

3-DAY OR 5 HALF-DAYS COURSE

Medical Device Risk Management



A disciplined approach to safer medical devices and better engineering decisions

Why Medical Device Risk Management?

Medical device manufacturers face increasing expectations to demonstrate that the benefits of their products outweigh their risks. At the same time, growing product complexity, software dependence, cybersecurity threats, and evolving regulatory requirements make effective risk management more challenging than ever.

This course teaches how to apply medical device risk management as a disciplined engineering activity that improves both product safety and business outcomes.

Built around ISO 14971, the course provides practical methods for identifying hazards, evaluating risks, implementing effective risk controls, and maintaining robust risk management throughout the product life cycle. Participants develop the knowledge needed to produce logical, defensible, and high-quality risk management files while supporting smoother regulatory approval, reducing costly corrective actions, and improving confidence in engineering decisions.

What You Will Learn

Participants develop a practical understanding of medical device risk management through a combination of theory, quizzes, and hands-on workshops. The course explores internationally recognized practices and demonstrates how structured risk management contributes directly to safer products and more successful development programs.

You will learn how to apply ISO 14971 confidently while integrating risk management into every stage of the medical device life cycle.

Areas of learning include:

- Applying the principles and requirements of ISO 14971
- Identifying hazards and reasonably foreseeable misuse
- Performing fault tree analysis (FTA) and failure modes and effects analysis (FMEA)
- Evaluating and controlling medical device risks
- Managing in particular software and cybersecurity risks
- Conducting benefit-risk analyses
- Applying effective post-market risk management practices.

Earn CE/CPD Credit

This course is recognized for professional development purposes:



**INCOSE CSEP
Renewal**

- 21 Continuing Education PDUs



**PMI Talent Triangle®
Suggested PDUs**

- 13 Ways of Working
- 1 Business Acumen

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Course Presenter and Author



Bijan Elahi is an expert on a world scale in risk management and systems engineering. He was presented with Educator of the Year Award by the International System Safety Society. In 2019 he received another award, this time in recognition of Outstanding Development of Analytical Methods to Support Medical Device System Safety.

[Learn more](#)

Who Should Attend and Why

This course is designed for professionals involved in the development, evaluation, manufacture, regulation, or support of medical devices. It is suitable for those new to medical device risk management and for experienced practitioners seeking a more structured and effective approach.

It is particularly valuable for professionals responsible for balancing patient safety, regulatory compliance, and engineering performance.

The course will benefit:

- Risk managers
- Systems engineering practitioners
- Design and manufacturing engineers
- Software and usability engineers
- Quality and quality assurance engineers
- Regulatory affairs professionals
- Engineering managers
- Clinical, marketing, packaging, and toxicology professionals involved in medical device development.

Training Methods and Materials

The course combines formal presentation, discussion, quizzes, and practical workshops to reinforce learning through application. Participants gain hands-on experience with widely used medical device risk management techniques, including Fault Tree Analysis (FTA) and Failure Modes and Effects Analysis (FMEA), while exploring software risk management, cybersecurity, and other specialist topics. **The emphasis is on developing practical skills that can be applied immediately within medical device development programs.**

Participants receive comprehensive presentation materials, templates, and reference resources to support ongoing application of the techniques learned. The companion textbook, ***Safety Risk Management for Medical Devices***, authored by course facilitator Bijan Elahi, is recommended as an additional reference and provides detailed guidance and worked examples to complement the course.

PPI Training Reviews



*"The text, **Safety Risk Management for Medical Devices**, is an excellent companion for the medical device developers and entrepreneurs. As part of our lean start-up strategy we wanted to complete as much of the development in-house as possible. Elahi's methods and resources enabled first-timers, such as ourselves, to implement a robust evidence-based risk management approach that supported the successful CE mark of our device."*

Devakar Epari,
Australia



"Bijan also was able to use real life examples to easily relate the importance of risk management to product development and the do's and don'ts. This course has given me the knowledge and expertise to practise risk management of medical devices in my own projects. This is one of the best and most relevant industrial courses that I have ever taken."

Course participant,
Netherlands

Medical Device Risk Management Course Syllabus

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, reduces field corrective actions, and achieves significant cost savings to the business.

Course Syllabus

1. Introduction to Medical Device Risk Management

- Why do we need to do medical device risk management?
- The benefits of medical device risk management
- History and origins of risk management
- Safety constraints
- Language of risk management
- Hazard theory
- Hazard Taxonomy
- How to identify reasonably foreseeable misuses

2. Medical Device Risk Management Standards

- ISO 14971 – the central standard in medical device risk management
- Risk management system
- Risk management process
- Requirements of ISO 14971
- Connections of ISO 14971 to: IEC 60601-1, IEC 62366, IEC 62304, ISO 10993, ISO 14155

3. Medical Device Risk Management as a Value-Added Activity

- How to use risk management to add value to product development

4. Medical Device Risk Management Activities and Artifacts

- Risk management plan
- Risk management report
- Risk management file
- Risk analysis, evaluation, control and monitoring

5. Foundations for Medical Device Risk Management

- Clinical Hazards List (CHL)
 - What it is
 - How to create it
- Harms Assessment List (HAL)
 - What it is
 - How to create it (two methods)

6. Medical Device Risk Management Tools and Techniques

- Fault Tree Analysis (FTA)
 - Introduction

- FTA workflow
- Example FTA
- Failure Modes and Effects Analysis (FMEA/FMECA)
 - Introduction
 - Distinction between risk management and FMEA
 - Relationship between FMEA and FTA
 - How to leverage FMEAs to determine Essential Design Outputs (EDOs)
 - Domains of Severity, Occurrence and Detectability
 - Risk management scaling via hierarchical-multi-level FMEA
 - DFMEA
 - PFMEA
- Usability Engineering and risk management
- Use/Misuse FMEA (UMFMEA)
 - Use failure distinctions
 - UMFMEA

7. Software Risk Management

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

8. Cybersecurity and Safety Risk Management

- Introduction to cybersecurity management
- Connection between cybersecurity and safety risk management
- Strategies for improving safety via cybersecurity

9. Medical Device Risk Assessment

- Preliminary Hazard Analysis (PHA)
- Risk Assessment and Control Table (RACT)
- Risk integration (FMEA, FTA, CHL, HAL, Risk Controls, Risk estimation & evaluation)
- RACT workflow
- P1 and P2, in-depth review
- Risk controls, distinction and proper crafting
 - Safe by design/manufacture
 - Protective Measures
 - Information for safety
- Risk controls end-point logic (when to stop risk reduction)
- Verification of risk controls
- Residual risk estimation
- Boolean algebra and quantitative risk computation
- Traceability analysis

10. Benefit-Risk Analysis (BRA)

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

Medical Device Risk Management Course Syllabus (Continued)

11. Risk Management Review

- Requirements for risk management review
- Outcomes from risk management review

12. Post-Market Medical Device Risk Management

- Basis and intention for post-market risk management
- Elements of post-market risk management
- Listening systems
- Surveillance
- Data monitoring
- Complaint handling
- Connection between post-market and premarket risk management

13. In Closing

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



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