



2ND CONNECTED MEDICAL DEVICES CYBERSECURITY SUMMIT 2019

December 10-12, 2019 | San Francisco, CA

www.connected-devices-summit.com

■ The conference was good with very experienced and knowledgeable speakers ■

Senior Specialist Regulatory Affairs,
Edwards Lifesciences LLC

Mitigating Medical Device Vulnerability throughout the Product Lifecycle to Alleviate Patient Risk



Ken Zalevsky
Director, Informatics
Bayer



David Presuhn
Sr Computer Systems
Security Engineer
Boston Scientific



Greg Garcia
Executive Director
for Cyber Security
**Health Sector
Coordinating
Council**



Kelly Aldrich
Chief Clinical Digital
Officer
**Center for Medical
Interoperability**



Jim Jacobson
Chief Product and
Solution Security Officer
Siemens Healthineers

Hosting Partner:



Media Partner:



drugDELIVERY

WELCOME TO THE 2ND CONNECTED MEDICAL DEVICES CYBERSECURITY SUMMIT 2019

Join medtech leaders from **healthcare delivery organizations, medical device manufacturers** and regulatory experts as we guide and maximize your response strategy to cybersecurity threat.

With 15+ case studies, this is your opportunity to hear the latest progress in medical cybersecurity from the likes of **Bayer, Health Sector Coordinating Council** and **Siemens Healthineers**. They will reveal how to navigate through the latest premarket FDA guidelines, legacy device challenges and leverage cybersecurity risk management frameworks.

This 3-day summit will enable you to design effective cybersolutions by applying practical takeaways from our expert speaker panel. Come to this conference to address life-cycle wide challenges and proactively enable successful vulnerability resolution.

Spotlight Case Studies - Enhancing your Threat Response Strategy



Bayer - Impact of FDA Premarket Guidance

Ken Zalevsky provides manufacturing expertise into securing devices by design and the benefits in sharing a cybersecurity bill of materials.



Health Sector Coordinating Council - Succeeding through a Collaborative Approach

Greg Garcia explains the latest developments including how the Medical Technology Joint Security Plan (JSP) is strengthening the security and resilience of the healthcare industry.



UC David Medical Center - Explore Device Risk Epidemiology

Jeffrey Tully reveals how to drive clinician awareness of cybersecurity issues to ensure secure implementation of novel medical devices.



Blue Cross Blue Shield of Massachusetts - The Adapting Responsibility of Healthcare Providers

Timothy Berendt shares how to execute organizational and cultural change within the healthcare industry to drive innovation.



Moses & Singer LLP - Being Cyber Compliant

Nora Lawrence Schmitt showcases how a "total lifecycle product" approach will address shared challenges between HDOs and device manufacturers.

“The diversity was welcome as it really emphasized the theme of the event: cybersecurity is a team sport.” **Principal Electrical Engineer, EBR Systems Inc**

EXPERT SPEAKER PANEL



Ken Zalevsky
Director, Informatics
Bayer



Greg Garcia
Executive Director for Cyber
Security
**Health Sector
Coordinating Council**



Jeffrey Tully
Resident Anesthesiologist
UC Davis Medical Center



Christopher Beeman
Business Development &
Connected Technologies
Manager
UL, LLC



Sabyasachi Roy
Senior Director - Regulatory
Affairs, Quality Assurance &
Compliance
Brainscope Company Inc



**Soundharya
Nagasubramanian**
Director, R&D, Product
Information Security
HillRom



Timothy Berendt
Director of Innovation
**Blue Cross Blue Shield of
Massachusetts**



Jim Jacobson
Chief Product and Solution
Security Officer
Siemens Healthineers



Avi Rubin
Professor, Computer Science
and Technical Director of the
Information Security Institute
John Hopkins University



David Snyder
President
42TEK, Inc.



Kelly Aldrich
Chief Clinical Digital Officer
**Center for Medical
Interoperability**



Nora Lawrence Schmitt
Attorney Associate
Moses & Singer LLP



Tim Gee
Principal
**Medical Connectivity
Consulting**



David Presuhn
Sr Computer Systems
Security Engineer
Boston Scientific

Overall great conference and
interaction. Speed networking
worked really well.

**Senior Manager, Software Quality,
Edwards Life Sciences**

PRE-CONFERENCE WORKSHOP DAY

TUESDAY DECEMBER 10, 2019

Workshop A

Beyond Security Frameworks: Operationalizing Cyber Security

09.00 am - 12.00 pm

Background: This session will explain how regardless of the data security framework that is adopted for new or existing devices, certain operational capabilities are required to support the installation and support of connected medical devices.

