



WORLD MEDICAL DEVICE ORGANIZATION

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WMDO USA  
3565 IDS Center 80  
South 8th Street, Minneapolis  
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Online Training for Medical Device Professionals

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**Course Title:**

## **Deviations and Non-Compliance Handling**

Product ID: 51

Level: CMDA

Duration: 15 mins

SME: Danielle Giroud

**Course Description:**

This course provides a review of the different types of deviations in regard to patient safety and clinical investigation outcomes. It includes an overview of the necessary steps to correct deviations early-on and to ensure subject safety and data quality. It also gives a general outline of deviation reporting requirements.

The course also covers on what to do if a site is non-compliant with the study requirements and not necessarily related to subject's participation and points to risk management section of the monitoring plan.

Watch the Course Trailer:

**Learning Objectives:**

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

- Ensure early detection of deviations and evaluate their urgency
- Minimize the occurrence of deviations by implementing the necessary preventive and corrective measures
- Apply pre-defined thresholds and ensure appropriate escalation process is understood
- Optimize overall compliance
- Secure 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 are all welcome to participate in this course.

**Related Resources:** Yes

**Prerequisite Knowledge**

An understanding of the basics of good clinical practice, medical device regulatory and ethics requirements, and the steps involved in site selection, initiation, and monitoring is required for this course.

**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.



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