Designing Next Generation Wireless Products that Advance Health Care and Control Risk

Boston, MA • May 7th, 2015

Product Development Opportunities in a Highly Regulated Environment 10:00am - 11:45am

Chair: Byron Mattingly, Ph.D., MPH, MBA, Chair-Elect, ASQ Software Division

10:00am State of the Industry panel: Balancing standards, risk and hospital requirements
- Discussing industry and government approaches to harmonizing regulatory, infrastructure and risk challenges while understanding global harmonized protocols for wireless devices
- Exploring resources available to medical device manufacturers for wireless product development
- What questions do hospitals ask when allowing a new wireless medical device into their environment

Michelle Jump, RAC, M.S., Principal Regulatory Affairs Specialist, Stryker Connected Care
Russell Johnson, EE, Regulatory Affairs Manager, HeartWare, Inc.
Rick Hampton, Wireless Communications Manager, Partners HealthCare System, Inc.

10:35am Business paradigms for bringing wireless devices to market (Workshop style format)
- Balancing medical vs. technological protocols for device design
- Exploring the technology road map ahead for innovation in wireless products
- Discussing device applications and use cases and how risk assessment is key to the product development cycle and pre-market clearance
- What do you need to include in your design process to accommodate connectivity with hospital EMR systems?
- Reviewing key questions to consider during the design or development process

Nias Puthenveettil, Director of the Chief Technology Office, Cerner Health Services (formerly Siemens Healthcare)

11:10am The future of implanted medical device battery and power systems: Trends impacting device features
- Reviewing new advances in batteries and energy harvesting technologies that will affect device form and function
- Design and selection criteria for batteries for implanted medical devices
- Examples of modeling approaches for predicting long term performance of medical device batteries

Prabhakar Tamirisa, Ph.D., Senior Principal Scientist, Battery Research & Technology Group, Medtronic Energy and Component Center

11:30am Ask the Experts Q&A Session

Meeting Platform and Interoperability Requirements 1:00pm - 2:30pm

Chair: Anura S. Fernando, Principal Engineer - Medical Software & Systems Interoperability, UL

1:00pm Hospital interoperability experts: Avoiding crosstalk in an increasingly complex setting
- Discussing the complexity of the hospital and outpatient environment from a clinician’s perspective
- Reviewing an example use case for interoperability demonstrating the challenges hospitals face when integrating wireless medical devices

James C. Fackler, MD, Associate Professor, Departments of Anesthesiology/Critical Care Medicine and Pediatrics, Johns Hopkins Medicine
Julian Goldman, MD, Medical Director of Biomedical Engineering, Partners HealthCare System and Director, MGH Medical Device Interoperability Program
1:25pm  Surviving the wild west of wireless platform development in a highly regulated environment
  • Regulatory challenges and standards considerations when deploying a single wireless technology platform
  • Balancing risk and innovation when designing wireless products for a regulated environment.
  • Implementing a strong risk management culture within your organizations to address both safety and security.

  Anura S. Fernando, Principal Engineer - Medical Software & Systems Interoperability, UL

1:45pm  Toward Trusted Wireless Healthcare
  • Applying risk management to wireless healthcare infrastructure
  • Validating and refining best practices guidelines using healthcare pilots
  • Establishing a laboratory for testing and conformance assessments

  Ken Fuchs, Executive VP, Interoperability R&D, Center for Medical Interoperability

1:55pm  Managing risk in the design of mobile wireless medical devices
  • Technical factors to consider when designing wireless devices for hospital environments
  • Exploring what hospitals want from wireless performance
  • Controlling risk by using best practices for getting a seat on your customers WiFi network

  Phil Raymond, Wireless Architect and Global Network Product Manager - Connected Care Solutions, Philips Healthcare

2:15pm  Ask the Experts Q&A Session

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**Big Data and Data Security**

2:45pm - 4:00pm

Chair: Michael C. McNeil, Global Products Security and Services, Philips Healthcare

2:45pm  Cyber security: Flaws in medical device security protocols that compromise data
  • Understanding security and safety protocols and their affect on wireless infrastructures
  • Addressing device security through device safety features and interoperability advancements
  • What it takes to create a solid risk management approach for device security

  Michael C. McNeil, Global Products Security and Services, Philips Healthcare

3:05pm  Data, data, data: Overcoming cloud storage and server platform challenges
  • Reviewing how security is tied to a product’s risk management assessment and how to ensure your product’s data is secure
  • Exploring immediate solutions for sharing secure data across various integrated systems
  • Understanding industry and the FDA’s role in collaborating to solve existing infrastructure challenges within the HIPAA, HITECH and ONC framework

  Ravi Kuppuraj, Chief Technology Officer, Infobionic

3:30pm  Panel discussion: Big data gathering, sharing and ownership: The future of connected health
  • Exploring how the industry is using the growing mass of information in ways that help device manufacturers while safeguarding patients
  • Bringing mHealth, mobile app development, and the consumerization of healthcare into your planning cycle
  • Exploring how the marketplace will drive innovation and models for data sharing and ownership
  • As we begin to realize this opportunity, how will it impact the future of health data privacy and security?

  Moderator: Michael C. McNeil, Global Products Security and Services, Philips Healthcare

  Ravi Kuppuraj, Chief Technology Officer, Infobionic

  Matthew Quinn, East Coast Managing Director, Healthcare and Life Sciences, Intel Corporation
Axel Wirth, Healthcare Solutions Architect, Symantec Corporation