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
**Programme**

### 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 directive 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 Requirements 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 Auditing 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

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 Mannheim 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
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)

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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.
2. If you have to cancel entirely we will charge the following processing fees:
   - Cancellation until 12 weeks prior to the conference 50 %
   - Cancellation 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)!

German law shall apply. Court of jurisdiction is Heidelberg.

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Conference language

The official conference language will be English.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this 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.

Early registration is recommended.

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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.

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Social Event

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)!

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Venue

Hotel Chester-Heidelberg
SRH Hotel Handels- und Betriebs GmbH
Bonhoefferstraße 10
69123 Heidelberg
Germany

Phone +49(0)6221/3983700
Email reservations@chester-heidelberg.de

Venue (Registration and coffee 08.30 – 09.00 h)

Date

Tuesday, 13 October 2020, 09.00 – 16.30 h

Wednesday, 14 October 2020, 08.30 – 16.30 h

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Fees (per delegate, plus VAT)

- ECA Members € 1,490
- APIC Members € 1,590
- Non-ECA Members € 1,690
- EU GMP Inspectorates € 845
- APIC Members € 1,590
- Non-ECA Members € 1,690
- ECA Members € 1,490

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For questions regarding reservation, hotel, organisation etc. please contact:
Mr Ronny Strohwald (Organisation Manager) at
+49(0)6221/844451 or at
strohwald@concept-heidelberg.de.

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For questions regarding content please contact:
Mr Sven Pommeranz (Operations Director) at
+49(0)6221/844470 or at
pommeranz@concept-heidelberg.de.

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

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The conference fee is payable in advance after receipt of invoice and includes conference documentation, refreshments on the first day, lunch on both days and all meals.

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