



## Speakers



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



**Yves Samson**  
Kereon AG



**Dr Franz Schönfeld**  
GMP Inspector



**Dr Wolfgang Schumacher**  
formerly F. Hoffmann-La Roche Ltd.

# Data Integrity Master Class

With an optional full-day pre-course session on  
Raw Data - Understanding, Defining and Managing

23 and 24-26 June 2020 | Berlin, Germany



## 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

## Objective

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

### Data, Information and Knowledge

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*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

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*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

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*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

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*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

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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?

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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

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

## 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 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 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

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- 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

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- 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

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



### Workshop on Data Flow Analysis

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Identification of data flow weaknesses and non-compliances

### Metrics for Data Integrity

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- 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

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- 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

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

## Second Person Review

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- 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

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- 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

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



## Workshop on QA Oversight for Data Integrity

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### Identification of QA oversight weaknesses

## Vulnerability of Records

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- 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

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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

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- 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

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

## Case study Data Migration

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

## Cybersecurity / Cloud Computing / Time synchronisation

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

## Results of a Data integrity audit from a contract laboratory

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- Audit context, Audit scope, Findings, Root causes

## Data Integrity Investigations

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- 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

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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.

## 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

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### 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 at

schopka@concept-heidelberg.de.

## Social Event

On 24 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



**Dr Bob McDowall**

R.D.McDowall Limited, Bromley, Kent, 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**

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 inspector at the centralised inspectorate for medicinal products of the government of Upper Bavaria. 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.

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

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### Reservation Form (Please complete in full)

- Raw Data – Understanding, Defining and Managing, 23 June 2020, Berlin, Germany
- Data Integrity Master Class, 24-26 June 2020, Berlin, Germany

Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

City

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

#### 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 2 weeks prior to the conference 10 %
  - Cancellation until 1 week prior to the conference 50 %
  - Cancellation within 1 week 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 can-

cellation 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.htm](http://www.gmp-compliance.org/eca_privacy.htm)). 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, 23 June 2020, 09.00 – 17.15 h

Data Integrity Master Class

Wednesday, 24 June 2020, 09.00 h – 18.00 h

(Registration and coffee 08.30 h - 09.00 h)

Thursday, 25 June 2020, 08.30 h – 18.00 h

Friday, 26 June 2020, 08.30 – 13.30 h

## Venue

InterCityHotel Berlin Hauptbahnhof

Katharina-Paulus-Straße 5

10557 Berlin, Germany

Phone +49(0)30 288 755 0

Email [berlin-hauptbahnhof@intercityhotel.de](mailto:berlin-hauptbahnhof@intercityhotel.de)

## Fees (per delegate plus VAT)

Raw Data

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.

Data Integrity Master Class

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, social event including dinner on the first day, two lunches and all refreshments. VAT is reclaimable.



## Save money and book both courses:

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, 3 lunches, social event including dinner, 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 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 message.

Or you register online at [www.gmp-compliance.org](http://www.gmp-compliance.org).