ECA ACADEMY

Meet the requirements of the new Guidelines on the formalised risk assessment for excipients!

How to qualify Pharmaceutical Excipients Suppliers

Risk-based approaches, certification schemes and auditable standards

12 – 13 May 2015, Heidelberg, Germany

SPEAKERS

JOHANNA EISELE
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Corden Pharma, Germany

KEVIN MCGLUE
Colorcon, UK

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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

QP ASSOCIATION

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

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Objectives

This course is designed to explain the particularities of pharmaceutical excipients manufacturing and distribution and gives an overview on appropriate GMP and GDP 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 to consider the requirements of the new guideline on the formalised risk assessment and how to implement them
- 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

According to the EU Directive 2001/83/EC all active pharmaceutical ingredients used in pharmaceutical manufacturing must be produced in compliance with current Good Manufacturing Practice (cGMP). However due to the complexity of the supply chains GMP and GDP requirements for excipients should be appropriate and not simply mirror those developed for APIs. 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.
In March 2015 the Commission has published such Guidelines entitled *"Guidelines on the formalised risk assessment for ascertaining the appropriate GMP for excipients of medicinal products for human use"* according to which the manufacturing authorisation holders have now to perform a formalised risk assessment 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
- Key requirements of the new Guidelines of the formalised risk assessment

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

- **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.

Please mark your choice on the registration form.

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

Social Event

On 12 May, 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

Dr Johanna Eisele, *Evonik Industries AG, 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 Industries at the IPEC Europe.

Dr Siegmund Kunz, *Corden Pharma, Germany*
Dr Kunz is Head of Quality, Compliance & SHE, Member of Executive Management of Corden Pharma GmbH in Plankstadt, Germany and since 2014 Director Compliance of Corden Pharma International GmbH. He has many years of experience as a leader in both project and line management and is registered as Qualified Person since 2005.

Kevin McGlue, *Colorcon Ltd., UK*
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'.

Heidelberg – Optimal Accessibility via Frankfurt

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Train
You can get on the train directly at the airport. Trains leave up to two times per hour and it takes less than one hour to get to Heidelberg.
www.bahn.de

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:

Reservation Form (Please complete in full)

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How to qualify Pharmaceutical Excipients Suppliers
12 – 13 May 2015, Heidelberg, Germany
Please choose ONE Workshop Session:
☐ Workshop 1: Determining the excipient GMP required using a risk assessment
☐ Workshop 2: Quality risk management in the manufacture of a pharmaceutical excipient

☐ 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

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CONCEPT HEIDELBERG
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2. If you have to cancel entirely we must charge the following processing fees: Cancellation
- until 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %,
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Date

Tuesday, 12 May 2015, 9.00 – 17.45 h
(Registration and coffee 8.30 – 9.00 h)
Wednesday, 13 May 2015, 9.00 – 16.00 h

Venue

Crowne Plaza Heidelberg
Kurfürstenanlage 1
69115 Heidelberg, Germany
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Fees (per delegate plus VAT)

ECA Members € 1,590
QP Association Members € 1,690
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 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

ECA has entrusted Concept Heidelberg with the organisation of this event.

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