ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified QA Manager

Speakers

Dr Gerhard Bauer
Bauer-Lewenz Consulting

Harald Rentschler
mdc medical device certification GmbH

Dr Heinrich Prinz
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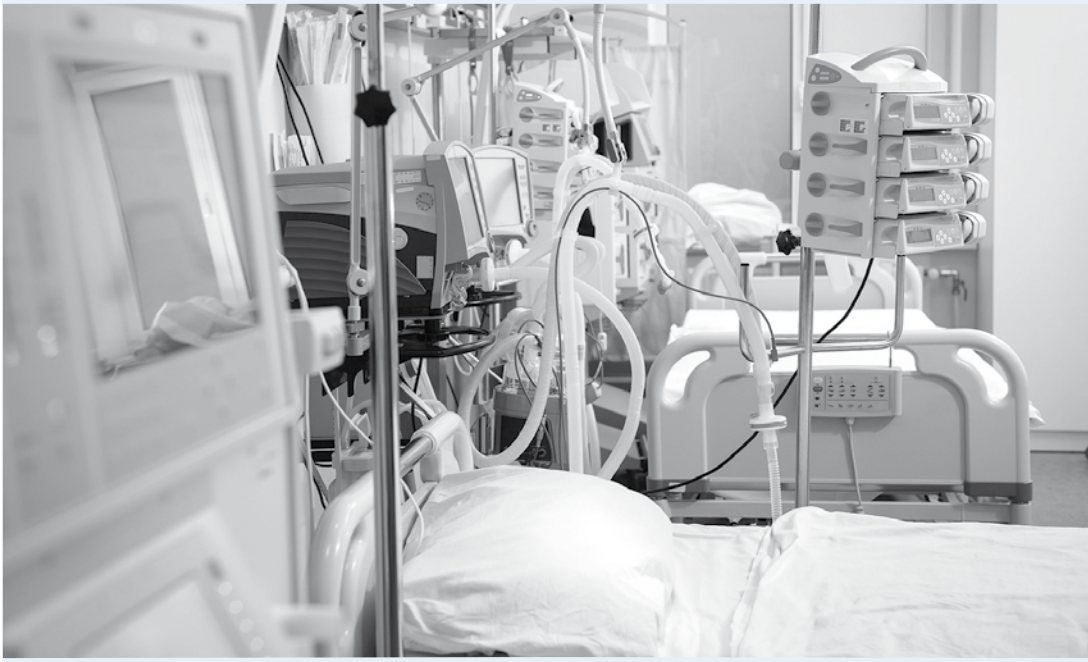
GMP for Medical Devices

EU versus USA

13/14 October 2020 | Heidelberg, Germany



Highlights

- Similarities/Differences Medical Devices/Medicinal Products
- Certification Procedure Under the European MDR
- Classification Rules and Submission
- GMP-Related Requirements of EN ISO 13485:2016
- Technical Documentation
- Combination Products
- Design Controls
- Validation /Qualification
- Regulatory Audits Under MDR and MDSAP
- CAPA and Complaint Handling

NEW: Update regarding EU Medical Device Regulation and ISO 13485:2016 Revision

Objective

The aim of the course is to identify similarities and differences between the regulations of the FDA and the European regulations for Medical Devices. The focus will be on

- Classification Rules and Submission in the USA
- Certification Procedures
- Technical Documentation vs Device History File and Device Master Record
- Combination Products
- Design Controls
- Validation / Qualification
- Regulatory Audits
- CAPA and Complaint Handling

A **Notified Bodies representative** will start the course by explaining the regulatory requirements, **especially regarding the new EU Medical Device Regulations.**

3 Parallel Workshops

concentrating on technical documentation, classification and submission and audit findings, will provide practical orientation:

Documentation
How to structure a technical documentation

Classification and Submission of Medical Devices in the USA
How to classify and submit Medical Devices in the USA?

Preparing for an Audit according to the New European MDR
For two examples of medical devices relevant sections of the new European MDR will be analysed in order to identify the main audit items, which contain new or enhanced requirements.

Background

Since 1996, the requirements for the development, the manufacture and the distribution of medical devices in the USA have been laid down in the revised cGMP regulations for Medical Devices (21 CFR 820, QSR). In the USA, medical devices are regulated by the FDA's Center for Devices and Radiological Health (CDRH). Inspections are primarily performed by the FDA.

In Europe, three EU directives (90/385/EWG, 93/42/EWG and 98/79/EG) and one amending directives regulate the medical devices industry. In May 2020, the new Medical Device Regulation will come into force. GMP regulations - strictly speaking - are not notified.

Instead, harmonised standards, especially ISO 13485, represent the state-of-the-art in the area of the EU. Inspections are primarily performed by Notified Bodies („New Approach for Product Regulations and Conformity Assessment").

With the revision of the ISO 13485 in 2016 there are also new ("GMP"-) requirements.

Statistical data about deficiencies of medical devices do only exist in the USA because of the Freedom of Information Act. For years now, CAPA/Complaint Handling, insufficient Design Controls, Management Responsibility, Process Controls and Process Validation and Quality Audits have been among the Top 10 deviations.

