

# GMP for Medical Devices

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

## SPEAKERS:



**Dr Gerhard Bauer**  
*Bauer-Lewenz Consulting,  
Germany*



**Harald Rentschler**  
*mdc, medical devices  
certification GmbH*



**Dr Heinrich Prinz**  
*PDM-Consulting*



## 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

### Also for free:

- FDA Medical Device Warning Letter Navigator on USB-Stick
- Validation of Processes for Production and Service Provision (including Software) - Essential Requirements



# GMP for Medical Devices

01 - 02 October 2019, Berlin, Germany

## Objectives

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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

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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

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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

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### 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 Organizations
- 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

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#### 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

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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

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**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 Chemengineering Group since 2004 and works as freelance consultant since 2019.



**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.



## Easy Registration

 **Reservation Form:**  
**CONCEPT HEIDELBERG**  
P.O. Box 10 17 64  
69007 Heidelberg  
Germany

 **Reservation Form:**  
+ 49 6221 84 44 34

 **e-mail:**  
info@concept-heidelberg.de

 **Internet:**  
www.gmp-compliance.org

### Date

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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

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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)

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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

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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

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Via the attached reservation form, by e-mail or by fax message. Or you register online at [www.gmp-compliance.org](http://www.gmp-compliance.org).

### Conference Language

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The official conference language will be English.

### Organisation and Contact

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

CONCEPT HEIDELBERG  
P.O. Box 10 17 64  
69007 Heidelberg, Germany  
Phone +49-62 21/84 44-0  
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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

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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](http://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](mailto:info@gmp-compliance.org)

We will be happy to design further GMP training courses for you on request.

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

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

CONCEPT HEIDELBERG

P.O. Box 101764

Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg

GERMANY

**Important: Please indicate your company's VAT ID Number**

**Purchase Order No. (if applicable)**

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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:

- until 2 weeks prior to the conference 10 %
- until 1 weeks 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 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)! (As of January 2012) 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\\_privacy.html](http://www.gmp-compliance.org/eca_privacy.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.

