COURSE

ISO 13485 MEDICAL DEVICES

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.

COURSE CONTENT

1. **Introduction to ISO 13485 Quality System**
2. **Quality management system.**
3. **Management responsibility.**
4. **Resource management.**
5. **Product realization.**
6. **Measurement, analysis, and improvement.**

Duration
Access to the course for six months

E-learning platform
Tools and templates

Hands to work
Simulated learning

Certification
After successful course completion

ISO 13485 MEDICAL DEVICES

At the end of the course you will be able to

- Understand the general connection and differences between the ISO 13485 and the 21 CFR Part 820.
- Now 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.
- Understand how the company's quality management system fulfils and is connected to the ISO 13485.
- 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.