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.
- 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.

Main topics

1. Overview.
2. Quality management system.
3. Management responsibility.
4. Resource management.
5. Product realization.
6. Planning of product realization.
7. Measurement, analysis, and improvement.

Course features

- Instructor Led
- Duration: 4 hours
- Tools and templates
- Simulated learning
- Course certification

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