PECB Certified ISO 13485 Foundation

Become acquainted with the best practices of Medical Devices Quality Management Systems (MDQMS) based on ISO 13485

Why should you attend?

ISO 13485 Foundation training enables you to learn the basic elements to implement and manage a Medical Devices Quality Management System (MDQMS) as specified in ISO 13485. During this training course, you will be able to understand the different modules of a MDQMS, including MDQMS policy, procedures, performance measurements, management commitment, internal audit, management review and continual improvement.

After completing this course, you can sit for the exam and apply for the "PECB Certified ISO 13485 Foundation" credential. A PECB Foundation Certificate shows that you have understood the fundamental methodologies, requirements, framework and management approach.

Who should attend?

- Individuals involved in Medical Devices Quality Management
- Individuals seeking to gain knowledge about the main processes of Medical Devices Quality Management Systems (MDQMS)
- Individuals interested to pursue a career in Medical Devices Quality Management

Learning objectives

- Understand the elements and operations of a Medical Devices Quality Management System (MDQMS)
- Acknowledge the correlation between ISO 13485 and other standards and regulatory frameworks
- Understand the approaches, methods and techniques used for the implementation and management of a MDQMS

Course agenda

DURATION: 2 DAYS

- Day 1: Introduction to Medical Devices Quality Management System (MDQMS) concepts as required by ISO 13485
- Day 2: Medical Devices Quality Management System requirements and Certification Exam

Prerequisites

- None

Examination

DURATION: 1 HOUR

The "PECB Certified ISO 13485 Foundation" 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)

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

Certification

Upon the successful completion of the exam, you can apply for the credential "PECB Certified ISO 13485 Foundaion". For more information about ISO 13485 certifications and the PECB certification process, please refer to the Certification Rules and Policies.

General information

- Certification and examination fees are included in the price of the training course
- Training material containing over 200 pages of information and practical examples will be distributed
- A participation certificate of 14 CPD (Continuing Professional Development) credits will be issued
- In case of exam failure, you can retake the exam within 12 months for free