ISO 13485 Lead Auditor "Quality management - Medical devices"

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QST-85 **5 Days (35 Hours)**

Description

By completing the ISO 13485 Lead Auditor training, you will develop the skills required to conduct Medical Device Quality Management Systems (QDMS) audits using the most commonly used audit principles, procedures and techniques. used.

This training will allow you to master the planning and carrying out of internal and external audits, in accordance with the ISO 19011 standard and the ISO/IEC 17021-1 certification process. Emphasis will be placed on practical exercises to enable you to master audit techniques and manage an audit program, an audit team, client communication and conflict resolution.

Once you have acquired the skills necessary to perform these audits, you can take the exam and apply to obtain the title of **"PECB Certified ISO 13485 Lead Auditor"**. This certificate is proof that you have acquired the skills necessary to audit organizations according to best auditing practices.

Who is this training for ?

For whom

- Auditors wishing to carry out and lead certification audits of the Quality Management System for Medical Devices (SMQDM)
- Managers or consultants wishing to master the audit process of the Quality Management System for Medical Devices
- Any person responsible for maintaining compliance with the requirements of the Medical Device Quality Management System
- Technical experts wishing to prepare an audit of the Medical Device Quality Management System
- Consultants specialized in medical device quality management

Prerequisites

Good knowledge of the ISO 13485 standard and in-depth knowledge of audit principles.

Training objectives

- The training will allow you to understand the operation of a quality management system for medical devices compliant with the ISO 13485 standard

- Participants will be able to explain the correlation between ISO 13485 and other standards and regulatory frameworks
- The training will allow you to understand the role of an auditor and to know how to plan, direct and monitor a management system audit in accordance with the ISO 19011 standard
- Participants will be able to lead an audit and an audit team, as well as interpret the requirements of ISO 13485 in the context of a SMQDM audit
- Through this training, participants will acquire the skills necessary to plan an audit, lead an audit, write reports and follow up on an audit in accordance with the ISO 19011 standard

Training program

programme

- Day 1: The training program includes a presentation of the Medical Device Quality Management System and the ISO 13485 standard.
- Day 2: Participants will learn the fundamental principles of the audit as well as the stages of preparation and implementation of the audit.
- Day 3: will be devoted to on-site audit activities.
- Day 4: Participants will be introduced at the end of the audit.
- Day 5: the last day of training will be dedicated to the certification exam.