

# Cybersecurity of Medical Devices: A Regulatory Science Gap Analysis

May 18-19-2017

## Preliminary Agenda

Day and Time	Activity
<b>Day 1 (5/18/2017)</b>	
7:00 am	Sign-in
8:00 am – 8:10 am	<p><b><u>Introduction and welcome</u></b> Edward Margerrison, Ph.D., Director, Office of Science and Engineering Laboratories (OSEL), Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA)</p> <p><b>General session I:</b></p> <p><b><u>What is Regulatory Science? (8:15am-8:25am):</u></b> Suzanne Schwartz, MD, MBA Associate Director for Science and Strategic Partnerships, Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA)</p> <p><b><u>Welcoming Remarks FDA (8:30am-8:40am)</u></b> Dinesh V. Patwardhan, PhD Associate Office Director, Office of Science and Engineering Laboratories (OSEL), Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA)</p> <p><b><u>NSF &amp; Medical Device Security/Privacy: Driving Future Research(8:40am-8:50am):</u></b> Jeremy Epstein, MS Deputy Division Director, Division of Computer and Network Systems (CNS), Computer and Information Science and Engineering Directorate (CISE), National Science Foundation (NSF)</p> <p><b><u>Welcoming Remarks DHS (8.50am-9:00am):</u></b> Daniel Massey, PhD Program Manager, Cyber Security Division (CSD), Science &amp; Technology Directorate Advanced Research Projects Agency, Department of Homeland Security (DHS)</p> <p><b><u>Relationship Between Security, Patient Safety, and Usability (9:00am-9:30am):</u></b> Pat Baird MS, MBA Regulatory Head of Global Software Standards, Philips</p>
8:15 am – 12:15 pm	

**Day and Time****Activity****Ruminations on Challenges in Securing Medical Devices****(9:30am-9:45am):**

Ken Hoyme, MSEE

Director of Product and Engineering Systems Security,  
Boston Scientific**BREAK (9:45am-10:15am)****Using CVSS in Medical Device Security Risk Assessment****(10:15am-10:30am):**Penny Chase, MS, Information Technology and Cyber  
Security Integrator, MITRE Corporation and Steve Christey  
Coley, BS, Principal Information Security Engineer, MITRE  
Corporation**How Medical Device Diversity and Uniqueness Drives  
Challenges (10:30am-11:00am):**

Kevin McDonald, CISSP

Director of Clinical Information Security, Mayo Clinic

**Building Cybersecurity Programs for Healthcare  
Technology: Our Only Security is Our Ability To Change  
(11:00am-11:30am):**

Rob Suarez, MS

Head of Product Security, Becton, Dickinson, and Company

**Even in Theory, Getting Medical Device Security Right is  
Difficult (11:30am-12:00pm):**

Todd Carpenter, BS

Chief Engineer, Adventium Labs

**Security "Hygiene" for the Medical Industry (12:00pm-  
12:15pm):**

Anura Fernando, MSE

Principal Engineer for Medical Software & Systems,  
Underwriters Laboratories (UL)

12:15 pm – 1:15 pm

**Lunch Break**

1:15 pm – 3:00 pm

**Breakout sessions****Breakout session structure:**

**Day and Time****Activity**

**Breakout Session 1: Relationship between medical device security and patient safety**  
(Moderators: Charles Farlow, Kevin Fu, Ken Hoyme, Anura Fernando) – *Great Room A*

**Breakout Session 2: Unique security and regulatory science challenges for medical devices** (Moderators: Nick Sikorski, Mike Jaffe, Michelle Jump) – *Great Room B*

**Breakout Session 3: The roles and intersection of information technology professionals and biomedical engineers** (Moderator: Rick Hampton) – *Room 1404*

**Breakout Session 4: Potential metrics and evaluation tools to test and quantify the security of medical systems and devices** (Moderator: John Hatcliff) – *Room 1406*

**Breakout Session 5: Automated and manual tools for communicating security information about medical device design and function** (Moderator: Stephanie Domas) – *Room 1408*

**Breakout Session 6: Best practices in security design, deployment, and post-deployment activities and procedures** (Moderator: George Samaras) – *Room 1506*

3:00 pm – 3:30 pm

**BREAK**

3:30 – 4:45 pm

**Breakout sessions**

**Breakout session structure:**

**Breakout Session 1: Relationship between medical device security and patient safety**  
(Moderators: Charles Farlow, Kevin Fu, Ken Hoyme, Anura Fernando) – *Great Room A*

**Breakout Session 2: Unique security and regulatory science challenges for medical devices** (Moderators: Nick Sikorski, Mike Jaffe, Michelle Jump) – *Great Room B*

**Breakout Session 3: The roles and intersection of information technology professionals and biomedical engineers** (Moderator: Rick Hampton) – *Room 1404*

**Breakout Session 4: Potential metrics and evaluation tools to test and quantify the security of medical systems and devices** (Moderator: John Hatcliff) – *Room 1406*

