Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

Medical Device Software: An Incremental Approach to Risk and Quality Management

San Diego, CA

June 11th & 12th, 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.*

Brian Shoemaker

Brian Shoemaker consults for healthcare products companies on computer system validation, software quality assurance, and electronic records and signatures. He has conducted validation both on product software and on internal software, developed software quality systems, audited software quality processes (including agile methodology), and evaluated 21 CFR Part 11 compliance. He has had clients in clinical diagnostics, medical device engineering, medical imaging, medical-device fabrics manufacturing, contract lyophilization, clinical trial software, dental prosthetics, and bone-repair implants. He has worked with companies in Germany and Switzerland as well as the U.S.

Overview :

Engineers are dedicated to making things work, so a focus on how they might fail and harm someone can seem alien.

Managing risk, however, is essential for all medical products- medical devices, including those involving software, have produced some painful examples of poor risk management with serious consequences.

Medical Device Software

Agenda:

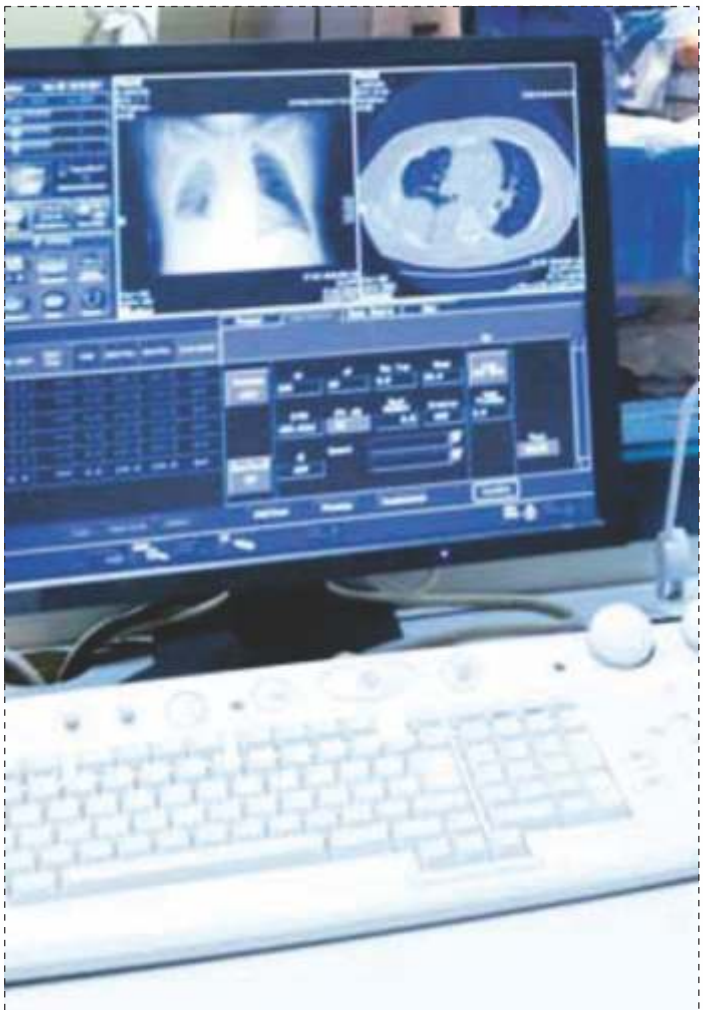
Day One

Lecture 1: Software brings great capability to medical devices, but also creates hazards

Lecture 2: Consider how the key standards lay out the roadmap for managing risk

Lecture 3: Understand the key concepts - hazard, risk, and harm

Lecture 4: Walk through ISO 14971 in detail - and consider IEC 80002-1 for specific software concerns



Day Two

Lecture 1: Fault tree analysis and FMEA complement each other for risk analysis

Lecture 2: Risk analysis for software is different from hardware - and needs a place in the lifecycle

Lecture 3: Story mapping helps bring risk management directly into development

Lecture 4: An incremental approach manages both risk and quality

Areas Covered in the Session:

- Software has introduced (or been blamed for) some serious safety hazards
- All medical device standards intersect on the topic of risk management
- Risk analysis starts with the intended use statement
- Risk information is available from multipl sources - use them!
- Note that safety is an emergent property
- Changes are often the biggest sources of risk
- Don't ignore the human factors side; understanding your users is crucial to safety
- Applying engineering risk methods to software requires us to translate some concepts
- Though standards draw a roadmap for risk management, WE must figure out the route
- Risks often arise when we add new features - so incremental risk management is the most effective

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

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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

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