WMDO
WORLD MEDICAL DEVICE ORGANIZATION

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**Course Title:**

# Introduction to Process Validation

Product ID: N135
Duration: 75 mins
SME: Steve Marshall
First Released On: 04/23/2012

**Course Description:**
This preparatory course provides a hands-on review of manufacturing process validation for medical devices. It lays out the key principles of process validation, including regulatory requirements. The basic statistical considerations for process validation are clearly illustrated in an example.
This course covers the following topics:
- What is process validation?
- What is verification?
- When should process validation take place in lieu of verification?
- Regulatory expectations
- The concept of “variation”
- The concept of “process capability”
- Process inputs
- General requirements for process validation
- The three phases of process validation
- European regulatory requirements for process validation
- US regulatory requirements for process validation
- Planning and outputs related to process validation
- Contribution of risk management to process validation

At the end of this course there is a brief slideshow of warning letters from the US FDA addressing findings related to process validation.

## Watch the Course Trailer:

**Learning Objectives:**
Upon successfully completing this course, trainees will be able to:
- Comprehend the regulatory framework relating to process validation in the manufacturing of medical devices
- Participate and contribute to process validation activities
- Evaluate the need for process validation within their organization

**Who Should Enroll:**
Development and manufacturing engineers and staff new to medical devices, supply chain and purchasing managers and associates involved in supplier audits, regulatory and quality associates needing an introduction to process validation, and executive management employees who wish to oversee compliance-related aspects of process validation are all welcome to participate in this course.

**Related Resources:** Yes

**Prerequsite Knowledge**
A basic understanding of the following courses is required:
- Risk Management for Medical Devices in EU and US (3-course series)
- The Design, Development and Industrialization of Medical Devices (ID 183) –*Under construction*
- ISO 13485: Foundation and Basic Principles (ID 196)
- Importance of Technical Standards in the Medical Device Sector (ID 185)

**Peer Reviwer:**
Steve Marshall
Peer Reviewer Date 03/28/2012

**Price:**

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**Premium:** €166.00.**- Basic:** €221.00.-

**Course Format:**
All WMDO professional online training courses are fully interactive and contain audio, video, graphic animation, online quizzes and include all necessary course materials. Trainees receive a minimum of 60 days of unlimited access in which to complete each course depending on course length and complexity. (See individual course descriptions for details). Courses include handouts, case studies, working documents and other useful links. After successful completion of your course, you will be able to download your WMDO Certificate of Completion for your training records.

Online courses are cross-browser compatible and require internet connection (minimum 300kbs) and Adobe Flash Player installed (Free download available at: http://www.adobe.com/products/flashplayer).

**Premium Account Holders:**
Premium account holders enrolling in this course will receive complimentary email access to subject matter experts for any questions, clarifications or feedback they may have concerning this course and its contents, including free automatic course updates for 1 full year.