EU versus USA

01 - 02 October 2019, Berlin, 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

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

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

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
- 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. Soon 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 also new (“GMP”) requirements will come.

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

Three add-ons for free

1. FDA Medical Device Warning Letter Navigator on USB-Stick
   - All participants receive the Medical Device Warning Letter Navigator. This USB-Stick contains:
     - The Medical Device-associated FDA and GHTF Guidelines with regard to Quality as pdf files
     - EU Medical Device-Directives and MedDev Documents
     - All Medical Device-associated FDA Warning Letters since 2002.

2. You will also receive the document „Validation of Processes for Production and Service Provision (including Software) - Essential Requirements“ developed by the Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices (ZLG) – English translation. This 8 page 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.

3. Change Control SOP
   - All delegates receive an example of a Change Control SOP with a Change Control Flowchart and a Change Application Form.

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.
Speakers

Dr Gerhard Bauer  
Chemineering Business Design GmbH  
Dr Bauer has more than 20 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. Since 2004 he is Head of the Business Unit Consulting of the Chemineering Group.

Harald Rentschler  
mdc medical device certification GmbH  
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.
Date

Tuesday, 01 October 2019, 09.00 – 18.00 h
(Registration and coffee 08.30 – 09.00 h)
Wednesday, 02 October 2019, 08.30 – 16.30 h

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone +49 (0)30 212 7 - 0
Email berlin@steigenberger.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 when you have registered for the event. 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 and Contact

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

CONCEPT HEIDELBERG
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For questions regarding content please contact:
Mr Sven Pommeranz (Operations Director) at +49-62 21/84 44 47, or per e-mail at pommeranz@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc. please contact:
Mr Ronny Strohwald (Organisation Manager) at +49-62 21/84 44 51, or per e-mail at strohwald@concept-heidelberg.de

GMP/GDP In-house Training Courses

Are you interested in a GMP/GDP training course at your facility for a larger group of people?

We offer practice-oriented GMP/GDP training courses on:

- Basic GMP
- APIs (ICH Q7)
- Medicinal Products
- Biopharmaceuticals
- Quality Assurance
- Quality Control
- Validation/Qualification
- Regulatory Affairs
- Sterile Manufacturing
- IT / Computer Validation
- Good Distribution Practice (GDP)
- Data Integrity

You will find a time schedule for each training course at www.gmp-compliance.com, button “Inhouse Training”

We also offer in-house training courses for Qualified Persons. Please contact us for more information: info@gmp-compliance.org

We will be happy to design further GMP training courses for you on request.
Reservation Form (Please complete in full)

**GMP for Medical Devices, 01 - 02 October 2019, Berlin, Germany**

Please choose ONE workshops:
- 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

- [ ] Mr.
- [ ] Ms.

Title, first name, surname

Company

Department

Important: Please indicate your company’s VAT ID Number

Purchase Order No. (if applicable)

Street/P.O. Box

City  Zip Code  Country

Phone/Fax

E-Mail (please fill in)

If the bill-to-address deviates from the specifications on the right, please fill out here:

**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 2 weeks prior to the conference 10%
     - until 1 week 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 confirm 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.

**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隱私.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.