



WORLD MEDICAL DEVICE ORGANIZATION

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Online Training for Medical Device Professionals

Course Title:

GHTF/IMDRF – Essential Principles of Safety and Performance for Medical Devices

Product ID: N182

Duration: 83 mins

SME: Shelley Tang

First Released On: 01/24/2013

Course Description:

This course takes a detailed look at the Essential Principles for safety and performance of medical devices, as developed by the Global Harmonization Task Force (GHTF) and now maintained under the International Medical Device Regulators' Forum (IMDRF). We explain the intent of each Essential Principle and provide guidance on how a manufacturer should demonstrate compliance.

Watch the Course Trailer:

Learning Objectives:

Upon completion of this course, trainees will have gained an understanding of what the Essential Principles are, what they mean and what is involved in demonstrating compliance.

Who Should Enroll:

Regulatory affairs professionals with an interest in the global market, manufacturers who wish to access markets in countries which have adopted the GHTF model, regulators involved in developing and implementing regulatory systems for medical devices

Related Resources: Yes

Prerequisite Knowledge

An understanding of the GHTF model for regulation of medical devices

Price:

Premium: €184.00.- **Basic:** €245.00.-

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.