Course technical sheet

Auditor/Lead Auditor ISO 13485 (Medical Devices – QMS)

Fee
99,00 €
Final exam only

Course code	Test duration	Passing score	Issued
ISO13485_LA	60 min	70%	28/05/2026

Executive summary

The "Auditor/Lead Auditor ISO 13485 (Medical Devices – QMS)" course is designed to train professionals capable of performing thorough audits according to the ISO 13485 standard, focusing on quality management systems in the medical device industry. The program prepares participants to verify compliance with regulatory requirements and to ensure continuous process improvement, incorporating audit principles based on ISO 19011 and certification guidelines from ISO/IEC 17021-1. The curriculum covers risk analysis related to sterile packaging, steam sterilization, process validation, management review, contamination control, technical assistance, and complaint management. Through practical case studies, the course develops the skills required for effective audits that ensure the safety and effectiveness of medical devices. The 60-minute duration allows for intensive, focused training, with a final exam requiring a 70% passing score to earn the certification. Suitable for auditors and lead auditors working or aiming to work in medical device quality management, the course provides essential theoretical and practical tools for the sector.

Certification process

- Registration or login to the Academy platform.
- Completion of the final course examination only. Any training or preparation may be completed externally or through other channels.
- The test questions refer to the objectives, skills and topics described in this technical sheet.
- Assessment of the result, possible validation and certificate issuance according to the rules applicable to the course.

Important note

On Academy, candidates take only the final course examination. Any training or preparation activity may be delivered externally or through other channels. The test questions refer to the topics described in this technical sheet and in the course syllabus summary.

Syllabus summary

ISO 13485; ISO 19011; ISO/IEC 17021-1

Learning Objectives

- Train auditors and lead auditors proficient in ISO 13485 for medical devices
- Deepen understanding of quality and safety requirements specific to the sector
- Develop effective auditing skills according to ISO 19011 and ISO/IEC 17021-1

Certification Bodies Management systems
IFZA Business Park - Building A2 - Nadd Hessa - Dubai Silicon Oasis
United Arab Emirates
Phone: +971 502475030
Email: info@certificatoiwz.org
VAT/Tax ID: 104216397000003

Skills Acquired

- Perform compliance and system audits in the medical device sector
- In-depth interpretation of regulatory requirements and critical controls
- Analysis and management of non-conformities and corrective actions

Target Audience

- Auditors and lead auditors working in medical devices
- Quality professionals seeking to strengthen audit skills

Prerequisites

- Basic knowledge of ISO 13485 and quality management systems
- Prior audit or quality experience recommended

Program

- Introduction to ISO 13485: structure and requirements
- Audit principles and techniques according to ISO 19011
- Deep dive into supplier control, sterilization processes, complaint management
- Process validation and management review
- Case studies and final exam preparation

Teaching Methodology

- Theoretical lessons combined with practical exercises
- Analysis of real cases and audit simulations

Evaluation Method

- Final test with a minimum passing score of 70%

Duration

- 60 minutes

Certification

- Certificate upon passing the final exam

Expected Outcomes

- Ability to conduct ISO 13485 audits with professional and critical approach