ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified QA Manager

Speakers

Harald Rentschler
mdc, medical devices certification GmbH

Dr Peer Schmidt
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Combination Products

Medicinal Products/Drugs meet Medical Devices

Live Online Training on 23/24 February 2021

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

How to handle Combination Products

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.

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. The medical devices industry is regulated now by an EU Medical Device Regulation (2017/745) 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 Factor Studies

- Usability Norm EN 62399

Crossmatrix EU/USA

- Comparision of EU/FDA Requirements

Q & A sessions

Three Q &A sessions (two on day 1 and one on day 2) ensure interaction and that your questions are answered.

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.

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Reservation Form (Please complete in full)

Combination Products, Live Online Training on 23/24 February 2021

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:
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Date Live Online Training

Tuesday, 23 February 2021, 09.00 – 17.30 h
Wednesday, 24 February 2021, 08.30 – 12.45 h

Technical Requirements

For our webinars, we use Cisco WebEx, one of the leading suppliers of online meetings.
At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members € 1,290
APIC Members € 1,390
Non-ECA Members € 1,490
EU GMP Inspectorates € 745
The conference fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance.

Organisation and Contact

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

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