



WORLD MEDICAL DEVICE ORGANIZATION

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Online Training for Medical Device Professionals

Course Title:

Data Safety & Monitoring Board (DSMB) Establishment

Product ID: 127

Level: CMDP

Duration: 90 mins

SME: Myra Daridan

First Released On: 08/06/2010

Course Description:

This course examines how Data Safety and Monitoring Boards (DSMBs) operate and make a significant difference in studies. It illustrates how independent, third-party assessments of study performances and patients not only ensure adequate protection of the patients participating in the study, but also guarantee regulatory bodies (notified bodies and competent authorities) that both safety and performance are sufficiently, continuously, and impartially assessed.

Watch the Course Trailer:

Learning Objectives:

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

- Comprehend, define, and apply the essential elements, responsibilities, and functions of DSMBs, including:
- Definition of DSMBs, their purpose, and how they function
- Overview of independence, ethics, and patient protection
- Standards and regulations
- Key operational steps
- Members and agreements
- Meetings
- Charters
- Protocol and continuation or discontinuation criteria
- Stopping rules
- Reporting
- DSMB statistics
- DSMB data management

Who Should Enroll:

Professionals or active members involved in establishing or managing DSMBs are welcome to enroll in this course.

Related Resources: Yes

Prerequisite Knowledge

There is no prerequisite knowledge required for this course; all areas of expertise are welcome.

Price:

Premium: €270.00.- **Basic:** €360.00.-

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.