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ECA
European Compliance Academy

SPEAKERS

DR JOHANNA EISELE
Evonik Röhm GmbH, Germany

KEVIN MCGLUE
Colorcon, UK

KARL METZGER
gmPlan GmbH, Germany

DR IAIN MOORE
Croda, United Kingdom

DR BERND RENGER
European QP Association

ALLAN WHISTON
QA Resolutions Ltd
United Kingdom

GMP and GDP for Pharmaceutical Excipients

Supplier qualification, formalised risk-based approaches, certification schemes and auditable standards

15 – 16 October 2013, Prague, Czech Republic

HIGHLIGHTS:

- GMP and GDP for Pharmaceutical Excipients – an update on regulatory aspects
- Suitable GMP and formalised risk assessment of Excipients and Excipient Manufacturers
- Risk based excipients supplier qualification – view of a QP
- GMP compliant manufacturing of a pharmaceutical excipient – a case study
- Excipients certification - schemes and auditable standards

Supported by

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QP ASSOCIATION

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

GMP and GDP for Pharmaceutical Excipients

15 - 16 October 2013, Prague, Czech Republic

Objectives

This course is designed to explain the particularities of pharmaceutical excipients manufacturing and distribution and gives an overview on GMP and GDP requirements appropriate for excipients. **Specialists from the pharmaceutical industry and excipients manufacturers** will share their **expert knowledge** on all important aspects relevant for producers and users of pharmaceutical excipients.
You will learn

- how suitable GMP and GDP standards for excipients may look like
- how to use risk considerations as a key point of supplier qualification
- how excipients can be classified and
- which auditable standards and certification schemes can be used

In parallel workshops you will elaborate and discuss case studies and practical examples.

Background

With the implementation of the EU Directive 2001/83/EC into national law, all active pharmaceutical ingredients used in pharmaceutical manufacturing must be produced in compliance with current Good Manufacturing Practice (cGMP). However due to the considerable complexity of the supply chains GMP and GDP requirements for excipients should be appropriate and not simply mirror those developed for active pharmaceutical ingredients. The fifth paragraph of Article 47 of Directive 2001/83/EC provides that "The Commission shall adopt guidelines on the formalised risk assessment for ascertaining the appropriate good manufacturing practice for excipients..." These guidelines are referred to in the second paragraph of point (f) of Article 46 of the Directive.

Quite recently the Commission has published such Guidelines. The manufacturing authorisation holders have now to determine the risk profile of the excipients used in their drug products and of the excipients manufacturer where they purchase the excipients. Based on this a control strategy has to be established in order to manage and mitigate the risks of use of the excipients.

Target Audience

This course addresses to employees and senior staff of pharmaceutical companies and manufacturers of excipients and raw materials as well as traders. The course is of particular interest to all those working in quality assurance, quality control laboratories, production and purchasing departments.

Programme

GMP and GDP for Pharmaceutical Excipients – Regulatory Aspects and Legal Initiatives

- Why do we need GMP for pharmaceutical excipients?
- GMP and GDP Guidelines for pharmaceutical excipients
- Risks related to distribution of pharmaceutical excipients and the role of traders and brokers
- Focus of GMP inspections at excipients manufacturers
- Future regulations for pharmaceutical excipients in the EU

Risk Management for Pharmaceutical Excipients Manufacturers

- ICH Q9 – Quality Risk Management
- How to establish a risk management process
- Key parameters
- Project Management – from scratch to GMP compliance
- Good Storage / Transportation Practice

Suitable GMP for Pharmaceutical Excipient Manufacture

- Difficulties in regulating excipients
- What is an appropriate GMP for excipients?
- Comparison with GMP for APIs (ICH Q7)
- GMPs for continuous processing
- Key points for distribution controls
- Suitable Guidance – IPEC PQG and GDP Guide

Risk-based Excipients Supplier Qualification – a QP Perspective

- The Qualified Person's role in Supplier Qualification
- Risk-based excipients classification & qualification requirements
  - Type and chemical class
  - Possible impurities & microbiological considerations
  - Intended use of the excipients
  - Type and dosage form of the drug product
- Audits and the role of the QP

Excipients Certification - Schemes and Auditable Standards

- Why excipients certification?
- Excipient classification
- Key principles of the Excipients Certification Project
- 3rd Party Auditing
- Excipient GMP & GDP Certification Scheme

Meeting the Requirements for GMP-compliant Manufacturing of a Pharmaceutical Excipient – A Case Study

- Key points and minimum requirements of the QA system
- Customers' GMP expectations
- Where to start GMP within the manufacturing process
- Risk identification and assessment
- Auditing and auditable standards
- Examples

Parallel Workshops

Please choose one out of two parallel workshops

- **Workshop 1**
  Using the Risk Assessment Guideline to ascertain the appropriate excipient GMP

- **Workshop 2**
  Risk management for pharmaceutical excipients manufacturers - practical examples

In these two workshops the participants will have the opportunity to work on practical examples. The elaborated solutions will be presented and discussed

