FDANEWS PRESENTS THE

Space Is Limited, Register Today!

SOFTWARE AND CYBERSECURITY RISK MANAGEMENT FOR MEDICAL DEVICES

UNDERSTANDING THE FDA'S POSITION AND BEST PRACTICES FOR COMPLIANCE

AN INTERACTIVE WORKSHOP PRESENTED BY FDANEWS AND GESSNET

MAY 11-12, 2015

HILTON WASHINGTON DC/ROCKVILLE HOTEL & EXECUTIVE MEETING CENTER • ROCKVILLE, MD

YOUR INSTRUCTOR

FUBIN WU
Workshop Leader and Co-Founder of GessNet — software and consulting company specializing in medical device risk management

Special Take-Home Resource Kit:

You'll take home a jam-packed resource kit with **more than 20 templates, checklists, case studies, guidances and supporting information.** These are the tools that will help you effectively carry out the lessons you've learned over the two-day conference.

This workshop — **chaired by internationally renowned expert Fubin Wu** — has been specifically designed to provide you with industry best practices to achieve compliance and effectively assure medical device software safety.

In fact, it's a once-in-a-lifetime opportunity **to learn how the FDA expects you to manage the risks of your medical devices that contain software.**

In two days of intensive sessions, you will be brought up to date on the FDA's latest research on medical device software best practices, software risk management related standards and guidances and key success factors for effective software risk management.

Plus, in a special bonus, you'll find out more about assurance levels — and what it will take to convince regulators — in one of **our seven invaluable case studies**, always a popular and valuable way to learn. Our seven case studies cover:

Spread throughout the course will be lessons in applying these key software risk management related standards and guidances to your software development processes:

- ISO 14971:2007 and EN ISO 14971:2012, IEC 62304 Medical Device Life Cycle Process, IEC TR 80002-1 Application of ISO 14971 for Software
- FDA Guidance on Mobile Medical Applications, Cybersecurity in Medical Devices, Infusion Pump Total Product Life Cycle

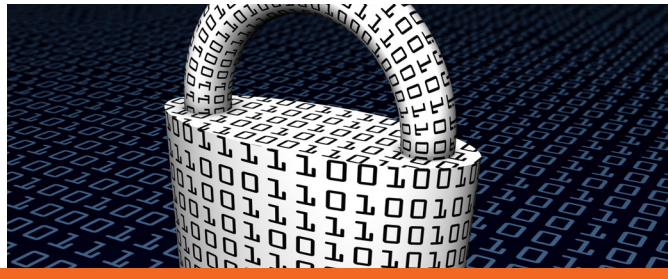
During each teaching session, Mr. Wu will share techniques and best practices on how to:

- Identify software related risks
- Identify software risk control and mitigation measures
- Assess and evaluate risk contributed/caused by software (premarket and post-market field issues)
- Assure the completeness and adequacy of risk management
- Communicate risk management information throughout the life of the product
- Key success factors for effective software risk management

Here's what you can expect to walk away with at the end of two intense days at **Software and Cybersecurity Risk Management for Medical Devices:**

- Understanding of how medical device manufacturers can overcome both technical and regulatory compliance challenges
- The resources and tools to help you succeed
- The medical device industry's best practices
- The FDA's latest updates on medical device software best practices

This conference has been pre-approved by RAPS as eligible for up to 12 credits towards a participant's RAC recertification.



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Tuesday May 11

8:00 a.m. – 8:30 a.m. | **REGISTRATION AND CONTINENTAL BREAKFAST**

8:30 A.M. – 9:00 A.M. | **WELCOME AND INTRODUCTIONS**

9:00 a.m. – 10:00 a.m.

I. FDA's Research on Medical Device Software Best Practices

II. FDA's Analysis of Software-Related Recalls

10:00 a.m. – 11:00 a.m.

III. Overview of Recent FDA Guidances

a. Cybersecurity in Medical Devices (draft, June 2013)

b. Radio Frequency Wireless Technology in Medical Devices (August 2013)

c. Mobile Medical Applications (September 2013)

d. Total Product Life Cycle: Infusion Pump (draft, April 2010)

11:00 a.m. – 11:15 a.m. | REFRESHMENT BREAK

11:15 a.m. – 12:15 a.m.

IV. Key Relevant Standards

a. ISO 14971:2007 and EN ISO 14971:2012, IEC TR 80002-1 Application of ISO 14971 for Software

b. IEC 62304 Medical Device Software Life Cycle Process - Risk Management Section

c. IEC 80001-1 Managing Medical IT-Networks and relevant Technical Reports

d. NIST Framework for Improving Critical Infrastructure Cybersecurity, 2014

12:15 p.m. – 12:45 p.m.

Morning Summary of FDA Perspectives and Group Discussion

12:45 p.m. – 1:45 p.m. | LUNCH

1:45 p.m. – 2:45 p.m.

