

2-day In-person Seminar:

Medical Device Software Risk Management and Assurance Case

By: **Markus Weber**, Principal Consultant, System Safety Inc.

Location : Los Angeles, CA | May 22-23, 2014 **Location :** Boston, MA | June 19-20, 2014

Course "**Medical Device Software Risk Management and Assurance Case**" has been pre-approved by RAPS as eligible for up to 12 credits towards a participant's RAC recertification upon full completion.



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Our services benefit the Medical Devices, Pharmaceutical, Bio Technology, Food Safety, Financial Accounting Standards, and IT Control & PCI Industries. Our clientele includes companies such as J&J, Pfizer, Sanofi Aventis, Pall Corp, Abbott, Merck, Bayer, and Roche, some of which are Fortune 500 companies.

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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.

Course Outline:

Day One - May 22, 2014

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
- Q&A

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 / FTA

Day Two - May 23, 2014

Lecture 3: 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 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

Pricing list:

Price for One Delegate pass Price: \$1,295.00

May 22-23, 2014 | Los Angeles, CA

Register now and save \$200. (Early Bird)

Until May 05, Early Bird Price: **\$1,295.00**

From May 06 to May 20, Regular Price: **\$1,495.00**

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Register now and save \$200. (Early Bird)

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From May 21 to June 17, Regular Price: **\$1,495.00**

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

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Who Will Benefit:

This course is developed to provide valuable assistance to all regulated companies that need to understand their processes including companies:

- Senior Quality Managers
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- Regulatory Professionals
- Compliance Professionals
- Project Managers
- Design Engineers
- Software Engineers
- Process Owners
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- Quality Auditors
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Contact Information: Event Coordinator

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

Look forward to meeting you at the seminar

Team GlobalCompliancePanel

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Registration Form:

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If you wish to cancel your attendance at our seminar, the person who has registered for this seminar has to submit written cancellations through fax or email at least 10 calendar days before the date of commencement of the event. This will entitle her/him to a full refund minus a \$150 administration fee. No cancellation request will be accepted or entertained and no refunds will be issued for requests made outside the stipulated period.

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You are allowed to make substitutions at any time till the start of the event. The substituting person should be present well in time for the event with proper written communication and company identity.

If registering on the date of the seminar, please make sure you pay for the event using your credit card or check just before the start of the event. To such attendees, we may not be able to give the conference materials on the spot. In such an event; we will send the same after the conclusion of the seminar.

No-shows will not be reimbursed.

If GlobalCompliancePanel cancels an event, we will not be reimbursing any airfare, accommodation, other costs or losses that the registrants may have incurred. GlobalCompliancePanel reserves the right to change topics and speakers without notice.

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