WMDO
WORLD MEDICAL DEVICE ORGANIZATION

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Course Title:

Initiation Visit

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

Course Description:
Provides practical guidance and instructions on the preparation, conduct and follow up on the initiation visit to ensure optimal compliance of all parties involved. The course includes several practical case studies to make the learner familiar with the many situations he or she may get into when conducting an initiation visit for a medical device clinical investigation.

Learning Objectives:
Upon completion of this course, trainees will be able to correctly and successfully:
- Prepare an Investigator file or regulatory binder.
- Optimize efficiency in the preparation, conduct and follow up of an intiation visit.
- Develop the training plan for each member of the clinical investigation site.
- Develop logistics and methods for an efficient start of a medical device clinical investigation at the investigation sites and ensure overall regulatory compliance and compliance with all requirements of the clinical investigation plan.
- Setup from the start an open communication with the site personnel, vital for an efficient collaboration.

Who Should Enroll:
Monitors, clinical project managers, investigators, study coordinators and regulatory, quality assurance or marketing professionals involved in the process of initiating a medical device clinical investigation. Clinical professionals coming from pharmaceuticals wanting to understand the differences for medical device clinical investigation initiation.

Related Resources: Yes

Prerequsite Knowledge
Learners will need an understanding of the basics of good clinical practices and good knowledge of the tasks that come before an initiation visit such as understanding what goes in a clinical investigation plan, investigator brochure, with a basic understanding of the medical device regulatoryenvironment. Knowhow of the requirements for ethics committees or instituational review board submission processes. Learners must have knowledge about the site qualification process and all action items resulting from such process so as to start with a clear program for the site initiation visit 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.

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