Participants will learn:

- How to minimize regulatory overhead when adopting patch management and other responses to security threats
- Insight behind how cybersecurity impacts corrective and protective action (CAPA)
- Best practices to prepare your supply chain for cybersecurity requirements
- The key infrastructure and resources required for cybersecurity

Workshop Leader



Tim Gee
Principal
Medical Connectivity Consulting

Workshop B

Cybersecurity & the Future of Remote Patient Monitoring

1.30 pm - 4.30 pm

Background: Healthcare delivery organizations need guidance on how to set up and support users who may not know how to make sure their home networks and mobile phones are secure.

This session shares how network-connected medical devices outside the clinical environment are integrated and installed securely. Come to this session to explore the importance of patching and monitoring for indications of abnormal behavior that may indicate device failure or compromise.

Participants will learn:

- The similarities and differences between network-connected medical devices in clinical settings versus residential environments
- The relative cybersecurity challenges and best practices throughout the lifecycle of remote devices

Workshop Leader



David Snyder
President
42TEK, Inc.

CONFERENCE DAY ONE

WEDNESDAY, DECEMBER 11, 2019

8.00 **Registration & Morning Refreshments**

8.45 **Chair's Opening Remarks**



Greg Garcia
Executive Director for
Cyber Security
**Health Sector
Coordinating Council**

Understanding the Security Requirements for Emerging Medical Devices

9.00 **The Effectiveness of Static Firmware Code Analysis in Medical Device Security Assessment**

- Insight into benefits of static code analysis on the process of testing and device debugging
- Advantages and cost benefits for updating embedded devices
- Recognising the importance of static analysis over additional software testing techniques



Avi Rubin
Professor, Computer
Science and Technical
Director of the Information
Security Institute
John Hopkins University

9.30 **Solving the "Last Mile" Problem**

- Outlining how independent security researchers have increased awareness of the importance of secure-by-design medical devices
- Insight to overcome the challenge of lack of resources facing health care delivery organizations
- Expertise behind the epidemiology on the actual risk of insecure medical devices and lacking infrastructure



Jeffrey Tully
Resident Anesthesiologist
UC Davis Medical Center

10.00 **Panel Discussion: HDO & Device Manufacturers - Building Upon the Key Relationship**



- Moving forward with the particular challenges behind legacy devices
- Establishing a common framework for assessing appropriate levels of risk
- The advantages and challenges of setting up minimum medical device cybersecurity requirements across the product life cycle



Ken Zalevsky
Director,
Informatics
Bayer



**Soundharya
Nagasubramanian**
Director, R&D,
Product Information
Security
HillRom



David Presuhn
Sr Computer Systems
Security Engineer
Boston Scientific



Avi Rubin
Professor, Computer
Science and Technical
Director of the Information
Security Institute
John Hopkins University

10.30 **Speed Networking**

Your opportunity to meet and engage with 60+ experts across the Medtech Landscape



11.00 **Morning Refreshments**

11.30 **FDA Premarket Guidance Impact on Medical Device Manufacturers**

- Outlining the advantages of securing devices by design
- An overview of product security assessments for device manufacturers
- The advantages and transparency in presenting a Cybersecurity Bill of Materials (CBOM)



Ken Zalevsky
Director, Informatics
Bayer

12.00 **Lunch**

CONFERENCE DAY ONE

WEDNESDAY, DECEMBER 11, 2019

Strategies to Overcome Post-Market Device Vulnerability

- 1.00 **UL LLC Panel Session**
Expertise insight behind the benefits of UL Cybersecurity Assurance Program (UL CAP) for Network Connectable Components of Healthcare and Wellness Systems
-   **Christopher Beeman**
Business Development & Connected Technologies Manager
UL, LLC
- 1.30 **Information Sharing: How Software Bill of Materials help HDOs Manage Risk**
 - Use cases for medical device Software Bill of Materials (SBOM)
 - SBOM Healthcare Proof of Concept and next steps in SBOM for medical devices
-  **Jim Jacobson**
Chief Product and Solution Security Officer
Siemens Healthineers
- 2.00 **Interactive Q/A Session**
Opening the floor to our audience to debate to discuss with speakers the latest medtech industry challenges
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- 2.30 **Afternoon Refreshments**
- 3.15 **Being Cyber Compliant – From Evolving Regulatory Frameworks to Software & Data Privacy of Your Connected Medical Devices**
This is an interactive session with practical takeaways for participants. We have invited leading cybersecurity law firm Moses & Singer LLP to share their expert Insight on the following subjects:

