Global CompliancePanel

Netzealous
Knowledge, a Way Forward...

2-day In-person Seminar:

Applying ISO14971 and IEC62304 – A guide to practical Risk Management

Boston, MA

June 14th & 15th, 2018

9:00 AM to 6:00 PM

Price

Price: **$1,495.00**

(Seminar for One Delegate)

Register for 5 attendees

Price: **$4,485.00** You Save: $2,990.0 (40%)*

~~$7,475.00~~

Register for 10 attendees

Price: **$8,222.00** You Save: $6,728.0 (45%)*

~~$14,950.00~~

ENROLL

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



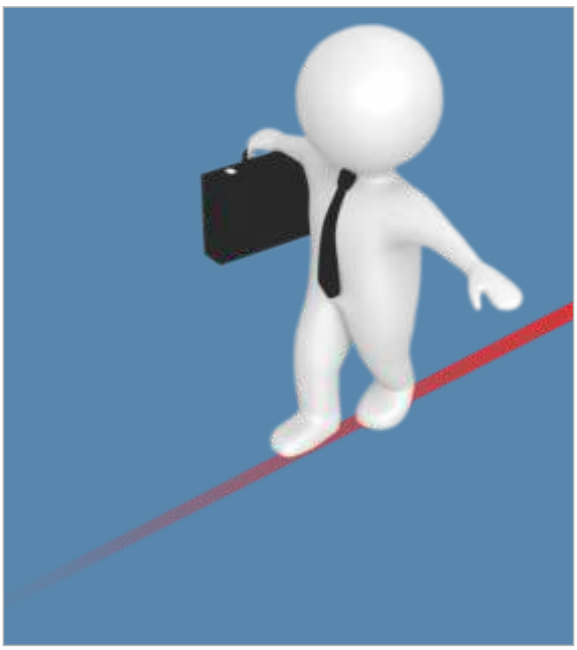
Markus Weber

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.

Overview :

Gaps, incorrect or incomplete implementation of safety functionality 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 devices in a regulatory compliant environment. This course will additionally address the software risk management and the resulting interfaces to device level risk management.



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

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: Usability and Risk Management

- Use errors as hazard source
- User intervention as hazard mitigation
- Usability engineering lifecycle
- Application specification
- Usability Specification
- Frequently used functions / primary operating functions
- Usability verification / validation
- Upcoming changes IEC62366:2014

Lecture 2: 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

Lecture 3: Software Risk Management (IEC62304 / FDA software reviewers' guidance):

- 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

Lecture 4: 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
2. Check: Kindly make the check payable to NetZealous DBA GlobalCompliancePanel and mailed to 161 Mission Falls Lane, Suite 216, Fremont, CA 94539, USA
3. PO: Please drop an email to support@globalcompliancepanel.com or call the our toll free +1-800-447-9407 for the invoice and you may fax the PO to 302 288 6884
4. Wire Transfer: Please drop an email to support@globalcompliancepanel.com or call our toll free +1-800-447-9407 for the wire transfer information

What You will get

1. Learning Objectives
2. Participation certificates
3. Interactive sessions with the US expert
4. Post event email assistance to your queries.
5. Special price on future purchase of web based trainings.
6. Special price on future consulting or expertise services.
7. Special price on future seminars by GlobalCompliancePanel.
8. Seminar Kit – includes presentation handout, ID card, brochure, trainings catalog, notepad and pen.
9. Networking with industry's top notch professionals

Contact Information: Event Coordinator

NetZealous LLC, DBA GlobalCompliancePanel

161 Mission Falls Lane, Suite 216,

Fremont, CA 94539, USA

Toll free: +1-800-447-9407

Fax: 302 288 6884

Email: support@globalcompliancepanel.com

www.globalcompliancepanel.com

Kindly get in touch with us for any help or information.

Look forward to meeting you at the seminar

GlobalCompliancePanel