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Course Title:

The ASEAN Common Submission Dossier Template (CSDT) and Its Contents

Product ID: N203
Duration: 70 mins
SME: Tan Ming Hao
First Released On: 09/29/2016

Course Description:
This course provides a detailed look at recommendations for the format and content of the ASEAN Common Submission Dossier Template (CSDT). The content of the ASEAN CSDT is prescribed in the ASEAN Agreement on Medical Device Directive, signed by representatives of the 10 ASEAN member states in November 2014.
This course also provides mapping and detailed comparison of the CSDT to the Summary Technical Documentation (STED), a set of guidelines developed by the Global Harmonization Task Force (GHTF) and now maintained under the International Medical Device Regulatory Forum (IMDRF). It also provides guidance on what manufacturers must include in CSDTs.

Watch the Course Trailer:

Learning Objectives:
Upon successfully completing this course, trainees will be able to:
- Gain an understanding of what documentation is required for developing Common Submission Dossiers (CSDs) in accordance to the CSDT
- Develop a CSD for submission to the appropriate regulatory authority

Who Should Enroll:
The following are encouraged to participate in this course:

- Regulatory affairs and quality assurance professionals with an interest in the ASEAN market, or markets to which compliance to the CSDT is a regulatory requirement.
- Manufacturers seeking to access markets in ASEAN countries, or markets to which compliance to the CSDT is a regulatory requirement
- Regulators involved in developing and implementing regulatory systems for medical devices

Related Resources: Yes

Prerequsite Knowledge
A basic understanding of widely-adopted medical device regulatory framework(s) –either the GHTF model for regulation of devices or the ASEAN AMDD regulatory framework on which it is based.

Price:

Premium: €150.00.- **Basic:** €200.00.-

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.