ECA Academy
Your GMP/GDP Information Source

Data Integrity and Good Documentation Practice

GMP-compliant instructions and records

SPEAKERS:

Bob McDowall
McDowall Ltd., UK

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All participants get a free copy of the current version of the ECA „Data Governance and Data Integrity for GMP Regulated Facilities" Guidance

9 – 11 April 2019, Barcelona, Spain

LEARNING OBJECTIVES:

- 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

This education course is recognised for the ECA GMP Certification Programme „Certified Data Integrity Manager".
Please find details at www.gmp-certification.eu

Data Integrity and Good Documentation Practice

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Objectives

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 form.

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

Overview of the Training Seminar

Data Integrity Principles

- Basements of Data Integrity
- Guidelines
- Implementation of Data Integrity Standards at a Side (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 on industry 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 from 1993 and 2016
- Process for creation of master templates
- Process for operational use of blank forms
- Reconciliation mechanisms

Facilitated Discussion: Control of Templates and Blank Forms

Records – Life Cycle and data integrity issues

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

GMP compliant document change management

- 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

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 is 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: Design of a Document Control SOP

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

- 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)

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

Speakers

Dr. Bob McDowall, *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 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., *Warner Chilcott Deutschland GmbH/An Allergan Company, Germany*
Stephan Dresen is Director Quality at Warner Chilcott Deutschland GmbH / Allergan plc. where he is responsible for the site in Germany and global Sponsor for QA/QC IT Systems. Before that he was Head of Quality, External Operations (TPM). Besides that he is also Managing Director at D|Consulting GmbH, dealing with pharmaceutical and medical knowledge management. He studied Chemistry and Linguistics and got his Ph.D. from Trinity College in Dublin, Ireland

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.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
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69007 Heidelberg
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Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

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

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Date

Tuesday, 9 April 2019, 9.00 – 17.45
(Registration and coffee 8.30 – 9.00)
Wednesday, 10 April 2019, 8.30 – 17.45
Thursday, 11 April 2019, 8.30 – 13.45

Venue

Barceló Sants Hotel
Plaça dels Països Catalans, s/n
08014 Barcelona, Spain
Phone +34 (93) 503 53 00
email sants@barcelo.com

Fees (per delegate plus VAT)

ECA Members € 1,790
APIC Members € 1,890
Non-ECA Members € 1,990
EU GMP Inspectorates € 995
The conference fee is payable in advance after receipt of invoice and includes conference documentation, social event on the first day, lunch on all days and all refreshments. VAT is reclaimable.

Accommodation

CONCEPT 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.

Social Event

In 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.

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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