EU versus USA
6-7 November 2018, Copenhagen, Denmark

HIGHLIGHTS:

- Similarities/Differences Medical Devices/Medicinal Products
- Regulatory Requirements Under Consideration of the New European MDR
- Classification Rules and Submission
- Certification Procedures Under Consideration of the New European MDR
- Technical Documentation
- Combination Products
- Design Controls
- Validation /Qualification
- Regulatory Audits
- 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
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

Regulatory Requirements
- European Directives
- FDA
- Standards
- 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

CE and ISO Certification under the Consideration of the new EU MDR
- Requirements of the EC/EU Directives
- Use of Standards
- ISO 13485 as a basic norm
- Implementing a system
- Certification Procedures
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

Audits

- Preparing for an Audit
- Performance of an Audit
- Nuts and bolts of an Audit
- The Audit report

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  
Chemgineering 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 Chemgineering 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  
Apceth GmbH & Co. KG, 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 and part of his time he is the Senior Supervisor ‘Production and Quality Assurance’ at Apceth, a biotech company.
**Date**

Tuesday, 06 November 2018, 09.00 – 18.00 h
(Registration and coffee 08.30 – 09.00 h)
Wednesday, 07 November 2018, 08.30 – 16.30 h

**Venue**

RadissonBLU Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S, Denmark
Phone +45 33 96 50 00
Scandinavia.meetings.events@radissonblu.com

**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.

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**Organisation and Contact**

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

CONCEPT HEIDELBERG
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For questions regarding content:
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.:
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, 6-7 November 2018, Copenhagen, Denmark

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)

CONCEPT HEIDELBERG
P.O. Box 101764
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D-69007 Heidelberg
GERMANY

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

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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 2 weeks prior to the conference 10 %
     - until 1 week prior to the conference 50 %
     - within 1 week prior to the conference 100 %
   - Terms of payment: Payable without deduction 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 do not appear at the event without having informed us, you will have to pay the full registration fee. If you have not paid the payment yet, your registration will be cancelled.

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