An Interactive Workshop Presented by GessNet™ and FDAnews

Three FDA experts and internationally renowned expert Fubin Wu to lead one-of-a-kind workshop — Attendance Is Limited, Act Today!

May 21-22, 2014 • Doubletree Bethesda Hotel • Bethesda, MD

Software and Cybersecurity Risk Management for Medical Devices

Learn Best Practices from FDA and Industry Experts

In the Conducting Software and Cybersecurity Risk Management for Medical Devices workshop, you will:

- Learn directly from the FDA's experts about best practices and how to manage the risks of your medical device that contains software
- Participate in 7 case studies that help attendees learn using practical examples
- Learn to conduct risk management and prepare documentation for software-related medical device safety and cybersecurity
- Learn how to build assurance cases that demonstrate device safety and cybersecurity
- Take home a jam-packed resource kit with more than 20 templates, checklists, case studies, guidances and supporting information
- Understand what new technical methods and techniques the FDA is researching to improve software-related devices

Fubin Wu
Lead Instructor and Co-Founder, GessNet™ — software and consulting company specializing in medical device risk management

Dr. Lisa Simone
Biomedical Engineer, Office of Science and Engineering Laboratories, Office of Biometrics and Surveillance, CDRH, FDA

Paul Jones
Senior Systems/Software Engineer, Office of Science and Engineering Laboratories, CDRH, FDA

Dr. Yi Zhang
Visiting Scientist, Office of Science and Engineering Laboratory, CDRH, FDA

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WORKSHOP AGENDA

DAY ONE
WEDNESDAY, MAY 21, 2014

8:00 a.m. – 8:30 a.m.
REGISTRATION & CONTINENTAL BREAKFAST

8:30 a.m. – 9:00 a.m.
WELCOME & INTRODUCTIONS

9:00 a.m. – 10:00 a.m.

I. **FDA's Research on Medical Device Software Best Practices** (Paul Jones (FDA))
II. **FDA's Analysis of Software-Related Recalls** (Lisa Simone (FDA))

10:00 a.m. – 11:00 a.m.

III. **Overview of Recent FDA Guidances** (Fubin Wu)
   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 p.m.

IV. **Key Relevant Standards** (Fubin Wu)
   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.
FDA Perspectives and Group Discussion (Paul Jones (FDA), Lisa Simone (FDA) and Yi Zhang (FDA))

12:45 p.m. – 1:45 p.m. **LUNCH**

1:45 p.m. – 2:45 p.m.

V. **Risk Management Documentation** (Paul Jones (FDA))
   a. What is viewed as best practices to demonstrate safety

VI. **Risk Management Documentation for Premarket Submissions** (Fubin Wu)
   a. **Case study for risk traceability matrix.** This study provides participants a template for and examples of best practices that are frequently requested for premarket 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 premarket 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** (Fubin Wu)
   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.
FDA Perspectives and Group Discussion (Paul Jones, Lisa Simone, Yi Zhang and Fubin Wu)

DAY TWO
THURSDAY, MAY 22, 2014

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

8:30 a.m. – 9:00 a.m.

VIII. **Characteristics for Medical Device Software** (Fubin Wu)
   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** (Yi Zhang (FDA))
   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** (Fubin Wu)
   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** (Yi Zhang (FDA) and Fubin Wu)
   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.
FDA Perspectives and Group Discussion (Paul Jones (FDA), Lisa Simone (FDA) and Yi Zhang (FDA))

Management For Medical Devices

FDA and Industry Experts

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MEET YOUR INSTUCTORS

Fubin Wu is the Co-Founder of GessNet™ — 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. Additionally he has worked on various medical device platforms from implantable devices and remote monitoring systems at Medtronic, infusion pumps at Hospira, and blood management systems at Haemonetics.

Paul Jones is a Senior Systems/Software Engineer within the Office of Science and Engineering Laboratories (OSEL) within CDRH. He serves as an in-house consultant on regulatory matters involving medical device software system safety, software engineering, risk management and safety assurance cases.

Dr. Lisa Simone is a Biomedical Engineer within the Office of Science and Engineering Laboratories (OSEL) and the Office of Biometrics and Surveillance (OSB) within CDRH. She provides software and biomedical engineering expertise for medical device premarket review, post-market analysis and regulatory guidance.

Yi Zhang received a PhD in computer science from North Carolina State University. After graduation, he joined the FDA, where he serves as a Visiting Scientist in the Office of Science and Engineering Laboratory, CDRH. His research interests include formal methods (especially model-based engineering and software static analysis), software testing, software engineering and cybersecurity.

12:15 p.m. – 1:15 p.m. LUNCH

1:15 p.m. – 2:15 p.m.

XII. **Risk Controls** (Yi Zhang (FDA) and Fubin Wu)

a. Risk control basics
b. Software lifecycle 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** (Fubin Wu)

a. Premarket risk assessment and evaluation
b. Post-market risk assessment and evaluation
c. Legacy product cybersecurity risk management
d. Maintenance and lifecycle risk management

3:15 p.m. – 3:45 p.m.

XIV. **Success Factors for Risk Management Programs** (Fubin Wu)

3:45 p.m. – 4:15 p.m.

FDA Perspectives and Group Discussion, Plus Workshop Wrap Up (Paul Jones (FDA), Lisa Simone (FDA), Yi Zhang (FDA) and Fubin Wu)

YOUR COURSE 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 cut-off 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 21-22, 2014
Doubletree Bethesda Hotel
8120 Wisconsin Avenue
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Toll free: (800) 560-7753 • Tel: +1 (301) 652-2000
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Room rate: $219 plus 13% tax
Reservation cut-off: May 1, 2014

TUITION

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

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 of 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.

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 (888) 838-5578 for details.

FOUR EASY WAYS TO REGISTER

Online: www.MedDeviceCybersecurity.com
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☑ **YES!** I want to attend **Software and Cybersecurity Risk Management for Medical Devices.** I understand the fee of $1,797 includes all workshop sessions, workshop materials, two breakfasts, two luncheons and daily refreshments.

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(Please see "Team Discounts" above for tuition discounts when you send a team of three or more.)

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