



WORLD MEDICAL DEVICE ORGANIZATION

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Online Training for Medical Device Professionals

Course Title:

Initiation Visit

Product ID: 48
Level: CMDA
Duration: 45 mins
SME: Danielle Giroud
First Released On: 09/30/2009

Course Description:

This course provides practical guidance and instructions on the preparation, conduct, and follow-up of initiation visits to ensure optimal compliance of all parties involved. It includes several case studies to familiarize learners with the many situations that can occur while conducting initiation visits for medical device clinical investigations.

Watch the Course Trailer:

Learning Objectives:

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

- Prepare an investigator file or regulatory binder
- Optimize efficiency in the preparation, conduct, and follow-up of initiation visits
- Create a training plan for each member of the clinical investigation site
- Develop logistics and methods to efficiently begin a medical device clinical investigation at an investigation site
- Ensure overall regulatory compliance with all clinical investigation plan requirements
- Establish open communication with site personnel, which is crucial for efficient collaboration

Who Should Enroll:

Monitors, clinical project managers, investigators, study coordinators, regulatory, quality assurance, or marketing professionals involved in the process of initiating medical device clinical investigations, and clinical professionals from the pharmaceutical industry wanting to understand medical device clinical investigation initiation visits are all welcome to participate in this course.

Related Resources: Yes

Prerequisite Knowledge

An understanding of the following material is required:

- Basics of good clinical practice
- Tasks that come before initiation visits, such as clinical investigation plans and investigator brochures
- Medical device regulatory environment
- Requirements for ethics committee or institutional review board submission processes
- The site qualification process and all action items resulting from such a process

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>).



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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.