# Data Integrity Master Class | Audit Trail Review


SPEAKERS:

Bob McDowall
*R.D.McDowall Ltd.*

Yves Samson
*Kereon AG*

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

Dr Arno Terhechte
*Bezirksregierung Münster*

Save up to € 290.- by booking both courses

20-22 and 23 June 2017, Berlin, Germany

HIGHLIGHTS:

**Data Integrity Master Class**

- Data Integrity in the Pharmaceutical Quality System
- Data Flow Analysis
- Metrics for Data Integrity
- Preparing your company for an Data Integrity inspection
- Control of Master templates
- Vulnerability of Records
- QA Oversight for Data Integrity
- Data Integrity Audit results
- Data Integrity interventions

**Audit Trail Review**

- Understand the regulatory requirements for an Audit Trails (review)
- Identifying GMP relevant data
- Review of Audit Trail entries
- Technical Controls to Aid Second Person Review of Audit Trails

Both courses are recognised for the ECA GMP Certification Programme „Certified Data Integrity Manager".
Please find details at www.gmp-certification.eu

# Data Integrity Master Class | 20-22 June 2017, Berlin, Germany

## Learning Goals

- 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 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 and 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 to 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

The Data Integrity Master Class is 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

## 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

- Which PQS elements need to be added or updated?
- The Data Integrity Program
  - Priorities (immediate/short/mid-term)
  - Capacity
  - Timing

### Data Integrity in paper documentation

- GMP requirements for good documentation practice
- Application to paper documents
- Common problems from FDA 483 observations and warning letters and how to avoid them

### Data flow analysis

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

### 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

### 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

### 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

## 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

## Time synchronisation

- Purpose and requirements
- TAI, UTC, time zone, legal time, local time, system time
- ntp - network time protocol
- Time management concept

## Software Suppliers Responsibility for Data Integrity Compliance

- Regulatory requirements for software systems: procedural and technical
- Role of software suppliers
- Regulations push vs market needs pull
- Implementing technical requirements for software: architecture, database and application
- Marketing literature versus marketing bullshit

## 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?

## Risk-based approach for manufacturing and laboratory audit trail review

- Regulatory requirements and expectations for audit trail review
- Is the application adequate for audit trail review?
- Application of a risk based approach to audit trail review

## Workshop on Audit Trail Review

Working in teams, the attendees will be presented with a series of scenarios involving computerised systems with audit trails. Based on the regulations and the team's assessment of risk, they will determine what they will review and how frequently they will review audit trails. Team outputs will be discussed with all participants.

## 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.

## QA oversight for data integrity

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

## Cyber security measures to assure data integrity

- Cyber security reality and concerns
- Possible security weaknesses
- Designing robust IT and automation infrastructures

## Data governance

- Governance responsibilities
- Data governance vs. IT governance
- Elements of a data governance
- Embedding data governance into the PQS

## Data integrity audit results of a contract laboratory

- Audit context
- Audit scope
- Findings
- Root causes

## Case study Data Migration - Production

- Migration of complex data collections
- Migration of a large collection of similar data
- Design of the migration process
- Risk-based elaboration of the verification strategy

## 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

## 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.

## Key Learning Points and Final Discussion

## Objectives

- You will learn the current regulatory requirements and regulatory expectations for an audit trail (review)
- All GMP-relevant data (changes and deletions) should be audit trailed – you will learn how to identify GMP-relevant data
- Event and audit logs: you will understand the differences between and what the regulators expect
- How should an audit trail review be performed? You will get familiar with the content and the frequency of an audit trail review

## Background

Audit Trail Reviews are required by international regulations like US 21 CFR Part 11 and EU GMP Guide Annex 11: Clause 9 requests:

"Consideration should be given, based on a risk assessment, to building into the system the creation of a record of all GMP-relevant changes and deletions (a system generated "audit trail"). For change or deletion of GMP-relevant data the reason should be documented. Audit trails need to be available and convertible to a generally intelligible form and regularly reviewed"

Regulators focus on the (creation), modification and deletion of (GMP-relevant) data while many IT systems are not able to generate audit trails at all or they are not able to generate audit trails for GMP-relevant data.

Therefore, this course is designed to support you to identify GMP-relevant data and how to perform and document an Audit Trail review as part of a second person review.

