



WORLD MEDICAL DEVICE ORGANIZATION

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Online Training for Medical Device Professionals

Course Title:

Introduction to the EU Regulatory System

Product ID: 160

Duration: 36 mins

SME: Carole Stamp

Course Description:

This course reviews the classification levels within European medical device directives, including related regulatory requirements and routes to the CE-mark. It emphasizes the need for good documentation practices and the required technical file setup and maintenance throughout the medical device lifecycle.

This course also highlights the importance of quality systems and how the design and early setup of one can help manufacturers ensure compliance and improve efficiency.

Watch the Course Trailer:

Learning Objectives:

Upon successfully completing this course, learners will be able to:

- Identify where information on medical device regulatory and product development requirements is found
- Comprehend how the EU Regulatory System works and the different parties involved
- Recognize the differences between pharmaceutical and medical device systems

Who Should Enroll:

Professionals new to the medical device industry, including inventors, managers, CEOs, or professionals wanting an overview of the global lifecycle of medical devices are all encouraged to enroll in this course.

Related Resources: Yes

Prerequisite Knowledge

The following course is required:

- The Lifecycle of Medical Devices from Idea to Market (ID 159)

Price:

Premium: €80.00.- **Basic:** €106.00.-

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.