT governance
- Elements of a data governance
- Embedding data governance into the PQS

Data flow analysis
- Objective and purpose
- Electronic data flow
- Complete data flow
- Identification of possible weaknesses

Workshop on Data Flow Analysis
Identification of data flow weaknesses and non-compliances

Metrics for Data Integrity
- Metrics in the context of a corporate data integrity programme
- Suggested metrics in the assessment phase
- Suggested metrics in the operational phase

Control of Master Templates and Blank Forms
- Why is control of master templates and blank forms important?
- Regulatory requirements from FDA, MHRA, WHO, EMA and PIC/S
- Devising and controlling the master template
- Operational use of the blank forms
- Do you really want to work this way?

DI Inspections
- Basis for Inspections: "PIC/S Good Practices for Data Management and Integrity in regulated GMP/GDP Environments"
- Data Integrity Assessment during Inspection
  - Quality Control │ Manufacturing
- Inspection Findings

Preparing your company for an Data Integrity inspection
- How to present the DI status and future approach?
- Gap analysis
- Training program coverage
- Experience from FDA inspections – Hot Buttons

Second Person Review
- Regulatory and guidance document requirements for the second person review
- Role of the second person review
- Scope of the second person review
- Documenting the review for paper, hybrid and electronic systems
- Facilitated discussion on Second Person review

Facilitated discussion on Second Persons Review

Quality Culture for Data Integrity
- Regulatory expectations for a data integrity quality culture
- Role senior management in creating the culture
- Components of a quality culture
- Reinforcement of the culture

QA oversight for data integrity
- Data integrity training
- Enforce data flows
- Reviews
- Internal inspection
- Audit of external organisations

Workshop on QA Oversight for Data Integrity
Identification of QA oversight weaknesses

Vulnerability of Records
- What is record vulnerability?
- Protection and security of electronic records requirements
- What can go wrong? Scope of misfortunes that can impact records
- Assessment of record vulnerability and implementation of control measures

Workshop on Vulnerability of Records
Working in teams, the attendees will be presented with a scenario of a computerised system that generates electronic records. They will assess the record vulnerability and determine the controls to put in place to protect the records and ensure data integrity. Team outputs will be discussed with all participants.

Audit trail review
- Regulatory Overview
- Essential Audit Trails in QA/QC/Manufacturing. Risk-based approach.
- What about legacy systems w/o Audit Trail?
- Who shall review Audit Trails? Documentation
- What process and documentation is appropriate in case of deviations/discrepancies?

Options for Long Term Data Retention of Laboratory Data
- Proprietary v open standards for laboratory data
- Options for long term retention:
  - Keep original system
  - Virtualisation
  - Data migration

Case study Data Migration
- Principles of data migration
- Design of the migration process
- Risk-based elaboration of the verification strategy – case study examples

Cybersecurity / Cloud Computing / Time synchronisation
- Cybersecurity securing data integrity
- Robust IT infrastructure
- Time synchronisation
- Qualification of time dissemination

Results of a Data integrity audit from a contract laboratory
- Audit context
- Audit scope
- Findings
- Root causes

Data Integrity Investigations
- What are data integrity investigations?
- Human and technical triggers for DI investigations
- Who should investigate the problem?
- Process description and how to document a DI investigation
- Should we inform regulatory authorities?

Workshop on Data Integrity Investigations
Based on a case study, attendees will be presented with key facts and determine what an organisation should do to investigate a data integrity issue. At the end of the workshop, during the discussion of the team outputs there will be a comparison with the work performed in the case study. outputs will be discussed with all participants.

Key Learning Points and Final Discussion

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
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www.concept-heidelberg.de

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

Social Event

In the evening of 5 June, 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

Ib Alstrup,
Danish Medicines Agency, DMA, Copenhagen, Denmark
Ib Alstrup is a GxP IT Medicines Inspector with the Danish Medicines Agency. With a background as a software designer and tester, he has specific focus and large experience in inspection of validation and operation of computerised systems throughout the GLP, GCP, GMP, GDP and GVP areas. He is a co-writer of the new PIC/S guide on Data Integrity and holds a B.Sc. in Electronic Engineering.

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.

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. In 2017, Yves launched the e-Compliance Requirements Initiative (eCRI) with the aim to help the regulated pharmaceutical industry and its suppliers to address and to implement accurately, consistently, and effectively the regulatory e-Compliance requirements.

Dr Wolfgang Schumacher,
formerly F. Hoffmann-La Roche Ltd., Switzerland
Dr Schumacher studied chemistry and pharmacy. After entering Asta Medica, he headed different positions. In 2001 he joined F. Hoffmann-La Roche, Basle, where he was Head of the Quality Computer Systems department. He is a member of the ECA Advisory Board.

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

Raw Data
Tuesday, 4 June 2019, 09.00 – 17.15 h

Data Integrity Master Class
Wednesday, 5 June 2019, 09.00 h – 18.00 h
(Registration and coffee 08.30 h - 09.00 h)
Thursday, 6 June 2019, 08.30 h – 18.00 h
Friday, 7 June 2019, 08.30 – 13.30 h

Venue of both events

Radisson Blu Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S, Denmark
Tel +45 33 96 50 00
Scandinavia.meetings.events@radissonblu.com

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 Master Class
(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:

Raw Data + **Data Integrity Master Class**
(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 5 June, lunch on 4, 5, and 6 June 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/POG when you have registered
for the event. Reservation should be made directly
with the hotel. Early reservation is recommended.

+ 49 6221 84 44 34

Reservation Form (Please complete in full)

☐ **Raw Data – Understanding, Defining and Managing,** 4 June 2019, Copenhagen, Denmark
☐ **Data Integrity Master Class,** 5-7 June 2019, 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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GERMANY

General terms and conditions
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 following process-
ing 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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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.