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WMDO USA
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Course Title:

Adverse Event Processes

Product ID: 59
Level: CMDA
Duration: 77 mins
SME: Danielle Giroud
First Released On: 08/25/2020
Course Updated On: 08/25/2020

Course Description:
This course provides a detailed review of the basics and fundamentals of safety reporting during clinical investigations prior to market approval. It outlines the entire process, using practical examples and flowcharts to illustrate each mechanism of the safety processes step-by-step.
This course covers the following topics:
- Objectives of safety reporting
- Definitions of the different classifications of adverse events and device deficiencies according to ISO 14155: 2011 principles
- Roles and responsibilities of the following parties: sponsors, monitors, investigators and their teams, critical event committees, and data monitoring boards
- Reporting obligations of each party
- Summary of the national differences in safety reporting, i.e. the US, Europe, and Japan
- Type of reports
- Examples and exercises of common errors
- Case studies of several real-life situations and step-by-step guidance on what to do as a monitor or sponsor

Watch the Course Trailer:

Learning Objectives:
Upon successfully completing this course, learners will be able to:
- Identify and categorize adverse events and device deficiencies
- Classify, document, and report safety information during clinical investigations in compliance with international GCP requirements (ISO 14155: 2011) for medical devices
- Take national differences into account

Note: For more on national regulatory requirements, please review the “Safety Reporting Requirements” (SID79) series of courses.

Who Should Enroll:
Monitors, clinical project managers and research associates, investigators, study coordinators, quality assurance associates and managers, regulatory and sales managers, marketing managers wanting to understand the general requirements of the safety reporting process, and clinical project managers from the pharmaceutical industry wanting to understand medical device adverse events, device deficiency definitions, and reporting requirements are all encouraged to enroll in this course.

Related Resources: Yes

Prerequsite Knowledge
The following courses are required:
- Introduction to Good Clinical Practice (ID 42)
- The Clinical Investigation Plan (ID 44)

Price:

Premium: €148.00.- **Basic:** €198.00.-

WORLD MEDICAL DEVICE ORGANIZATION

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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.