1. Evaluating compliance risks of your connected medical device – and the liabilities as a device manufacturer, HDO and pharmaceutical company

2. Why you should embed a “total lifecycle product” approach to address common challenges between HDO and device manufacturers

3. Regulatory requirements and variation from country to country on: software as a medical device, data privacy and patient privacy

4. What if? Prepare for the worst case scenario: during a cyber attack, what should you do?



Nora Lawrence Schmitt
Attorney Associate
Moses & Singer LLP

4.00 **Feedback from Roundtable Discussion**



4.30 **Chair's Closing Remarks**



Greg Garcia
Executive Director for Cyber Security
Health Sector Coordinating Council

CONFERENCE DAY TWO

THURSDAY, DECEMBER 12, 2019

8.00 **Coffee & Refreshments**

8.45 **Chair's Opening Remarks**



Greg Garcia
Executive Director for
Cyber Security
**Health Sector
Coordinating Council**

Gain the Edge in Medical Cybersecurity Threat Response

9.00 **Shared Challenge, Shared Responsibility**

- Explore how the healthcare industry is moving towards a more collaborative approach that recognizes cybersecurity as a shared challenge and hence a shared responsibility
- Sharing insight behind how the Medical Technology and Joint Security Plan (JSP) advances a model for more transparent patch management and vulnerability disclosure between vendors and customers



Greg Garcia
Executive Director for
Cyber Security
**Health Sector
Coordinating Council**

9.30 **How can a Healthcare Payer Embrace Disruption through Innovation?**

- A complete organizational and cultural change for real innovation – how to execute this effectively?
- A different approach: progress inside and outside of a skunkworks operation
- The KYC benefits: develop a product that your customers want and will use



Timothy Berendt
Director of Innovation
**Blue Cross Blue Shield
of Massachusetts**

10.00 **A Healthcare - Specific Approach to Cybersecurity**

- Establishing good security hygiene as a top priority for software developers
- Adapting to the latest threats – learn how to monitor the behavior of devices to apply software patches against vulnerabilities

**Reserved for Program
Sponsor**

10.30 **Interactive Panel Discussion: Validating Cybersecurity Framework Selection - Guiding Large to Medium Sized Manufacturers**



- The advantages and limitations of current cybersecurity frameworks for large and medium sized organizations
- Advantages of defining proper use of personal and employer-provided devices; and creation of a cyberattack response plan
- Comparison of NIST, HITRUST and ITIL – utilizing a combination- what are the benefits?



Sabyasachi Roy
Senior Director –
Regulatory Affairs, Quality
Assurance & Compliance
Brainscope Company



Kelly Aldrich
Chief Clinical Digital
Officer
**Center for Medical
Interoperability**



Jim Jacobson
Chief Product and
Solution Security Officer
Siemens Healthineers

11.00 **Morning Refreshments**

Standardizing Medical Device Risk Assessment

11.30 **Interoperability for Better Care**

- Outlining how medical device interoperability can improve patient care
- Driving the potential to safely, securely and effectively exchange and use information between one or more devices
- Insight behind the infrastructure independent model in supporting HDOs adopt wireless devices



Kelly Aldrich
Chief Clinical Digital
Officer
**Center for Medical
Interoperability**

CONFERENCE DAY TWO

THURSDAY, DECEMBER 12, 2019

12.00 **The Common Vulnerability Scoring System (CVSS) for Medical Devices - Benefits and Limitations**

- How does the CVSS reflect the clinical environment and potential patient safety impacts?
- What changes are necessary to create a standardised assessment system?



Sabyasachi Roy
Senior Director -
Regulatory Affairs, Quality
Assurance & Compliance
Brainscope Company Inc

12.30 **Interactive Q/A Session**

Opening the floor to our audience to debate to discuss with speakers the latest medtech industry challenges



12.45 **Lunch**

1.45 **It Starts With Good Architecture – Software & Cybersecurity for Connected Medical Devices**

- Medical device design and software by design – why it is different from other consumer products?
- The importance of data security as a focal point of design and operations
- Cybersecurity assessment and provider/hospital interactions – it's an ongoing project



Soundharya Nagasubramanian
Director, R&D, Product
Information Security
HillRom

2.15 **Challenges Patching of Legacy Devices**

- Initial design considerations- where have we come from?
- The original issue of tackling disconnected devices
- Boston Scientific case study-led insight into patch challenges and lessons learn



David Presuhn
Sr Computer Systems
Security Engineer
Boston Scientific

2.45 **Interactive Q/A Session**

Opening the floor to our audience to debate to discuss with speakers the latest medtech industry challenges



3.00 **Chair's Closing Remarks**



Greg Garcia
Executive Director for
Cyber Security
**Health Sector
Coordinating Council**

Engaging, relevant, expert.

