Extended V&V course

This course is designed to give you the tools to making an informed decision regarding the testing and the ability to explain this decision in a manner acceptable to the regulatory authorities.

- Review the issue of product verification and validation, from defining the issues to building a protocol, executing and writing a report.
- How to read right V&V standards and to create V&V protocols that are applicable to specific device, by understanding the standards terminology.
- What you need to consider when designing a sterile device including a review on the different types of sterilization, packaging requirement for sterilization and the pros and cons of all the options.
- We will discuss about how do you define clean and disinfected? How do you validate a process that you do not control? A brief overview of the different processing methods used throughout the world.
- Determining what your packaging validation requirements are. How to build the protocol. What has to be addressed in a packaging validation.

Course Summary

The course will cover verification and validation, beginning with defining the subjects through to preparing a protocol, executing, and writing the report.

Basic Requirements

Basic understanding of medical device processes and at least two years' experience.

Target Audience

Engineers and Quality personnel

Link to Syllabus

Certification course

for more information

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