



WORLD MEDICAL DEVICE ORGANIZATION

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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 brings us to the responsibility sections to start with the roles and responsibilities of the sponsor which includes those of the monitor. Section 8 is divided again in the main areas of responsibilities starts with the specific sponsor responsibilities within the clinical quality assurance and quality control. Further the sections are divided as per work flow, first with preparation and planning of a clinical investigation Next sections handle the responsibilities during the clinical investigation, including all responsibilities regarding monitoring, safety handling. The section also describes the responsibility of the sponsor with regards to outsourcing and the communication with regulatory authorities.

Learning Objectives:

After taking this course the trainee has reviewed the ISO 14155 requirements with regards to the sponsor's including monitor responsibilities during setup, conduct and close down of the clinical investigation; will know if the Sponsor wants to outsource any of the functions or duties, these remain the Sponsor's primary responsibility, so appropriate sub-contractor agreements including checks on sub-contractor's performance must be in place.

Who Should Enroll:

Any party involved in a clinical investigation, primarily Sponsors, monitors, investigators, ethics committees, regulatory authorities and 3rd party reviewers.

Related Resources: Yes

Prerequisite Knowledge

A basic understanding of what is a clinical investigation as well as knowledge of the previous ISO 14155 course contents will enable learners to apply the content of this course.

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 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.