3-Day In-Person Seminar

Applying ISO14971 / IEC62304 / IEC62366-1 - A Practical Guide On How To Implement Risk Management

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SPEAKER

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Markus Weber, Principal Consultant with System Safety, Inc., specializes in safety engineering and risk management for critical medical devices. Mr. Weber graduated from Ruhr University in Bochum, Germany with a MS in Electrical Engineering. Before founding System Safety, Inc., he was a software safety engineer for the German approval agency, TUV. Since 1991, he has been a leading consultant to the medical device industry on safety and regulatory compliance issues, specifically for active and software-controlled devices.

In conjunction with the FDA, he has published works on risk management issues and software-related risk mitigations. He has helped multiple companies, from startups to Fortune 500 firms.

COURSE DESCRIPTION

Risk management is a mandatory and necessary process during the entire device life. Not only will it help to design and maintain devices efficiently, but it also ensures that the device will be as safe as possible and prevents harms to patients, users, and the environment.

Like any process that tries to produce repeatable and consistent results, the risk management process must be clearly understood, including the strengths but also the limitations.

By attending this seminar you will learn the main elements of ISO 14971, ISO 13485, IEC62304, IEC62366-1/-2, risk management life cycle steps and benefits, and FDA software reviewers' guidance.

LEARNING OBJECTIVES

Upon completing this course participants should:

- Understand the risk management process, the activities, and deliverables as well as the organization framework necessary
- Be able to Interpret and discuss the requirements of ISO 14971
- Develop a risk analysis framework document
- Be able to conduct risk analysis team meetings
- Recognize how and where to use the various techniques during the design life cycle.
- Understand how to apply ISO 14971 into development process
- Know how to document your Risk Management
- Explain how your Risk Management system fits into quality system and business practices.
- Perform risk assessments effectively

AGENDA

Day One (8:30 AM - 4:30 PM)

08.30 AM - 09.00 AM: Registration

Lecture 1: Introduction To Risk Management And Quality System Integration

- Why Perform Risk Management?
- Historical Perspective
- International Regulatory / Statutory Requirements
- Risk Management Lifecycle And Stakeholders
- Over-Reaching Concept
- Integration Into ISO13485
- Lifecycle Steps
- Risk Management Benefits
- Liability Issues
- Streamlining Product Development
- Improving Product Safety And Quality
- How To Implement Risk Management Into ISO13485
- SOP Framework
  - Planning And Execution
  - Monitoring And Control

Lecture 2: Risk Management To ISO 14971:2012

- Risk Management Planning
- Risk Management Life Cycle
- Hazard Identification
  - Hazard Domains
  - Hazard Latency Issues
- Risk Rating Methods
- Initial (Unmitigated) Risk Assessment
- Mitigation Strategies And Priorities
- Mitigation Architectures
- Alarm Systems As Mitigations
- Risk Control Bundles
- Post Mitigation Risk
- Residual Risk
- Risk-Benefit Analysis
- Safety Integrity Levels
- European Special Requirements (Z-Annexes)
- Safety Requirements
- Hazard Mitigation Traceability
- Verification Planning
- Architectures, Redundancy, And Diversity
- Failure Rates / Modes / Types
- Failure Mode And Effect Analysis
- Tips And Tricks
- Q&A

Day Two (8:30 AM - 4:30 PM)

Lecture 3: Software Risk Management
Software Risk Management (IEC62304 / FDA Software Reviewers' Guidance)

- Critical Software Issues
- Software Hazard Mitigation Strategies
- Software Item, Unit, And System Definition
- Software Failures As Hazard Sources
- Software Requirements And Design
- Software Specification
- Tools And Development Environment
- Software Unit And Integration Verification / Testing
- Real-Time System Challenges
- Software Verification And Validation
- Mitigation Traceability And Effectiveness
- Software Maintenance And Configuration Control
- Software Risk Management Process - Integration Into ISO14971
- Legacy Software Issues
- FDA Documentation Requirements
- Potentially upcoming changes (Committee Draft 3/2017)

Lecture 4: Software Risk Management
Other Software Issues

- Verification of Safety Properties
  - Type Testing / Sample Testing
  - Verification Testing
  - Inspections
  - Analyses
- Qualification of Manufacturing / QMS software
  - Fit-for-use concept
  - Defining the use functionality
  - Evaluating risks of used functionality
  - Creating objective evidence for use functionality
- FDA Part 11 Requirements o Document Integrity
  - User Authorization and Authentication
  - User enrolment / user rights
  - Audit trails and data security
- Cybersecurity aspects
  - Access Control
  - Data Integrity and transfer security
  - Threat assessements

Day Three (8:30 AM - 4:30 PM)

Lecture 5: Software And Usability In Risk Management
Usability And Risk Management (IEC62366-1/-2 / FDA Human Factors Guidance)

- Use Errors As Hazard Source
- User Intervention As Hazard Mitigation
- Usability Engineering Lifecycle
- Usability Evaluation Methods
- Usability Specification
- User Interface Specification
- Formative Testing / Summative Evaluation
- Usability Verification / Validation
- The New Issues In IEC62366-1:2015

Risk Management Report And Safety Case

- Safety / Assurance Case
- Safety Classification
- Basic Safety / Environment
- Documentation Of Basic Safety
  - Electrical Safety
  - Mechanical Safety
  - EMC / RFI Safety
  - Safety Margins

Lecture 5: Risk Management Report and Documentation

- Documentation Of Essential Performance
- What Is Essential Performance?
- Device Architectures And Mitigation Allocation
- Device Specific Mitigations
- Software Mitigations
- External Safety
- User Intervention And Alarms
- Organizational Measures
- Levels Of Protection Concept
- Verification Of Safety Properties
  - Type Testing / Sample Testing
  - Verification Testing
  - Inspections
  - Analyses
- Assurance Case Vs. Risk Management Report
- General Safety And Hazard Avoidance
- Device / Application Specific Issues

WHO WILL BENEFIT

This course is relevant to managers, supervisors, QA / RA, and design/system engineers. Even experienced personnel will benefit from the "across industry" perspective and the illustration of standard practices that only a presenter with extensive experience in more than 100 projects can provide. Specific positions that would benefit are:

- Senior Quality Managers
- Quality Professionals
- Regulatory Professionals
- Compliance Professionals
- Project managers
- Risk managers
- Engineering management
- Quality Assurance personnel
- System and design engineers
- Software Engineers
- Usability Engineers
- Verification / validation personnel