Introduction to Risk Management for Medical Devices

Course Description

This course is designed to provide participants with an understanding of the impact that ISO 14971:2009 has on the decision making process at medical device manufacturing firms. This one-day training course helps medical device professionals gain an understanding of how ISO 14971 can improve their business and risk management efforts. Participants will also understand how ISO 14971 applies to ISO 13485.

The training includes exercises, and participants will have the chance to ask questions about how ISO 14971 and risk management apply to their organizations.

Course Benefits

- Gain an understanding of the impact that ISO 14971:2009 has on the decision making process when manufacturing medical devices.

Learning Objectives

Upon completion of this training, delegates will be able to:

- Identify the links between ISO 13485 (QMS) and ISO 14971 (RM)
- Explain how risk management relates to the product lifecycle
- Define risk management terminology
- Outline the stages of the risk management process
- Define the key deliverables of the risk management process.

Intended Audience

- Regulatory, quality, design (including design changes), development, manufacturing, marketing managers and personnel
- Decision makers on management system strategy
- Internal auditors.

Course Duration

1 Day.

Prerequisites

Participants should have experience with or basic knowledge of quality management systems for the medical device industry. Recommended is a basic awareness of medical devices, quality assurance, and ISO 13485.