

Course Title:

The Hong Kong Regulatory System for Medical Devices

Product ID: 186

Duration: 72 mins

SME: Jeremy Yung

First Released On: 05/27/2011

Course Description:

This course reviews Hong Kong's background, the legislation behind their medical device regulations, special terms within their regulatory system, how to register a product in Hong Kong, and their grouping and classification system for devices.

At the end of this course, there is a complete and comprehensive demonstration of a hypothetical device undergoing Hong Kong's regulatory system.

Watch the Course Trailer:

Learning Objectives:

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

- Recall the legislative history of Hong Kong's device regulations
- Gain a general understanding of Hong Kong's medical system
- Identify the steps needed to register a medical device in Hong Kong and what supporting documents are required

Who Should Enroll:

Regulatory, marketing, and quality assurance managers involved in product registration and compliance in Hong Kong are encouraged to enroll in this course.

Related Resources: Yes

Prerequisite Knowledge

Learners should understand the basic medical device regulatory principles outlined in the GHTF/IMDRF documents and explained in the series of courses GHTF/IMDRF:

- pre-market Regulatory Model (ID N170).
- Post market regulatory model (ID N171)
- Supporting documents (ID N172)
- International Implementation (ID N173)
- Essential principles of safety and performance of medical devices (ID N182)
- STED and its contents (ID N187)

Price:

Premium: €159.00.- **Basic:** €213.00.-

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.



WORLD MEDICAL DEVICE ORGANIZATION

WMDO SA
Route de Denges 28C
1027 Lonay
Switzerland
Tel. +41 21 349 96 36
Fax +41 21 349 96 37
contact@wmdo.org

WMDO USA
3565 IDS Center 80
South 8th Street, Minneapolis
MN 55402, USA

Online Training for Medical Device Professionals
