



WORLD MEDICAL DEVICE ORGANIZATION

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Online Training for Medical Device Professionals

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:

What exactly is a medical device and how are they classified? What are the stages involved within a medical device clinical investigation or how to read objectives of a clinical investigation plan in terms of safety, performance and effectiveness? Get straight answers to these sometimes confusing questions by unearthing the real significance behind clinical investigations for medical devices delivered in this richly detailed and comprehensive course.

Learning Objectives:

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

- Comprehend the basics of the regulatory background in Europe and USA when involved in a medical device clinical investigation
- Distinguish major medical device classification systems when reading an investigator brochure
- Illustrate the major stages involved throughout the development of a medical device
- Explain and apply safety, performance and effectiveness in the objectives of a clinical investigation plan

Who Should Enroll:

Monitors or Clinical Research Associates, clinical project managers, investigators, study coordinators. Monitors from pharmaceutical industry needing to understand the basic medical device regulatory environment.

Related Resources: Yes

Prerequisite Knowledge

A good understanding of the basics of good clinical practices are essential before starting 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.