ISO 13485 Lead Implementer "Quality management - Medical devices"

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

Description

The ISO 13485 Lead Implementer training will allow you to develop the skills necessary to guide an organization in the establishment, implementation, management and maintenance of a medical device quality management system (QMSD) compliant with ISO 13485.

This training will allow you to gain expertise in best practices in QMSD and develop your skills to improve the overall performance of the organization by consistently providing safe and quality medical devices.

After having assimilated all the concepts related to SGQDM, you will be able to take the exam and obtain the **“PECB Certified ISO 13485 Lead Implementer”** certification. This PECB certification demonstrates your practical ability and professional skills to implement ISO 13485 within an organization.

Who is this training for ?

For whom

- Managers or consultants involved in the quality management of medical devices
- Specialized advisors wishing to master the implementation of a Quality Management System for medical devices
- Any person responsible for maintaining compliance with SMQDM requirements Members of 'a SMQDM team

Prerequisites

Participants in this training should have a fundamental understanding of ISO 13485 and in-depth knowledge of implementation principles.

Training objectives

- The correlation between ISO 13485 and other standards and regulatory frameworks must be understood
- The concepts, approaches, methods and techniques necessary to effectively implement and manage a SMQDM must be mastered
- The requirements of the ISO 13485 standard must be interpreted in a specific context of the organization

- An organization must be supported in the planning, implementation, management, monitoring and updating of the SMQDM
- The expertise necessary to advise an organization on the implementation of best practices relating to the Medical Device Quality Management System must be acquired

Training program

Jour 1 : Introduction à ISO 13485 et initiation d'un SMQDM

- The first day of training would be dedicated to the presentation of the ISO 13485 standard and the initiation of the quality management system for medical devices (QMSD). Participants will learn the requirements of the ISO standard 13485, the associated terminology, as well as the basic principles of SMQDM.

Jour 2 : Planification de la mise en œuvre d'un SMQDM

- On the second day, participants will learn how to plan the implementation of SMQDM. This will involve understanding the requirements of ISO 13485, identifying relevant processes, defining objectives and performance indicators keys, and to put in place an action plan.

Jour 3 : Mise en œuvre d'un SMQDM

- The third day will be dedicated to the implementation of the SMQDM. Participants will learn how to set up the necessary processes, identify the necessary resources, train staff and implement documented procedures to support the implementation of the SMQDM.

Jour 4 : Surveillance, mesure, amélioration continue et préparation de l'audit de certification d'un SMQDM

- On the fourth day, participants will learn to monitor and measure the effectiveness of the SMQDM. They will also learn to identify opportunities for continuous improvement, implement corrective and preventive actions and prepare for the SMQDM certification audit.

Jour 5 : Examen de certification

- The fifth day will be dedicated to the certification exam. Participants will take an exam to assess their understanding of ISO 13485 and SMQDM implementation. Those who pass the exam will receive certification of their competence in quality management for medical devices in accordance with the ISO 13485 standard.