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WMDO USA
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South 8th Street, Minneapolis
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Course Title:

BIMO: IDE Investigator Obligations

Product ID: 155
Level: CMDP
Duration: 190 mins
SME: Barry Sands
First Released On: 02/17/2011

Course Description:
This course focuses specifically on the primary investigator's responsibilities at clinical study sites with investigational medical devices in the US. It offers a comprehensive look at 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 particular areas that the FDA reviews during bioresearch monitoring visits to specific clinical study sites
- Anticipate what will be expected from investigators and study personnel during BIMO inspections and prepare accordingly
- 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 the 21 CFR 812 US FDA regulations

Who Should Enroll:
Clinical project managers, senior clinical research associates, data managers, biostatisticians, clinical quality and quality managers involved in auditing and quality systems of clinical investigations for medical devices, regulatory managers dealing with FDA inspections, and clinical investigators and study coordinators involved in medical device clinical investigations are all welcome to participate in this course.

Related Resources: Yes

Prerequsite Knowledge
The following material is required for sponsor personnel:
- 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)
- Clinical Project Management Complete 10 Course Suite (series; IDs 97–106)
- BIMO: US FDA BIMO Compliance Program (ID 143)

The following material is required for investigation site personnel:
- A full understanding of good clinical practice and the mechanisms of conducting clinical investigations Medical Device GCP for Investigators (IDs 193, 200, 212, 202, 204, 206)

Price:

Premium: €446.00.- **Basic:** €594.00.-

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.