



ISO 13485 Medical Devices

Course description

The objective of the course is to provide students with the understanding of the ISO 13485:2016 and the quality management systems requirements which are essential to organizations involved in the design, production, installation and servicing of medical devices and related services.

Through hands-on activities and case studies, students will gain valuable experience in navigating compliance challenges and addressing quality management issues.

At the end of the course you will able to:

- Understand the general connection and differences between the ISO 13485 and the 21 CFR Part 820.
- Know key factors to comply and maintain compliance to the ISO 13485.
- Understand how a company's quality management system fulfils and is connected to the ISO 13485.
- Learn to interpret ISO 13485 general requirements in the specific context of the medical device industry.
- Learn the general requirements from each clause of the ISO13485 and how they correlate to the company quality system and procedures.
- Experience and apply ISO 13485 requirements to solve real case situations during the class that a professional in this industry could face to maintain compliance.

Main topics

- 1 Overview.
- 2 Quality Management System.
 - General requirements
 - Documentation requirements
- 3 Management responsibility.
 - Management commitment
 - Customer focus
 - Quality policy
 - Planning
 - Responsibility, authority and communication



ISO 13485 Medical Devices

Main topics

- 4 Resource management.
 - Provision of resources
 - Human Resources
 - Infrastructure
 - Work environment and contamination control
- 5 Product realization.
 - Planning of product realization
 - Customer-related processes
 - Design and development
 - Purchasing
 - Production and service provision
 - Control of monitoring and measuring equipment
- 6 Measurement, analysis, and improvement
 - Monitoring and measurement
 - Control of nonconforming product
 - Analysis of data
 - Improvement

Contact

 www.smdlearning.com

 info@smdlearning.com

 +506 8544 7000

 Costa Rica

Course features

- Instructor Led 
- Duration: 4 hours 
- Tools and templates 
- Applied learning 
- Course certificate 