

Online Training for Medical Device Professionals

Course Title:

ISO 14155:2011 - Responsibilities of Sponsor

Product ID: 66

Level: CMDA

Duration: 45 mins

SME: Danielle Giroud

First Released On: 10/29/2009

Course Description:

This course examines the roles and responsibilities of the sponsor and monitor during clinical investigations.

It covers the following topics:

- Major areas of responsibility
- Specific sponsor responsibilities with clinical quality assurance, quality control, and outsourcing
- General work flow
- Preparation and planning of clinical investigations
- Monitoring and safety handling during clinical investigations
- Communication with regulatory authorities

Watch the Course Trailer:

Learning Objectives:

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

- Monitor responsibilities during the setup, conduct, and close out of clinical investigations
- Be informed of whether the sponsor wants to outsource any functions or duties
- Understand that any outsourced work remains the sponsor's primary responsibility
- Ensure all appropriate sub-contractor agreements are in place before the outsourcing process begins, including sub-contractor performance checks

Who Should Enroll:

Clinical research associates (monitors), clinical study coordinators, assistant senior clinical research associates, clinical project and data managers, data entry personnel, ethics committee and institutional review board members, regulators, and notified body personnel involved in auditing clinical evaluations are all welcome to participate in this course.

Related Resources: Yes

Prerequisite Knowledge

The following material is required:

- A basic understanding of clinical investigations
- ISO 14155: 2011 - Scope (ID 61)
- ISO 14155: 2011 - Ethical Considerations (ID 62)
- ISO 14155: 2011 - Clinical Investigation Planning (ID 63)
- ISO 14155: 2011 - Clinical Investigation Conduct (ID 64)
- ISO 14155: 2011 - Clinical Investigation Close Out (ID 65)

Price:

Premium: €103.00.- **Basic:** €137.00.-

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



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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.