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MedTech Quality Journal

“FDA must foster innovation that spurs the development of safer, more effective technologies and assures timely patient access.”
- Medical Device Safety Action Plan, FDA



FDA has taken the first step in this direction by issuing a new guidance to encourage development of safer medical devices. In our feature article this month, we discuss the eligibility criteria for new, innovative devices to be considered for the Safer Technologies Program (STeP). We are also talking about a new tool for device risk management that can help you utilize an outcome-based severity scale developed by medical professionals. Use of such tools can significantly improve the quality of your risk assessments.

Check out 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

A New FDA Guidance Encourages Development of Safer Medical Devices



Substantial safety innovations will benefit from FDA engagement during development and priority review of submissions.

Insight: Investing in innovations to improve patient safety can help you get to market faster.

[Read More >>>](#)

RISK MANAGEMENT

A Risk Management Tool for MedTech



An outcome-based, medically-focused severity classification framework offers a robust approach for risk assessments.

Insight: This tool is on FDA’s radar for benefit-risk assessments.

[Read More >>>](#)

PERSPECTIVE

Risky or Not?



Just like beauty, risk is in the eye of the beholder! It is important to be aware of how individual risk perception can influence your risk assessments.

Insight: Introduce diversity in your risk assessment teams to ensure all viewpoints are heard and evaluated.

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RESOURCES

Cybersecurity - Next Frontier of Risk Management



Our presentation at the ASQ Jacksonville Section meeting explores the risks of cyber attacks and offers 3 recommendations for medical device risk management.

[Learn More >>>](#)

EVENTS

PMI Northeast Florida Chapter Dinner Meeting



We gave a presentation at the PMI Northeast Florida Chapter dinner meeting on the topic of Art and Science of Risk Management. Slides coming soon!

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