WMDO
WORLD MEDICAL DEVICE ORGANIZATION

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Course Title:

Overview of US FDA Quality System Regulation

Product ID: 118
Duration: 75 mins
SME: Maria E. Donawa
First Released On: 06/18/2010

Course Description:
According to the FDA's Quality System Regulation (QSR) for medical devices, all manufacturers are required to establish and follow quality systems to help ensure that their products consistently meet applicable requirements and specifications. But what are the important requirements of the QSR and what must a quality system include to be compliant with the QSR?
Anyone involved with QSR compliance will truly appreciate this highly informative Overview of US FDA Quality System Regulation that will explain what the QSR is all about and how it works, including Management and Design Controls, Production and Process Controls, and Post-production Requirements.

Learning Objectives:
Upon completion of this course, trainees will be able to correctly and successfully:
- Identify and comprehend the basis of the QSR and its provisions
- Distinguish the key differences between the QSR and ISO 13485
- Recognize how the FDA interprets important QSR provisions
- Acquire insight on key areas of the QSR of which the FDA places the most emphasis.

Who Should Enroll:
Any medical device professional who has any responsibility that involves being in compliance with the QSR.

Related Resources: Yes

Prerequsite Knowledge
None

Price:

Premium: €225.00.- **Basic:** €300.00.-

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.