

Online Training for Medical Device Professionals

Course Title:

US FDA 510(k) Notification Process

Product ID: 92

Duration: 50 mins

SME: Carole Stamp

First Released On: 03/31/2010

Course Description:

This course provides a fundamental and expansive overview of the US FDA 510(k) Notification Process and how it works. It covers the following topics:

- How the FDA defines and classifies medical devices using the FDA review and clearance process
- The preparation of a traditional 510(k) notification
- Examples of how and when to submit a new 510(k) for device modifications made during the post-market phase
- Direct links to FDA guidance documents, FDA forms, and various databases for classifications, predicate devices, and recognized standards
- Interactive multi-scenario case studies
- Audio and video presentations
- Glossary items
- Detailed charts
- Models and graphics

Watch the Course Trailer:

Learning Objectives:

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

- Formulate what constitutes a medical device according to FDA definitions
- Determine and classify medical devices according to recognized FDA standards
- Prepare a basic 510(k) notification submission
- Explain and identify the FDA review and clearance process
- Identify post-market changes that may prompt the need for a new 510(k)

Who Should Enroll:

Regulatory or quality professionals who wish to understand the US FDA 510(k) Notification Process are encouraged to enroll in this course.

Related Resources: Yes

Prerequisite Knowledge

WMDO course Overview of US FDA Quality System Regulation is recommended but not required.

Price:

Premium: €114.00.- **Basic:** €152.00.-

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.