



## Speakers



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# Data Integrity and Good Documentation Practice

GMP-compliant instructions and records



Live Online Training from 04 – 06 May 2021



## 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
- Life cycle of documents and Data Integrity issues
- GMP-compliant document change management
- 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 Live Online Training 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 Live Online Training 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

### Overview of the Training Seminar

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#### 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?

#### GMP-compliant Document Change Management

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- How to establish a compliant and pragmatic change control process?
- The GMP Document Roadmap
- Document inventory and reconciliation
- Industry best practice for record retention timelines - GMP requirements vs. Knowledge Management

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

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## 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

## 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 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 25 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.

### 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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## Data Integrity and Good Documentation Practice, Live Online Training from 04 – 06 May 2021

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## Date of the Live Online Training

Tuesday, 04 May 2021, 9.00 – 17.30 h CEST  
Wednesday, 05 May 2021, 9.00 – 16.15 h CEST  
Thursday, 06 May 2021, 9.00 – 15.30 h CEST

## Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At <http://www.webex.com/test-meeting.html> you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

## 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.

## 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 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.

## Your Benefit: 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 seminar in detail and with which you document your training.

## Organisation and Contact

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