Medical Devices Basics for Transportation and Logistics Companies

Course description

This course provides an overview of the medical device industry, addressing product types, common regulatory concepts, applicable regulations and good manufacturing practices, with emphasis on basic packaging concepts and the sterilization process to ensure compliance with applicable regulations.

At the end of the course you will able to:

- Acquire an overview of the medical device industry. Types of products, common regulatory concepts.
- Know the generalities of the regulations applicable to the manufacture of medical devices and the requirements of quality systems.
- Understand the importance of GDPs and GMPs for medical device manufacturers, as well as the basics of auditing and non-conforming product.
- Understand the basic concepts of packaging, the most common standards and the sterilization process.

Main topics

1 Medical Devices Industry
   - Basics and background

2 Regulatory environment
   - Regulatory agencies
   - Devices classification

3 ISO 13485: 2016

4 21 CFR Part 820

5 Good Manufacturing Practices
   - GMPs / GDPs
   - Audits
   - Nonconformities

6 Packaging considerations
   - Basic concepts
   - Packaging design
   - Packaging process
   - Sterilization process

Course features

Instructor Led

Tools and templates

Applied learning

Course certificate

Contact

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