

**Course Title:**

## **Introduction to Medical Device and Clinical Investigation Planning**

Product ID: 43

Level: CMDA

Duration: 45 mins

SME: Danielle Giroud

First Released On: 09/30/2009

**Course Description:**

This course provides a comprehensive overview of what exactly medical devices are and how they are classified. It explores the stages involved in medical device clinical investigations and how to understand clinical investigation plan objectives in terms of safety, performance, and effectiveness.

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

**Learning Objectives:**

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

- Comprehend the basic EU and US regulatory backgrounds for medical device clinical investigations
- Distinguish major medical device classification systems in investigator brochures
- Illustrate the major stages of medical device development
- Explain and apply safety, performance, and effectiveness objectives to clinical investigation plans

**Who Should Enroll:**

Monitors or clinical research associates, clinical project managers, investigators, study coordinators, and monitors from the pharmaceutical industry needing to understand the basic medical device regulatory environment are welcome to enroll in this course.

**Related Resources:** Yes

**Prerequisite Knowledge**

A strong understanding of the basics of good clinical practice is required for this course.

**Price:**

**Premium:** €100.00.- **Basic:** €133.00.-

**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.