



WORLD MEDICAL DEVICE ORGANIZATION

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Online Training for Medical Device Professionals

Course Title:

GCP for Investigators: Clinical Investigation Close out or Termination

Product ID: 206

Level: CMDA

Duration: 23 mins

SME: Danielle Giroud

First Released On: 10/29/2009

Course Description:

In this course we will review under what circumstances a clinical investigation may need to be suspended or prematurely terminated and the role of each party involved. We will further outline all major activities required in order to close a clinical investigation, including all necessary reporting to sponsor, ethics committee or IRB and competent authority or FDA.

This course has been developed according to the requirements outlined in:

- ISO 14155:2011 –Clinical Investigation of medical devices for human subjects –Good clinical practice
- 21 CFR part 812 –Investigational device exemption
- Declaration of Helsinki
- 21 CFR part 50 –Protection of Human Subjects.

Learning Objectives:

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

- Perform the appropriate actions when a suspension or premature termination of a clinical investigation is needed and/or perform all close out activities necessary at the end of a clinical investigation.

Who Should Enroll:

Principal and co-investigators, study coordinators, site managers, and other hospital staff or ancillary staff involved in the clinical side of a medical device clinical investigation.

Related Resources: Yes

Prerequisite Knowledge

Learners must have an understanding of what a clinical investigation is about and a basic understanding of the medical device regulatory and good clinical practices environment. Introduction to medical devices (ID 193), how to qualify for a medical device clinical investigation (ID 200), ethics and legal processes (ID 212), initiating a clinical investigation (ID 202), and conduct of and reporting during a clinical investigation (ID 204) provide the pre-requisite knowhow.

Price:

Premium: €45.00.- **Basic:** €60.00.-

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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