ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Data Integrity Manager

Speakers

Bob McDowall
R.D.McDowall Ltd., UK

Yves Samson
Kereon AG, Switzerland

Dr Franz Schönfeld
GMP Inspector, Germany

Dr Wolfgang Schumacher
formerly F. Hoffmann-La Roche Ltd., Switzerland

NEWS

Stay informed with the GMP Newsletters from ECA

The ECA offers various free of charge GMP newsletters for which you can subscribe to according to your needs.

To subscribe, simply scan the QR code on the right or visit www.gmp-compliance.org/gmp-newsletter

Data Integrity Master Class

With an optional full-day pre-course session on

Raw Data - Understanding, Defining and Managing

Live Online Training on 29 August and 30 August - 1 September 2023

Save up to € 590,- by booking both courses!

Highlights

- 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

Objectives

The aim of this one-day course is to understand what can be defined as raw data and to 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.

Programme

Tuesday, 29 August 2023

Data, Information and Knowledge

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

- Data vs information vs knowledge
  - From knowledge to insight
- DIKI model
- Product, Process, Data

Regulations

- 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

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

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.

Case Study/Workshop : What are Raw Data for Quality Decisions

Programme “Data Integrity Master Class”

Objectives

- Your 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 a 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

Wednesday, 30 August 2023

Regulatory Update

- EU GMP Requirements
  - Chapter 4, Annex 11
- Guidance Documents Overview (state of the art)
- “These Guides are not intended to impose additional regulatory burden upon regulated entities”. Is this correct?
  - Data Governance, Dynamic Data

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

Data Flow Analysis

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

Case Study/Workshop on Data Flow Analysis

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

QA Oversight for Data Integrity

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

Case Study/Workshop on QA Oversight for Data Integrity

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?

Programme “Data Integrity Master Class”

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

Thursday, 31 August 2023

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?

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 Person Review

Preparing your Company for a Data Integrity Inspection

- How to present the DI status and future approach?
- Gap analysis
- Training program coverage
- Experience from FDA inspections – Hot Buttons

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

Case Study/Workshop: Data Inspection Findings

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

Case Study/Workshop on Vulnerability of Records

Case Study Data Migration: Preserving Content and Meaning

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

Friday, 1 September 2023

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?

Case Study/Workshop on Data Integrity Investigations

Options for Long Term Data Retention

- Proprietary v open standards for laboratory data
- Options for long term retention:
  - Keep original system, Virtualisation, Data migration

Case Study/Workshop: Justifying Long Term Solutions

Key Learning Points and Final Discussion

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 34
info@concept-heidelberg.de
www.concept-heidelberg.de

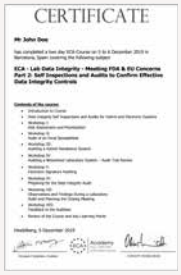
For questions regarding content please contact:
Dr. Andreas Mangel (Operations Director) at
+49(0)62 21/84 44 41, or at
mangel@concept-heidelberg.de.

For questions regarding organisation etc. please contact:
Ms Marion Grimm (Organisation Manager) at
+49(0)62 21/84 44 18, or at
grimm@concept-heidelberg.de.

Your Benefits

Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires:„… All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,…". This is why you receive an acknowledged participant certificate, which lists the contents of the Live Online Training in detail and with which you document your training.


CERTIFICATE

This Training Course is recognized for the GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropiate supplement to acquire this qualification. This Live Online Training is the first element for your additional certification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance. Please find more information at www.gmp-certification.org

This could be of interest for you as well

Why not online? GMP/GDP seminars, webinars and e-learning
Take advantage of the wide range of „on demand" training opportunities offered by the ECA Academy. You can use various online offers at any time without software installation. There is an extensive selection of courses available. Simply book online - with a certificate of completion, of course.

Find out more at https://www.gmp-elearning.com and https://www.gmp-compliance.org/recordings.

Speakers

Dr Bob McDowall
R.D.McDowall Limited, Bromley, Kent, UK

Analytical chemist with over 45 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 his book on Data Integrity and Data Governance: Practical Implementation in Regulated Laboratories.

Yves Samson, Kereon AG
Basel, 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 Franz Schönfeld
District Government of Upper Franconia, Germany

Dr Franz Schönfeld is a GMP and GDP inspector at the local inspectorate for medicinal products and active substances of the District Government of Upper Franconia. He is head of the expert working group for APIs at the Central Authority of the Federal States for Health Protection.

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.

PE/14062023

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

_____

_____

_____

_____

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

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Live Online Courses

☐ Raw Data – Understanding, Defining and Managing, 29 August 2023
☐ Data Integrity Master Class, 30 August - 1 September 2023

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

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 processing fees:
- Cancellation until 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, 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 HEIDELBERGwill not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
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 July 2022).
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 https://www.gmp-compliance.org/privacy-policy). 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.

Dates of the Live Online Training Courses

Raw Data
Tuesday, 29 August 2023, 09.00 h – 17.15 h CEST

Data Integrity Master Class
Wednesday, 30 August 2023 , 09.00 h – 18.00 h CEST
Thursday, 31 August 2023, 09.00 h – 18.00 h CEST
Friday, 1 September 2023, 09.00 h – 16.00 h CEST

Technical Requirements

We use Webex for our live online training courses and webinars. At https://www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. Webex is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate plus VAT)

Raw Data
ECA Members € 990
APIC Members € 1090
Non-ECA Members € 1,190
EU GMP Inspectorates € 595
The conference fee is payable in advance after receipt of invoice.

Data Integrity Master Class
ECA Members € 2,090
APIC Members € 2,190
Non-ECA Members € 2,290
EU GMP Inspectorates € 1,145
The conference fee is payable in advance after receipt of invoice.

Save money and book both online courses:

ECA Members € 2,690
APIC Members € 2,790
Non-ECA Members € 2,890
EU GMP Inspectorates € 1,445
The conference fee is payable in advance after receipt of invoice.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

You cannot attend the Live Event?

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.