COURSE

PROCESS VALIDATION (EQ, OQ, PQ, MVP)

ISO 13495 and 21 FDA CFR 820 requires the manufacturing process to be properly validated or verified, to consistently procedure results or a medical device product that meets all predetermined requirements for a finished good being safe to be used.

Although the regulation and standards are good tools and serve as a baseline for a medical device manufacturer, these documents often can be confusing, difficult to interpret and, in many cases, they don't offer much guidance on how to achieve compliance with a particular clause.

This is a practical course that uses a "hands-on" methodology, providing students with the opportunity to experience in a practical way, real-world situations, and examples that a professional working for this industry could face. You will learn the entire process validation cycle and the key elements such as VMP, EQ, OQ and PQ, and the correlation with the regulations and standards.

This course will take you from the conceptual to the practical space and provide you with key concepts and tools that you can immediately apply to your workplace.

Duration

24 hours

E-learning platform

Tools and templates

Hands to work

Simulated learning

Certification

After successful course completion

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COURSE CONTENT

1. Process Validation Principles

- Purpose of process validation
- Process validation from the regulation perspective
- Elements of process validation (IQ, OQ, TMV, PQ)
- What is the starting point (MVP)
- Other elements to get started
- Process validation lifecycle – Maintaining the state of the art

2. Equipment Qualification

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

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COURSE CONTENT

3. Operational Qualification

- Elements of operational qualification
- Operational qualification phases
- Definition of worst cases scenarios
- Definition of sampling plans based on risk indexes
- Execution requirements
- Data analysis
- Best practices

4. Performance Qualification

- Elements of performance qualification
- Performance qualification phases
- Definition of worst cases scenarios
- Definition of sampling Plans based on risk indexes

Duration
24 hours

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Tools and templates

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COURSE CONTENT

5. Operational Qualification

- Purpose of the VMR
- Validation Master Report
- Typical content and sections
- Considerations when creating and VMR
- Class example of VMR

Duration
24 hours

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At the end of the course you will be able to

- Understand the purpose of Process Validation (PV) in the medical device industry.
- Learn about key process validation elements and their purpose for:
    - Validation Master Plan (VMP)
    - Test Method Validation (TMV)
    - Performance Qualification (PQ)
    - Equipment Qualification (EQ)
    - Operational Qualification (OQ)
- Learn about a solid understanding of the Validation Master Plan, the typical content and requirements captured in this document and the regulatory requirements associated to the medical device manufacturer associated to process validation planning.
- Know the typical process phases of equipment validation going from defining the requirements for construction to installation and qualification.
- Know the different elements and best practices of the OQ and apply the acquired knowledge in the elaboration of an OQ protocol.
- Know through the different elements and best practices of the PQ and apply the acquired knowledge in the elaboration of an PQ protocol.
- Guide the student through the different elements associated to the VMR.