

Course Title:

GCP for Investigators: How to Qualify for Medical Device Clinical Investigations

Product ID: 200

Level: CMDA

Duration: 32 mins

SME: Danielle Giroud

First Released On: 10/22/2011

Course Description:

This course explains the importance of the clinical investigation site qualification process in determining whether a given clinical site has the appropriate resources to conduct an investigation.

The qualification process must provide principal investigators the opportunity to evaluate the scientific value, clinical value, and design of the device in question.

The content of this course is based on:

- ISO 14155: 2011: Clinical Investigation of Medical Devices for Human Subjects
- The Declaration of Helsinki
- 21 CFR 812: Investigational Device Exemption
- 21 CFR 50: Protection of Human Subjects

Watch the Course Trailer:

Learning Objectives:

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

- Prepare for and participate in a site qualification visit
- Follow up on post-visit site action items
- Perform regulatory and ethics submissions

Who Should Enroll:

Clinical site investigators, study coordinators and nurses, administrators, and those performing clinical investigation activities at clinical sites are all welcome to enroll in this course.

Related Resources: Yes

Prerequisite Knowledge

The following course is required:

- GCP for Investigators: Introduction to Medical Devices (ID 193)

Price:

Premium: €65.00.- **Basic:** €86.00.-

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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Online Training for Medical Device Professionals

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