medídee®

Medidee Services SA
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Training Catalog

From basic knowledge to advanced understanding, Medidee offers a wide variety of trainings within its different locations (Switzerland, Germany, Denmark, Belgium).

For each topic, duration can vary from a half day to two days depending on the level of coverage. The duration set below is for trainings delivered at Medidee premises.

Topics	Objectives	Duration
MDR Overview	Understand the key changes ongoing in the European regulatory framework of MDR. Be able to analyze the new regulatory requirements and their impact on product portfolio. Be ready to outline a transition plan to MDR compliance.	1 day
IVDR Introduction	Understand the key changes ongoing in the European regulatory framework of IVD. Be able to analyze the new regulatory requirements and their impact on product portfolio. Be ready to outline a transition plan to IVDR compliance.	½ day
ISO 13485:2016 Requirements for regulatory purposes	Identify the impact of the changes in 13485:2016. Understanding of the requirements through concrete examples of implementation. Understand the difference between ISO 13485:2016 and ISO 9001:2015.	1 day
QSR implementation (USA Regulation)	Understand the US requirements VS ISO 13485 for MD and IVD's manufacturers. Understand the objectives of the FDA.	1 day
Regulatory pathway workshop introduction	Workshop designed to help you to identify the key steps for regulatory pathway definition for a new product.	½ day
Active Medical Devices – What needs to be considered?	Know the CE-Marking procedure for an active medical device Understand the relationship between standards of standard family IEC/EN 60601 Know which documents are relevant for IEC/EN 60601 evaluation and what to look for.	½ day
Clinical Evaluation MEDDEV 2.7/1 rev.4	Understand the key concept of Clinical Evaluation requirements.	1 day
General CER writing	Understand the key components of a CER structure.	½ day
GCP – Clinical investigations for MD	Develop clinical investigations according to Good Clinical Practices. Understand local regulation.	1 day
Internal and Supplier Audit	Understand how to prepare and organize internal and supplier audits. Understand the specificities of supplier auditor and contracts. Be able to classify audit results and generate an audit report.	1 day

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Topics	Objectives	Duration
EN 62304 Software Lifecycle	Understand regulatory considerations on software as a medical device. Understand the key concepts associated with IEC 62304.	1 day
EN 60601 Electrical Requirements	Understand basic electrical & mechanical safety. Understand the risk management related to IEC 60601. Be able to understand test reports for different markets.	1 day
EN 62366 Usability	Identify key usability dimensions in order to understand what needs to be examined. Formalize the usability activities within the design process. Understand how usability shall be verified and validated. Formalize the content of the usability engineering file.	1 day
IFU, UDI and Labels	Understand the requirements, the impact and how to implement the UDI system for EU and USA. Learn how to replace the traditional IFU in a paper format with an e-IFU. Discover how the MDR and the IVDR will impact your device marking, labelling and the IFU.	½ day

This list is not exhaustive, additional topics can be proposed throughout the year.

Training cost per person when delivered at Medidee premises

Full day training incl. course material, certificate, lunch and beverages	CHF 750 / EUR 650
Half day training incl. course material, certificate and beverages	CHF 400 / EUR 350

All costs are excluded VAT

Tailored trainings

Get employees involved to make them aware their role is of great importance for general operations and product regulatory compliance. Medidee's trainer would be pleased to come to your office for dedicated trainings. All of the above topics listed in the Training Catalog can be organized in-house.

In addition, below are examples of company-specific trainings Medidee can deliver:

- ISO 13485 general overview and focus on chapters you want to emphasize
- Sterilization (EO, Gamma, Steam,…)
- Regulatory requirements in a specific market you want to penetrate
- Clinical trial design
- MDSAP
- PMS & Vigilance
- …

Costs

Contact us for a personalized offer: training@medidee.com

General Conditions

Medidee Services SA reserves the right to cancel a training if a minimum of participant is not reached.

Discount: 2-4 participants of a same company: 10% on the total invoice
From 5 participants of a same company, please contact us for a personalized offer.

Cancellation fees: < 24h before: 100% training cost is due
48-72h before: 50% training cost is due