Process Validation

Course description

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.

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.

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 the key process validation elements and their purpose for:
  - Validation Master Plan (VMP)
  - Equipment Qualification (EQ)
  - Operational Qualification (OQ)
  - Performance Qualification (PQ)
- 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.
- Understand the different elements associated to the VMR.

Main Topics

1. Process Validation Principles
2. Equipment Validation
3. Operational Qualification
4. Performance Qualification
5. Validation Master Report

Contact

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Course features

- Instructor Led
- Duration: 24 hours
- Tools and templates
- Simulated learning
- Course certification