

Speakers



Dr Gerhard Bauer
Bauer-Lewerenz Consulting



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mdc medical device certification



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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

NEW: ISO 13485/GMP Matrix
available for download

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.

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 Chemengineering 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.



For practical assistance:
ISO 13485/GMP Matrix available for download

The matrix compares the ISO 13485 requirements with GMP-requirements regarding EU GMP Guideline Part I for medicinal products

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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		
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Phone / Fax		
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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/recording.

Organisation and Contact

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

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