WMDO
WORLD MEDICAL DEVICE ORGANIZATION

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Course Title:

Biological Evaluation of Medical Devices: A Risk-Based Approach

Product ID: N134
Duration: 63 mins
SME: Arthur Brandwood
First Released On: 04/23/2012

Course Description:
This introductory course provides an overview of the biological evaluation of medical devices following the guidance contained within the ISO 10993 series of international standards. It offers a first-hand look at how to plan and conduct the biological evaluation of a medical device, and, more importantly, how such an evaluation sits within the activities of design control and risk management according to ISO 14971.

The course will familiarize the learner with:
- The ISO 10993 series of standards
- How the biological evaluation sits within the activities of design control and risk management according ISO 14971
- Biological evaluations and regulations
- Biological safety testing
- The risk management paradigm

A discussion of the biological safety report concludes this course.

Learning Objectives:
Upon completion of this course, trainees will be able to correctly and successfully:
- Comprehend the regulatory framework relating to the biological evaluation of medical devices
- Evaluate the need for biological evaluation in the framework of risk management for the devices your organization is manufacturing
- Participate and contribute to the biological evaluation activities for your medical devices

Who Should Enroll:
Development engineers. Regulatory and quality associates needing an introduction to the biological evaluation of medical devices. Regulatory professionals wanting to get an update on ISO 10993. Executive management who wish to oversee compliance-related aspects of biological evaluation for medical devices.

Related Resources: Yes

Prerequsite Knowledge
Participants should have a basic understanding of the knowledge areas covered within the following WMDO training courses:
- ID 77 –Risk Management for Medical Devices in EU and US (3 course suite)
- ID 183 –The Design, Development and Industrialization of Medical Devices
- ID 196 –ISO 13485: Foundation and Basic Principles
- ID 185 –Importance of Technical Standards in the Medical Device Sector

Peer Reviwer:
Arthur Brandwood
Peer Reviewer Date

Price:

Premium: €144.00.**- Basic:** €186.00.-

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.