



PECB CERTIFIED ISO 13485 FOUNDATION

BECOME ACQUAINTED WITH THE BEST PRACTICES FOR IMPLEMENTING AND MANAGING MEDICAL DEVICES QUALITY MANAGEMENT SYSTEM (MDQMS) BASED ON ISO 13485

SUMMARY

This course enables participants to learn about the best practices for implementing and managing Medical Devices Quality Management System (MDQMS) as specified in ISO 13485:2016. The participant will learn the different components of MDQMS manual, required procedures, records, measuring performance, management’s commitment, internal audit, management review and maintaining effectiveness.

COURSE AGENDA

Day 1	Introduction to Medical Devices Quality Management System (MDQMS) concepts as required by ISO 13485
Day 2	Implementing requirements from ISO 13485 and Certification Exam PECB Certified ISO 13485 Foundation exam is available in different languages. The candidates who do not pass the exam will be able to retake it for free within 12 months from the initial exam date.

A certificate of PECB Certified ISO 13485 Foundation will be issued to participants who successfully pass the ISO 13485 Foundation Exam:

- ▶ No experience requirements
- ▶ Certification fee is included in the exam price
- ▶ No annual maintenance fee
- ▶ Certified for life

GENERAL INFORMATION

- ▶ Participant manual contains more than 200 pages of information and practical examples
- ▶ A participation certificate of 14 CPD (Continuing Professional Development) will be issued to the participants