Global CompliancePanel

Netzealous
Knowledge, a Way Forward...

2-day In-person Seminar:

Risk Management in Medical Devices Industry

Seattle, WA

April 27th & 28th, 2017

9:00 AM to 6:00 PM

Price

Price: **$1,295.00**

(Seminar for One Delegate)

Register now and save $200. (Early Bird)

Register for 5 attendees

Price: **$3,885.00** You Save: $2,590.0 (40%)*

~~$6,475.00~~

ENROLL

***Please note the registration will be closed 2 days (48 Hours) prior to the date of the seminar.*

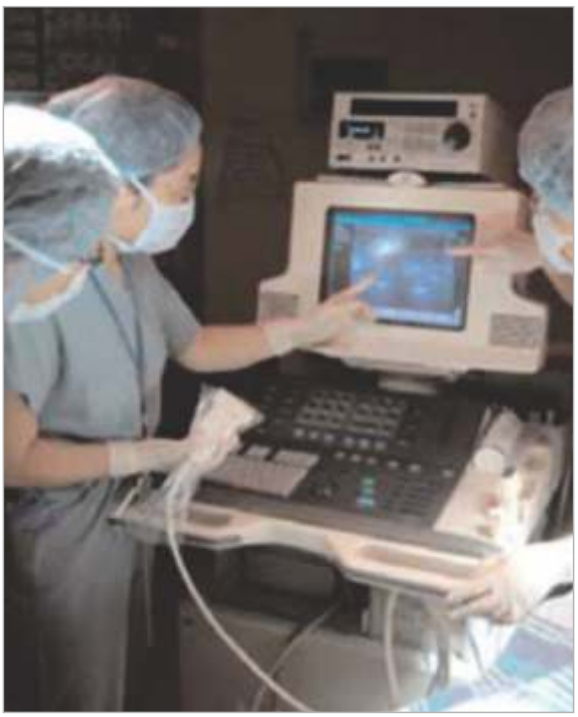
Markus Weber

Principal Consultant, System Safety Inc.

Markus Weber, Principal Consultant with System Safety, Inc., specializes in safety engineering and risk management for critical medical devices. He 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, Mr. Weber 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.

Overview :

Gaps, incorrect or incomplete implementation of software can delay or make the certification/approval of medical products impossible. Most activities cannot be retroactively performed since they are closely linked into the development lifecycle. Diligent, complete and correct implementation of risk management from the start of product development is therefore imperative. This course will introduce all necessary steps to design, implement and test critical medical device software in a regulatory compliant environment. Software risk management has to be embedded into the bigger scope of overall risk management. Therefore this course will additionally address the system level risk management and the resulting interfaces to software.



Agenda:

Day One

Lecture 1: Introduction into Risk Management and Quality System Integration

- Why 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
- Tips and tricks

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
  - Safety Integrity Levels
- European special requirements (Z-Annexes)
- Safety Requirements
- Hazard Mitigation Traceability
- Verification Planning
- Architectures, Redundancy and Diversity
- Failure Mode and Effect Analysis
- Tips and Tricks
- Q&A

Day Two

Lecture 1: 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 Specification
- Software Tools and Development Environment
- Software Unit and Integration 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
- Upcoming changes in IEC62304:2014
- Tips and Tricks
- Q&A

Lecture 2: Safety / Assurance case

- Safety classes
  - Basic Safety / Environment
  - Essential performance
- Documentation of Basic Safety
  - Electrical Safety
  - Mechanical Safety
  - EMC / RFI safety
  - Safety margins
- 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
  - Software verification testing
  - Inspections
  - Analyses
- Assurance case vs. Risk Management Report
  - General safety and hazard avoidance
  - Device / application specific issues
- Tips and Tricks
- Q&A

Group Participation

10%	2 Attendees to get offer
20%	3 to 6 Attendees to get offer
25%	7 to 10 Attendees to get offer
30%	10+ Attendees to get offer

Payment Option

1. Credit Card: Use the Link to make Payment by Visa/Master/American Express card click on the register now link
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Kindly get in touch with us for any help or information.

Look forward to meeting you at the seminar

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