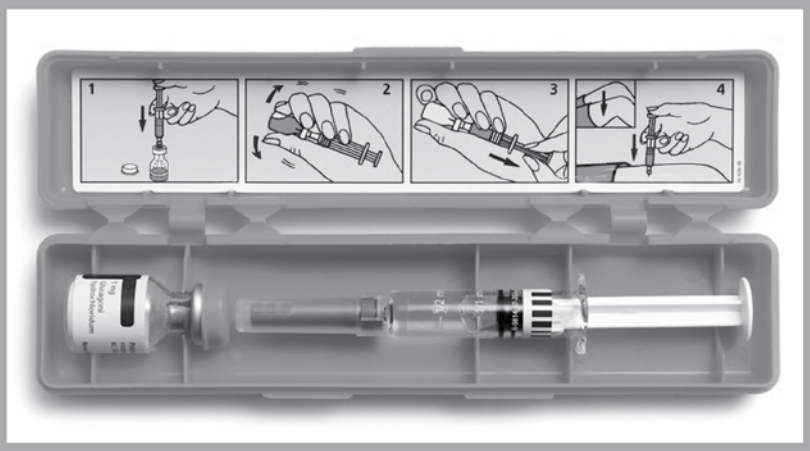

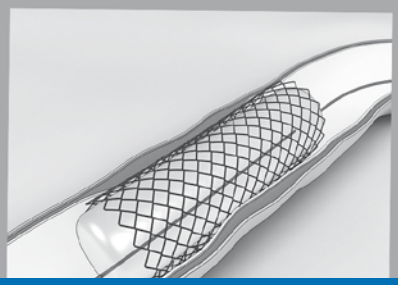

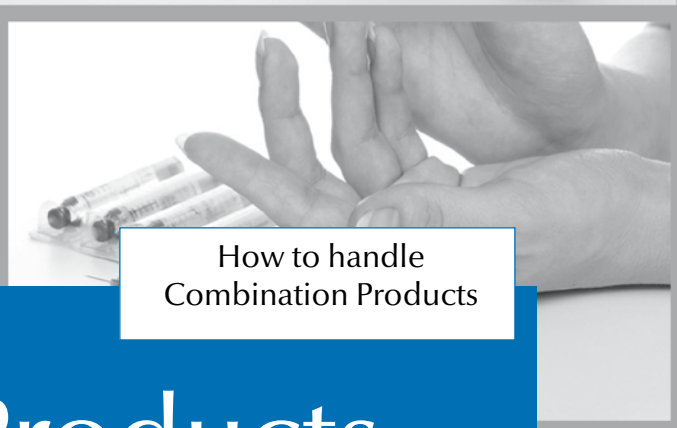

How to handle Combination Products

Combination Products

Medicinal Products /Drugs meet Medical Devices

5 - 6 April 2016, Munich, Germany

SPEAKERS:

Dr Heinrich Prinz
Apceth GmbH & Co. KG

Harald Rentschler
mdc, medical devices certification GmbH

Dr Andrea Weiland-Waibel
Explicat GmbH

LEARNING GOALS:

- Regulatory Requirements Medicinal Products/Drugs
- Regulatory Requirements Medical Devices
- How to get a Combination Product on the market?
- QM System for Combination Products
- Case Study: Registration of a Combination Product
- Workshops:
  - Approval of Combination Products in the EU and US
  - Notified Body requirements on Combination Products

ECA ACADEMY

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

Combination Products

5 - 6 April 2016, Munich, Germany

Objectives

The aim of the course is to identify similarities and differences between FDA´s and European regulations for Combination Products.

During the course speakers will cover the various regulatory requirements for Medicinal Products/ Drugs and Medical Devices and present their similarities and differences. How to launch a Combination Product on the market will also be part of the presentations. Moreover Case Studies about approval procedures of combination products will give practical orientation. It is also important to know which QM system fits the US and the EU requirements and what their similarities are? Also this topic will be discussed.

A **Notified Bodies** representative will explain the EU certification procedure for Medical Devices.

3 parallel workshops – concentrating on approval processes of Combination Products in the EU and the US and examples of Notified Body requirements on Combination Products will provide practical orientation.

Background

Combinations of Medicinal Products/Drugs, Medical Devices and/or Biologics are becoming more and more important for the market, e. g. for the delivery of a medication. Such "Combination Products" meet two worlds: the pharmaceutical regulation world and the world of the Medical Devices Regulations.

In the EU the GMP requirements for Medicinal Products are laid down in the GMP Guideline based on an EC regulation from 2003. The medical devices industry is regulated by three EU directives (90/385/EWG, 93/42/EWG and 98/79/EG) and one amending directive. The distribution of Medical Devices in Europe is based on a CE Certification. Medical Devices Inspections are primarily performed by Notified Bodies.
The basis for the approval process of Medicinal Products /Drugs is for both the EU and the USA the ICH Common Technical Document (CTD). Inspections are performed by authorities. In the USA, there are special approval processes for Medical Devices.

The US-FDA has developed own GMP regulations for Drugs (21 CFR 210/211) , Medical Devices (21 CFR 820), Biologics (21 CFR 600 – 680) and tissue-based products (21 CFR 1271) So far, there had been no standalone GMP regulations for combination products. This has changed only at the FDA since 22 July 2013 with the publication of FDA's 21 CFR Part 4 (cGMP Requirements for Combination Products). An Office of Combination Products is responsible for this products in the USA. Until now, there is nothing comparable to 21 CFR 4 regarding Combination Products in the EU.

