



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 all activities related to the monitoring of a clinical investigation after initiation including:

- How to prepare for the visit,
- How to plan and confirm the visit,
- How to handle deviations including several case studies,
- How to handle personnel changes or changes in resources including case studies,
- Ensuring accurate reporting of data including safety data,
- How to report any findings during the visit and follow up on actions required by the site personnel.

Learning Objectives:

Upon completion of this course, trainees will be able to correctly and successfully:

- Plan effectively a periodic monitoring visit, setup an accurate agenda and ensure efficiency during the visit,
- Detect and handle non-compliances from the site personnel,
- Ensure appropriate reporting from the site to Ethics Committees or Institutional Review Boards and where needed to regulatory authorities,
- Develop a system for organizing monitoring visits including effective logistics and time management,
- Develop a system for accurate follow up after a monitoring visit and ensure compliance of the site personnel.

Who Should Enroll:

Monitors / Clinical research associates, clinical trial assistants, clinical trial coordinators.

Related Resources: Yes

Prerequisite Knowledge

Understand the basis of Good Clinical Practice (ID 42), what is a clinical investigation plan (ID 44), an informed consent process (ID 45) and adverse event processes (ID 59) is needed to have a meaningful understanding of this course. This course should be taken in combination with the course on source document verification (ID 52), device accountability (ID 50), deviations and non-compliance handling (ID 51) and 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.

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.