WMDO
WORLD MEDICAL DEVICE ORGANIZATION

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Course Title:

Labeling Requirements for Medical Devices in the US

Product ID: N144
Duration: 70 mins
SME: Carole Stamp

Course Description:
This course provides a detailed review of the labeling requirements for medical devices in the US.
The content of this course is based on the Code of Federal Regulations (CFR) and the following guidance documents:
- FDA Guidance G91-1: “Device Labeling Guidance”
- FDA Guidance 89-4203: “Labeling: Regulatory Requirements for Medical Devices”
- Guidance on medical device patient labeling
- Guidance for industry and FDA reviewers (19 April 2001)
- General device labeling 21 CFR 801

The final part of this focuses on recommendations from the SME.

Watch the Course Trailer:

Learning Objectives:
Upon successfully completing this course, trainees will be able to:
- Plan labeling activities for the US market
- Apply regulations and guidance documents to the labeling process
- Support development of device labeling
- Apply different requirements for OTC, prescription devices, and restricted devices
- Evaluate compliance with regard to misbranding

Who Should Enroll:
Regulatory affairs professionals in charge of labeling, developmental engineers and clinical research managers who contribute to the setup of medical device labeling, and quality managers and engineers who are responsible for change control of technical documents (including labeling) are all welcome to participate in this course.

Related Resources: Yes

Prerequsite Knowledge
A strong comprehension of the pre-market notification (510k) and pre-market approval process for market access in the US is required. Knowledge of the principles of risk management processes, including human factors, engineering requirements, and impacting labeling is also required for this course.

For more information on the topics above, please review the following courses:
- Risk Management for Medical Devices in EU and US (ID 77)
- US FDA 510(k) Notification Process (ID 92)
- US FDA Investigational Device Exemption (IDE) Overview (ID 121)

Peer Reviwer:
Carole Stamp
Peer Reviewer Date

Price:

Premium: €155.00.**- Basic:** €207.00.-

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.

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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.