MEDICAL DEVICE RISK MANAGEMENT

LEARN HOW TO MANAGE MEDICAL DEVICE RISKS WITH CLARITY AND CONFIDENCE

3-DAY COURSE

This 3-day training course delivered worldwide provides a comprehensive coverage of topics that are needed for successful management of safety risks of medical devices in conformance with the international standard ISO 14971. The scope of risk management includes both product development, and post market risk management. The course commences with the fundamentals of medical devices risk management, then builds upon the fundamentals, and teaches a practical, sensible and efficient way of performing medical devices risk management. The course includes multiple quizzes and hands-on workshops to deepen the learning, and create an engaging learning experience.

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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COURSE OUTLINE

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
- Connections of ISO 14971 to IEC 60601-1, IEC 62366, IEC 62304, ISO 10993
- ISO 10993 – Introduction
- IEC 60601-1 – Introduction
- IEC 62304 – Introduction

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

- Risk management contribution to the various life cycles in product development
- Not just a check-in-the-box. Not a neccessary evil, but a welcomed and appreciated contributor.

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
- Introduction to Vivio AED – the test bed for in-class workshops
- Clinical Hazards List (CHL)
  - What it is
  - How to create it
  - Example
- ***Workshop - Create a CHL***
- Risk estimation
  - Classic and advanced methods
- Harms Assessment List (HAL)
  - What it is
  - How to create it
  - Example
- ***Workshop - Create a HAL***
- Quiz

7. Medical Device Risk Management Tools and Techniques

- Fault Tree Analysis (FTA)
  - Introduction
  - FTA workflow
  - Example FTA
- Mind Map
  - Introduction
  - Workflow
  - Example Mind Map
  - ***Workshop - Mind Map***
- Preliminary Hazard Analysis
  - Introduction
  - Workflow
  - ***Workshop - Preliminary Hazard Analysis***
- Failure Modes and Effects Analysis (FMEA/FMECA)
  - Introduction
  - Is FMEA risk management?
  - Relationship between FMEA and FTA
  - Domains of Severity, Occurrence and Detectability
  - What does Severity mean?
  - What does Occurrence mean?
  - What does Detectability mean?
  - Risk management scaling via hierarchical-multi-level FMEA
  - FMEA cascade
  - DFMEA workflow
  - ***Workshop - DFMEA***
  - PFMEA Introduction
  - ***Workshop - Process Flow Design***
  - PFMEA workflow
  - ***Workshop - PFMEA***
- Usability Engineering and risk management
- IEC 62366 -- Introduction
- Use/Misuse FMEA (UMFMEA)
  - UMFMEA Introduction
  - Language of Useability Engineering
  - Use failure model
  - Types of Use
  - How to distinguish reasonably foreseeable misuse
  - UMFMEA workflow
  - ***Workshop - UMFMEA***
  - Quiz

8. Software Medical Device Risk Managment

- Introduction
- Software failure model
- Language of SW risk management
- Contribution of software to system hazards
- Software risk
- Examples of SW faults
- SW risk management workflow
- Software FMEA (SFMEA)
- Software FMEA workflow
- Software FMEA ground rules
- ***Workshop - SFMEA***

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
- Boolean algebra and quantitative risk computation
- Quiz
- ***Workshop - RACT***
- Traceability

10. Benefit-Risk Analysis

- FDA guidance
- Criteria for benefit-risk analysis
- FDA decision-making factors
- ***Workshop - Benefit-Risk Analysis***

11. Post Market Medical Device Risk Management

- Listening systems
- Surveillance
- Complaint handling
- Assessment of production and post-production information
- Update to the risk management file from post market data

12. In Closing

- Medical device risk management as a team effort
- Challenges with doing medical device risk management
- 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

contact@ppi-int.com

www.ppi-int.com

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