Quality Management System Regulation (QMSR)

Course description

The objective of this course is to provide the students with top to bottom understanding of the Quality Management System Regulation (QMSR) and the interpretation clause -by clause of this regulation for a medical device manufacturer. Throughout the course, students will engage in hands-on learning experiences, applying their knowledge of regulation requirements to tackle real-world case scenarios typical of the medical device industry.

At the end of the course you will able to:

- Understand the importance, purpose, and the framework of general requirements for the design and manufacture of medical devices per FDA Quality Management System Regulation (QMSR).
- Know key factors to comply and maintain compliance to the QMSR.
- Understand how the company's quality management system fulfils and is connected to the FDA QSR.
- Learn the general requirements from all Sub-parts Quality Management System Regulation (QMSR). and how they correlate to the company quality system to support day-to-day activities.
- Experience and apply FDA QMSR requirements to solve in class real case situations that could be faced by a professional in this industry and to maintain compliance according to the standards.

Main topics

1. Change context
2. Scope
3. Definition
4. Incorporation by reference - ISO 13485:

- Quality Management System.
  - General requirements
  - Documentation requirements

- Management responsibility.
  - Management commitment
  - Customer focus
  - Quality policy
  - Planning
  - Responsibility, authority and communication

- Resource management.
  - Provision of resources
  - Human Resources
  - Infrastructure
  - Work environment and contamination control

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Main topics

4 Incorporation by reference - ISO 13485:

- Product realization.
  - Planning of product realization
  - Customer-related processes
  - Design and development
  - Purchasing
  - Production and service provision
  - Control of monitoring and measuring equipment

- Measurement, analysis, and improvement
  - Monitoring and measurement
  - Control of nonconforming product
  - Analysis of data
  - Improvement

5 Requirements for a Quality Management System
6 Control of records
7 Device labeling and packaging controls

Course features

Instructor Led
Duration: 6 hours
Tools and templates
Applied learning
Course certificate

Contact

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