COURSE TECHNICIAN DEVELOPMENT

The objective of this course is to provide basic knowledge for Technicians Development in the Medical Devices Industry, with topics such as good manufacturing practices, good documentation practices, general aspects of clean rooms and clothing, equipment validation, equipment documentation, management of work orders, interpretation of plans and audits and failures to the quality system.

All these topics aimed at ensuring that the Quality System Requirements are met.

Duration

10 hours

E-learning platform

Tools and templates

Hands to work

Simulated learning

Certification

After successful course completion

COURSE TECHNICIAN DEVELOPMENT

COURSE CONTENT

1. Good Manufacturing Practices.

- Definition.
- Quality system.
- Cleaning and hygiene.
- Documentation.
- Productive process.
- Quality assurance.

2. Good Documentation Practices (GDP).

- Definition.
- Types of documentation.
- Requirements of GDP
- Application of GDP.

3. General Aspects of Clean Rooms and Gowning.

- Definition of clean room.
- Considerations within the clean room and Gowning
- Types of clean rooms and their classification.
- Validation of clean rooms.

4. Equipment Qualification.

- What is equipment qualification.
- Typical steps to validate and qualify equipment.
- User Requirement Specification URS.
- Factory Acceptance Test FAT.
- Installation Qualification IQ.
- Best practices for equipment qualification and validation.

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10 hours

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COURSE CONTENT

5. Work/Service Orders Management.

- Concept.
- Function.
- Purpose.

6. Drawings Interpretation.

- Introduction to technical drawing.
- Dimensioning and bounding of technical diagrams.
- Fits and tolerances.
- Introduction to geometric tolerances.
- General plans and exploded views.

7. Audits and Failures to the Quality System.

- The purpose of the audits.
- Participation in an audit.
- Quality system failures.

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At the end of the course you will be able to

- Understand the regulatory framework of medical device manufacture.
- Apply eneral 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.
- Learn and review general considerations for cleanrooms and gowning.
- Know the basic principles in the interpretation of blueprint, generalities and considerations.
- Understand the concept, function and purpose of Work Orders, as well as the essential elements to generate and close a Work Order.

At the end of the course you will be able to

- To provide the student with the knowledge of the typical process phases of equipment validation going from defining the requirements for construction to installation and qualification
    - User Requirement Specification URS.
    - Factory Acceptance test FAT.
    - Installation Qualification IQ.
- 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.