



WORLD MEDICAL DEVICE ORGANIZATION

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Online Training for Medical Device Professionals

Course Title:

The Periodic Monitoring Visit

Product ID: 56

Level: CMDA

Duration: 120 mins

SME: Danielle Giroud

First Released On: 09/30/2009

Course Description:

This course provides an in-depth review of the activities related to monitoring clinical investigations after initiation.

It covers the following topics:

- Preparing for visits
- Planning and confirming visits
- Case studies of handling deviations, personnel changes, or changes in resources
- Ensuring accurate reporting of data, including safety data
- Reporting findings during visits
- Following up on actions required by site personnel

Watch the Course Trailer:

Learning Objectives:

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

- Plan an effective periodic monitoring visit
- Set up a logical agenda and ensure efficiency during the visit
- Detect and handle non-compliance from site personnel
- Ensure appropriate reporting from the site to ethics committees, institutional review boards, or regulatory authorities when necessary
- Create a system for organizing monitoring visits, including logistics and time management
- Develop a system for accurate follow-up after monitoring visits and ensure compliance of site personnel

Who Should Enroll:

Monitors, clinical research associates, and clinical trial assistants and coordinators are all welcome to enroll in this course.

Related Resources: Yes

Prerequisite Knowledge

The following courses are required:

- Introduction to Good Clinical Practice (ID 42)
- The Clinical Investigation Plan (ID 44)
- The Informed Consent Process (ID 45)
- Adverse Event Processes (ID 59)
- Device Accountability (ID 50)
- Deviations and Non-Compliance Handling (ID 51)
- Source Document Verification (ID 52)
- The Case Report Form Process (ID 53)

Price:

Premium: €266.00.- **Basic:** €354.00.-

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.



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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.