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.

### Why should you 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

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

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### Course agenda
- 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
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.

### 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

For additional information, please contact us at marketing@pecb.com or visit www.pecb.com