MEDICAL DEVICE RISK MANAGEMENT

3-DAY or 5 HALF-DAYS

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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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

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

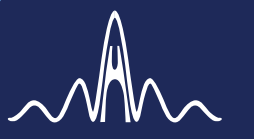
To register visit our website or call our friendly registration team:

PO Box 2385
Ringwood North
Victoria, 3134
Australia

+61 3 9876 7345

enquiries@ppi-int.com

www.ppi-int.com



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