MEDICAL DEVICE RISK MANAGEMENT

LEARN HOW TO MANAGE MEDICAL DEVICE RISKS WITH CLARITY AND CONFIDENCE

2 HALF-DAYS

This 2 half-days training course delivered worldwide, provides an introduction to product safety risk management in conformance with the International Standard ISO 14971:2019. The course covers both pre-market and post-market phases of the product lifecycle, and shows how to derive real value from risk management towards efficient product development and faster regulatory approvals. The learners are presented with tools and techniques for practical, sensible, and efficient performance of medical devices risk management. There are multiple quizzes and interactions with the learners to create an engaging experience and deep, persistent learning. In closing, common mistakes in risk management are discussed and tips and wisdom are shared with the learners to ensure success in their work.

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
- 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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