V. Risk Management Documentation to Support Regulatory Filings and Inspections

a. What is viewed as best practices to demonstrate safety

VI. Risk Management Documentation for Pre-market Submissions

a. Case study for risk traceability matrix. This study provides participants a template for and examples of best practices that are frequently requested for pre-market submissions or during establishment inspections

b. Case study for cybersecurity risk traceability matrix. This study provides participants a template for and examples of best practices that are frequently requested for pre-market submissions or during establishment inspections

2:45 p.m. – 3:00 p.m. | REFRESHMENT BREAK

3:00 p.m. – 4:30 p.m.

VII. Risk Management Completeness, Adequacy, Effectiveness and Reviewability

a. Introduction of assurance case concepts and how they are used in industry

b. Case study for medical device safety assurance case. This study illustrates how to document information in a story telling fashion and convince internal/external reviewers (e.g. ODE reviewers) that a risk analysis is adequate and complete

c. Case study for medical device cybersecurity assurance case. This case study illustrates how to document information in a story telling fashion and convince internal/external reviewers (e.g. ODE reviewers) that a cybersecurity risk analysis is adequate and complete.

4:30 p.m. – 5:00 p.m.

Day One Summary of FDA Perspectives and Group Discussion

Wednesday May 12

8:00 a.m. – 8:30 a.m. | CONTINENTAL BREAKFAST

8:30 a.m. – 9:00 a.m.

VIII. Characteristics for Medical Device Software

a. Understanding the difference between software and hardware

b. Understanding software quality and reliability engineering

c. Challenges of software risk management and cybersecurity

9:00 a.m. – 9:30 a.m.

IX. Emerging Methods and Techniques

a. Learn what new technical methods and techniques the FDA has been researching and looking into to improve the safety of software related medical devices

9:30 a.m. – 10:30 a.m.

X. Risk Identification

a. Preliminary hazard analysis

b. Top down analysis, fault tree analysis

c. Bottom up analysis – including design FMEA, function FMEA, process FMEA, usability FMEA, common causes of software failures

d. Connectivity analysis between top down and bottom up

e. Multi perspective analysis

f. Case study. This study provides participants an opportunity to apply techniques on how to identify and connect hazards, hazardous situations/causes using device examples.

10:30 a.m. – 10:45 a.m. | REFRESHMENT BREAK

10:45 a.m. – 11:45 a.m.

XI. Cybersecurity Risk Identification

a. Medical device cybersecurity basics

b. Asset profiling

c. Threat identification

d. Vulnerability identification

e. Software vulnerabilities

f. Connectivity between cybersecurity and safety risk analysis

g. Case study. This study provides participants an opportunity to apply techniques on how to identify and connect assets, threats and vulnerabilities using device examples.

11:45 a.m. – 12:15 p.m.

Morning Summary of FDA Perspectives and Group Discussion

12:15 p.m. – 1:15 p.m. | **LUNCH**

1:15 p.m. – 2:15 p.m.

XII. Risk Controls

a. Risk control basics

b. Software life cycle process control measures

c. Safety requirements identification

d. Cybersecurity capability and requirements identification

e. Special considerations for cybersecurity risk controls

f. Control measures implementation and effectiveness

g. Case study. This study provides participants an opportunity to identify, apply risk controls and establish traceability of its implementation using device examples.

2:15 p.m. – 3:15 p.m.

XIII. Software-Related Medical Device Risk Assessment and Evaluation

a. Pre-market risk assessment and evaluation

b. Post-market risk assessment and evaluation

c. Legacy product cybersecurity risk management

d. Maintenance and life cycle risk management

3:15 p.m. – 3:45 p.m.

XIV. Success Factors for Risk Management Programs

3:45 p.m. – 4:15 p.m.

Day Two Summary of FDA Perspectives and Group Discussion Plus Workshop Wrap Up

WHO WILL BENEFIT

- Software systems design engineers and managers
- Quality, reliability and risk management engineers and managers
- Project managers involved in design and development
- Medical staff evaluating risk, safety or effectiveness
- Quality managers
- Regulatory affairs specialists and managers
- Medical device app developers
- IT systems development managers
- Contract manufacturers
- General/corporate counsel

MEET YOUR INSTRUCTOR

Fubin Wu is the Co-Founder of GessNet. GessNet is a software and consulting company specializing in medical device risk management (www.GessNet.com). He designed and led the development of TurboAC™ risk management and assurance case software, in concert with the FDA, Association for the Advancement of Medical Instrumentation (AAMI), medical device manufacturers, hospitals and industry experts. Mr. Wu has spent more than 16 years in medical device quality management systems, hardware/software reliability engineering and risk management, serving various roles from quality engineer to quality director.