Target Audience

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

Programme

Overview about similarities/differences between Medicinal Products and Medical Devices

- Regulatory Submission
- Guidelines
- Supervision

Certification Procedure under the European MDR

- Economic Operators
- Classification of medical devices
- Selection of certification procedure
- Certification by Notified Bodies

Differences between EU and FDA Requirements

- European Requirements
- FDA Requirements
- Differences and common interests

Classification and Premarket Submission of Medical Devices in the USA

- Classification rules in the USA
- IDE
- 510k, PMA
- De novo, HDE

GMP-Related Requirments of EN ISO 13485:2016

- Role of ISO 13485:2016
- Documented procedure
- Key requirements

Technical Documentation vs. DHF/DMR

- Content of Technical Documentation
- Technical Documentation as a linking document between production and quality control
- Change Management – Retests
- Content of the DHF
- Relation to the DMR
- Link to Technical Documentation
- Audit and inspection findings

Combination Products

- The Guidance for Industry and FDA Current Good Manufacturing Practice for Combination Products – an overview
- Combination products in the EU – Guidelines and Definitions
- How to classify the combination product
- Conformity assessment
- The consultation procedure

Design Controls

- Introduction of regulatory requirements
- Common aspects/differences regarding the requirements of the ISO 13485 and 21 CFR 820
- How to implement Design Controls in the whole life cycle process
- Modern concepts of development of products
- Audit and inspection findings

Qualification and Validation

- Regulatory requirements (FDA, Standards, GHTF)
- Risk assessments
- Qualification
- Validation
- Audit and inspection findings

Regulatory Audits under MDR and MDSAP

- Purpose of the MDSAP
- DSAP Audtiting Organizatons
- Focus point on regulatory audits
- Unannounced audits by Notified Bodies

CAPA/Complaint Handling

- Regulatory requirements (EU, FDA, Standards, GHTF)
- Common aspects/differences regarding the requirements of the ISO 13485 and 21 CFR 820
- New ISO 13485:2016 requirements
- CAPA – the motor for continuous improvement
- Monitoring as a subsystem
- Interface complaint handling /CAPA System
- Audit and inspection findings

All participants will get a link to the Medical Device Warning Letter Navigator. This link will lead you to:

- The Medical Device-associated FDA and GHTF Guidelines with regard to Quality as pdf files
- EU Medical Device-Directives and MedDevDocuments
- All Medical Device-associated FDA Warning Letters since 2002.

PLUS the document **„Essential Requirements Validation of Processes for Production and Service Provision (including Software)"** developed by the Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices (ZLG) – English translation. This 8 pages document aims at reaching a common understanding of validation of processes, including validation of software among notified bodies, manufacturers and the competent authorities, and at defining uniform requirements on the validation of processes to be met by the manufacturers and on the auditing of these processes by notified bodies or certification authorities.

Speakers

Dr Gerhard Bauer
Bauer-Lewenz Consulting, Germany

Dr Bauer has more than 25 years of professional experience in the Life Science Industry. He has experience as project manager, Head of Controlling, Head of Procurement, external and internal consulting (GMP Compliance), Audits of pharmaceuticals, medical devices, and API manufacturers in the EU, Asia, and the US. After 12 years with the Fresenius Group he served as consultant and manager with the Chemgineering Group since 2004 and works as freelance consultant since 2019.

Harald Rentschler
mdc medical device certification GmbH, Germany

Mr Rentschler is a Biomedical Engineer and since more than 22 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 Heinrich Prinz
PDM-Consulting, Germany

Dr Prinz worked with Boehringer Mann-heim before he joined Biotest where he was Head of Quality Assurance, responsible for both the pharmaceutical and the medical device division. Since 2003 he works as a freelance consultant.

Participant's comment (October 2019)
„One of the best courses I attended."
Nicolas Bonhoure, PhD, Sunstar Suisse SA, Switzerland

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GERMANY

Reservation Form (Please complete in full)

GMP for Medical Devices, 13/14 October 2020, Heidelberg, Germany

Please choose ONE workshop:

☐ *Workshop 1 Technical Documentation*
☐ *Workshop 2 Classification and Submission of Medical Devices in the USA*
☐ *Workshop 3 Preparing for an Audit According to the New European MDR*

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:
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- Cancellation within 1 week prior to the conference 100 %.

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German law shall apply. Court of jurisdiction is Heidelberg.

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Date
Tuesday, 13 October 2020, 09.00 – 18.00 h
(Registration and coffee 08.30 – 09.00 h)
Wednesday, 14 October 2020, 08.30 – 16.30 h

Venue
Hotel Chester Heidelberg
SRH Hotel Handels- und Betriebs GmbH
Bonhoefferstraße 10
69123 Heidelberg, Germany
Phone +49(0)6221 9983 700
Email reservations@chester-heidelberg.de

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/POG when you have registered for the conference. Reservation should be made directly with the hotel.
Early reservation is recommended.

Social Event
In the evening of the first course 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.

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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