Appropriate GMP for pharmaceutical Excipients
A risk-based approach to qualify suppliers and the supply chain

SPEAKERS:

Dr Johanna Eisele
Evonik Industries AG, Germany

Ralf Gengenbach
Gempex, Germany

Dr Martin Melzer
Chemengineering Business Design GmbH, Germany

Dr Bernd Renger
Immediate Past Chair of the European QP Association; Renger Consulting, Germany

Rico Schulze
GMP/GDP Inspectorate, Germany

15 – 16 November 2016, Prague, Czech Republic

HIGHLIGHTS:

- The European Guideline on the formalised risk assessment for ascertaining the appropriate GMP for excipients
- Performing a formalised risk assessment
- Quality agreements in pharmaceutical excipients supply
- How to keep the oversight of complex supply chains
- Audits at excipients manufacturing sites
- What to do when an audit is not possible
- Authorities expectations regarding GMP/GDP for pharmaceutical excipients

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

This course addresses the principles of appropriate GMP and GDP as laid down in the European Guideline on the formalised risk assessment for ascertaining the appropriate GMP for excipients. It aims to explain how to implement these principles to meet the requirements of the Guideline and the authorities’ expectations. Specialists from the industry and authority will share their expert knowledge on all important aspects with respect to appropriate GMP/GDP for pharmaceutical excipients.

You will learn
- how appropriate GMP and GDP standards for excipients should look like,
- how to perform a formalised risk assessment for pharmaceutical excipients,
- how Quality Agreements between excipients suppliers and customers should be designed,
- how the oversight of complex supply chains can be kept and what to do when an audit is not possible,
- what authorities expect regarding excipients qualification.

In a workshop you will elaborate a risk assessments on 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. The course is of particular interest to all those working in quality assurance, quality control laboratories, production and purchasing departments.

Programme

The European Guideline on appropriate GMP for Excipients – an introduction
- History & Scope
- Legal & International context (USP, WHO, other organizations)
- Risk Analysis: GMP-requirements of excipient versus GMP-capability of excipient manufacturer

How to perform a formalised risk assessment
- Step-by-Step practical approach
- Ongoing risk review of excipient manufacturer & supplier
- Embedding the Formalized Risk Assessment in overall context of existing supplier risk assessment

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

Suppliers, brokers, vendors – how to keep the oversight from supply chain mapping to qualification
- Understand your excipient’s history
- How to get information about excipient supply chains
- What if...
- Rational qualification approaches

Audits at Excipients manufacturing sites
- General auditing considerations
- Basic requirements for excipient GMP inspections
- Quality-critical processing steps
- Audit check points
- Audits at sites in Far East – what has to be considered?

What to do when an audit is not possible (or necessary)
- Do we really always have to audit?
- How to use the formalised risk assessment
- Reliable sources of information
- EXCIPIACT™ and other initiatives
Appropriate GMP and GDP for pharmaceutical excipients – authorities’ expectations

- Legal background of the guideline
- Why do we need a European Guideline on a formalised risk assessment of Excipients?
- Consequences of the Guideline
- What does a GMP inspector expect of the Manufacturing Authorisation Holder?

**Workshop:**
Performing Formalized Risk Assessments on practical examples

In this workshop the participants will have the opportunity to work on practical examples and elaborate risk assessments for various excipients. The elaborated solutions will be presented and discussed.

**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.

**Ralf Gengenbach**  
*gemex, Germany*  
Mr Gengenbach is founder and managing director of gemex Co. Ltd., Germany. He is member of different organisations, among others DIN UA2 (Board for standards ‘biotechnology’), of DECHHEMA and ISPE. He is approved Quality Auditor according to DIN ISO 9000ff.

**Dr Martin Melzer**  
*Chemengineering Business Design GmbH, Germany*  
Dr Martin Melzer is Senior Consultant GMP Compliance. Before that he was GMP Inspector in a German Field Inspectorate in Hannover. During that time he was representing the German inspectorates in EMA and PIC/S Working Groups for the preparation of the new GDP-Guidelines. He was heading the GDP Expert Group of the German GMP inspectors from 2008 up to 2011. Before that he was working at Solvay Pharmaceuticals GmbH and a company of the Diapharm Group.

**Dr Bernd Renger**  
*Bernd Renger Consulting, Germany*  
Dr Bernd Renger is a member of the ECA Advisory Board and was Chairman of the European QP Association. Since 2011 he is running his own consultancy business. Before that he was VP 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 management positions at Mundipharma, Altana Pharma and Baxter BioScience.

**Rico Schulze**  
*GMP Inspectorate, Local Authorities Dresden, Germany*  
Rico Schulze is a Pharmacist and holds a degree in Economics. Since 2003, he is GMP and GDP Inspector at the Local Inspectorate in Dresden. From 2008 to 2011 he was working at the Saxon State Ministry of Social Affairs. He is also the Head of the German Authorities’ Radiopharmaceuticals Working Group.

**Social Event**

On 15 November 2016, 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, and colleagues from other companies in a relaxed atmosphere.
**Reservation Form**

**Appropriate GMP for pharmaceutical Excipients**

15 – 16 November 2016, Prague, Czech Republic

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Important: Please indicate your company's VAT ID Number

Street/P.O. Box

City  Zip Code  Country

Phone  Fax  E-Mail (please fill in)

**Date**

Tuesday, 15 November 2016, 9.00 – 17.30 h  
(Registration and coffee 8.30 – 9.00 h)

Wednesday, 16 November 2016, 8.30 – 13.00 h

**Venue**

Hotel InterContinental Prague  
Parizska 30  
110 00 Prague 1, Czech Republic  
Phone  +420 296 631 111  
Fax  +420 224 810 071

**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 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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For questions regarding reservation, hotel, organisation etc.:  
Ms Susanne Ludwig (Organisation Manager) at +49-(0)62 21/84 44 44, or per e-mail at ludwig@concept-heidelberg.de

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1. Your registration for the conference involves the following obligations:
2. If you have to cancel or are unable to attend the conference:
   - You can cancel your participation until 2 weeks prior to the conference free of charge.
   - From 2 weeks to 1 week prior to the conference, 50% of the conference fee will be charged.
   - From 1 week to 0 days prior to the conference, 100% of the conference fee will be charged.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.

Terms of payment: Payable without deductions within 10 days after receipt of invoice.

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