

February 2020

MedTech Quality Journal

“How much you can learn when you fail determines how far you will go into achieving your goals.”

- Roy T. Bennett, author of *The Light in the Heart*

A recall is a very difficult and costly event for a medical device company. The month of February is not over yet, and already there have been seven Class I recall announcements by the FDA. Our view is that a recall is also an opportunity to learn and identify systemic issues in our Quality Management System that must be corrected to improve its effectiveness.



In our Feature Article this month, we review a recent Class I recall of a pediatric device used to provide life-critical breathing support to consider a few questions for risk management that can drive system-wide improvements. We are also discussing interoperability and how it can unlock the key to innovation in connected medical devices. The market for these devices is projected to grow at a very high rate. It is important to learn how the FDA is enabling innovation in this area so you can develop an agile, resilient regulatory strategy.

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

Risk Management Lessons from a Class I Recall



A Class I recall of a pediatric device used to provide life-critical breathing support offers important lessons for Risk Management.

Insight: Consider these 3 questions to drive improvements in your risk management process and QMS.

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INDUSTRY NEWS

FDA Unlocks the Key to Innovation in Interoperable Medical Devices



Interoperability holds the key to interconnected medical devices. A recent De Novo classification of software for diabetes management shows the way forward.

Insight: Focus on strengthening risk management, design verification/validation, post-market surveillance, and regulatory strategy.

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REGULATORY COMPLIANCE

ISO 14971 Basic Concepts – Hazard, Hazardous Situation and Harm



These basic concepts are foundational to risk analysis, yet poorly understood. Here we review the definition of these terms, highlight areas of confusion and give examples to increase understanding.

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RESOURCES

Cybersecurity - Next Frontier of Risk Management



Slides from our recent presentation at ASQ Orlando offer a quick overview of cybersecurity and 3 recommendations for risk management.

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EVENTS

Archimedes Medical Device Security 101



We attended the Archimedes Medical Device Security 101 Conference in New Orleans. Updates on cybersecurity coming soon!

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