



# MEDICAL DEVICE RISK MANAGEMENT

**2 HALF-DAY,  
6 HALF-DAY  
or 3 FULL DAY**

## LEARN HOW TO MANAGE MEDICAL DEVICE RISKS WITH CLARITY AND CONFIDENCE

Expectations by Regulatory bodies of medical device companies in producing quality, logical and defensible risk management files are rising. This course teaches a disciplined, systematic approach to the analysis, estimation, evaluation, and control of safety risks associated with medical devices. The course provides a comprehensive coverage of the topics needed for successful management of safety risks in conformance with international standard ISO 14971. The scope of risk management includes both pre-market product development and post-market risk management. Application of formal risk management techniques can help predict and prevent serious harm to patients and losses to businesses. The course is authored and delivered by leading expert and author Bijan Elahi.



*Most medical device companies struggle with risk management. Compliance with ISO 14971 is not straightforward. Many practitioners struggle with even the language of risk management. This can lead to confusion, wasted time and effort. This course aims to create clarity for the product developers and risk management practitioners so they can do their work with confidence and efficiency.*

**- Bijan Elahi, Course Presenter & Principal Consultant, PPI**



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## 1. The Value Proposition for World Class Medical Device Risk Management

Proper risk management is a value-adding activity to medical device product development. Efficient, intelligent, and effective risk management ensures smooth product approvals, reduced field corrective actions, and achieves significant cost savings to the business.

## 2. Introduction to Medical Device Risk Management

- Why do we need to do medical device risk management?
- The benefits of medical device risk management
- Safety as an emergent system property
- History and origins of risk management
- Safety constraints
- Cybersecurity and safety risk management
- Language of risk management
- Hazard theory
- Hazard Taxonomy
- How to distinguish subtle concepts in risk management
- Quiz

## 3. Medical Device Risk Management Standards

- ISO 14971 – the central standard in medical device risk management
- Requirements of ISO 14971
- Other related safety standards: IEC 60601-1, IEC 62366, IEC 62304, ISO 10993

## 4. Medical Device Risk Management as a Value-Added Activity

- Risk management contribution to the various lifecycles in product development

## 5. Medical Device Risk Management Activities and Artifacts

- Risk management plan
- Risk management report
- RM file
- RM process
- Risk analysis

## 6. Foundations for Medical Device Risk Management

- System types
- Clinical Hazards List (CHL)
- What it is
- How to create it
- Risk estimation
- Classic and advanced methods
- Harms Assessment List (HAL)
- What it is
- How to create it
- Quiz

## 7. Medical Device Risk Management Tools and techniques

- Fault Tree Analysis (FTA)
- Preliminary Hazard Analysis
- Failure Modes and Effects Analysis (FMEA/FMECA)
- Is FMEA risk management?
- Relationship between FMEA and FTA
- Domains of Severity, Occurrence and Detectability
- Risk management scaling via hierarchical-multi-level FMEA
- FMEA cascade
- Usability Engineering and risk management
- How to distinguish reasonably foreseeable misuse

## 8. Software Medical Device Risk Management

- Introduction
- Software failure model
- Language of SW risk management
- Contribution of software to system hazards
- Software risk

## 9. Medical Device Risk Assessment

- Risk Assessment and Control Table (RACT)
- Risk integration
- RACT workflow
- P1 and P2
- Risk controls
- Safe by design
- Protective Measures
- Information for safety
- Risk controls end-point logic
- Verification of risk controls
- Residual risk
- Traceability

## 10. Benefit-Risk Analysis

- FDA guidance
- Criteria for benefit-risk analysis
- FDA decision-making factors

## 11. Post-market Medical Device Risk Management

- Listening systems
- Surveillance
- Complaint handling

## 12. In Closing

- Common mistakes in medical device risk management
- Tips and wisdom for success.

To register visit our website or call our friendly registration team:



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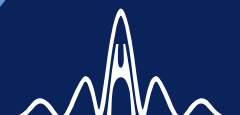
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