Target Audience

This event has been especially designed for the manufacturers who are subject to Combination Products and want to become familiar with the **practice-oriented implementation** of the legal requirements in the USA AND in Europe.

Moderator

Dr Heinrich Prinz, Apceth GmbH & Co. KG, Germany

Programme

Regulatory Requirements regarding Medicinal Products / Drugs

- European Directive about GMP
- EU GMP Guide
- Guide to Inspections of/ Guidances for Industry
- Office of Combination Products
- Marketing Authorisation
- Regulatory Supervision

Regulatory Requirements regarding Medical Devices in the USA

- 21 CFR 800ff
- Guide to Inspections of/ Guidances for Industry
- Classification EU vs USA
- Marketing Authorisation in the USA

How to launch a Combination Product on the market? Combination Product

- 21 CFR 210/211/600ff vs 21 CFR 800ff
- Guide to Inspection of/Guidances for Industry
- Classification of Medical Devices in the USA
- Marketing Authorisazion in the USA
- "Combination product"- 21CFR 3.2 e in the US-versus "combination products" in the EU
- What do medical device companies need to know about medicinal products what does the pharmaceutical industry need to know about medical devices how to develop a combination – if the combination product is a single entity, or as a unit co-packaged ("kit"), or also available separately
- The medicinal product "container or primary packaging" versus the medical device containing a medicinal product
- The importance of the primary mode of action (US) and the intended use (Europe)

QM-System for Combination Products

- Quality Management System for Drugs
- Quality Management System for Medical devices
- Similarities and differences
- Qualifying of Suppliers
- Quality Management System for the combination of Medicinal Products with a Medical Devices

Crossmatrix EU/USA

- Comparision of EU/FDA Requirements

Case Studies
Approval Process for Combination Products in the EU

- Case Study for a single entity "combination" product – a medical device containing a drug substance having an ancillary action
- Case Study for an investigational medicinal product to be combined with a CE marked medical device (nebulizer)
- Case Study – drug eluting stents – requirements regarding the in vitro- in vivo correlation of the sustained release drug substance in carrier

3 Parallel Workshops

- **Comparison of the Requirements for Combinations Products to be distributed in Europe and the US Market.**
  Similarities and Differences of the Regulatory Requirements and the Quality Management System to be followed and implemented.
- **Approval of Combination Products in the EU**
  The workshop is intended to lay down the basis for a strategy for a „combination product" taking into account the fact, that in the EU the regulatory frames of medical devices, medical devices containing a drug substance having an ancillary action and medicinal products and the respective quality management systems have to be taken into consideration.

  Two cases will be studied:
  1. A medicinal product having a marketing authorization shall be combined with a medical device in development. How can this be accomplished? What needs to be done, where are possible pitfalls?

  2. A medical device marked with a CE shall be combined with a medicinal product that is authorized for marketing. What needs to be done, where are possible pitfalls?
- **Notified Body requirements on Combination Products**
  The workshop is intended to assess examples of Notified Body audit findings and how to react.

Speakers

Dr Heinrich Prinz
Apceth GmbH & Co KG, Munich

Dr Prinz worked with Boehringer Mannheim before he joined Biotest. Until recently he was Head of Quality Assurance, responsible for both the pharmaceutical and the medical device division of Biotest AG. Since 2003 he works as a freelance consultant and part of his time he is the Senior Supervisor of Quality Control and Quality Assurance System of Apceth GmbH & Co KG.

Harald Rentschler
mdc medical device certification GmbH

Mr Rentschler is a Biomedical Engineer and since more than 17 years performing conformity assessment activities for medical devices. He is General Manager of mdc medical device certification GmbH, a Notified Body with broad experience in the field of medical devices and in-vitro diagnostic devices. Mr Rentschler is a member of national and international working groups in the field of medical devices and quality system certification.

Dr Andrea Weiland-Waibel,
Explicat Pharma GmbH, Hohenbrunn

Dr Weiland is a Ph.D. pharmacist in pharmaceutical technology (Ludwig-Maximilians-University Munich). After several leadership positions within Pfizer in production and development, she worked as Director Pharmaceutical Development at IDEA AG, a biotechnology company in Munich. She is since 2005 a founder and managing director of Explicat Pharma GmbH and specializes in CMC (Chemistry-Manufacturing-Controls) - Technical Project management for pharmaceutical development projects.

Social Event

On 5 April 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.

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)

Combination Products
5 - 6 April 2016, Munich, Germany

Please choose ONE workshop:
☐ Approval of Combination Products in the US
☐ Approval of Combination Products in the EU
☐ Notified Body requirements on Combination Products

☐ Mr ☐ Ms

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number **PO Number if applicable**

Street/P.O. Box

City Zip Code Country

Phone Fax

E-Mail (please fill in)

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

D-69007 Heidelberg
GERMANY

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 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

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.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of January 2012)

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date

Tuesday, 5 April 2016, 09.00 – 18.00 h
(Registration and coffee 08.30 – 09.00 h)
Wednesday, 6 April 2016, 08.30 – 15.30 h

Venue

Holiday Inn Munich -City Centre
Hochstraße 3
81669 Munich, Germany
Tel +49 (0)89 - 4803 0
Fax +49 (0)89 – 448 7170

Fees (per delegate plus VAT)

ECA Members € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845
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 r egistered for the conference. 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 /Contact

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

CONCEPT HEIDELBERG
P.O.Box 10 17 64
69007 Heidelberg, Germany,
Phone +49(0)62 21/84 44-0
Fax +49(0)62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Mr Sven Pommeranz (Operations Director) at +49(0)62 21/84 44 47, or at pommeranz@concept-heidelberg.de.

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