

2-day In-person Seminar:

Software Risk Management

-  Philadelphia, PA
-  September 24th & 25th, 2018
-  9:00 AM to 6:00 PM



Markus Weber

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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. Mr. Weber has helped multiple companies, from startups to Fortune 500 firms.

Overview :

The seminar will address the specific challenges software poses for the risk management process. Basic risk management concepts will be introduced and then applied to software specific applications.



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.*

Agenda:

Day One

Lecture 1 (90 Mins):

Legal and regulatory requirements for risk management

Risk management and quality systems

Lecture 2 (90 Mins): [Risk Management Basics](#)

- What are hazards / hazardous situations
- Hazard characteristics
- Risk and risk rating
- Residual risk

Lecture 3 (90 Mins): [Software failures](#)

- Random and systematic faults
- Fault control means
- Software failure effects

Lecture 4 (90 Mins):

- [System Architectures](#)
- [Software Architecture](#)
- [Software Tools and Methods](#)
- [Multiprocessor systems](#)
- [Real-time challenges](#)

Why you should attend:

Risk Management is a regulatory and statutory requirement for medical devices. The generic procedure to perform risk management is outlined in ISO14791, however, as soon as software is used challenges arise. How to address these specific software issues and the application of FDA and IEC requirements for development of safety-critical software used in medical devices is the content of this seminar.

Day Two

Lecture 1 (90 Mins): [Software Criticality Classification](#)

- IEC criticality classed
- FDA level of concern

Lecture 2 (90 Mins): [The 62304 Development Process](#)

- Life Cycle
- Documentation

[Comparison to FDA requirements](#)

Lecture 3 (90 Mins):

[Software Risk Management](#)

[Software Configuration Management](#)

[Software Problem Resolution](#)

[Software Maintenance](#)

Lecture 4 (90 Mins):

[Legacy Software](#)

[Risk-based verification](#)

[Third-party software \(SOUP, COTS\)](#)

Who Will Benefit:

- Project managers
- Software Engineers
- Regulatory specialists
- Quality assurance specialists
- Documentation specialists
- Test managers
- Software team leaders and lead developers

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
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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

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

Look forward to meeting you at the seminar

GlobalCompliancePanel