# AdvaMed Cybersecurity Summit
# Wednesday, November 13, 2025

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| **8:15 am – 9:00 am** | **Continental Breakfast and Registration Open** |
| **9:00 am – 9:05 am** | **Welcome Remarks**<br>***Zach Rothstein, Executive Director, AdvaMedDx, AdvaMed*** |
| **9:05 am – 9:55 am** | **The Regulator's Perspective: Navigating the FDA's Evolving Cybersecurity Framework**<br>The U.S. Food and Drug Administration (FDA) continues to refine its medical device cybersecurity expectations, placing greater emphasis on a "secure by design" approach and a total product lifecycle (TPLC) perspective. This session will feature a senior FDA official from the Center for Devices and Radiological Health (CDRH) to discuss the latest premarket and postmarket expectations. Key topics will include the integration of cybersecurity into Quality System Regulations, the role of the Software Bill of Materials (SBOM) in transparency and vulnerability management, and the agency's focus on emerging technologies like Artificial Intelligence (AI) and Machine Learning (ML) in medical devices.<br><br>**Speakers:**<br>• **Justin Post, Policy Analyst (Cybersecurity), Center for Devices and Radiological Health (CDRH), FDA**<br>• **Suzanne Schwartz, Office Director, Office of Strategic Partnerships and Technology Innovation, Center for Devices and Radiological Health (CDRH), FDA** |
| **9:55 am – 10:45 am** | **Beyond the Device: The Interplay of Privacy and Security in a Connected Health Ecosystem**<br>The lines between data privacy and cybersecurity are increasingly blurred, especially with the proliferation of connected medical devices that collect, transmit, and store sensitive patient information. This session will dissect the latest developments in the HIPAA Security Rule and other privacy regulations. The discussion will address the compliance challenges for manufacturers, the implications of data breaches involving medical devices, and the legal and reputational risks associated with inadequate privacy and security controls.<br><br>**Speakers:**<br>• **TBD** |

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| **10:45 am – 11:35 am** | **The Inevitable Sunset: Strategizing for End-of-Life and End-of-Support**<br>The lifecycle of a medical device inevitably includes an end-of-life (EOL) and end-of-support (EOS) phase, which presents significant cybersecurity challenges for both manufacturers and healthcare providers. This session will provide best practices for developing and communicating clear EOL/EOS policies. It will cover how to transparently communicate timelines, manage residual risks in legacy devices, and provide guidance to customers on secure device retirement and transition, a topic of increasing focus for regulators and healthcare organizations.<br><br>**Speakers:**<br>• **Erin Bissonnette, Principal Specialist, Division Quality, Stryker** |
| **11:35 am – 12:25 pm** | **A View from the Front Lines: A Dialogue with Healthcare Delivery Organizations**<br>This session will feature a keynote a prominent hospital CISO, offering invaluable perspectives on the real-world challenges of securing medical devices within a clinical environment. The discussion will cover the critical need for seamless collaboration between manufacturers and hospitals, the impact of device vulnerabilities on patient care and hospital operations, and the evolving expectations of healthcare delivery organizations (HDOs) regarding device security features, transparency, and incident response support.<br><br>**Speakers:**<br>• **TBD** |
| **12:25 pm – 1:35 pm** | **Networking Lunch** |
| **1:35 pm – 2:25 pm** | **Fireside Chat with Jessica Wilkerson, Techchnical Lead, Cybersecurity - Quality Partnering and Digital Controls Team, Roche**<br><br>**Moderator:**<br>• **Chris Reed, Senior Director of Cybersecurity Policy \| Global Regulatory Affairs, Medtronic**<br>**Speaker:**<br>• **Jessica Wilkerson, Technical Lead, Cybersecurity - Quality Partnering and Digital Controls Team, Roche** |
| **2:25 pm – 3:15 pm** | **Session 6: Beyond the Device: The Interplay of Privacy and Security in a Connected Health Ecosystem**<br>The lines between data privacy and cybersecurity are increasingly blurred, especially with the proliferation of connected medical devices that collect, transmit, and store sensitive patient information. This session will dissect the latest developments in the HIPAA Security Rule and other privacy regulations. |

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| | The discussion will address the compliance challenges for manufacturers, the implications of data breaches involving medical devices, and the legal and reputational risks associated with inadequate privacy and security controls.<br><br>**Speakers:**<br>• |
| **3:15 pm - 4:05 pm** | **Coordinated Defense: The Power of Vulnerability Disclosure with CISA**<br>The Cybersecurity and Infrastructure Security Agency (CISA) plays a crucial role in facilitating coordinated vulnerability disclosure (CVD) and sharing threat intelligence across critical infrastructure sectors, including healthcare. This session will discuss the importance of public-private partnerships in identifying and mitigating vulnerabilities, the process for reporting and coordinating disclosures, and the resources and support CISA provides to medical device manufacturers to enhance their cybersecurity posture.<br><br>**Speakers:**<br>• **Greg Garcia, Executive Director, Health Sector Coordinating Council Cybersecurity Working Group, Health Sector Council** |
| **4:05 pm – 4:55 pm** | **Building a Culture of Security: Embedding Cybersecurity into the Corporate DNA**<br>Technology and policies alone are not enough to ensure robust cybersecurity. This session would focus on the "human element" of security, featuring a Chief Information Security Officer (CISO) from a leading medical device manufacturer. The discussion would cover strategies for fostering a security-conscious culture across all departments, from R&D to marketing, and the importance of executive leadership in championing cybersecurity as a core business imperative.<br><br>**Speakers:**<br>• **Stacie Brough, IT Director, Baxter Global Product Security – Risk & Compliance, Baxter**<br>• **Nidhi Luthra, CISO, Baxter** |
| **4:55 pm – 5:00 pm** | **Closing Remarks**<br>***Zach Rothstein, Executive Director, AdvaMedDx, AdvaMed*** |