

**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:**

Manufacturers planning to market their devices in Europe are required to furnish clinical data in line with the European Directives.

This course provides professionals with an expert overview of the EU regulations and how they can positively impact global market access as well as a detailed outline of the necessary steps to follow to achieve immediate and lasting compliance of their clinical evaluation.

**Learning Objectives:**

Upon completion of this course, trainees will be able to correctly and successfully:

- Distinguish the different methods to obtain clinical data for EU market access and understand how the conduct of a critical review of existing data lays the basis for a decision to embark upon a prospective clinical investigation or not.

**Who Should Enroll:**

Senior clinical managers, Director Clinical Research, VP Clinical Research, Medical Writer, Senior Regulatory managers, Director Regulatory affairs, VP regulatory affairs involved in the strategic planning of clinical evaluations for EU and Global market access of a medical device.

**Related Resources:** Yes

**Prerequisite Knowledge**

Understand the requirements of the Directives 93/42/EEC, 90/385/EEC, as outlined in the course on the European Union Regulatory System for Medical Devices (ID 145) ISO 14155:2011 as outlined in either ISO 14155:2011 an in depth review (ID 68) or ISO 14155 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.