

January 2020

## MedTech Quality Journal

“A ship in harbor is safe, but that is not what ships are built for.”  
- William G.T. Shed, American Theologian (1820-1894)

Just as in a ship, a lot of engineering goes into designing medical devices. Trade-offs are often made based on the benefit-risk balance to launch commercially viable and safe medical products. ISO 14971, the International Standard on application of risk management to medical devices, has guided the industry for many years in this area. A revised version of this standard has now been just released.



In our feature article this month, we discuss 5 key changes in ISO 14971:2019. In our view, these changes are aimed at clarifying requirements to improve the effectiveness of risk management. As you consider your next steps, we advise taking a high-level view first to understand the overall intent of these requirements. We are also providing guidance for implementation of newly added risk requirements in ISO 13485 in another article.

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

## 5 Key Changes in ISO 14971:2019



The third edition of ISO 14971 aims to clarify requirements and improve effectiveness of medical device risk management. Here is a high-level overview of five key changes.

**Insight: Review the big picture first to see how you can improve your risk management process.**

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### REGULATORY COMPLIANCE

## Understanding Risk Management Requirements in ISO 13485:2016



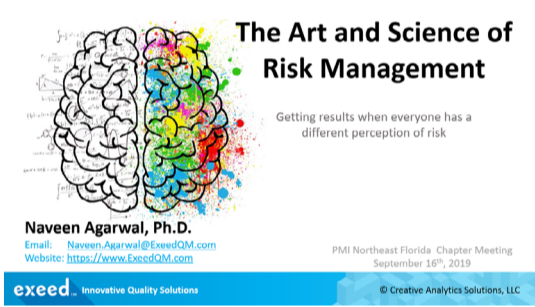
The current revision of ISO 13485:2016 has new requirements for risk management. Here are some questions to consider and guidance for implementation.

**Insight: Your QMS needs to be sufficiently resilient to respond to rapidly evolving risks.**

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### RISK MANAGEMENT

## Risk Management Tools and Tips for Project Managers



Risk management is critical to the success of any project. Here are a few tools and tips you can use to manage project risks.

**Insight: Use the Plan-Do-Check-Act method to manage risks throughout the project lifecycle.**

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### PERSPECTIVE

## The Journey Continues – Lessons from Second Year as an Independent Consultant



We share some of the lessons we learned about marketing on social media as an independent consultant.

**Insight: Build a credible social media presence to help you beat the feast-or-famine cycle!**

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### EVENTS

## ASQ 1509 Orlando Section January 2020 Dinner Meeting



We are speaking about Cybersecurity and Artificial Intelligence at the ASQ Orlando Section on Jan 23, 2020.

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