



CONNECTED DEVICES: CYBERSECURITY & COMPLIANCE

SUMMIT 2018

Book by Friday
October 12 to
SAVE UP TO \$700

December 11 - 12, 2018 | **San Francisco**

www.connected-devices-summit.com

“Great speakers and case studies which brought great discussions to current challenges and opportunities.”

Previous Device Series Event Attendee, **Allergan**

Bulletproof Your Smart Device from Cyber Vulnerabilities by Developing a Compliance Program & Collaborating With Your Stakeholders

15 Expert Speakers Including:



Greg Garcia
Executive Director,
Cybersecurity
**Healthcare Sector
Coordinating Council**



Deb Muro
Chief Information
Officer
El Camino Hospital



Paul Upham
Senior Principal
Roche



David Scott
Product Security
Officer
BD



Jeffrey Moore
Global Head of Cyber
Security
**Novartis Institute for
Biomedical Research**



WELCOME TO THE CONNECTED DEVICES: CYBERSECURITY & COMPLIANCE SUMMIT

Uniting Industry Pioneers to Deliver a Secure & Compliant Connected Device

About Us

With an expected market size of \$29.2 billion by 2024, the connected medical device industry is growing at an alarming rate. While these new features and innovations will undoubtedly help deliver a more quality patient care, security and compliance have been repeatedly mentioned by drug and device developers as the biggest barriers to advance projects.

As part of our device series, we're very excited about the launch of this unique summit to unite the community this December, **addressing key challenges including defining a cybersecurity framework, selecting the right partners for long-term relationships, devising quality and validation strategy** and finally, **ensuring interoperability** within the ecosystem with healthcare providers.

Incorporating insights from the likes of **Healthcare Sector Coordinating Council, Novartis Institute of Biomedical Research, Roche, BD** and many others, you'll hear practical case studies and lessons learned to prepare you for a successful launch of your connected device.

Spotlight Case Studies

1. **Roche** will reveal how to develop a secured and compliant connected device in a global market
2. **Novartis Biomedical Research Institute** will demonstrate how pharma/biotechs should re-develop their cybersecurity program, ensuring you stay GDPR compliant
3. **NIST** will explain their cybersecurity guidance for connected and mobile medical devices, helping you to address interoperability and collaboration with healthcare providers.
4. **Healthcare Sector Coordinating Council** will present their latest guidelines on connected devices for device manufacturers, pharma and healthcare providers, helping you navigate the ecosystem
5. **BD** will discuss the need to align cybersecurity programs with next generation products, ensuring patients' safety

“Informative, collaborative and great expert speakers!”

Previous Device Series Event Attendee, **EMD Serono**

EXPERT SPEAKER PANEL



Greg Garcia
Executive Director,
Cybersecurity
Healthcare Sector
Coordinating
Council



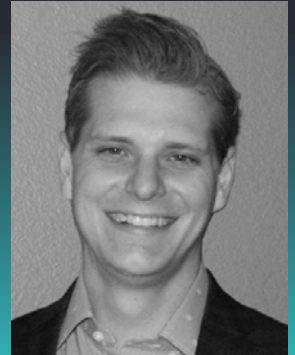
Jeffrey Moore
Global Head of Cyber
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for Biomedical
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Paul Upham
Senior Principal
Roche



Deb Muro
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Officer
El Camino Hospital



Jason Johnson
Information Security
Officer
Marin General
Hospital



David Scott
Product Security
Officer
BD



Christy Peel
Global Information
Security Officer IS&RM
Novartis Institute for
Biomedical Research



Timothy Berendt
Director of Innovation
Blue Cross
Blue Shield of
Massachusetts



Matthew Jones
Clinical Engineering
Security Specialist
Intermountain
Healthcare



Andrea Arbelaez
Senior Leader,
Cybersecurity
NIST



Mary Ann Smith
Senior Director,
Quality Assurance
& Regulatory
Affairs
Advanced Cell
Diagnostics



Ed Harshberger
Independent
Cybersecurity
Architect



David Snyder
President
42TEK, Inc.



Christine Sublett
President
& Principal
Consultant
Sublett
Consulting, LLC



David Presuhn
Connected
Device
Management
Boston
Scientific



Senior
Representative
UL

08.00 **Breakfast & Registration**

09.00 **Chair's Opening Remarks**



Greg Garcia
Executive Director,
Cybersecurity
**Healthcare Sector
Coordinating Council**

Connected Device – Regulatory Framework Evolution

09.15 **The Fast Evolving IoT World – How Can You Ensure Your Patients' Data is Safe?**

- Introduction of NIST and recent projects in cybersecurity
- Addressing the increasingly connected world and devices – where should you save your patients' data and how do you know it's safeguarded?
- Understanding the healthcare system and network infrastructure to mitigate cybersecurity risks



Andrea Arbelaez
Senior Leader,
Cybersecurity
NIST

09.45 **Developing a Risk Management Framework for Your Connected Device**

- Design an organizational understanding to manage cybersecurity risks
- Define your traceability metrics and implement a safeguarding program
- Ongoing monitoring to proactively identify potential threats with timely response procedures
- Implement a CAPA process and improve your compliance and cybersecurity program resilience



