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MedTech Quality Journal

"We recommend that manufacturers design devices that are trustworthy."
- FDA Draft Guidance, Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

In our feature article this month, we discuss FDA's recommendations for designing "trustworthy" medical devices from a cybersecurity point of view. Cybersecurity is such a new, and rapidly evolving field, that both industry and FDA are trying to figure out a practical and effective solution to ensure patient safety. We have summarized the FDA guidance and three main areas of concern from the industry. Stay tuned; there is much more to come in the near future!

Stay updated on the latest industry news in less than 15 minutes. Please let me know if there are future topics you would like discussed by contacting me here.

– Naveen Agarwal, Ph.D

FEATURE ARTICLE

## How FDA is Shaping a Regulatory Policy for Device Cybersecurity

FDA is proposing recommendations for design, labeling, and premarket documentation for cybersecurity. See how these may impact your devices and what others are saying.

Insight: Stay informed on this rapidly evolving field and start developing your strategy

Read More >>>

RISK MANAGEMENT

The Softer Side of Risk Management
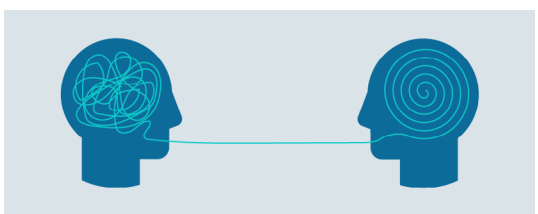
Everyone feels differently about risk. In this video presentation, we explore how individual perceptions influence risk analysis and decisions.

Insight: Create an environment to harness the power of diverse viewpoints

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RESOURCES

The Art and Science of Risk Management

The Art and Science of Risk Management

Getting results when everyone has a different perception of risk

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PMI Northeast Florida Chapter Meeting
September 16th, 2019

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Here are the accompanying slides our video presentation.

Download PDF >>>

EVENTS

ISO 13485:2016 Lead Auditor (TPECS)

bsi.

We are conducting an in-house ISO 13485:2016 Lead Auditor training for an industry-leading device manufacturer on behalf of BSI in Boston.
Contact us if you would like a customized training session for your team.

Learn More >>>

HAPPY *thanksgiving*

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