

ISO 13485 Foundation

ISO 13485 Foundation (PECB)



About this Course:

- 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.

Course Goals/Skills:

- 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 Format:

<input type="checkbox"/>	<input type="checkbox"/>
Присъствен (Classroom) Курс в Учебната ни зала или В Офис на Клиент	Онлайн (Online/Virtual) Курс във виртуална зала с инструктор

Course Language Option:

<input type="checkbox"/>	<input type="checkbox"/>
Български (Bulgarian)	Английски (English)

You can choose the language in which the training will be conducted – Bulgarian or English. All our instructors are fluent in English.

Student Guides:



The training materials are available in electronic format. They can be used online / offline on any device. Lifetime access.

Lab Environment:



Each student has their own lab environment where the exercises are conducted, part of the course. You do not need to install software on a computer or special hardware requirements.

Participants in a face-to-face format in our Training Center have an individual computer during the training.

At Course Completion:

Lifetime Access - Video Archive 24/7	Certificate of Course Completion

Lifetime access to a video archive with recording of each individual lecture.

Official internationally recognized certificate for completed training course.

Course Duration:



- 2 working days (09:00 – 17:00)
or
16 hours training (theory and practice) in non-working hours lasting 2 weeks
Saturday and Sunday 10:00 – 14:00, 14:00 – 18:00, 18:00 – 22:00
Monday and Wednesday 19:00 – 23:00
Tuesday and Thursday 19:00 – 23:00
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Payments:



An application for an invoice shall be accepted at the time of entry of the relevant course.

An invoice is issued within 7 days of confirmation of payment.

Next Class:

Jun 6

6 June 2026 @ 10:00 - 28 June 2026 @ 14:00 EEST 📌

[Linux Professional Institute LPIC-1 prep](#)


for 101-500 and 102-500 (4 weeks)

Jun 8

8 June 2026 @ 09:00 - 12 June 2026 @ 17:00 EEST 


EC-Council – Certified Ethical Hacker (CEHv13 EN)

Jun 15

15 June 2026 @ 09:00 - 19 June 2026 @ 17:00 EEST 

EC-Council – Certified Ethical Hacker (CEHv13 EN)

Jun 22

22 June 2026 @ 09:00 - 26 June 2026 @ 17:00 EEST 

EC-Council – Certified Ethical Hacker (CEHv13 EN)

Jun 29

29 June 2026 @ 09:00 - 3 July 2026 @ 17:00 EEST 

EC-Council – Certified Ethical Hacker (CEHv13 EN)

[View Calendar](#)

For more information, use the contact format. We will contact you to confirm the data.