ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified QA Manager

Speakers

Dr Gerhard Bauer
Bauer-Lewerenz Consulting

Harald Rentschler
mdc medical device certification

Dr Cornelia Siegl
Marinomed Biotech

Jesper Wagner
NIRAS

ISO 13485 Requirements for Medical Devices

Comparison to GMP

Live Online Training on 25/26 November 2025

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

EU versus USA

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.**

In the further presentations particular attention will be paid to findings made during FDA inspections. **Where possible, there will be links between ISO 13485 and GMP.**

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 2026 this will change and the ISO 13485 will become state of the art also in the USA. 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 used to regulate the medical devices industry. Since May 2021, the new Medical Device Regulation has been in 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

- Medical devices versus medicinal products – the key differences
- 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 define a combination product in the EU and US
- Roles of Competent Authorities (CA) and Notified Bodies (NB)

Design Controls

- Introduction of regulatory requirements
- Common aspects/differences regarding the requirements of the ISO 13485 and 21 CFR 820
- New ISO 13485:2016 requirements
- 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

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, Regulations 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.

Regulatory Audits under MDR and MDSAP

- Purpose of the MDSAP
- MDSAP Auditing Organisations
- 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

Q&A sessions

Four Q &A sessions (two on day 1 and day 2) ensure interaction and that your questions are answered

Speakers

Dr Gerhard Bauer
Bauer-Lewerenz 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 Cornelia Siegl
Marinomed Biotech AG, Austria
Dr Siegl holds a PhD in chemistry and has been working for Marinomed since 2015. She was a project manager for 5 years and is now Head of Solv4U, Marinomed´s partnership program. Cornelia is author of different scientific articles.

Jesper Wagner
NIRAS, Denmark
Jesper Wager holds a M.Sc in Chemical Engineering and is an IRCA certified auditor. He is a senior consultant and has more than 24 years experience from production and project execution within the life science industry (e.g. medical devices, IVDs, pharmaceuticals, APIs and IT/Automatisation), both domestic and international.

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CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
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Reservation Form (Please complete in full)

ISO 13485 Requirements for Medical Devices, Live Online Training on 25/26 November 2025

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.
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- Cancellation until 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
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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 July 2022).
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). 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.

Date of the Live Online Training

Tuesday, 25 November 2025, 09.00 – 16.30 h
Wednesday, 26 November 2025, 08.30 – 17.15 h
All times mentioned are CET.

Technical Requirements

We use Webex for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. Webex is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members € 2,090
APIC Members € 2,190
Non-ECA Members € 2,290
EU GMP Inspectorates € 1,145
per delegate plus VAT. The conference fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 22043.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

You cannot attend the Live Event?

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

Organisation and Contact

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

CONCEPT HEIDELBERG
P.O.Box 10 17 64
69007 Heidelberg, Germany
Phone +49(0)62 21/84 44-0
Fax +49(0)62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Mr Sven Pommeranz (Operations Director) at
+49(0)62 21/84 44 47, or at
pommeranz@concept-heidelberg.de.

For questions regarding organisation please contact:
Mr Max Bauer (Organisation Manager) at
+49(0)62 21/84 44 25, or at
bauer@concept-heidelberg.de.