



WORLD MEDICAL DEVICE ORGANIZATION

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Online Training for Medical Device Professionals

Course Title:

IRB Review of Medical Devices

Product ID: 148

Level: CMDA

Duration: 153 mins

SME: Erica Heath

First Released On: 12/13/2010

Course Description:

This six-part course offers a highly practical and informative look at Institutional Review Boards (IRBs), groups who analyze and review research to ensure that the rights and welfare of human research subjects are protected.

This course covers the following topics:

- Historical development, structure, and function of IRBs
- Ethical standards regarding IRBs
- A review of medical device research protocols and related materials

Watch the Course Trailer:

Learning Objectives:

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

- Comprehend the function and structure of an IRB
- Identify the role and responsibilities of an IRB in the review of medical device clinical studies
- Recognize the correlation between a device's classification, market trajectory, and investigational status

Who Should Enroll:

Clinical research associates (monitors), senior clinical research associates, clinical project and compliance managers, clinical quality associates and managers, clinical affairs directors, regulatory affairs managers, clinical investigators, and clinical study coordinators and marketing and sales managers involved in clinical investigations are all encouraged to enroll in this course.

Related Resources: Yes

Prerequisite Knowledge

The following courses are required:

- Introduction to Good Clinical Practice (ID 42)
- Introduction to Medical Device and Clinical Investigation Planning (ID 43)
- The Informed Consent Process (ID 45)
- Ethics Committee (EC)/Institutional Review Board Requirements (ID 46)

Price:

Premium: €339.00.- **Basic:** €452.00.-

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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updates for 1 full year.