"All instructors were very knowledgeable and had expertise in the industry. Well done."

—May 2014 Workshop Participant

"The class had a good pace. It covered standard risk management well."

—May 2014 Workshop Participant

"[I liked the] small discussion groups and intimate setting"

—May 2014 Workshop Participant

COURSE BINDER MATERIALS

Each participant will receive a folder and flash drive packed with tools and reference materials in a combination of both electronic and hard copy format you can put to use right away, including:

- Copies of slides from PowerPoint presentations
- Interactive exercise worksheets
- Copies of case study examples
- Hazard analysis example
- Fault tree analysis example
- Example of FMEA analysis and connectivity with hazard analysis
- Risk traceability matrix example
- Cybersecurity risk analysis example
- Safety assurance case example
- Cybersecurity in Medical Devices (FDA draft guidance, June 2013)
- NIST Framework for Improving Critical Infrastructure Cybersecurity (Version 1.0, 2014)
- Software-Related Recalls: An Analysis of Records (by Lisa K. Simone of FDA, AAMI BI&T Nov/Dec 2013 Issue)
- Reducing Risks and Recalls: Safety Assurance Cases for Medical Devices (by Sherman Eagles and Fubin Wu, AAMI BI&T Jan/Feb 2014 Issue)
- Hazard Analysis for a Generic Insulin Infusion Pump (by Yi Zhang, Paul Jones, and Raoul Jetley of FDA, J Diabetes Sci Technol. Mar 2010)
- Total Product Life Cycle: Infusion Pump (FDA draft guidance, April 2010)
- Radio Frequency Wireless Technology in Medical Devices (FDA guidance, August 2013)
- Mobile Medical Applications (FDA guidance, September 2013)
- Risk Management in the Design of Medical Device Software Systems (by Paul Jones PL, Biomed Instrum Technol 2002 Jul-Aug; 36(4):237-66)

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LOCATIONS AND HOTEL ACCOMODATIONS

To reserve your room, call the hotel at the number below. Be sure to tell the hotel you're with the FDAnews workshop to qualify for the reduced rate. Only reservations made by the reservation cutoff date are offered the special rates, and space is limited. Hotels may run out of discounted rates before the reservation cutoff date. The discounted rate is also available two nights before and after the event based on availability. The hotel may require the first night's room deposit with tax. Room cancellations within 72 hours of the date of arrival or "no-shows" will be charged for the first night's room with tax.

LODGING AND CONFERENCE VENUE

May 11-12, 2015

Hilton Washington DC/Rockville Hotel and Executive Meeting Center
1750 Rockville Pike, Rockville, MD 20852
Tel: +1 (301) 468-1100 • Toll free: (800) HILTONS
www.RockvilleHotel.com
Room rate: $199 plus 13% tax
Reservation cut-off date: April 19, 2015

TUITION

Tuition rate is $1,797 per person and includes all workshop sessions, workshop materials, two breakfasts, two luncheons and daily refreshments.

TEAM DISCOUNTS

Significant tuition discounts are available for teams of two or more from the same company. You must register at the same time and provide a single payment to take advantage of the discount. Call +1 (703) 538-7600 for details.

CANCELLATIONS AND SUBSTITUTIONS

Written cancellations received at least 21 calendar days prior to the start date of the event will receive a refund -- less a $200 administration fee. No cancellations will be accepted -- nor refunds issued -- within 21 calendar days from the start date of the event. A credit for the amount paid may be transferred to any future FDAnews event. Substitutions may be made at any time. No-shows will be charged the full amount. In the event that FDAnews cancels the event, FDAnews is not responsible for any airfare, hotel, other costs or losses incurred by registrants. Some topics and speakers may be subject to change without notice.

FOUR EASY WAYS TO REGISTER

Online: www.fdanews.com/cybersecuritymd
Fax: +1 (703) 538-7676
Phone: Toll free (888) 838-5578 (inside the U.S.)
or +1 (703) 538-7600
Mail: FDAnews, 300 N. Washington St., Suite 200
Falls Church, VA 22046-3431 USA

Register Early — *Space Is Limited*

Hurry — register early because space is limited! Your tuition of $1,797 includes the two-day workshop, all workshop materials, continental breakfast each day and lunch on both days.

Payment is required by the date of the conference. We accept American Express, Visa and MasterCard. Make checks payable to FDAnews.

☑ **YES!** I want to attend **Software and Cybersecurity Risk Management for Medical Devices.**

FDANEWS
300 N. Washington St., Suite 200
Falls Church, VA 22046-3431

Attendee 1: Name _____ Title _____ Email _____

Attendee 2: Name _____ Title _____ Email _____
(Please see "Team Discounts" above for tuition discounts when you send a team of two or more.) Email address (so you can receive order acknowledgements, updated news, product information and special offers)

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