Training Catalog

From basic knowledge to advanced understanding, Medidee offers a wide variety of trainings at Medidee premises (Switzerland, Germany, Denmark and Belgium), online or at the client's site. The duration set below can be tailored to your needs.

Topics	Objectives	Duration
EU Market Access for Medical Devices	Get familiar with the EU Regulation Legislation for Medical Devices (MDR & IVDR). Understand Quality Management System in compliance with ISO 13485:2016	1 day
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 Overview	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.	1 day
Borderline products	The key methods and resources to determine the primary nature of a borderline product. The communication channels and deliverables with regulatory authorities to target product certification.	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. ISO 13485:2016 training can be extended/separated into 2-4h sections to cover the following topics in detail: Quality Management System Architecture, Documentation requirements, Management requirements, Resource management, Product realization, Measurement, analysis, and improvement: CAPA and NC and Management Innovation + deployment overview.	1 day
QMS transition to MDR/ IVDR	Understand key changes introduced by EU regulations (MDR and IVDR); Assess impact on QMS processes; Establish transition plan and implementation.	½ day
QSR implementation (USA Regulation)	Understand the US requirements VS ISO 13485 for MD and IVD's manufacturers. Understand the objectives of the FDA and insights on FDA audit.	1 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. Understand the requirements for cybersecurity, data protection and software development according to IEC 62304.	1 day

Combination products	Regulatory requirements for combination products in the EU and US.	½ day
Active Implantable Medical Device	Define the general regulatory framework of active implantable medical devices, for the EU and the US. Provide high-level considerations in relation to V&V and the criticalities of managing testing at component level and at system level. Identify key area of interaction between R&D and clinical that ensure that clinical inputs are taken into account during the D&D. Show how the regulatory strategy and the clinical strategy are critically interrelated.	½ day
Substance based products	Regulation requirements in EU and US for substance-based products. Impact of the MDR on the medicinal product directive for drug/device combination product.	½ day
Clinical Evaluation of Medical devices under MDR	Understand the MEDDEV 2.7/1 rev.4 medical device regulation – clinical evaluation requirements, key changes and clarifications. Know the MDCG (Medical Device Coordination Group) and its guidance documents in accordance with Article 105 of the MDR.	1 day
Performance Evaluation of IVD under IVDR	Learn how to demonstrate safety and performance according to the intended use. Understand the process by which data are assessed and analyzed to demonstrate scientific validity, analytical and clinical performance.	1 day
GCP – Clinical investiga- tions for MD ISO 14155	Develop and document clinical investigations for Medical Devices according to Good Clinical Practices. Understand local regulation.	1 day
GCP – Clinical investiga- tions for IVD ISO 20916	Develop and document clinical investigations for IVD 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
Impact of the MDR on the medicinal product directive for drug/device combination product	Understand how the development of drug/device combination products (e.g., pre-filled syringes, drug-delivery systems) is impacted by the MDR. Identify the relevant regulations and guidelines. Understand the requirements in terms of design and development process and related documentation. Understand the role of Notified Bodies in the drug approval process and how it impacts project timelines.	1 day
The US regulations for MD	Understand the basis of US MD regulations and main regulatory pathways.	1 day
MDSAP audit program	Understand principles and approach of MDSAP program. Get to know the main requirements of the MDSAP audit processes, the structure and scope. Understand the legal framework for medical devices in MDSAP jurisdictions.	1 day

Risk management for MD and IVD	Understand the approach to safety risk management and the tolls which may be used to facilitate the process. Learn the theoretical aspects and methodologies for risk management.	1 day
Cybersecurity and data protection for MD and IVD	Learn essential safety requirements for MD & IVD including principles of risk management, information security, as well as the minimum requirements concerning IT security measures.	1 day
Regulatory requirements for economic operators (importers, distributors, authorized representatives)	Understand the obligations of importers, distributors and authorized representatives for Medical devices and IVD. Understand the process for handling all aspects of economic operators including criteria for initial selection, evaluation, monitoring and re-evaluation.	½ day
Verification and validation sampling strategy for MD	Understand how to implement a sampling strategy that is supported by adequate (statistical) rationale. Understand the links between risk management activities and sampling strategy.	½ day
EN 62304 Software Lifecycle	Understand regulatory considerations on software as a medical de- vice. Understand the key concepts associated with IEC62304.	1 day
DiGA (Digital Health Applications)	Understand DVG Act Germany; DiGA Fast track process, QMS and TD requirements, specific requirements related to DVG Act, application with BfArM.	½ day
ISMS ISO 27001	Basics of information security and management systems; Introduction to ISO 27000 family; Understand requirements of ISO 27001; certification options	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 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. 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.	1 day
EUDAMED	Understanding EUDAMED and its functional specifications. Interpret EUDAMED data structures, requirements, business rules and data exchange requirements. Impact of EUDAMED on QMS of economic operator	½ day
An introduction to Technical Documentation	Get to know the relevant documents needed to be MDR compliant and learn how to present the information in a clear and comprehensive way.	1 day
PRRC	Understand the regulatory context of PRRC roles and responsibilities; Understand the qualification needed to fulfil the role of PRRC; Registration on EUDAMED; Impact on QMS processes.	½ day

An introduction to Technical Documentation	Get to know the relevant documents needed to be IVDR compliant and learn how to present the information in a clear and comprehensive way.	½ day
PMS overview	Understand the key MDR/IVDR requirements on Post Market Surveillance. Get to know the relevant databases, and what is relevant to report.	½ day
GDPR	Providing an extended understanding of the requirements related to the General Data Protection Regulation (EU) 2016/679 ("GDPR"). The GDPR requirements will be presented in relation to other state legal frameworks. Applicability of GDPR during Clinical Investigations and ISO 14155.	1 day
Market access to UK/Australia/Switzerland and Canada	Understand the main regulatory contexts of UK, Australia, Switzerland and Canada. Have an overview of the requirements to get access to the different markets. Understand the difference in terms of requirements in each country	½ day
Borderline products: key concepts in determining the regulatory pathway of your product	This training is specific to products that have an unclear definition – are they medical devices? Medicinal product? Biologics? This training presents the key methods and sources of information to determining the primary nature of a product, the key communication channels with regulatory authorities, and what are the key deliverables to be used in the communication with regulatory authorities.	½ day
Regulatory framework for AI/ML based medical devices in the US and EU	Brief overview of relevant standards for development and verification of medical device software leveraging AI. Clinical Evaluation of medical device software in the EU.	½ day

This list is not exhaustive, please contact us in case a topic you are interested in is missing.

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 the above topics listed in the Training Catalog can be organized in-house or online.

In addition, Medidee can deliver other company-specific trainings.
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.

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