ECA Academy
Your GMP/GDP Information Source

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
Chemgineering 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 Managerr".
Please find details at www.gmp-certification.eu

Appropriate GMP for pharmaceutical Excipients

15 – 16 November 2016, Prague, Czech Republic

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 e**xpert 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
- EXCiPACT™ 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.

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.

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

Dr Martin Melzer
Chemgineering 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.

Easy Registration

Reservation Form:
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69007 Heidelberg
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+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

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www.gmp-compliance.org

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

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Reservation Form (Please complete in full)

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☐ 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

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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 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
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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 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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