ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Data Integrity Manager

Speakers

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Good Documentation Practice and Data Integrity

GMP-compliant instructions and records

01 – 03 April 2025 | Heidelberg, 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
- USP<1029> Good Documentation Practice
- 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 „GMP, GCP and GDP Data Governance and Data Integrity“ Guidancee.

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

- 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

- 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?

- 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

Records and Life Cycle and Data Integrity Issues

- Record and data lifecycle
- Understanding complete data / information and raw data
- Controls for paper and electronic records
- Scanning and destroying paper records

Electronic Document Management and Change Control Systems to Ensure Data Integrity

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

Data Integrity and Digital Signatures

- 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

- 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

USP<1029> Good Documentation Practice

- Key points of the current version
- Where does the general chapter fit with regulatory and industry guidance documents
- Proposed update for USP <1029>

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

- 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 I: **Designing a Good Documentation Practice** SOP
Workshop II: **Document Control Process Flow**

- Develop an SOP for document control
- Identify the dos and don'ts for both paper and electronic records

How to Train Staff in Good Documentation Practice and Data Integrity

- 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

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

- Learning from the worst: the FDA annual list of 483 observations
- Identifying the top 5 documentation failures from the list
- Suggestions to avoid getting a citation in your facility

Management and Control of Multilingual Documents (Data Integrity Expectations)

- 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 over 30 years and has nearly 40 years experience with CSV. He is the author of Data Integrity and Data Governance: Practical Implementation for Regulated Laboratories.

Stephan Dresen, Ph.D.
D|Consulting GmbH, Germany
Stephan Dresen is Managing Partner and General Manager of D|Consulting GmbH, Germany. He has more than 20 years of leadership experience in quality in the pharma industry. Until end of 2024 he was Executive Director / Head of Quality Control at Daiichi Sankyo Europe. Prior to that he was Director Quality / Regional Head of Quality at Warner Chilcott / Allergan, Corden Pharma and Abbott / AbbVie.

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.

Social Event

On the evening of the first day, 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.

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Reservation Form (Please complete in full)

Good Documentation Practice and Data Integrity, 01 – 03 April 2025, Heidelberg, Germany

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 %.

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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). 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
Tuesday, 01 April 2025, 9.00 – 17.30 h
(Registration and coffee 8.30 – 9.00 h)
Wednesday, 02 April 2025, 8.30 – 17.00 h
Thursday, 03 April 2025, 8.30 – 13.45 h
All times are mentioned in CEST.

Venue
NH Collection Heidelberg
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Fees (per delegate, plus VAT)
ECA Members € 2,090
APIC Members € 2,190
Non-ECA Members € 2,290
EU GMP Inspectorates € 1,145
The fee is payable in advance after receipt of invoice and includes lunch/business 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 – or search and register directly at www.gmp-compliance.org under the number 21819.

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.
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