



WORLD MEDICAL DEVICE ORGANIZATION

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South 8th Street, Minneapolis
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Online Training for Medical Device Professionals

Course Title:

Complaint Handling and Reporting Process for Medical Devices

Product ID: 141

Duration: 65 mins

SME: Scott.T Long

First Released On: 10/26/2010

Course Description:

This course provides a comprehensive overview of complaint handling and an outline of the reporting process for commercially-released medical devices.

It focuses on the following topics:

- Product safety assurance
- Basic principles of the complaint handling and reporting processes
- The complaint handling cycle
- Adverse event reporting in the post market phase

Watch the Course Trailer:

Learning Objectives:

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

- Define what constitutes a complaint
- Distinguish when a complaint or adverse event is reportable
- Comprehend and apply a high-level Product Safety Assurance Model and know where the complaint handling process fits into this cycle
- Understand the importance of having the appropriate resources within your Complaint Handling Unit to ensure that all complaints are properly reviewed and assessed based on risk severity
- Identify which agencies require an adverse event to be reported
- Acknowledge that all adverse events should be reported within a designated time period to the applicable agencies

Who Should Enroll:

Regulatory Affairs Associate, Regulatory Affairs Manager, Quality Assurance Associate, Quality Assurance Manager, Quality Assurance Engineer, Manufacturing Engineer, Supply Manager, Purchasing Manager, Design Engineer, Validation Engineer, Electrical Safety Engineer, Internal Auditor, Lead auditor, Pre-Clinical Study Manager, Export Manager, Clinical Affairs Director, and R&D Engineer are all encouraged to take this course.

Related Resources: Yes

Prerequisite Knowledge

There is no prerequisite knowledge required for this course; all areas of expertise are welcome.

Price:

Premium: €144.00.- **Basic:** €192.00.-

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.