PECB Certified ISO 13485
Lead Implementer

Master the implementation and management of Medical Devices Quality Management Systems (MDQMS) based on ISO 13485

Why should you attend?

ISO 13485 Lead Implementer training enables you to develop the necessary expertise to support an organization in establishing, implementing, managing and maintaining a Medical Devices Quality Management System (MDQMS) based on ISO 13485. During this training course, you will also gain a thorough understanding of the best practices of Medical Devices Quality Management Systems and be able to improve an organization`s overall performance by consistently providing safe and qualitative medical devices.

After mastering all the necessary concepts of Medical Devices Quality Management Systems, you can sit for the exam and apply for a “PECB Certified ISO 13485 Lead Implementer” credential. By holding a PECB Lead Implementer Certificate, you will be able to demonstrate that you have the practical knowledge and professional capabilities to implement ISO 13485 in an organization.

Who should attend?

- Managers or consultants involved in Medical Devices Quality Management
- Expert advisors seeking to master the implementation of a Medical Devices Quality Management System
- Individuals responsible for maintaining conformance with MDQMS requirements
- MDQMS team members

Course agenda

Duration: 5 days

Day 1 | Introduction to ISO 13485 and initiation of a MDQMS

- Course objectives and structure
- Standard and regulatory framework
- Medical Devices Quality Management System (MDQMS)
- Fundamental principles of quality and medical devices
- Initiating the MDQMS implementation

Day 2 | Plan the implementation of the MDQMS

- Understanding the organization and clarifying the quality objectives
- Analysis of the existing management system
- Leadership and approval of the MDQMS project
- MDQMS scope
- Quality Policy
- Definition of the organizational structure

Day 3 | Day 3: Implementation of a MDQMS

- Definition of the document management process
- Design of controls and drafting procedures
- Communication plan
- Training and awareness plan
- Product Realization
- Operations Management

Day 4 | MDQMS monitoring, measurement, continuous improvement and preparation for a certification audit

- Monitoring, measurement, analysis and evaluation
- Internal audit
- Management review
- Treatment of problems and non-conformities
- Improvement
- Preparing for the certification audit
- Competence and evaluation of implementers
- Closing the training

Day 5 | Certification Exam

Learning objectives

- Acknowledge the correlation between ISO 13485 and other standards and regulatory frameworks
- Master the concepts, approaches, methods and techniques used for the implementation and effective management of a MDQMS
- Learn how to interpret the ISO 13485 requirements in the specific context of an organization
- Learn how to support an organization to effectively plan, implement, manage, monitor and maintain a MDQMS
- Acquire the expertise to advise an organization in implementing Medical Devices Quality Management System best practices

Examination

Duration: 3 hours

The "PECB Certified ISO 13485 Lead Implementer" exam fully meets the requirements of the PECB Examination and Certification Programme (ECP). The exam covers the following competency domains:

Domain 1 | Fundamental principles and concepts of a Medical Devices Quality Management System (MDQMS)

Domain 2 | Medical Devices Quality Management System (MDQMS)

Domain 3 | Planning a MDQMS implementation based on ISO 13485

Domain 4 | Implementing a MDQMS based on ISO 13485

Domain 5 | Performance evaluation, monitoring and measurement of a MDQMS based on ISO 13485

Domain 6 | Continual improvement of a MDQMS based on ISO 13485

Domain 7 | Preparing for a MDQMS certification audit

For more information about exam details, please visit Examination Rules and Policies.

Certification

After successfully completing the exam, you can apply for the credentials shown on the table below.
You will receive a certificate once you comply with all the requirements related to the selected credential.

For more information about ISO 13485 certifications and the PECB certification proces, please refer to the Certification Rules and Policies.

Credential	Exam	Professional experience	MDQMS project experience	Other requirements
PECB Certified ISO 13485 Provisional Implementer	PECB Certified ISO 13485 Lead Implementer Exam or equivalent	None	None	Signing the PECB Code of Ethics
PECB Certified ISO 13485 Implementer	PECB Certified ISO 13485 Lead Implementer Exam or equivalent	**Two years:** One year of work experience in Medical Devices Quality Management	Project activities: a total of 200 hours	Signing the PECB Code of Ethics
PECB Certified ISO 13485 Lead Implementer	PECB Certified ISO 13485 Lead Implementer Exam or equivalent	**Five years:** Two years of work experience in Medical Devices Quality Management	Project activities: a total of 300 hours	Signing the PECB Code of Ethics
PECB Certified ISO 13485 Senior Lead Implementer	PECB Certified ISO 13485 Lead Implementer Exam or equivalent	**Ten years:** Seven years of work experience in Medical Devices Quality Management	Project activities: a total of 1,000 hours	Signing the PECB Code of Ethics
PECB Certified ISO 13485 Master	ISO 13485 Lead Implementer + ISO 13485 Lead Auditor (4 additional foundation exams)	**Fifteen years:** Ten years of work experience in Medical Devices Quality Management	Audit activities: 700 hours Project activities: 700 hours	Signing the PECB Code of Ethics

Note: *PECB Certified Individuals who do possess the Lead Implementer and Lead Auditor Credentials are qualified for the respective* ***PECB Master Credential****, given they have taken 4 additional Foundation Exams which are related to this scheme. For more detailed information about the Foundation Exams and the overall Master Requirements, please go to the following link: https://pecb.com/en/master-credentials.*

General information

- Certification and examination fees are included in the price of the training course
- Training material containing over 450 pages of information and practical examples will be distributed
- A participation certificate of 31 CPD (Continuing Professional Development) credits will be issued
- In case of exam failure, you can retake the exam within 12 months for free