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WMDO USA
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South 8th Street, Minneapolis
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Course Title:

The Japanese Regulatory System for Medical Devices

Product ID: 146
Duration: 95 mins
SME: Jeremy Yung

Course Description:
This course begins by outlining the historical background of Japan's Regulatory System for Medical Devices, including a detailed overview of the necessary company and manufacturing prerequisites to market medical devices in Japan, relevant product standards and classifications, various application routes for market approval, and the necessary preparations for completing submissions.
This course also offers the added element of lending crucial insight into Japanese culture, which can help learners establish good working relationships with regulatory authorities in Japan.
Note: The laws were recently updated on 25 November 2014

Watch the Course Trailer:

Learning Objectives:
Upon successfully completing this course, trainees will be able to:
- Comprehend and define the working fundamentals of the Japanese Regulatory System for Medical Devices, which includes:
- Background of Japan's Regulatory System for Medical Devices
- Company prerequisites to market medical devices in Japan
- Manufacturing prerequisites to market medical devices in Japan
- Relevant product standards and classifications
- Application routes for market approval
- Preparation needed after completing a submission

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 Affairs Director, Clinical Project Manager, Export Manager, and R&D Engineer involved in the Japanese registration and compliance process are welcome to enroll in this course.

Related Resources: Yes

Prerequsite Knowledge
Learners should have a basic understanding of both the principles outlined in the GHTF documents (now IMDRF) and the principles explained in the series of courses under SID N25 GHTF/IMDRF: "Regulatory Model for Medical Devices."

Price:

Premium: €210.00.- **Basic:** €280.00.-

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.