Good Documentation Practices for Operators

Course description

The objective of this course is to provide basic knowledge for the Development of Operators in the Medical Device Industry in Good Manufacturing Documentation. This topic aim to provide operators with the sensibility and tools to ensure the Quality System Requirements.

At the end of the course you will able to:

- Understand the regulatory framework of medical device manufacture.
- Apply general understanding of what Good Documentation Practices (GDP) mean in the Medical Device Industry, and why they are relevant in compliance to the quality system.
- Understand the definition, purpose and key elements associated with Good Documentation Practices (GDP).
  - Definition
  - Purpose and types of documentation
  - Requirements of good documentation practices
  - Application of good documentation practices
- Understand the importance of GMP audits and how they can help companies comply with guidelines set by regulatory authorities.
- Learn about quality and discuss how quality products are important for safety and efficacy.
- Apply gained knowledge to solve multiple real case situations throughout the class.

Main topics

1. Definition.
2. Purpose and types of documentation.
3. Requirements of good documentation practices.
4. Application of good documentation practices.

Course features

- Instructor Led
- Duration: 2 hours
- Tools and templates
- Simulated learning
- Course certification

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