

FOUNDATION PECB CERTIFIED ISO 13485 Course Agenda



Course Overview:

Program Overview:

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

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

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.

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

Prerequisites

- ▶ None

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.

