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

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

Visit www.MedDeviceCybersecurity.com or call (888) 838-5578

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!
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 Guidelines (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)
   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

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 provides 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)

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))

Visit www.MedDeviceCybersecurity.com or call (888) 838-5578
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)
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.

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

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