



MEDCON

C O N F E R E N C E

Columbus, OH • April 24-27, 2023

CO-SPONSORED BY THE FDA

The Solution Exchange

MedCon 2023

The Solution Exchange

Purpose

1. Engage with your colleagues
2. Generate ideas, questions, concerns about topics that will be addressed during the summit
3. Focus on “how to” for the patient, instead of “why not”
4. Foster rich dialog during the Q&A sessions
5. Have fun in this lively, engaging session!

The Scenario



- “I didn't have time to stop [the alarm] and I passed out.”
- What if this was your mother, wife, sister, or loved one?
- How do you design a medical device to address specific patients’ needs?
 - Identify solutions to get the medical device into patients’ hands
 - Understand the challenges inherent to the technology to address patients’ needs

[Video Link](#)

Topics for Discussion

Grey Tables:
Innovation by Design

Orange Tables:
Cybersecurity & Digital Health

Blue Tables:
Strategy Challenges

Grey Section Scenario

Innovation by Design

Your patients (or your loved ones) depend upon you to ensure medical devices are reliable and available and meet their needs, so they never have to worry if their device will be available when they need it most. In the last few years, the med tech industry has encountered major crises, including the recent pandemic. As an industry, we recognize the value of collaboration with various stakeholders both within the organization and outside the organization to ensure we keep innovative products on the market.

- 1. What strategies do you have in place when your company or development team faces a major crisis?*
- 2. Have these recent crises broadened how you evaluate different risks (e.g., business risks, innovation risks, and regulatory risks)?*

Orange Section Scenario

Cybersecurity & Digital Health

With the continued and rapid development of integrated technologies connecting devices across the entire healthcare spectrum, cybersecurity is critical. To that end, medical devices can be vulnerable to security breaches, potentially impacting the safety and effectiveness of the device. A major medical device company has recently reported a cybersecurity incident that affected more than 1 million patients.

- 1. How is your company creating awareness of healthcare privacy issues, including those beyond cybersecurity (e.g., GDPR, HIPAA, state-level privacy regulations)?*
- 2. How do you account for potential harm associated with your medical devices resulting from cybersecurity or data privacy issues within the risk management and/or legal processes at your company?*
- 3. How might cybersecurity issues impact interoperability or introduce new risks due to interoperability, especially within their clinical operating environments?*

Blue Section Scenario

Strategy Challenges

In today's interconnected world, medical devices are frequently marketed across borders. To ensure that patients have access to safe and effective therapies and diagnostics, it's essential to prepare your team for the challenges of manufacturing and marketing your device in multiple jurisdictions.

- 1. What practical strategies can you employ to streamline the regulatory processes across global markets?*
- 2. How do you equip your team to navigate potential hurdles and build resilience into your supply chain and distribution channels?*

Table Discussions and Readout

Innovation by Design

Discuss how you ensure your medical devices are available and reliable to meet patients' needs even through times of crisis.

Cybersecurity & Digital Health

Discuss how you design and maintain data privacy and cybersecurity while accounting for the potential resulting harms.

Strategy Challenges

Discuss the challenges or opportunities your company may face with different regions' medical device regulations and supply chain challenges.

Continuing the Mission

Manufacturers in partnership with FDA and other regulators:

- Assure safety, efficacy, and security of medical devices
- Accelerate patient access to innovative devices and diagnostics
- Foster collaboration to ensure ability to respond during emergency or pandemic-related situations and device shortages
- Work toward harmonization of regulatory standards and requirements



[Video Link](#)