Jeffrey Moore
Global Head of Cyber Security
**Novartis Institute for
Biomedical Research**

Technology Opportunities & Challenges

10.15 **A Shift of Mindset – How to Develop a Secured and Compliant Connected Device**

- From pharma/ device manufacturers to tech – a forward looking step and change of mind and skill set
- How to develop a secured and compliant connected device, particularly from a software perspective
- Thinking ahead – your launch designation and compliance landscape, comparing and contrasting US and EU requirements



Paul Upham
Senior Principal
Roche

10.45 **Morning Refreshments & Speed Networking**

12.15 **Challenges with Remote Monitoring and Data Ownership**

- Plug and play - how to build a secured remote monitoring program with connected devices
- Healthcare on-demand – who owns the data?
- How to safeguard confidentiality of patient data
- Data encryption, integrity and usability



Session reserved for
Program Partner

12.45 **Panel Discussion: Future Opportunities of Connected Companion Diagnostics Solutions**

- The rise of 'smart' connected devices and possibility of companion diagnostics and personalized treatment
- The uncertainty of regulatory standpoint and validation process
- How to handle increased risk and exposure to cyber-attacks



Led by
UL

13.30 **Lunch & Networking**

“A very engaging, comprehensive and collaborative meeting!”

Previous Device Series Event Attendee, **Merck**

Ensuring Collaboration with Your Multiple Stakeholders

14.30 How Can A Healthcare Provider Embrace Technology Disruption?

- A complete organizational and cultural change for real innovation – how to execute this?
- 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

15.00 **INTERACTIVE WORKSHOP: Cybersecurity For Medical Devices Is A “Team Sport”**

Interoperability and compatibility of network-connected medical devices in hospitals and clinics have been key concerns for pharma and device manufacturers and now cybersecurity, too.

This interactive workshop will focus on how pharma and device developers can collaborate with hospitals and clinics to help make sure these medical devices are set up and managed to protect patients’ privacy and safety.

Through exercises and open discussion, pharma and device manufacturers can reflect on the perspectives of hospitals and clinics regarding best practices.

This highly interactive and hands-on session will be conducted by a team with diverse backgrounds, including a hospital CIO, a clinical engineer, a hospital information security officer, and two neutral cybersecurity consultants to facilitate and moderate. By the end of this session, you will be equipped with:

- Considerations during procurement, integration and operations
- Defining best practice for device inventory management and monitoring device behavior and network traffic for potential cybersecurity attack indications
- Ways of thinking about the issues in term of people, process, and technology
- Views on how connected medical device cybersecurity can be approached as a ‘team sport’ involving collaboration among manufacturers, regulators, providers (hospitals and physicians), supply chain, and patients
- Understanding of how hackers plan their attacks
- Ideas for ways potential risks may be mitigated

There will be group exercises and case studies for the best learning experience. An afternoon networking break will be served half-way through this session.



David Snyder
President
42TEK, Inc.



Deb Muro
Chief Information Officer
El Camino Hospital



Jason Johnson
Information Security Officer
Marin General Hospital



Matthew Jones
Clinical Engineering
Security Specialist
Intermountain Healthcare



Christine Sublett
President & Principal
Consultant
Sublett Consulting, LLC

17.30 Chair’s Closing Remarks



Greg Garcia
Executive Director,
Cybersecurity
**Healthcare Sector
Coordinating Council**

17.40 Close of Day One

“It was a very well organized conference where participants were very engaged and brought good energy and discussions to the meeting.”

Previous Device Series Event Attendee,
Novo Nordisk



08.00 **Registration & Refreshments**

09.00 **Chair's Opening Remarks**

Bullet-Proofing Your Connected Devices

09.10 **Keynote: Managing a Shared Challenge: Cyber Risk Management for MedTech & Health Providers**

For too long medical equipment manufacturers and healthcare providers have, in practice, not been aligned towards protecting patient safety from cybersecurity threats. The Health Sector Coordinating Council has finally brought together these key stakeholders to acknowledge a shared responsibility and hammer out a joint security plan – a mutual commitment of medical technology companies and hospitals to maintain and improve cyber risk management programs for medical technology manufacture and implementation. This presentation will highlight the plan and the way forward for driving national adoption and measures of success.



Greg Garcia
Executive Director,
Cybersecurity
**Healthcare Sector
Coordinating Council**

09.40 **Developing a Risk Management Framework for Your Connected Device**

- Design an organizational understanding to manage cybersecurity risks
- Define your traceability metrics and implement a safeguarding program



Ed Harshberger
Independent
Cybersecurity Architect

10.10 **How to Execute Patching and Why Patch Management Is Important**

- Brief history of OS patching
- Why do we patch? And how to patch?
- FDA's stance on patching
- Best practices to patch a medical device
- Gotchas!



