

Online Training for Medical Device Professionals

Course Title:

GHTF/IMDRF: The Pre-Market Model

Product ID: N170

Duration: 30 mins

SME: Shelley Tang

First Released On: 10/30/2012

Course Description:

This course follows ID N169: "Introduction to the GHTF or IMDRF" and describes in further detail the GHTF/IMDRF recommendations for a pre-market regulatory model for medical devices. It provides an overview of the elements of the pre-market system and how they fit within the overall regulatory system for medical devices.

Watch the Course Trailer:

Learning Objectives:

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

- Understand the elements which comprise the GHTF/IMDRF pre-market system
- Apply these components to demonstrate the safety and performance of medical devices

Who Should Enroll:

Regulatory affair, quality assurance, and clinical professionals in the industry, and regulators with an interest in the global market are all encouraged to enroll in this course.

Related Resources: Yes

Prerequisite Knowledge

The following course is required:

- Introduction to the GHTF or IMDRF (ID N169)

Additionally, knowledge of the European system for device regulation is useful but not required.

Peer Reviewer:

Shelley Tang

Peer Reviewer Date

Price:

Premium: €66.00.- **Basic:** €89.00.-

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.