

Online Training for Medical Device Professionals

Course Title:

BIMO: IDE Sponsor Obligations

Product ID: 150

Level: CMDP

Duration: 180 mins

SME: Barry Sands

First Released On: 12/13/2010

Course Description:

This course focuses specifically on the sponsor's responsibilities during clinical studies with investigational medical devices in the US. It provides a comprehensive illustration of the areas the US FDA reviews during bioresearch inspections and outlines common deficiencies identified by the US FDA.

Watch the Course Trailer:

Learning Objectives:

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

- Distinguish the areas the US FDA reviews during bioresearch monitoring visits to sponsor locations
- Recognize and define the regulatory pathways where human clinical research involving investigational medical devices is obtained
- Demonstrate how the ISO 14155: 2011 standard relates to the US FDA BIMO program and why clinical sites located outside of the US must comply with US FDA regulations

Who Should Enroll:

Clinical project managers and senior research associates, data managers, biostatisticians, clinical quality and quality managers involved in auditing and quality systems of clinical investigations for medical devices, and regulatory managers dealing with FDA inspections are all encouraged to enroll in this course.

Related Resources: Yes

Prerequisite Knowledge

The following material is required:

- A full understanding of good clinical practice and all processes involved in clinical investigations
- Effective Monitoring of Medical Device Clinical Investigations (series; IDs 41–48, 59, 56, 50–55, 108, 96)
- US FDA Investigational Device Exemption (IDE) Overview (ID 121)
- Auditing Medical Device Clinical Investigations (series; IDs 217–219)
- Clinical Project Management Complete 10 Course Suite (series; IDs 97–106)
- BIMO: US FDA BIMO Compliance Program (ID 143)

Price:

Premium: €411.00.- **Basic:** €549.00.-

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>).



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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.