

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 ISO 10993 standard international guidance. It offers a first-hand look at how to plan and conduct biological evaluations of medical devices and where such evaluations fit within the areas of design control and risk management.

This course covers the following topics:

- The ISO 10993 series of standards
- Biological evaluations and regulations
- Biological safety testing
- The risk management paradigm

At the end of this course there is a discussion of biological safety reports.

Watch the Course Trailer:

Learning Objectives:

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

- Comprehend the regulatory framework relating to biological evaluations of medical devices
- Evaluate the need for devices to undergo biological evaluation
- Participate in and contribute to biological evaluation activities for medical devices

Who Should Enroll:

Development engineers, regulatory and quality associates needing an introduction to biological evaluation, regulatory professionals wanting an update of ISO 10993, and executive management employees who wish to oversee compliance-related aspects of biological evaluation are all encouraged to enroll in this course.

Related Resources: Yes

Prerequisite Knowledge

A basic understanding of the following courses is required:

- Risk Management for Medical Devices in EU and US (3-course series)
- The Design, Development, and Industrialization of Medical Devices (ID 183) –*Under construction*
- ISO 13485: Foundation and Basic Principles (ID 196)
- Importance of Technical Standards in the Medical Device Sector (ID 185)

Peer Reviewer:

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.

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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Online Training for Medical Device Professionals

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.