PECB CERTIFIED ISO 13485
LEAD AUDITOR

MASTERING THE AUDIT OF MEDICAL DEVICES QUALITY MANAGEMENT SYSTEM (MDQMS) BASED ON ISO 13485, IN COMPLIANCE WITH THE REQUIREMENTS OF ISO 19011 AND ISO 17021-1.

SUMMARY

This five-day intensive course enables the participants to develop the necessary expertise to audit Medical Devices Quality Management System (MDQMS) based on ISO 13485:2016 and to manage a team of auditors by applying widely recognized audit principles, procedures and techniques. During this training, the participant will acquire the necessary knowledge and skills to proficiently plan and perform internal and external audits in compliance with ISO 19011 and certification audits according to ISO 17021-1. Based on practical exercises, the participant will develop the skills (mastering audit techniques) and competencies (managing audit team and audit program, communicating with customers and conflict resolution) necessary to efficiently conduct an audit.

WHO SHOULD ATTEND?

- Internal auditors
- Auditors wanting to perform and lead Quality Management System (QMS) certification audits in the medical device industry
- Project managers or consultants wanting to master Medical Devices Quality Management System audit process
- Individuals responsible for the quality or conformity in an organization
- Members of a quality team
- Expert advisors in Medical Devices Quality Management Systems
- Regulatory affairs managers
- Technical experts wanting to prepare for a quality audit function in the medical device industry

COURSE AGENDA

DURATION: 5 DAYS

DAY 1

Introduction to Medical Devices Quality Management System (MDQMS) concepts as required by ISO 13485

- Normative frameworks and methodologies related to Quality and Medical Devices
- Fundamental principles of Quality and Medical Devices Management
- ISO 13485 certification process
- Medical Devices Quality Management System (MDQMS)
- Detailed presentation of the clauses 4 to 8 of ISO 13485

DAY 2

Planning and initiating an ISO 13485 audit

- Fundamental audit concepts and principles
- Audit approach based on evidence
- Preparation of an ISO 13485 certification audit
- MDQMS documentation audit
- Conducting an opening meeting

DAY 3

Conducting an ISO 13485 audit

- Communication during the audit
- Audit procedures: observation, document review, interview, sampling techniques, technical verification, corroboration and evaluation
- Audit test plans
- Formulation of audit findings
- Documenting nonconformities

DAY 4

Concluding and ensuring the follow-up of an ISO 13485 audit

- Audit documentation
- Quality review
- Conducting a closing meeting and conclusion of an ISO 13485 audit
- Evaluation of corrective action plans
- ISO 13485 surveillance audit
- ISO 13485 internal audit management program

DAY 5

Certification Exam

LEARNING OBJECTIVES

- To acquire expertise to perform an ISO 13485 internal audit following ISO 19011 guidelines
- To acquire expertise to perform an ISO 13485 certification audit following ISO 19011 guidelines and ISO 17021-1 specifications
- To acquire the expertise necessary to manage MDQMS audit team
- To understand the operation of an ISO 13485 conformant Medical Devices Quality Management System
- To understand the relationship between Medical Devices Quality Management System and compliance with customer and regulatory requirements.
- To improve the ability to analyze the internal and external environment of an organization, and audit decision-making in the context of MDQMS

EXAMINATION

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

1 **Domain 1: Fundamental principles and concepts in Medical Devices Quality Management**

Main Objective: To ensure that the ISO 13485 Lead Auditor candidate can understand, interpret and illustrate the main Medical Devices Quality Management concepts related to Medical Devices Quality Management System (MDQMS)

2 **Domain 2: Medical Devices Quality Management System (MDQMS)**

Main Objective: To ensure that the ISO 13485 Lead Auditor candidate can understand, interpret and illustrate the main concepts and components of Medical Devices Quality Management System based on ISO 13485

3 **Domain 3: Fundamental Audit Concepts and Principles**

Main Objective: To ensure that the ISO 13485 Lead Auditor candidate can understand, interpret and apply the main concepts and principles related to MDQMS audit in the context of ISO 13485

4 **Domain 4: Preparation of an ISO 13485 audit**

Main Objective: To ensure that the ISO 13485 Lead Auditor candidate can prepare appropriately MDQMS audit in the context of ISO 13485

5 **Domain 5: Conduct of an ISO 13485 audit**

Main Objective: To ensure that the ISO 13485 Lead Auditor candidate can conduct efficiently MDQMS audit in the context of ISO 13485

6 **Domain 6: Conclusion and follow-up of an ISO 13485 audit**

Main Objective: To ensure that the ISO 13485 Lead Auditor candidate can conclude MDQMS audit and conduct follow-up activities in the context of ISO 13485

7 **Domain 7: Management of an ISO 13485 audit program**

Main Objective: To ensure that the ISO 13485 Lead Auditor understands how to establish and manage MDQMS audit program

- The "Certified ISO 13485 Lead Auditor" exam is available in different languages, including English, French, Spanish and Portuguese
- Duration: 3 hours
- For more information about the exam, please visit: www.pecb.com

CERTIFICATION

- After successfully completing the exam, participants can apply for the credentials of Certified ISO 13485 Provisional Auditor, Certified ISO 13485 Auditor or Certified ISO 13485 Lead Auditor depending on their level of experience. Those credentials are available for internal and external auditors
- A certificate will be issued to participants who successfully passed the exam and comply with all the other requirements related to the selected credential:

Credential	Exam	Professional Experience	QMSMD Audit Experience	QMSMD Project Experience	Other Requirements
ISO 13485 Provisional Auditor	ISO 13485 Lead Auditor Exam	None	None	None	Signing the PECB code of ethics
ISO 13485 Auditor	ISO 13485 Lead Auditor Exam	**Two years** One year of Medical Devices Management work experience	Audit activities totaling 200 hours	None	Signing the PECB code of ethics
ISO 13485 Lead Auditor	ISO 13485 Lead Auditor Exam	**Five years** Two years of Medical Devices Management work experience	Audit activities totaling 300 hours	None	Signing the PECB code of ethics

GENERAL INFORMATION

- Certification fees are included in the exam price
- Participant manual contains over 450 pages of information and practical examples
- A participation certificate of 31 CPD (Continuing Professional Development) credits will be issued to participants
- In case of failure of the exam, participants are allowed to retake it for free under certain conditions