Meet the CfQcc Team

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Call to Action

Volunteers Needed

The CfQcc is seeking volunteers from Small and Mid sized medical technology companies to participate in our current and potential new initiatives.

Have something new and exciting to spotlight? Volunteer writers are needed for the next issue of IMPACT.

For further information contact our Team members or CfQcc@MDIC.org

Upcoming Events

MAY

• #makeCAPA Cool White Paper Publication

Join us May 2 at 2:00pm EST for an MDIC Live session on Taming CAPA To Be Cool

JUNE

• CfQcc Quality Summit in Washington D.C. on June 20-21
Spotlight on Quality

This New CAPA Approach Is Faster and Easier (and Regulators Like It)

Finally, finally there’s a smart strategy for corrective and preventive action (CAPA). It’s called “#makeCAPAcool and I’ll explain it more in a moment. But first, let’s talk about what CAPA is and why it vexes industry and regulators.

CAPA is designed to collect and analyze device data, investigate product and quality problems, and produce corrective and preventive action. The question is how to do all of this effectively and this question confuses industry and frustrates regulators.

Industry also feels the pain. A search for CAPA strategies produces results like “Let’s Stop Confusing Everyone With CAPA,” “CAPA Overload and Other Perils To Avoid,” and “The CAPA Conundrum.” These messages wouldn’t get traction if CAPA was easy to understand and satisfy.

Who Benefits?

- Patients - patients get better-quality products that gain from design improvements and good problem-solving.
- FDA - FDA has more confidence in device design (and redesign) and production. This lets the agency direct resources to other priorities.
- Industry - Better devices mean happier customers - that’s a competitive advantage. Better devices also mean happier regulators, which means less business disruption.

Steve Silverman is the president of The Silverman Group, a consultancy that serves medical product companies on regulatory, strategy, and policy issues. At the FDA, Steve directed the CDRH Office of Compliance, where he led device-quality initiatives, engaged Congress and the press, and guided the office’s reorganization.

The Solution: #makeCAPAcool

#makeCAPAcool is a CAPA redesign. It maps how CAPA could be simpler and more efficient while satisfying regulators and meeting industry needs. The new model highlights high-risk issues and deprioritizes less important ones. The model shifts the focus from paper production to CAPA’s real purpose: problem solving. #makeCAPAcool is not a new regulatory requirement; it’s a better way to meet current requirements.

Why Is #makeCAPAcool a Rosetta Stone?

The Rosetta Stone unlocks unknown meaning, which is how many device makers (and some regulators) would describe CAPA today.

makeCAPAcool promises to dispel this confusion. It helps device makers understand and meet regulatory requirements. This satisfies regulators, while benefiting device makers and their customers. Like the Rosetta Stone, #makeCAPAcool makes the unknown known.
Collaborative Connections

» #MDICLive Event with MDIC’s Case for Quality Collaborative Community
Taming CAPA To Be Cool May 2nd at 2:00 PM ET - #makeCAPAcool

Join us with industry and FDA to learn and gain insights from the MDIC Case for Quality Collaborative Community #makeCAPAcool study. The study has transformed participating companies from a burdensome traditional approach to one of problem solving, risk management and quality improvements leading to greater efficiencies, higher product quality, and enhanced patient safety.

If you have not already, mark your calendar for May 2nd at 2:00 PM ET and join us

» CfQcc 2-Day Quality Summit on June 20-21 in Washington, DC
Case for Quality Collaborative Community - A ROI Value and Impact Analysis

Attendees will learn about the advances, impacts, and ROI from CfQcc programs like the Voluntary Improvement Program (VIP), CAPA Improvement pilot (#makeCAPAcool), Leadership Engagement-Culture of Quality, Safe Space, and Supplier Resilience in driving towards higher quality medical devices and patient safety with greater investment returns. Emphasis will be towards strategic and practical adoption techniques for small and medium sized medical technology organizations.

More information coming soon!

Thank you for reading and stay connected!

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