



WORLD MEDICAL DEVICE ORGANIZATION

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Online Training for Medical Device Professionals

Course Title:

Deviations and Non-Compliance Handling

Product ID: 51

Level: CMDA

Duration: 15 mins

SME: Danielle Giroud

First Released On: 09/30/2009

Course Description:

This course provides a reviews of the different types of deviations depending on their seriousness with regards to patient safety and clinical investigation outcome. We provide the learners with an overview of the necessary actions to be taken to correct deviations early on to ensure subject safety and data quality. The course also gives a general outline of the reporting requirements of deviations..

Learning Objectives:

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

- Take measures to ensure early detection of deviations and evaluate their seriousness.
- Minimize the occurrence of deviations by implementing the necessary corrective and preventive actions and optimize overall compliance.
- Ensure regulatory compliance through appropriate reporting requirements.

Who Should Enroll:

Monitors, investigators, study coordinators, clinical project managers and regulatory, and marketing professionals involved in clinical investigations.

Related Resources: Yes

Prerequisite Knowledge

Learners will need to understand the basics of good clinical practices, medical device regulatory and ethics requirements as well as understand what is involved in site selection, initiation and monitoring.

Price:

Premium: €33.00.- **Basic:** €44.00.-

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 updates for 1 full year.