Veeva MedTech

4 Takeaways from Teleflex on Quality Assurance and Regulatory Affairs Transformation

Medical device companies are navigating constantly changing and tightening health authority regulations, like EU MDR and IVDR, along with the consequential demands posed by EUDAMED. Teleflex, a global provider of medical technologies with a diverse portfolio in the fields of vascular access, interventional cardiology and radiology, anesthesia, emergency medicine, surgical, urology, and respiratory care, has embraced these regulatory challenges as an opportunity to rethink its digital technology and unify operations. "We work in an ever-changing environment of new international regulations that are only becoming more and more stringent," says Dominik Reterski, the company's Corporate Vice President, Quality Assurance and Regulatory Affairs. "Unless you have a unified eQMS platform, staying compliant can be difficult."

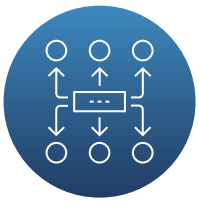
Despite increasing regulatory requirements, a majority of medtech organizations still rely on disparate and outdated systems – especially to manage regulatory affairs (RA). The Veeva MedTech 2023 Regulatory Benchmark Report found that only 14% of study participants have a single-source-of-truth platform for sharing strategic plans across functions in place, which indicates a lack of unified systems for new product development. The study also reveals that:

- 75% report key content misalignment across functions
- 53% see personnel changes have at least a medium impact on regulatory renewal processes
- Over 34% of regulatory affairs professionals stated that reviews of substantiation and claims are siloed or lack a transparent process

Disconnected RA supporting systems and data silos can have significant implications, including:

- **Operational inefficiency and revenue delays** cause delays in product launches and potential revenue loss.
- **Compliance risks** due to misalignment of key content across functions and data inconsistencies potentially result in penalties, product recalls, and harm to company reputation.
- **Resource drain** from time-consuming efforts to search for, duplicate, and verify regulatory data.

Instead of continuing with manual information-sharing methods, medtech companies can meet the moment in this challenging regulatory environment by leveraging digital technologies to unify business operations. Here are the key takeaways Reterski shared at Veeva MedTech Summit from Teleflex's regulatory and quality affairs (QA) modernization journey.



TAKEAWAY #1
Establish a clear QA/RA transformation framework

For Reterski, the first step is establishing a clear image of your QA/RA transformation goals. Ask yourself: what do you want to accomplish? What is your ultimate goal? Cross-functional teams should flesh out and agree on these plans before software migration begins. He also recommends medtech companies distinguish between "must haves" and "nice to haves." "Don't try to address every problem all at once because you won't be able to," Reterski says.

Reterski's main objective was to consolidate seven global business units that each had their own RA functions. Many of these employees joined Teleflex during acquisitions and previously operated independently. "When you integrate new businesses, you often have to bring together different systems and processes," he says.

Teleflex formed a product management regulatory organization to unify disparate teams that consolidated all its legacy business unit regulatory teams under one leader. This consolidation also allowed the company to reevaluate its processes and lighten the administrative workload on regulatory team members. "We created a shared service center of regulatory operations to take over the administrative work, freeing up time for our regulatory team to focus on their business product portfolios," Reterski explains. When establishing the transformation framework, the primary focus was placed on commencing the digital transformation with an eQMS before embarking on regulatory information management, ensuring a solid foundation for subsequent development.

TAKEAWAY #2
Don't underestimate the role of company culture

When embarking on a large-scale technology transformation, ensure it aligns with your company's culture. For example, one of Teleflex's core values is entrepreneurial spirit. Reterski credits this spirit with helping the company smoothly transition to a unified QA/RA system. This alignment encompasses multiple facets, including people, organizational structure, processes, and technology integration. "I've been in this industry for 25 years," he says. "Compared to my previous attempts to consolidate systems and processes, it went much faster and easier at Teleflex."

To keep employees engaged and tied to the company's core values, vision, and purpose, Teleflex also invests in building a culture that puts people at the center of everything they do. Patient testimonies play a key role in advancing this mission. "We want people to see how their work, regardless of what they do at Teleflex, is impacting patients," says Reterski. "Our purpose is to improve the health and quality of people's lives, and we want to stay true to that."

TAKEAWAY #3
Look for cloud-based, digital eQMS solutions

When looking for ways to streamline, look toward cloud-based and digital QMS solutions. Digital tools for centralized regulatory data management enable real-time team collaboration. They can also help your organization generate a digital audit trail to ensure compliance.

When interacting with auditors, having access to real-time data is a must for Teleflex. “There’s nothing more frustrating to auditors than having to wait for records or data,” Reterski says. “It immediately changes the tone of the conversation”.

TAKEAWAY #4
Collaborate with IT for a smooth transition

Reterski also credits the quality team’s strong collaboration with IT colleagues to facilitate a smooth eQMS transition. “We live in a digital world. It would be a missed opportunity to not include IT in whatever you have planned,” he says. “Involving IT helped us integrate our eQMS with our existing systems more easily.”

Before deploying the new system, the Teleflex quality team spent significant time testing tools and use cases in the sandbox. “Above all, you don’t just want to create a solution for people; you want to create it with them,” he says. “That involves working together to understand end-user challenges and pain points truly.”

For Reterski, the critical key to ensuring success lay in selecting the right platform capable of supporting both QA and RA teams, along with making the right vendor choice. He encourages companies to invest in their relationships with vendors, especially since large-scale transformation is often a lengthy and costly endeavor. “We did a careful selection process to identify a vendor that would be a true partner in this journey, and we’ve found that in Veeva,” he says. “Vendors work with multiple different companies, so they have a wealth of diverse experiences to draw from.” Rather than functioning as a solitary point solution, the implementation of eQMS serves as the cornerstone of our collaborative transformational journey with Veeva.

Request a demo of Veeva Vault eQMS for Medtech to learn more.