



WORLD MEDICAL DEVICE ORGANIZATION

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Online Training for Medical Device Professionals

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**Course Title:**

## **Clinical Evaluation for EU Market Approval: Process and Regulatory background**

Product ID: 116

Level: MMDP

Duration: 80 mins

SME: Monica Tocchi

First Released On: 06/04/2010

**Course Description:**

This course provides an expert overview of EU regulations and how they positively impact global market access. It includes a detailed outline of the necessary steps to achieve immediate and lasting compliance of clinical evaluations.

**Note:** Manufacturers planning to market their devices in Europe are required to furnish clinical data in accordance with European directives.

### **Watch the Course Trailer:**

**Learning Objectives:**

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

- Distinguish different methods of obtaining clinical data for EU market access
- Understand how the conduct of a critical review of existing data is the basis for deciding whether to embark on a prospective clinical investigation or not

**Who Should Enroll:**

Senior clinical and regulatory managers, clinical research directors and vice presidents, medical writers, regulatory affairs directors, and regulatory affairs vice presidents involved in the strategic planning of clinical evaluations for the EU and medical device global market access are all encouraged to participate in this course.

**Related Resources:** Yes

**Prerequisite Knowledge**

The following courses are required:

- The European Union Regulatory System for Medical Devices (ID 145)
- ISO 14155: 2011 - A Summary Review (ID 144)

**Price:**

**Premium:** €246.00.- **Basic:** €328.00.-

**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.