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Course Title:

GCP for Investigators: Clinical Investigation Close out or Termination

Product ID: 206
Level: CMDA
Duration: 23 mins
SME: Rita Herrenknecht
First Released On: 10/29/2009

Course Description:
This course examines the circumstances in which a clinical investigation may need to be suspended or prematurely terminated and the role of each party involved. It outlines all major activities required to close clinical investigations, including mandatory reporting to sponsors, ethics committees, institutional review boards, competent authorities, or the FDA.
The content of this course is based on:
- ISO 14155: 2011: Clinical Investigation of Medical Devices for Human Subjects
- The Declaration of Helsinki
- 21 CRF 812: Investigational Device Exemption
- 21 CRF 50: Protection of Human Subjects

Watch the Course Trailer:

Learning Objectives:
Upon successfully completing this course, learners will be able to:
- Perform the appropriate actions to suspend or prematurely terminate a clinical investigation
- Conduct all necessary close-out activities at the end of a clinical investigation

Who Should Enroll:
Principal and co-investigators, study coordinators, site managers, and hospital or ancillary staff involved in the clinical side of medical device clinical investigations are all welcome to enroll in this course.

Related Resources: Yes

Prerequsite Knowledge
The following courses are required:
- GCP for Investigators: Introduction to Medical Devices (ID 193)
- GCP for Investigators: How to Qualify for Medical Device Clinical Investigations (ID 200)
- GCP for Investigators: Ethics and Legal Processes for Medical Device Clinical Investigations (ID 212)
- GCP for Investigators: Clinical Investigation Conduct and Reporting (ID 204)

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

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updates for 1 full year.