



Including Implications of
EU-GMP Chapter 4

Document Management

GMP Requirements and Best Practice

20–21 April 2015, Prague, Czech Republic

SPEAKERS:

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LEARNING OBJECTIVES:

- GMP Needs
- Paper – Hybrid - Electronic
- Raw Data
- Multilingual Documents and Translations
- Periodic Document Review
- Digital Signature
- XML
- Archiving



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Objectives

Learn how to implement, optimise and efficiently establish a GMP-compliant Document Management System through specialised lectures and examples. For this, various possibilities will be presented, like for example management via simple databases, handling of hybrid forms or methods, and full electronic document management. This will be discussed also in the light of the revised chapter 4 of the EU-GMP Guide and FDA's emphasis on data integrity under CPG 7346.832.

Background

Documentation is an essential element of every GxP-relevant activity. Indeed, various documents are necessary to define precisely what has to be done, how it has been performed and which results have been created. This gives rise to large quantities of paper and electronic data - which must be reviewed, properly organised and managed efficiently. **The new chapter 4 of the EU-GMP Guide** requires a „system of documentation“ as part of a Quality Management System (QMS) to ensure the accuracy, the completeness and the proper control of all documents. According to this chapter “Good documentation constitutes an essential part of the quality assurance system and is key to operating in compliance with GMP requirements.”

It must be noted that documents aren't created for the inspector but for the company to gather comprehensive documentation about its procedures and workflows and also for control and traceability purposes.

Target Audience

This Education Course is directed at all those employees who are responsible for the creation and the management of GMP relevant documents and who are searching for implementation and optimisation possibilities.

Programme

An Introduction to Pharmaceutical Documentation

- GMP requirements
- The implications of EU-GMP Chapter 4
- The interface to EU-GMP Chapter 11
- Recommendations

Presentation and Discussion of EU GMP Chapter 4 Document Types

- Documents in quality control, quality assurance, manufacturing, IT, engineering
- Forms and templates

Definition of Raw Data: what you need to know

- EU and FDA requirements
- How to define raw data
- Data integrity
- Raw data management

Efficient Usage of electronic Documentation Management Systems (example Documentum®)

- Customisation and user requirements: what do you really need
- Example: SOP Management

The Management and Storage of Records

- Where to store
- How to store
- Practical implementation and documentation
- Paper-based system vs. hybrid systems vs. electronic system

Paper - hybrid - electronic: what you need to know

- Concept
- Practical implementation
- Paper based system vs. hybrid systems electronic system

Workshop: Periodic Review

- Review of various documents
- Systematic approach
- Concepts
- IT support

Management and Control of multilingual Documents

Part 1: Basics

- Workbench
- Translation
- Synchronisation

Part 2: Implementation and Management

- Responsibilities
- GMP status
- Versions
- Signatures
- Change Control

Digital Signatures

Part 1: Basic requirements

- Definitions
- When and how to use the various electronic signatures
- Technical considerations

Part2: Implementation and Processes

- Workflows
- Delegation

XML -based Document Management

- Possibilities
- Advantages (single source, compliance, ...)
- Challenges (change control, ...)

Workshop: Archiving

- Requirements
- External or internal?
- Database and search algorithm
- How to archive paper
- Retrieval

Documentation

You cannot take part in this event? Just order the documentation at the price of € 380.- + VAT + postage and packing. You can use the registration form for this purpose. Please note: In order to ensure that the documentation is complete, the conference folder will be available not until 2 weeks after the event.

Speakers



Stephan Dresen, Ph.D.

Warner Chilcott Deutschland GmbH/ Actavis PLC Deutschland

Stephan Dresen is Head of Quality at Warner Chilcott Deutschland GmbH. Before that, he was Senior Manager and Head of Global Change Control and Documentation at Abbott. 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.



Bob McDowall, Ph.D.

R.D.McDowall Limited, UK

Bob McDowall is Director of R.D. McDowall Limited, UK and has more than 30 years working experience including 15 years working in the pharmaceutical industry. 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. Bob is the writer of the Questions of Quality (LC-GC Europe) and is a member of the Editorial Advisory Boards of several Journals.

Social Event

On 20 April, 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.



Easy Registration



Reservation Form:
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69007 Heidelberg
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Reservation Form (Please complete in full)

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 - until 2 weeks prior to the conference 10 %
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Date

Monday, 20 April 2015, 09.00h – 18.00h
(Registration and coffee 08.30h – 9.00h)
Tuesday, 21 April 2015, 8.30h – 15.30h

Venue

Corinthia Hotel Prague
Kongresova 1
14069 Prague 4, Czech Republic
Phone +420 (261) 191 111
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Fees (per delegate plus VAT)

ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both 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 with all further information when you have registered for the event. 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.

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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