Suitable Quality Agreements in Pharmaceutical Excipients Supply

- Why quality agreements?
- Objectives and contents of Quality Agreements
- Negotiations of Quality Agreements – who should be involved?
- Quality agreements with distributors and manufacturers
- Quality agreements and commercial agreements

Auditing for GMP Compliance

- General auditing considerations
- Basic requirements for excipient GMP inspections
- Quality-critical processing steps
- Audit check points
- Auditor competency
- Suitable Guidance for auditing excipient manufacturers – the Joint IPEC-PQG GMP Audit Guideline

Speakers

Dr Johanna Eisele, *Evonik Röhm GmbH, Germany*
Dr. Johanna Eisele is Head of Regulatory Affairs, Pharma Polymers, an Evonik business line that manufactures acrylic copolymers for use in oral and dermal dosage forms. Amongst other duties her responsibility includes negotiation of quality agreements with pharmaceutical customers and introducing such agreements into the supply chain with the distributors of Pharma polymer products. Dr Johanna Eisele represents Evonik Röhm Pharma Polymers at the IPEC Europe.

Kevin McGlue, *Colorcon Ltd., United Kingdom*
Mr Kevin McGlue is Director, Global Quality Assurance of Colorcon Ltd. with overall responsibility for all QA activities worldwide. He is a former member of the Board of IPEC Europe, was a member of the IPEC team that produced the 2001 revision of their Excipient GMP guide and was a member of the team responsible for the production of the latest joint IPEC / PQG Excipient GMP guide. He is also a past chair of the IPEC Europe GMP committee.

Karl Metzger, *gmPlan GmbH, Germany*
Karl Metzger is Managing Partner of gmPlan GmbH. He is APIC certified ICH Q7 Auditor and has more than 15 years experience in global auditing of chemical, biotechnological and pharmaceutical manufacturers. Previous to his current position he held appointments with BASF Pharma, Concept Heidelberg, Euroengineering and finally with Welding as Management responsible for the company's integrated Management System and deputy QP for APIs. Furthermore Karl was vice chairman of FECC's 'Good Trade and Distribution Committee'.

Dr Iain Moore, *Croda Europe Ltd., UK*
Dr Iain Moore is Product and Quality Assurance Manager at Croda Europe Ltd, a manufacturer of speciality and performance chemicals. He is one of the co-authors of the IQA PQG PS 9100:2002 guide for pharmaceutical excipients, the IPEC-PQG GMP Guide for Pharmaceutical Excipients and the EFfCI GMP Guide 2005 for Cosmetic Ingredients. Currently he is Excipients Certification Project Coordinator.

Dr Bernd Renger, *European QP Association, Germany*
Dr Bernd Renger is a member of the ECA Advisory Board and Past Immediate Chairman of the European QP Association. Since 2011, he is running his own consultancy business. Before that he was Director of Quality Control at Vetter Pharma-Fertigung. He started his career at Hoechst AG as a research and development chemist. Since then, he has held several quality positions at Mundipharma, Altana Pharma and Baxter.

Allan Whiston,
QA Resolutions Ltd, United Kingdom
Mr Allan Whiston is a professionally qualified Quality Practitioner (CQP) and Chartered Engineer (CEng) with 40 years' experience in the Pharmaceutical Industry. As a past Chair and current member of the IPEC Europe GDP Committee, he has developed and co-authored IPEC's GDP Guide and GDP Audit Guideline. He is member of the PQG and has played a key role in the development of the new EXCIPACT Certification Standard.

Social Event

On 15 October, 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:
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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

GMP and GDP for Pharmaceutical Excipients, 15 - 16 October 2013, Prague, Czech Republic
Please choose **one** parallel workshop

☐ Workshop 1 Using the Risk Assessment Guideline to ascertain the appropriate excipient GMP
☐ Workshop 2 Risk management for pharmaceutical excipients manufacturers - practical examples

☐ Mr ☐ Ms

Title, first name, surname

Company | Department

Important: Please indicate your company's VAT ID Number | **P.O. Number (if applicable)**

Street/P.O. Box

City | Zip Code | Country

Phone/Fax | E-Mail (please fill in)

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

CONCEPT HEIDELBERG
P.O. Box 101764
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D-69007 Heidelberg
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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.
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- until 2 weeks prior to the conference 10 %
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

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Date

Tuesday, 15 October 2013, 9.00 – 16.45 h
(Registration and coffee 8.30 – 9.00 h)
Wednesday, 16 October 2013, 8.15 – 16.30 h

Venue

Corinthia Hotel Prague
Kongresova 1
14069 Praha 4
Czech Republic
Phone +420 (261) 191 111
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Fees

ECA Members € 1,590.- per delegate plus VAT
IPEC Members € 1,690.- per delegate plus VAT
QP Association Members 1,690.- per delegate plus VAT
APIC Members € 1,690.- per delegate plus VAT
Non-ECA Members € 1,790.- per delegate plus VAT
EU GMP Inspectorates € 895.- 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 when you have registered for the event. Please use this form for your room reservation to receive the specially negotiated rate for the duration of your stay. 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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