## Target Audience

This course is designed for managers and staff from health care industries as well for auditors who are responsible for the organisation and execution of audit trail (reviews) in their companies.

## Programme

### Why Is An Audit Trail and Its Review Important?

- Part 11 and Annex 11 / Chapter 4 requirements for audit trail
- Regulatory requirements for audit trail review
- Guidance documents for audit trail review
- Do I really need an audit trail?

### What is in a Name?

- What do we look for in an application for auditing?
- Pros and cons for event logs and audit logs?
- Which audit trail(s) should I review?

### Workshop 1: Which Audit Trail to Review?

Attendees will be presented with an overview of the audit trails within an application and the content of each one . Which audit trails should be reviewed and when?

### What are GMP-Relevant Data?

- Annex 11 requires that audit trails monitor GMP-relevant data – what are GMP relevant data?

### Workshop 2: Identifying GMP Relevant Data

Attendees will be presented with a list of records to identify if they are GMP records and how critical they are to help focus the second person review of audit trail data. Examples from production, laboratory and QA examples of GMP relevant data will be provided

### Review of Audit Trail Entries

- Guidance for frequent is "frequent review" of audit trails
- Process versus system: avoiding missing data integrity issues when only focussing on a per system review
- What are we looking for in an audit review?
- Suspected data integrity violation - What do we need to do?

### Workshop 3: Reviewing Audit Trail Entries

Attendees will be provided with the output of an audit trail to review and see if any potential issues are identified for further investigation.

### Technical Controls to Aid Second Person Review of Audit Trails

- Technical considerations for audit trail review e.g.
- Identifying data that has been changed or modified – how the system can help
- Documenting the audit trail review has occurred
- Review by exception – how technical controls can help
- Have you specified and validated these functions?

## Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the InterCity Hotel Berlin for both courses. The Steigenberger Hotel am Kanzleramt is located next to the InterCity Hotel Berlin. 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.

## Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

## Conference language

The official conference language will be English.

## Organisation and Contact

CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
Fax +49 (0) 62 21/84 44 34
E-mail: info@concept-heidelberg.de
www.concept-heidelberg.de

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

**For questions regarding reservation, hotel, organisation etc.:**
Mr Rouwen Schopka (Organisation Manager) at +49-62 21 / 84 44 13, or per e-mail at schopka@concept-heidelberg.de.

## Social Event

On the first day of the Data Integrity Master Class, 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. Within ISPE he was an active member of the working group "IT Infrastructure Compliance and Control".

**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.

**Dr Arno Terhechte**
**Bezirksregierung Münster, Germany**
After 5 years in the pharmaceutical industry he was from 1998 – 2003 in the Bezirksregierung Düsseldorf. Since 2003 he is inspector in the Bezirksregierung Münster. Arno Terhechte is member of the German expert group 11 "computerised systems".

**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**

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☐ **Data Integrity Master Class**, 20-22 June 2017, Berlin, Germany
☐ **Audit Trail Review**, 23 June 2017, Berlin, Germany

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## Date and Venue "Data Integrity Master Class"

Tuesday, 20 June 2017, 09.00 h – 17.30 h
(Registration and coffee 08.30 h - 09.00 h)
Wednesday, 21 June 2017, 08.30 h – 17.30 h
Thursday, 22 June 2017, 08.30 – 16.00 h

InterCityHotel Berlin Hauptbahnhof
Katharina-Paulus-Straße 5
10557 Berlin, Germany
Phone +49 (0)30 288 755 0
Fax +49 (0)30 288 755 900

## Date and Venue "Audit Trail Review"

Friday, 23 June 2017, 09.00 – 16.30 h

Steigenberger Hotel am Kanzleramt
Ella-Trebe-Straße 5
10557 Berlin, Germany
Phone +49 (0)30 921 0257 0
Fax +49 (0)30 921 0257 99

## Fees (per delegate plus VAT, VAT is reclaimable)

**Data Integrity Master Class**
Non-ECA Members € 1,990
ECA Members € 1,790
APIC Members € 1,890
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 all days and all refreshments.

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

**Data Integrity Master Class + Audit Trail Review**
Non-ECA Members € 2,590
ECA Members € 2,390
APIC Members € 2,490
EU GMP Inspectorates € 1,440
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on all days and all refreshments.