Introduction to Risk Management (ISO 14971:2019)

This course provides participants with fundamental knowledge and practical understanding of Risk Management principles based on ISO 14971:2019. Participants will learn the concepts, terminology, risk management processes, responsibilities, documentation requirements, and implementation approaches for product and process risk management, including post-market activities and corrective/preventive actions.

Objective:
Upon completion of this course, participants will be able to:

- Understand the principles and concepts of risk management
- Interpret key terms and definitions in ISO 14971:2019
- Understand the risk management process and lifecycle
- Identify management responsibilities in risk management activities
- Develop and implement a risk management plan
- Understand risk management documentation and record control requirements
- Apply product and process risk management concepts
- Conduct basic risk assessment and risk control activities
- Understand post-market monitoring and CAPA concepts

Target Participants

- Quality Assurance / Quality Control Personnel
- Regulatory Affairs Personnel
- Production and Engineering Teams
- Risk Management Team Members
- Internal Auditors
- Management Representatives
- Personnel involved in Medical Device Quality Management Systems

Course Timetable

09.00-10.30	Introduction to risk management Risk concept, Term & definition
10:30-10:45	Coffee break
10:45-12:00	Risk management process Management responsibilities Risk management plan
12:00-13:00	Lunch break
13:00-14:00	Risk management documents & records control Product risk management Process risk management
14:00-14:45	Workshop II: Process risk management
14:45-15:00	Coffee break
15:00-15:45	Post market phase & Corrective / Preventive action
15:45-16:00	Question & Answer

หมายเหตุ
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