



## **ISO 14971 Risk Management**

1-Day

This one-day course is intended to provide the participants with an understanding of the Risk Management activities for Medical Devices defined in the ISO 14971 standard.

### **Target Audience:**

Personnel in the Quality Assurance, Design and Development, Manufacturing, Clinical Functions and others who are involved with and maybe included in any Risk Management activities related to Medical Devices should attend this course.

The participant will be walked through the Risk Management Lifecycle which includes:

- Risk Policy
- Risk Management Plan
- Risk Management File
- Risk Analysis
- Risk Evaluation
- Risk Control
- Risk Reduction
- Residual Risk Evaluation
- Risk/Benefit Analysis
- Risk Management Report
- Production and Post-Production Information (Feedback)

For each of the Risk Management Activities, examples of methods to comply with the requirements will be reviewed. Different types of Risk Analysis will also be reviewed (User Hazard Analysis, Clinical Hazard Analysis, Design FMEA, Process FMEA, etc).

Although not specifically stated as an ISO 14971 requirement, many of the Quality Management System processes are becoming Risk Based. ISO 13485 states in section 7.1 "*The organization shall establish documented requirements for risk management throughout product realization*". As part of this course, discussions will include how Risk Management is integrated within various processes (Document Control, Supplier Management, Inspection, Internal Audits, Corrective & Preventive Action, Complaints, etc) within the Quality Management System.