

Blue Goat Cyber Expands into Asian Market at Mednovation MedTech Forum

Blue Goat Cyber expands into the Asian market, offering cybersecurity and FDA compliance support to medical device manufacturers at Mednovation in Shanghai.

SCOTTSDALE, AZ, UNITED STATES, October 24, 2024 /EINPresswire.com/ -- Blue Goat Cyber, a leader in medical device cybersecurity, is excited to announce its participation in the Mednovation International MedTech Forum in Shanghai, China, on November 4-5, 2024.



This strategic engagement marks a significant step in Blue Goat Cyber's global expansion, focusing on providing cybersecurity solutions to Asian medical device manufacturers, with an emphasis on FDA approval support.

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Mednovation in Shanghai is a pivotal opportunity for us to empower Asian manufacturers to drive innovation, achieve compliance, and deliver safer, cutting-edge solutions for patients.”

Christian Espinosa, Blue Goat Cyber Founder and CEO

Expanding Expertise to the Asian Market

Blue Goat Cyber's decision to participate in Mednovation aligns with its mission to support Asian medical device manufacturers in meeting the stringent cybersecurity requirements necessary for market entry into the United States.

With evolving regulations emphasizing cybersecurity, manufacturers face the challenge of balancing compliance with innovation. Blue Goat Cyber aims to bridge this gap by offering tailored solutions that meet FDA requirements and international standards like the EU MDR and IEC 62304

Enhancing Cybersecurity Preparedness for FDA Approvals

The U.S. Food and Drug Administration (FDA) has emphasized the need for robust cybersecurity measures in its premarket guidance, focusing on protecting patient safety and ensuring device integrity throughout the product lifecycle. Blue Goat Cyber will share insights into the Total Product Life Cycle (TPLC) approach, integrating cybersecurity from the design phase through post-market management.

Supporting Medical Device Manufacturers in China and Beyond

Mednovation provides an ideal platform for Blue Goat Cyber to engage with stakeholders in the Asian medical technology market. As China's medical device industry grows, many manufacturers seek to enter the U.S. market while adhering to global regulatory standards. Blue Goat Cyber offers services such as:

- Cybersecurity Risk Management: Assisting manufacturers in identifying and mitigating cybersecurity risks in compliance with FDA guidance and ISO 14971 standards.
- Threat Modeling and Security Design: Developing threat models using frameworks like STRIDE to identify potential security risks throughout the device lifecycle.
- Premarket Submission Support: Guiding manufacturers through the FDA's premarket submission process, including the use of eSTAR templates for 510(k) submissions.
- Postmarket Surveillance: Creating robust postmarket surveillance plans for ongoing compliance and rapid response to new threats.

About Blue Goat Cyber

Founded by Christian Espinosa, Blue Goat Cyber is a leader in medical device cybersecurity, offering solutions tailored to the unique needs of the healthcare sector. The company's mission is to ensure that life-saving medical devices remain secure against cyber threats throughout their lifecycle, enhancing patient safety and supporting healthcare innovation.

For more information, visit <https://bluegoatcyber.com>.

About Mednovation International MedTech Forum

Mednovation is a leading international forum for medical technology, bringing together industry experts to discuss trends and advancements in the field. For more information, visit <https://www.mednovation.net>.

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