



Test Methods Validation

Course description

Test Method Validation (TMV) is a key element to quality and process controls. According to the Title 21 of the Code of Federal Regulations Part 820.72... "Each manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and it is capable of producing valid results."

Choosing the correct methods can help the organization to minimize risk which could be associated to over-rejection or worst, shipping defective product to a customer.

At the end of the course you will be able to:

- Understand the purpose of Test Methods Validation in the medical device industry.
- Learn about calibration terminology and methods.
- Explain the various components of a calibration system.
- Understand the concepts, applications and tools necessary for test method validation to comply with requirements of the FDA's Quality System Regulation and ISO 13485 and other regulatory requirements.
- Learn about appropriate and effective methods of implementing Test Method Validation.
- Understand common issues you might find in Test Method Validations.
- Experience in a practical way, real-world situations, and examples that a professional working for this industry could face.

Main topics

- 1 Calibrations Overview
 - Definitions
 - Calibration Inputs
 - Purpose
 - Calibration Procedures
 - Calibration Methods
- 2 Test Method Validation
 - Definitions
 - Tools
 - Concepts
 - Validation
 - Applications
 - Pitfalls

Contact

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Course features

- Instructor Led 
- Duration: 12 hours 
- Tools and templates 
- Simulated learning 
- Course certification 