

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 will provide you with an excellent overview of the complaint handling and reporting process for commercially released medical devices with emphasis on the reporting of complaints and adverse events including:

- Product safety assurance
- Basic principles of complaint handling and reporting
- The complaint handling cycle
- Adverse event reporting.

Learning Objectives:

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

- Comprehend and apply a high level Product Safety Assurance model and know where the Complaint Handling Process fits into this cycle
- Define what constitutes a complaint
- Distinguish when a complaint or adverse event is reportable
- Identify to what agencies an adverse event is required to be filed
- Comprehend the importance of having the resources in place with your Complaint Handling Unit to ensure that all complaints are reviewed and assessed for proper reporting based on risk severity and that all adverse events be reported according to defined timelines to the applicable agencies as required.

Who Should Enroll:

Regulatory/Quality and Clinical Assistants, Administration Staff, Regulatory and Clinical Affairs Associates.

Related Resources: Yes

Prerequisite Knowledge

None

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>).

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.