

Course Title:

Overview of US FDA Quality System Regulation

Product ID: 118

Duration: 75 mins

SME: Maria E. Donawa

Course Description:

This course presents a highly informative overview of the US FDA's Quality System Regulation (QSR). It explains what a QSR is and how it works, including management and design controls, production and process controls, and post-production requirements.

According to the US FDA's QSR for medical devices, all manufacturers are required to establish quality systems to ensure that their products consistently meet the standard requirements and specifications. This course examines the key QSR requirements and what a quality system must include to be compliant with the QSR.

Watch the Course Trailer:

Learning Objectives:

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

- Identify and comprehend the basis of the US FDA QSR and its provisions
- Distinguish the key differences between the US FDA QSR and ISO 13485
- Acquire insight on which key areas of the QSR the FDA emphasizes the most
- Discern how the FDA interprets important QSR provisions

Who Should Enroll:

Medical device professionals who are responsible or involved in compliance with the US FDA QSR are encouraged to take this course.

Related Resources: Yes

Prerequisite Knowledge

There is no prerequisite knowledge required for this course; all areas of expertise are welcome.

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.