ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Data Integrity Manager

## Speakers

**Bob McDowall**
R.D.McDowall, UK

**Yves Samson**
Kereon, Switzerland

**Dr Franz Schönfeld**
GMP Inspector, Germany

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

NEWS

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# Data Integrity Master Class

With an optional full-day pre-course session on

## Raw Data - Understanding, Defining and Managing

25 August and 26 - 28 August 2026
Copenhagen, Denmark


## Highlights

- What are Raw Data? Understanding GMP Definitions and Regulations
- Interpretation of Raw Data
- True Copy vs. Raw Data
- Data Integrity in the PQS / Data Governance
- Data Flow Analysis
- Metrics for Data Integrity
- Data Integrity Inspection / Preparing your Company for a Data Integrity Inspection
- Audit Trail Review vs Second Person Review
- Control of Master Templates
- Vulnerability of Records
- Data Migration
- QA Oversight for Data Integrity
- Data Integrity Audit Results
- Data Integrity Investigations

With particular reference to Chapter 4 Draft 2025 and Annex 11 Draft 2025 of the EU GMP Guide

## 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

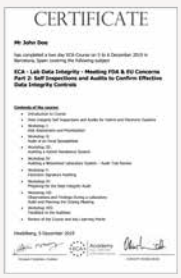
FDA GMP in 21 CFR 211 requires “complete information” for manufacturing records and “complete data” for laboratory records. In contrast, Chapter 4 of EU GMP on documentation contains in the Principle three sentences that are in apparent contradiction to the United States regulations:

- 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.

### 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 appropriate supplement to acquire this qualification. 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.

## Programme

### Data, Information and Knowledge

- 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 + Chapter 4 Draft 2025

### Understanding GMP Definitions and Regulations for Raw Data

- 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

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

### Interpretation of Raw Data for Laboratory Systems

- 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

### Can a True Copy be Raw Data?

### Workshop : What are Raw Data for Quality Decisions

# 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 expect 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

## Regulatory Update

- EU GMP Requirements
  - Chapter 4 + Chapter 4 Draft 2025
  - Annex 11 + Annex 11 Draft 2025
- 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

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

Workshop on QA Oversight for
Data Integrity

## 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

# Programme “Data Integrity Master Class”

## 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

### 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

### Workshop on Vulnerability of Records

## Cloud Computing

- Cloud and GxP regulatory expectations
- Management models for cloud services
- Business continuity & resilience

## 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?

## 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

## 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?

## Time Synchronisation

- Why is Time Synchronisation important?
- Qualification of time dissemination

### 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

### Workshop: Justifying Long Term Solutions

## Case Study: Planning Long Term Data Retention

- Document life cycle
- Compliant handling of transient data
- E-Archiving

### Key Learning Points and Final Discussion

## Organisation and Contact

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

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

# Social Event

On 26 August, 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.

## This could be of interest for you as well

**Would you like to train a larger group of participants in your company?**
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
- Packaging
- Medical Devices
- Technical Operations

You will find a time schedule for each training course at https://www.gmp-compliance.org/training/gmp-gdp-in-house-trainings.

# 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. He was a contributor and reviewer of the GAMP Guide on Records and Data Integrity and two associated Data Integrity Good Practice Guides.

### 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 is member of GAMP Europe Steering Committees, chairman and co-founder of GAMP Francophone and editor of the French version of GAMP 4/5.

### 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.

Attendees will get a free electronic copy of ECA Guide "GMP, GCP and GDP Data Governance and Data Integrity", Version 3.

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

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CONCEPT HEIDELBERG
P.O. Box 101764
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D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

☐ Raw Data – Understanding, Defining and Managing, 25 August 2026, Copenhagen, Denmark
☐ Data Integrity Master Class, 26 - 28 August 2026, Copenhagen, Denmark

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 HEIDELBERG will 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.

## Date & Venue

**Raw Data**
Tuesday, 25 August 2026, 09.00 – 17.15 h
(Registration and coffee 08.30 h - 09.00 h)

**Data Integrity Masterclass:**
Wednesday, 26 August 2026, 09.00 h – 17.30 h
(Registration and coffee 08.30 h - 09.00 h)
Thursday, 27 August 2026, 08.30 h – 17.30 h
Friday, 28 August 2026, 08.30 – 15.30 h

All times mentioned are CEST.

## Venue

Radisson Blu Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S, Denmark
Phone: +45 3396 50 00
guest.copenhagen@radissonblu.com

## Fees (per delegate plus VAT)

**Raw Data**
ECA Members € 1,090
APIC Members € 1,190
Non-ECA Members € 1,290
EU GMP Inspectorates € 695
The conference fee is payable in advance after receipt of invoice and includes conference documentation, lunch and all refreshments. VAT is reclaimable.

**Data Integrity Master Class**
ECA Members € 2,290
APIC Members € 2,390
Non-ECA Members € 2,490
EU GMP Inspectorates € 1,245
The conference fee is payable in advance after receipt of invoice and includes conference documentation, social event including dinner on the first day, lunch on each day and all refreshments. VAT is reclaimable.

## Save money and book both courses:

We will offer you a discount of € 600 if you book both training courses.

## 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 conference. Reservation should be made directly with the hotel. Early reservation is recommended.

## Registration

Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the numbers 22288, 22289, 22290.
To avoid incorrect information, please give us the exact address and full name of the participant.

## Conference language

The official conference language will be English.