

ISO 13485 Lead Implementer

ISO 13485 Lead Implementer (PECB)



About this Course:

- ISO 13485 Lead Implementer training enables you to develop the necessary expertise to support an organization in establishing, implementing, managing and maintaining a Medical Devices Quality Management System (MDQMS) based on ISO 13485. During this training course, you will also gain a thorough understanding of the best practices of Medical Devices Quality Management Systems and be able to improve an organization's overall performance by consistently providing safe and qualitative medical devices.

After mastering all the necessary concepts of Medical Devices Quality Management Systems, you can sit for the exam and apply for a "PECB Certified ISO 13485 Lead Implementer" credential. By holding a PECB Lead Implementer Certificate, you will be able to demonstrate that you have the practical knowledge and professional capabilities to implement ISO 13485 in an organization.

Course Goals/Skills:

- Acknowledge the correlation between ISO 13485 and other standards and regulatory frameworks
 - Master the concepts, approaches, methods and techniques used for the implementation and effective management of a MDQMS
 - Learn how to interpret the ISO 13485 requirements in the specific context of an organization
 - Learn how to support an organization to effectively plan, implement, manage, monitor and maintain a MDQMS
 - Acquire the expertise to advise an organization in implementing Medical Devices Quality Management System best practices
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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:



- 5 working days (09:00 – 17:00)
or
40 hours training (theory and practice) in non-working hours lasting 4 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 1

1 June 2026 @ 09:00 - 5 June 2026 @ 17:00 EEST 🗓

[**EC-Council – Certified Ethical Hacker \(CEHv13 EN\)**](#)

Jun 1

1 June 2026 @ 09:00 - 5 June 2026 @ 17:00 EEST 🗓

[**EC-Council – Certified Ethical Hacker \(CEHv13 EN\)**](#)

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

09:00 - 17:00 EEST 🗓

[**VMware vSphere: Install, Configure, Manage \[v8\]**](#)

Jun 8

8 June 2026 @ 09:00 - 12 June 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.