

## Speakers



Bob McDowall  
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# Data Integrity and Good Documentation Practice

GMP-compliant instructions and records

10 – 12 May 2022 | Hamburg, Germany



## Highlights

- Principles of Good Documentation Practice and Data Integrity
- Instructions, blank forms and records – Life cycle and Data Integrity considerations
- Good Documentation Practices for linked paper and electronic records
- Advantages and Disadvantages of Document Management Systems: Paper based - Hybrid – Electronic
- Life cycle of documents and Data Integrity issues
- How to perform Second Person Review of Batch Records in different formats
- How to train staff in Good Documentation Practice and Data Integrity
- Management and Control of multilingual Documents
- Typical documentation failures and how to avoid them

All participants get free access to the current version of the ECA „Data Governance and Data Integrity for GMP Regulated Facilities“ Guidance.

## Objective

During this Course you will get to know the **principles of Good Documentation Practices** in the light of **Data Integrity requirements**.

You will learn

- How to control blank forms and templates
- How to maintain Data Integrity for physical, hybrid and electronic records
- How to establish a compliant and pragmatic change control process
- How poor documentation practices and falsification can be detected
- How to train staff in Good Documentation Practice and Data Integrity
- How multilingual documents can be managed and controlled
- How to avoid typical documentation failures

Experts will show what you need to consider to maintain GMP-compliant documentation systems throughout their life cycle.

## Background

Despite numerous regulatory guidelines poor documentation practice has become more and more a global problem and in most cases it leads to severe violations of Data Integrity principles. The citations regarding Data Integrity issues in FDA warning letters have been increasing dramatically over the past 3 years and also European Regulatory Agencies are concerned about Data Integrity failures in poor documentation not only in companies located in far East but also within Europe.

Both FDA and UK's MHRA have reacted to this situation by issuing guidances containing clear provisions regarding Data Integrity and documentation e.g. FDA's CPG objective 3 which covers the laboratory Data Integrity audit or MHRA's Guidance for Industry on Data Integrity. Also WHO has published a guidance which provides provisions for data governance and contains expectations for records in both paper and electronic forms.

## Target Audience

This Education Course is designed for Managers and staff from Manufacturing, QC/QA and Analytical Development Laboratories of pharmaceutical companies and API manufacturers. Laboratory and QA personnel from Contract Research Organisation and Contract Manufacturing Organisations as well as Auditors responsible for performing self-inspections or external audits will also benefit from this course.

## Programme

### Data Integrity Principles

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- Basements of Data Integrity
- Guidelines
- Implementation of Data Integrity Standards at a Site (Praxis Example)
- CARs Model (Critical Application Risks) – an implementation model based on Quality Risk Management

### Current Inspection Observations and their Potential Resolution

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- Examples from current inspections
- Potential CAPAs on observations
- Watch-Outs and defense packages
- Inspectors expectations from different authorities: FDA, ANVISA, MHRA, German MoH ...

### Why is Control of Blank Forms Important?

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- Instructions and blank forms – Life cycle and Data Integrity considerations
- FDA requirements for control
- Process for creation of master templates
- Process for operational use of blank forms
- Reconciliation mechanisms

### Facilitated Discussion: Control of Templates and Blank Forms

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### Records – Life Cycle and Data Integrity Issues

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- GMP Record Lifecycle
- Control Mechanisms
- Data Integrity for physical vs. electronic Records
- How to manage record copies without violating Data Integrity rules?

### Advantages and Disadvantages of Document Management Systems: Paper Based - Hybrid – Electronic

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- Paper archives - cheap and secure?
- Requirements for an eDMS
- eDMS server-based solution vs. SaaS in the Cloud
- How to transfer paper documents into electronic records?

### Electronic Document Management and Change Control Systems to Ensure Data Integrity

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- Data Integrity expectations on an Electronic Document Management System (EDMS) and Change Control System
- Audit Trail Review / Log File Review
- Fundamentals of a modern EDMS
- Traceability
- Mapping ALCOA principles on EDMS and Change Control
- Expectations from Inspections

## Data Integrity and Digital Signatures

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- What exactly is an electronic signature?
- Advanced vs qualified digital signature
- Technical implementation
- Change of Workflows
- Parallel processes
- How to manage replacements

