Medtronic Engineering the extraordinary

QMS Transformation Program

Medtronic Mindset in Action

Kathryn Merrill, Quality/Regulatory Program Director

The "Medtronic Mindset in Action" series shares stories of how the QMS Transformation program simplifies and streamlines shared processes across Medtronic. Its goal is to make work easier and less complex - highlighting key tenets of the Medtronic Mindset.

Taking a risk to #makeCAPAcool pays off with valued support from leaders and stakeholders

Although in its infancy, the #makeCAPAcool program has been in the works since 2019. The initiative started when the FDA identified an industry-wide issue with the current Corrective and Preventive Actions framework, or CAPA as it's more widely known. The purpose of this collaboration of medical device manufacturers, the Medical Device Innovation Consortium (MDIC), and the FDA was to recast the Corrective and Preventive Action (CAPA) process as a less burdensome continuous risk-based improvement process to improve product quality and patient safety.

When starting the #makeCAPAcool initiative, thoughts were that it might not be possible to significantly impact the rate of improvement, given the regulatory environment and expectations. Here, at Medtronic, corrective actions could take a year or more to be implemented, with similar rates of improvement seen across the Med-Device industry. Quality/Regulatory Program Director, Kathryn Merrill, was there from the beginning and sat down with Change Management Lead, Jennifer Koss, to discuss the journey to #makeCAPAcool.

With so many people involved, from FDA, industry leaders to internal stakeholders, and more, Merrill, and Koss, were fascinated by the collaborative spirit of the team.

"You've got people that are interested in digging just a little bit deeper and seeing if there's something there, and you have the push and momentum from leaders who are willing to go the distance and give people some coverage," explained Koss, "When you have that recipe of the right people, the encouragement from leaders, and the funding to keep digging, there's something sort of magical that happens."

> *"It's so satisfying. We put so much work into [this project]. Everyone shared the same vision of making sure improvement was easier"*
>
> *-- Kathryn Merrill*

Even though no one could predict the outcome, leaders forged ahead into the valley of risk and supported Merrill's leadership of the industry wide MDIC team.

"They [Leadership] gave me the Charter [the bandwidth and support we needed] to spend all the time needed to facilitate the external working group. I was grateful for this support, and the courage of the Medtronic pilot teams who stepped into the unknown. They knew that if we were successful, it would really pay off," said Merrill.

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Once the #makeCAPAcool program had the framework developed, the participating companies piloted the approach. Through the pilots, CAPA cycle times have seen an 80% improvement and positive audit results. Pilot site leaders have remarked that it's been refreshing to move from a compliance mindset to problem-solving. Results from the industry pilot have been drafted into a whitepaper that can be found on the Global Quality Advocacy Sharepoint site as well as the Medical Device Innovation Consortium (MDIC) website after it is cleared by FDA.

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Transforming the CAPA process helped improve the simplification of work and aided in the ability to implement actions faster and more accurately to maintain competitiveness, illustrating two key tenets of the Medtronic Mindset: **Act Boldly** and **Delivering Results the Right Way.**

"I'm excited for what's next," said Merrill, "If we [Medtronic] could stay committed to something for that long, we'll be able to do this again in an area that's going to be equally [as challenging] and transformative. It's a risk-benefit payoff [we invested in] and this time we really benefitted from it."

Learn more about the QMS Transformation Program at the Enterprise QMS Governance SharePoint site.