PECB BEYOND RECOGNITION



PECB Certified ISO 13485
Lead Auditor

Master the Audit of Medical Devices Quality Management Systems (MDQMS) based on ISO 13485

Why should you attend?

ISO 13485 Lead Auditor training enables you to develop the necessary expertise to perform a Medical Devices Quality Management System (MDQMS) audit by applying widely recognized audit principles, procedures and techniques. During this training course, you will acquire the necessary knowledge and skills to plan and carry out internal and external audits in compliance with ISO 19011 and the certification process according to ISO/IEC 17021-1.

Based on practical exercises, you will be able to master audit techniques and become competent to manage an audit program, audit team, communication with customers, and conflict resolution.

After acquiring the necessary expertise to perform this audit, you can sit for the exam and apply for a "PECB Certified ISO 13485 Lead Auditor" credential. By holding a PECB Lead Auditor Certificate, you will demonstrate that you have the capabilities and competencies to audit organizations based on best practices.



Who should attend?

- Auditors seeking to perform and lead Medical Devices Quality Management System (MDQMS) certification audits
- Managers or consultants seeking to master a Medical Devices Quality Management System audit process
- Individuals responsible for maintaining conformance with Medical Devices Quality Management System requirements
- Technical experts seeking to prepare for a Medical Devices Quality Management System audit
- Expert advisors in Medical Devices Quality Management

Course agenda

Duration: 5 days

Day 1 | Introduction to Medical Devices Quality Management Systems (MDQMS) and ISO 13485

- Course objectives and structure
- Standards and regulatory frameworks
- Certification process
- Fundamental principles of Medical Devices Quality Management Systems
- Medical Devices Quality Management System (QMS)

Day 2 | Audit principles, preparation and launching of an audit

- Fundamental audit concepts and principles
- Audit approach based on evidence and risk
- Initiating the audit
- Stage 1 audit
- Preparing the stage 2 audit (on-site audit)
- Stage 2 audit (Part 1)

Day 3 | On-site audit activities

- Stage 2 audit (Part 2)
- Communication during the audit
- Audit procedures
- Creating audit test plans
- Drafting audit findings and non-conformity reports

Day 4 | Closing the audit

- Documentation of the audit and its review
- Closing the audit
- Evaluating action plans by the auditor
- Beyond the initial audit
- Managing an internal audit programme
- Competence and evaluation of auditors
- Closing the training

Day 5 | Certification Exam



Learning objectives

- Understand the operations of a Medical Devices Quality Management System based on ISO 13485
- Acknowledge the correlation between ISO 13485 and other standards and regulatory frameworks
- Understand an auditor's role to: plan, lead and follow-up on a management system audit in accordance with ISO 19011
- Learn how to lead an audit and audit team
- Learn how to interpret the requirements of ISO 13485 in the context of a MDQMS audit
- Acquire the competencies of an auditor to: plan an audit, lead an audit, draft reports, and follow-up on an audit in compliance with ISO 19011

Examination

Duration: 3 hours

The "PECB Certified ISO 13485 Lead Auditor" 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 | Fundamental audit concepts and principles

Domain 4 | Preparation of an ISO 13485 audit

Domain 5 | Conducting an ISO 13485 audit

Domain 6 | Closing an ISO 13485 audit

Domain 7 | Managing an ISO 13485 audit program

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 process, please refer to the Certification Rules and Policies.

Credential	Exam	Professional experience	MDQMS audit experience	Other requirements
PECB Certified ISO 13485 Provisional Auditor	PECB Certified ISO 13485 Lead Auditor Exam or equivalent	None	None	Signing the PECB Code of Ethics
PECB Certified ISO 13485 Auditor	PECB Certified ISO 13485 Lead Auditor Exam or equivalent	**Two years:** One year of work experience in Medical Devices Quality Management	Audit activities: a total of 200 hours	Signing the PECB Code of Ethics
PECB Certified ISO 13485 Lead Auditor	PECB Certified ISO 13485 Lead Auditor Exam or equivalent	**Five years:** Two years of work experience in Medical Devices Quality Management	Audit activities: a total of 300 hours	Signing the PECB Code of Ethics
PECB Certified ISO 13485 Senior Lead Auditor	PECB Certified ISO 13485 Lead Auditor 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