

ISO 13485 Lead Auditor

ISO 13485 Lead Auditor (PECB)



About this Course:

- ISO 13485 Lead Auditor training enables you to develop the necessary expertise to perform a Medical Devices Quality Management System (MDQMS) audit by applying widely recognized audit principles, procedures, and techniques.

During this training course, you will acquire the knowledge and skills to plan and carry out internal and external audits in compliance with ISO 19011 and ISO/IEC 17021-1 certification process.

Based on practical exercises, you will be able to master audit techniques and become competent to manage an audit program, audit team, communication with customers, and conflict resolution.

After acquiring the necessary expertise to perform this audit, you can sit for the exam and apply for a “PECB Certified ISO 13485 Lead Auditor” credential. By holding a PECB Lead Auditor Certificate, you will demonstrate that you have the capabilities and competencies to audit

organizations based on best practices.

Course Goals/Skills:

- Understand the operations of a Medical Devices Quality Management System based on ISO 13485
 - Acknowledge the correlation between ISO 13485 and other standards and regulatory frameworks
 - Understand an auditor's role to: plan, lead and follow-up on a management system audit in accordance with ISO 19011
 - Learn how to lead an audit and audit team
 - Learn how to interpret the requirements of ISO 13485 in the context of a MDQMS audit
 - Acquire the competencies of an auditor to: plan an audit, lead an audit, draft reports, and follow-up on an audit in compliance with ISO 19011
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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 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 \(CEHv13 EN\)](#)

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 \(CEHv13 EN\)](#)

[View Calendar](#)

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