## Handling Hybrid Records: Good Documentation Practices for Linked Paper and Electronic Records

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- Chapter 4 and 21 CFR 11 regulations for linking signatures to electronic records
- Are you saving the underlying electronic record?
- Checks and technical controls to ensure the signature are linked to the record
- Common pitfalls in record-signature linking

## Second Person Review of Batch and Analytical Records: Paper, Hybrid and Electronic Formats

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- Importance of a second person review for Data Integrity
- What will a reviewer review with paper, hybrid and electronic records?
- Training for second person review
- Detection of poor documentation practices and falsification
- Risk-based second person reviews of records and audit trails



Workshop:  
Design of a Document Control SOP

## How to Train Staff in Good Documentation Practice and Data Integrity

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- Pre-requisites: Data Integrity policy with effective training
- Procedure for good documentation practices is essential
- Options for training: read and understand, instructor led training (ILT) and ILT with check for understanding

## Data Integrity: Praxis Example of Implementation of the Requirements at a Pharma Site Based on Quality Risk Management Principles

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## Typical Documentation Failures and how to Avoid them – Key Learning Points

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- Analysis of FDA 483 and warning letter citations for poor documentation practices
- Identification of top 5 documentation failures
- Ways to avoid them e.g. through changes in working practice, training and technical controls

## Management and Control of Multilingual Documents (Data Integrity Expectations)

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- Part 1: Basics
  - Workbench
  - Translation
  - Synchronisation
- Part 2: Implementation and Management
  - Responsibilities
  - GMP status
  - Versions
  - Signatures
  - Change Control

## Speakers



**Dr Bob McDowall**  
McDowall Limited, UK

Analytical chemist with nearly 50 years' experience including 15 years working in the pharmaceutical industry. Bob has been a consultant for nearly 30 years and has been involved with computer validation for 35 years. Bob is the writer of the Questions of Quality (LC-GC Europe) and Focus on Quality (Spectroscopy) columns and is a member of the Editorial Advisory Boards of several journals. He was a contributor to the GAMP Good Practice Guide for Validation of Laboratory Computerised Systems and a contributor and reviewer of the GAMP Guide on Records and Data Integrity and two associated Data Integrity Good Practice Guides. He is the author of Data Integrity and Data Governance: Practical Implementation for Regulated Laboratories.



**Stephan Dresen, Ph.D.**  
Daiichi Sankyo Europe GmbH, Germany

Stephan Dresen is Executive Director / Head of Quality Control at Daiichi Sankyo Europe in Pfaffenhofen. Formerly he was Director Quality / Regional Head of Quality at Warner Chilcott / Allergan. With more than 18 years of experience in leading positions within the pharma industry (Abbott/AbbVie, Allergan, Corden Pharma) he was responsible for the sites in Germany, Serbia and Greece. Also he had been global strategic Business-Sponsor for all QA/QC IT Systems. For multiple years he was Head of Quality for all External Operations in Europe (TPM). Next to this he is Managing Director at D|Consulting GmbH, developing and implementing pharmaceutical and medical knowledge management systems.



**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 department of Quality Computer Systems. Since August 2016 he works as an independent Pharma consultant. He is a member of the ECA Advisory Board and chairman of the IT Compliance Group, an interest group of the ECA Foundation.

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Reservation Form (Please complete in full)

## Data Integrity and Good Documentation Practice, 10 – 12 May 2022, Hamburg, Germany

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Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

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### 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 %
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- CONCEPT HEIDELBERG reserves the right to change the materials, instructors,

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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.html](http://www.gmp-compliance.org/eca_privacy.html)), 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

Tuesday, 10 May 2022, 9.00 – 17.30

(Registration and coffee 8.30 – 9.00)

Wednesday, 11 May 2022, 8.30 – 17.45

Thursday, 12 May 2022, 8.30 – 13.45

## Venue

Barceló Hotel Hamburg

Ferdinandstrasse 15

20095 Hamburg, Germany

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On site, we will implement the necessary and required hygiene measures in close co-operation with the hotel. If infection rates and/or travel restrictions generally do not permit an on site event, it will be conducted live online. In this case, you will be informed in due time.

## Fees (per delegate, plus VAT)

ECA Members € 1,790

APIC Members € 1,890

Non-ECA Members € 1,990

EU GMP Inspectorates € 995

The fee is payable in advance after receipt of invoice and includes lunch on all days 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 course. 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).

## Presentations/Certificate

The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

## 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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### For questions regarding reservation, hotel, organisation etc. please contact:

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