ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Data Integrity Manager

Speakers

Bob McDowall
McDowall Ltd.

Stephan Dresen
Daiichi Sankyo Europe

Data Integrity and Good Documentation Practice

GMP-compliant instructions and records

18 – 20 June 2024 | Vienna, Austria

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
- 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

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: Design of a Document Control 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 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 Controlat 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.

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.

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

_____

_____

_____

_____

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49(0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Data Integrity and Good Documentation Practice, 18 – 20 June 2024, Vienna, Austria

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 %.

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 HEIDELBERGwill 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 cancellation 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). 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, 18 June 2024, 9.00 – 18.00
(Registration and coffee 8.30 – 9.00)
Wednesday, 19 June 2024, 8.30 – 17.45
Thursday, 20 June 2024, 8.30 – 13.00

Venue
Doubletree by Hilton Vienna Schönbrunn
Schlossallee 8
1140 Vienna, Austria
Phone +43/1/89110
Email info@doubletree-schonbrunn.at

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 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.

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

For questions regarding content please contact:
Ms Anne Günster (Operations Director) at
+49(0)62 21/84 44 50, or per e-mail at
guenster@concept-heidelberg.de

For questions regarding organisation etc. please contact:
Ms Sonja Nemec (Organisation Manager) at
+49(0)62 21/84 44 24, or per e-mail at
nemec@concept-heidelberg.de.