**Breakout Session 5: Automated and manual tools for communicating security information about medical device design and function** (Moderator: Stephanie Domas) – *Room 1408*

**Breakout Session 6: Best practices in security design, deployment, and post-deployment activities and procedures** (Moderator: George Samaras) – *Room 1506*

4:45 pm - 5:00 pm

**Return from Breakouts and End of Day 1**

**Day and Time****Activity****Plans for Next Day (Session Moderators Only)**

5:00 pm – 5:30 pm  
Dinesh V. Patwardhan, PhD  
Associate Office Director, Office of Science and Engineering  
Laboratories (OSEL), Center for Devices and Radiological  
Health (CDRH), Food and Drug Administration (FDA)  
and  
Eugene Y. Vasserman, PhD  
Associate Professor, Kansas State University,  
ORISE Fellow, Office of Science and Engineering  
Laboratories (OSEL), Center for Devices and Radiological  
Health (CDRH), Food and Drug Administration (FDA)

**Day 2 (5/19/2017)****Welcome, Announcements, Day 1 Recap:**

8:00 am – 8:15 am  
Brian Fitzgerald, BSc  
Senior Technical Advisor, Office of Science and Engineering  
Laboratories (OSEL), Center for Devices and Radiological  
Health (CDRH), Food and Drug Administration (FDA)

8:15 am – 10:15 am      **Breakout sessions**

**Breakout session structure:**

**Breakout Session 1: Relationship between medical device security and patient safety**  
**(subtopics TBD)** (Moderators: Charles Farlow, Stephanie Domas) – *Great Room A-1*

**Breakout Session 2: Relationship between medical device security and patient safety**  
(Moderators: Anura Fernando, Rick Hampton) - *Great Room A-2*

**Breakout Session 3: Relationship between medical device security and patient safety**  
**devices (subtopics TBD)** (Moderator: Beau Woods) – *Room 1404*

**Breakout Session 4: Relationship between medical device security and patient safety**  
**devices (subtopics TBD)** (Moderator: Mike Jaffe) – *Room 1406*

**Breakout Session 5: Unique security and regulatory science challenges for medical**  
**devices (subtopics TBD)** (Moderator: Kevin Fu, George Samaras) – *Great Room B-1*

**Breakout Session 6: Unique security and regulatory science challenges for medical**  
**devices (subtopics TBD)** (Moderator: Nick Sikorski, Michelle Jump) – *Great Room B-2*

**Breakout Session 7: Unique security and regulatory science challenges for medical**  
**devices (subtopics TBD)** (Moderator: Ken Hoyme) – *Room 1408*

**Breakout Session 8: Unique security and regulatory science challenges for medical devices**

**Day and Time****Activity**

(subtopics TBD) (Moderator: Aftin Ross) - Room 1506

10:15 am – 10:45 am

**BREAK**

10:45 am – 12:15 pm

**Breakout sessions**

**Breakout session structure:**

**Breakout Session 1: Relationship between medical device security and patient safety (subtopics TBD)** (Moderators: Charles Farlow, Stephanie Domas) – *Great Room A-1*

**Breakout Session 2: Relationship between medical device security and patient safety** (Moderators: Anura Fernando, Rick Hampton) - *Great Room A-2*

**Breakout Session 3: Relationship between medical device security and patient safety devices (subtopics TBD)** (Moderator: Beau Woods) – *Room 1404*

**Breakout Session 4: Relationship between medical device security and patient safety devices (subtopics TBD)** (Moderator: Mike Jaffe) – *Room 1406*

**Breakout Session 5: Unique security and regulatory science challenges for medical devices (subtopics TBD)** (Moderator: Kevin Fu, George Samaras) – *Great Room B-1*

**Breakout Session 6: Unique security and regulatory science challenges for medical devices (subtopics TBD)** (Moderator: Nick Sikorski, Michelle Jump) – *Great Room B-2*

**Breakout Session 7: Unique security and regulatory science challenges for medical devices (subtopics TBD)** (Moderator: Ken Hoyme) – *Room 1408*

**Breakout Session 8: Unique security and regulatory science challenges for medical devices (subtopics TBD)** (Moderator: Aftin Ross) - *Room 1506*

12:15 pm – 1:15 pm

**Lunch Break**

**General Session II:****Breakout Reports (1:00pm-2:00pm)**

Session Moderators

1:15 pm – 5:00 pm

**BREAK (2:00pm-2:30pm)**

**Breakout Reports and Discussion (2:30pm-3:45pm)**

**BREAK (3:45pm-4:15pm)**

**Workshop Report Drafting (4:15pm-5:00pm)**

Session Moderators

**Day and Time**

**Activity**

5:00 pm – 5:15 pm	<p><b><u>Workshop Recap and Closing Remarks</u></b> Eugene Y. Vasserman, PhD Associate Professor, Kansas State University, ORISE Fellow, Office of Science and Engineering Laboratories (OSEL), Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA)</p>
5:15 pm – 6:30 pm	<p><b><u>(Optional) Continued Report Drafting (Session Moderators Only)</u></b> Session Moderators</p>