MEDDEV SOLUTIONS
A Trinzo Company

PROCESS VALIDATION & EQUIPMENT QUALIFICATION

INDUSTRY-LEADING TRAINING SOLUTIONS

FOR THE MEDICAL DEVICE AND PHARMACEUTICAL INDUSTRY

About **This Course**

2 Day Course

Ensuring Compliance and Quality through Effective Validation

Process validation and equipment qualification are core disciplines in regulated life sciences manufacturing to demonstrate product quality and compliance. This comprehensive 2-day course will give individuals a greater understanding of the requirements of regulations in the EU and US, plus practical examples of how to meet them.

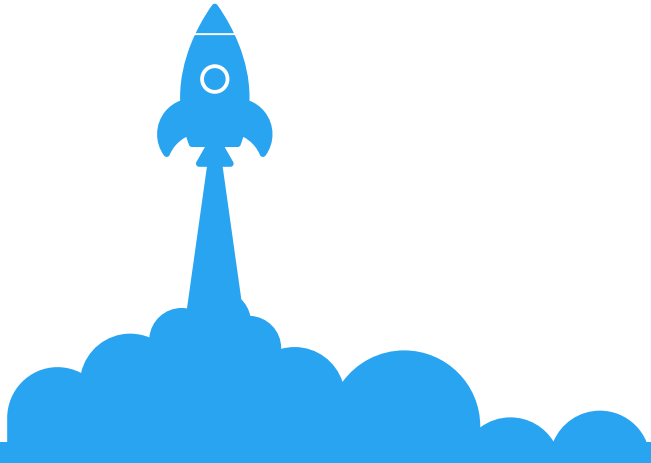
LEARNING OBJECTIVES

- Understand the key concepts of process validation and the associated benefits
- Appreciate how process validation links with the product development process
- Understand how ISO 13485, regulations and guidance (such as the IMDRF) applies to manufacturers of medical devices
- Correctly Identify when a manufacturing process requires validation
- Describe the elements involved in performing process validation from planning to execution
- Explain how to apply a risk-based approach to process validation
- Illustrate the importance of a validation master plan (VMP) and validation protocols
- Apply concepts learnt to develop a comprehensive VMP
- Understand the difference and purpose of installation (IQ), operational (OQ) and performance qualification (PQ)
- Apply concepts learnt to develop IQ, OQ and PQ protocols
- Define and create relevant acceptance criteria
- Understand and apply common statistical techniques used in process validation
- Outline how to maintain a state of validation through the lifecycle (Including revalidation)

WHO WILL BENEFIT FROM ATTENDING?

This training course has great value for anyone who needs an understanding of or is engaged in validation activities.

Audience learning level: Basic to intermediate



Course **Content**

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Day 1

- Welcome & introductions
- Aims, objectives & structure
- What is process validation?
- What regulations, standards and guidance applies to process validation?
- Which processes require validation
- The process validation process
- Q&A

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Day 2

- Day 1 review
- How process validation links with product development
- Building a team
- Risk based approach to process validation
- Mapping the process to be validated
- How to develop a Validation Master Plan (VMP)
- Q&A

Ready to Go?

Register Now

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Day 3

- Day 2 review
- Equipment Qualification (IQ, OQ, PQ)
- Establishing protocols and the different types of protocol
- Understanding acceptance criteria
- Statistical techniques and tools
- Q&A

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Day 4

- Day 3 review
- Protocol execution
- How to handle discrepancies and deviations
- Validation reports
- Validation life cycle, VMP and revalidation
- Q&A

Meet the **Industry Expert**

Rod

Rod brings a wealth of worldwide regulatory knowledge and quality assurance experience to companies wanting to design, manufacture, and market compliant medical devices.

Rod has a bachelor's degree with first class honours in engineering and management. He also holds the prestigious Regulatory Affairs Certification (Global Scope) from the Regulatory Affairs Professionals Society and is a Lean Sigma Green Belt. Rod has worked in the medical device and pharmaceutical industry for over 22 years, including time spent in some of the largest medical device and pharmaceutical manufacturers.

Rod's experience has involved providing regulatory strategy from product development to worldwide market registration, creation of technical documentation, implementation of full 13485 compliant QMS systems, standards compliance, clinical evaluations, risk management files, project management and remediation activities. Rod has also spent time working for a notified body, conducting audits against ISO 9001, ISO 13485, 21CFR820, MDSAP, cGMP and GDP.

Rod's device experience covers Class I, II and III devices, including software as a medical device, drug delivery devices, IVDs, and active implantable medical devices. More recently, Rod has helped clients update their clinical evaluation processes to the requirements of the MDR, updating risk management systems to the latest standard and delivering training on MDR, IVDR, clinical evaluation, risk management, MDSAP and QMS systems.

Let's discuss your next training opportunity

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