Including Implications of EU-GMP Chapter 4

Document Management

GMP Requirements and Best Practice

6-7 June 2013, Prague, Czech Republic

SPEAKERS:

Stephan Dresen
Warner Chilcott

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LEARNING OBJECTIVES:

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

ECA
EUROPEAN COMPLIANCE ACADEMY

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

Document Management

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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.

Moderator

Wolfgang Schmitt

Programme

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

GMP-relevant Documents: an Overview
- Documents in quality control, quality assurance, manufacturing, IT, engineering
- Forms and templates

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

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

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

Social Event

On 6 June, 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.

Speakers

Stephan Dresen, Ph.D.
Warner Chilcott GmbH, Germany
Stephan Dresen is Head of QA External Operations Europe at Warner Chilcott. 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.

Dr Bob McDowall
McDowall Consulting, UK
Bob McDowall is Principal of McDowall Consulting, 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 (LCGC Europe) and and is a member of the Editorial Advisory Boards of several Journals.

Wolfgang Schmitt
Concept Heidelberg, Germany
Before Wolfgang Schmitt started as Director Operations at Concept Heidelberg in 2006, he worked for Abbott. He was Head of Quality Management at SOLIQS (Abbott's global Drug Delivery Business Unit) and later an Associate Director and Qualified Person at Abbott's Global Pharmaceutical Research and Development QA, where he was responsible for GMP/GLP-Compliance.

Documentation

You cannot take part in this event? Just order the documentation at the price of € 180.- + 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.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

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:

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

D-69007 Heidelberg
GERMANY

+ 49 6221 84 44 34

Reservation Form (Please complete in full)

Document Management
6-7 June 2013, Prague, Czech Republic
☐ Mr. ☐ Ms.

Title, first name, surname

Company | Department

Important: Please indicate your company's VAT ID Number | **Purchase Order No. (if applicable)**

Street/P.O. Box

City | Zip Code | Country

Phone/Fax

E-Mail (please fill in)

☐ We order the course documentation at the price of € 180.- + VAT + postage and packing

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 2 weeks prior to the conference 10 %
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Terms of payment: Payable without deductions within 10 days after receipt of invoice.
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Date

Thursday, 6 June 2013, 09.00h – 18.00h
(Registration and coffee 08.30h – 9.00h)
Friday, 7 June 2013, 8.30h – 15.30h

Venue

Corinthia Hotel Prague
Kongresova 1
14069 Prague 4, Czech Republic
Phone +(0) 420 261 191 111
Fax +(0) 420 261 225 011

Fees

ECA Members € 1,490.- per delegate plus VAT
APIC Members € 1,590.- per delegate plus VAT
(does not include ECA membership)
Non-ECA Members € 1,690.- per delegate plus VAT
EU GMP Inspectorates € 845.- per delegate plus VAT
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

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per e-mail at w.schmitt@concept-heidelberg.de.
For questions regarding reservation, hotel, organisation etc.: Mr Ronny Strohwald (Organisation Manager) at
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