David Presuhn
Connected Device
Management
Boston Scientific

10.40 **Morning Refreshments & Networking**

Excellent Quality & Risk Management Systems

11.10 **Developing a First Class Cybersecurity Program for Your Critical and Connected Devices**

- Assess cyber-attack risks and design counter-measures
- How to reduce your exposure and system weaknesses to enhance overall cybersecurity, particularly for smart combination product devices
- Integrate cybersecurity and response incident as part of your QRMS



David Scott
Product Security
Officer
BD

11.40 **How to Embrace and Accelerate Partnerships through Robust Due Diligence?**

- The challenges of outsourcing software to create a connected device from a pharma/ device manufacturer perspective
- Who to partner with?
- The importance of a due diligence program to drive quality assurance and mitigate risks



Mary Ann Smith
Senior Director,
Quality Assurance &
Regulatory Affairs
**Advanced Cell
Diagnostics**

12.10 **Decrypting HIPAA and GDPR – Impacts and Implications on Your Connected Devices**

- Putting your patients' safety first – HIPAA and GDPR risk analysis
- Implementing a compliant security and data program while connecting with your patients and HCPs



Christy Peel
Global Information
Security Officer IS&RM
**Novartis Institute for
Biomedical Research**

12.40 **Master Mind: The audience can choose a specific topic to discuss and share their challenges with colleagues. Through open dialogues, we hope to facilitate knowledge exchange and spark inspirations to help you find solutions to your daily problems.**

- Track 1:** What is the criteria for selecting the right partners and platforms for your connected devices?
- Track 2:** Handling post-launch and legacy products' compliance and security issues – from industry standards to designing a fit-for-purpose program
- Track 3:** How to perform user research to improve validation and testing on your connected device's usability and security

**Roundtable
Discussion**

13.30 **Chair's Closing Comments & End of Conference**



Greg Garcia
Executive Director,
Cybersecurity
**Healthcare Sector
Coordinating Council**

WHO WILL YOU MEET?



60+
ATTENDEES

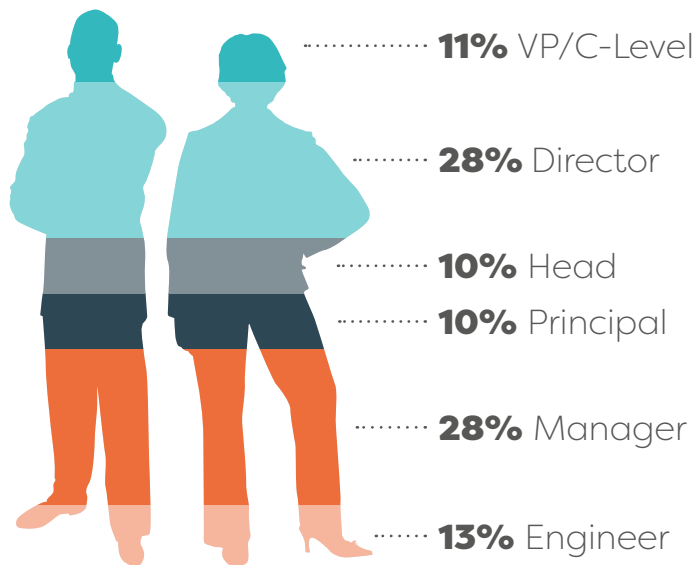


12+
HOURS OF DEDICATED
LEARNING & NETWORKING



3
INTERACTIVE
SESSIONS

Seniority*



Companies by Type*



Pharma & Biotech..... **50%**
 Device Manufacturer..... **30%**
 Software..... **10%**
 Consultancy..... **5%**
 Academic & Regulatory Agency **5%**

*Based on figures from our previous device series meetings in 2017-2018

Previous Device Series' Attendees Include:



“The networking opportunity was fantastic. The meeting had a broad range of topics which interested a diverse panel of participants.”

Previous Device Series Event Attendee,
Safety & Systems-Self Administration Injection Systems

PARTNER WITH US

The connected device community is eager to stay ahead of the curve through assessing innovative technologies. If your company offers services and solutions that would benefit our audience, we'd love to hear from you.

Pharma and device manufacturers are racing for the the next connected device product launch and are urgently seeking solutions in the following areas:



SOFTWARE PARTNERS

who can help develop a compliant and patient-centric app



CYBERSECURITY EXPERTS

from systems to validation to consultancy who can advise our audience on defining a bulletproof framework



DATA COMPLIANT & MANAGEMENT CONSULTANCIES

who can ensure device manufacturers and pharma's use of patients are within GDPR and HIPAA guidelines

If you have a solution or product to help our community, please get in touch to discover bespoke partnership opportunities that will connect you with them.

Who Will You Meet?

60+ VPs, Directors, Heads, Principals of:



Connected Devices
& Device Leads



Cybersecurity



Regulatory Affairs
& Compliance



Quality
Assurance



Product
Management

from pharma, biotech, device manufacturers and healthcare providers



PANEL 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 patient-centric 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



MEDIA PARTNER

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www.ondrugdelivery.com



Let's Talk

Bashir Langhi

Partnerships Director

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“A good platform for us to engage and meet with all industry experts under one roof!”

Previous Device Series Event Attendee, **Minnetronix**

READY TO REGISTER?

3 EASY WAYS TO BOOK



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Package Details	Register & Pay by Friday, October 12	Standard Rate
Conference Only	\$3099 (SAVE \$700)	\$3,799

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