COURSE OPERATOR DEVELOPMENT

The objective of this course is to provide basic knowledge for Operators Development in the Medical Devices Industry, with topics such as good manufacturing practices, good documentation practices, quality system audits and failures to the quality system. All these topics aim to provide operators with the sensibility and tools to ensure the Quality System Requirements.

COURSE CONTENT

1. **Good Manufacturing Practices.**
   - Definition.
   - Quality system.
   - Cleaning and hygiene.
   - Documentation.
   - Productive process.
   - Quality assurance.
2. **Good Documentation Practices (GDP)**
   - Definition.
   - Purpose and types of documentation.
   - Requirements of GDP
   - Application of GDP.
3. **Audits and Failures to the Quality System.**
   - The purpose of the audits.
   - Participation in an audit.
   - Quality system failures.

Duration
4 hours

E-learning platform
Tools and templates

Hands to work
Simulated learning

Certification
After successful course completion

At the end of the course you will be able to

- Understand the regulatory framework of medical device manufacture.
- Apply general understanding of what Good Manufacturing Practices (GMPs) and Good Documentation Practices (GDP) mean in the Medical Device Industry, and why they are relevant in compliance to the quality system.
- Understand the basic principles of Good Manufacturing Practices (GMPs) in the Medical Device Industry.
    - Definition.
    - Quality system.
    - Cleaning and hygiene.
    - Documentation.
    - Productive process.
    - Quality assurance.

At the end of the course you will be able to

- 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.