ISO 14971 Risk Analysis & FMEA for Medical Devices

Learn Risk Analysis, Failure Mode and Effects Analysis (FMEA) and Management for Medical Devices

Two-day interactive workshop to learn steps of risk management as per requirements of ISO 14971 Risk Analysis and FMEA for medical devices. Get an in-depth understanding of how FMEA is managed as a process. This course is a dynamic, hands-on learning opportunity to gain practical knowledge.

BENEFITS

- Conduct risk analysis and failure mode and effects analysis to identify hazards
- Apply risk analysis methodologies to medical devices
- Learn risk evaluation and risk control principles that affect decision making
- Identify design or process failures and opportunity for development
- Improved risk management

TARGET GROUP

- Program Managers
- Product Managers
- Quality Managers
- Design Engineers
- Manufacturing Engineers
- R&D Managers / Engineers
- Quality Assurance Managers / Engineers
- Management Representatives
- Design Teams
- Design Review Teams
- Project Managers
- Internal and External Auditors

PREREQUISITES

- Knowledge of product design,development or manufacturing
- Knowledge of basic quality assurance concepts

COURSE INFORMATION

Language	English
Format	Classroom
Duration	2 Days

COURSE TOPICS

- Expectations of the Food and Drug Administration (FDA) and the EU in applying risk analysis to medical devices
- Risk management requirements and the purpose of ISO 14971
- The application of ISO 14971 to medical devices
- The application of risk analysis methodologies such as FMEA to medical devices
- The principles of risk management planning in developing procedures and practices to analyse, evaluate and control risks
- Sources of information and further development

DEGREE

Certificate