ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified QA Manager

Speakers

Harald Rentschler
mdc, medical devices certification

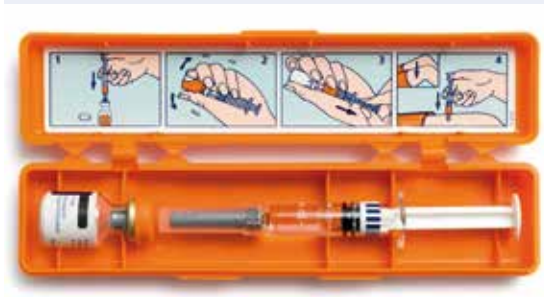
Dr Peer Schmidt
AbbVie

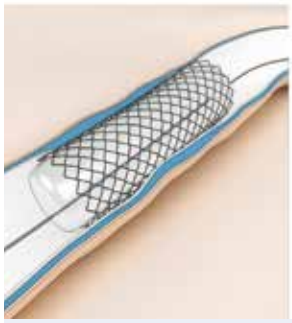
Dr Andrea Weiland-Waibel
Explicat

Combination Products

Medicinal Products/Drugs meet Medical Devices

11/12 February 2025 | Heidelberg, Germany





Highlights

- Regulatory Requirements Medicinal Products/Drugs
- Regulatory Requirements Medical Devices
- Classification of Medical Devices in the USA
- How to get a Combination Product on the market?
- QM System for Combination Products
- Case Study: Registration of a Combination Product
- Workshops:
  - Application of Quality Risk Management to Combination Products
  - Approval of Combination Products in the EU
  - Notified Body requirements on Combination Products
  - Primary Packaging

How to handle Drug-Device Combinations

Objective

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 EU regulation. The medical devices industry was regulated by three EU directives and one amending directive in the past. The Medical Device Regulation has changed this in 2021. 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.

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

Classification of Medical Devices in the USA

- How to classify Medical Devices in the USA
- Examples

How to Launch a Combination Product on the Market?

- "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
- 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 Device

Workshop on Primary Packaging Material vs. Medical Devices

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

Human Factors/Application of Usability Engineering to Medical Devices EN 62366-1

- Usability Norm EN 62366

Cross-Matrix EU/USA

- Comparision of EU/FDA requirements

3 Parallel Workshops

- **Application of Quality Risk Management to Combination Products**
  You discuss in the workshop risk management aspects regarding the medicinal product and medical device.

- **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

Harald Rentschler
mdc medical device certification GmbH

Mr Rentschler is a Biomedical Engineer and since more than 25 years involved in regulatory requirements regarding 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 member of national and international working groups in the field of medical devices and quality system certification.

Dr Peer Schmidt
AbbVie Deutschland GmbH & Co. KG, Ludwigshafen

Peer Schmidt brings more than 15 years of experience in the development, manufacturing, registration and supervision of Medicinal Products, Medical Devices and Combination Products. As Senior Manager Global Quality Systems, he leads the AbbVie Center of Excellence for Quality Risk Management. He also acts as EU Authorized Representative and Management Representative for AbbVie´s Medical Devices. He holds a Ph.D. in Molecular Biology and was previously the Head of Quality Assurance at Abbott Biotechnology Germany.

Dr Andrea Weiland-Waibel
Explicat Pharma GmbH

Dr Weiland is a Ph.D. pharmacist in pharmaceutical technology. After several leadership positions within Pfizer and IDEA AG she now is managing director of Explicat Pharma GmbH and specialises in CMC (Chemistry-Manufacturing-Controls) - Technical Project management for pharmaceutical development projects.

Social Event

In the evening of the first day, 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.

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CONCEPT HEIDELBERG
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Fax +49 6221 / 84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Combination Products on 11/12 February 2025 in Heidelberg, Germany

Please choose one of the following Workshops

☐ *Application of Quality Risk Management to Combination Products.*
☐ *Approval of Combination Products in the EU*
☐ *Notified Body requirements on Combination Products*

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

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 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks prior to the conference 100 %.

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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 July 2022).
German law shall apply. Court of jurisdiction is Heidelberg.

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, 11 February 2025, 09.00 - 18.15 h
(Registration and coffee 08.30 - 09.00 h)
Wednesday, 12 February 2025, 08.30 - 15.30 h

Venue
NH Collection Heidelberg
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nhcollectionheidelberg@nh-hotels.com

Fees (per delegate, plus VAT)
ECA Members € 1,890
APIC Members € 1,990
Non-ECA Members € 2,090
EU GMP Inspectorates € 1,045
The conference fee is payable in advance after receipt of invoice and includes 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/POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration
Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 21645.

Conference language
The official conference language will be English.

Presentations / Certificate
The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

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