Head of Smart Devices,

Genentech

PARTNER WITH US



Hosting Partner

The UL Life & Health Sciences division is dedicated to healthcare industry innovation. We help clients with their biggest challenges in regulatory management, market access, and connected device risk mitigation i.e. safety, security, usability, and interoperability. We ensure that medical devices are safe to deploy and use in an increasingly patientcentric and connected environment. UL brings decades of the most advanced technical, regulatory and clinical expertise to solve the toughest challenges in the market with the goal of improving access to advanced safe healthcare around the world. Our technical experts and biomedical engineers each average of over 10 years' experience and are active members of industry standards writing and technical committees. Throughout the UL family of companies, we offer services that life and health sciences companies need for business success and improving patient outcomes.

www.ul.com/healthcare

The medtech landscape is an ever changing market. With the increased challenge from new threats and regulatory guidelines it is clear that Cyber-Security has become a main priority for healthcare organizations.

The **2nd Connected Medical Devices Cybersecurity summit** is your chance to share software solutions and consultancy expertise among 60+ industry experts from **regulatory organizations, HDOs and medical device manufacturers.**

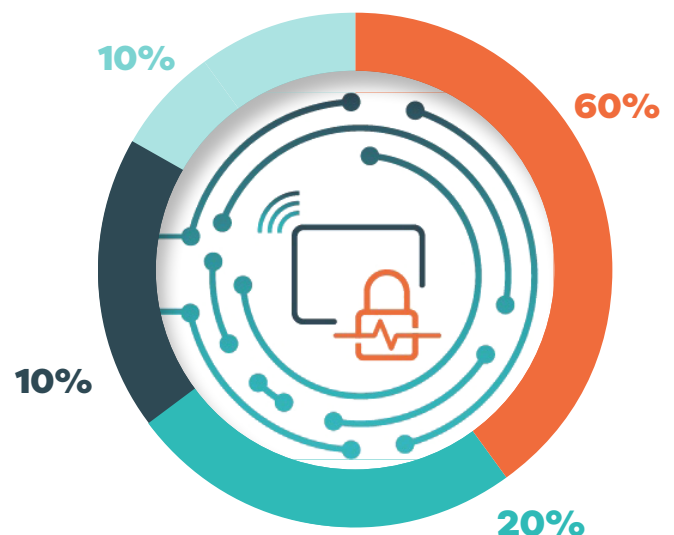
This forum is your unique opportunity to position yourself as an industry trailblazer and show how your solutions can solve their challenges.

Our audience has highlighted interest in hearing from:

- Cybersecurity platform providers
- Connected Devices Software providers
- Regulatory Consultants

If your company offers services and solutions that would benefit our audience, we'd love to hear from you.

ATTENDING INDUSTRY SECTORS



- Medical Device Manufacturer
- Healthcare Delivery Services
- Regulatory Organizations
- Pharmaceutical Companies

LET'S TALK



Kurt Salih

Partnerships Director

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READY TO REGISTER?

3 EASY WAYS TO BOOK



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Email: register@hansonwade.com



Web: www.connected-devices-summit.com/

Team Discounts

10% discount – 2 delegates

15% discount – 3 delegates

20% discount – 4 or more delegates

Please note that discounts are only valid when three or more delegates from one company book and pay at the same time.

Secure Your Place

Industry Pricing	Register & Pay before Friday October 25, 2019	Standard Price
Conference + 2 Workshops	\$2,697 (save \$1000)	\$3,297 (save \$400)
Conference + 1 Workshop	\$2,598 (save \$700)	\$3,198 (save \$100)
Conference Only	\$2,499 (save \$400)	\$2,899
Workshop Day Only	\$399	

Solution Provider Pricing	Register & Pay before Friday October 25, 2019	Standard Price
Conference + 2 Workshops	\$3,997 (save \$1000)	\$4,597 (save \$400)
Conference + 1 Workshop	\$3,698 (save \$700)	\$4,298 (save \$100)
Conference Only	\$3,399 (save \$400)	\$3,799
Workshop Day Only	\$599	



VENUE

Hotel Kabuki

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www.jdvhotels.com

TERMS & CONDITIONS

Full payment is due on registration. Cancellation and Substitution Policy: Cancellations must be received in writing. If the cancellation is received more than 14 days before the conference attendees will receive a full credit to a future conference. Cancellations received 14 days or less (including the fourteenth day) prior to the conference will be liable for the full fee. A substitution from the same organization can be made at any time.

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