



Computer Software Validation Fundamentals

Course description

This course provides an exploration of software validation principles within the context of medical device manufacturing. Participants will delve into the background and rationale behind software validation, gaining a clear understanding of key definitions and regulatory requirements. The course covers various aspects of software validation, including the software validation life cycle, spreadsheet validation, electronic records management, and best practices for software validation. Emphasis is placed on practical application, ensuring participants develop the skills needed to effectively validate software systems and maintain compliance with regulatory standards.

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

- Gain insight into the historical context and rationale behind software validation
- Understand relevant regulations and standards.
- Be equipped to conduct change assessments and analyze the impact of changes on software validation.
- Learn software validation best practices, including tying validation to change management, testing only relevant software features, and validating software output.
- Acquire practical insights into software validation challenges and solutions encountered in the medical devices industry.

Main topics

- 1 Introduction: Software Definitions and Scope
- 2 Software Validation Regulatory Requirements
- 3 GAMP5
- 4 Software Validation Life Cycle
- 5 Spreadsheet Validation
- 6 Electronic Records (ER)-Electronic Signature (ES) Management and General principles for Data Integrity
- 7 QMS and Automated process equipment Software Validation
- 8 Software validation best practices

Contact

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Course features

Instructor Led	
Duration: 16 hours	
Tools and templates	
Applied learning	
Course certificate	