Competitive Advantage, Not Compliance, Should Drive Medtech Quality Investment Discussions

by Carl Ning, senior director, quality strategy, Veeva

Though the industry is emerging from the impacts of COVID-19, it is likely only a matter of time before another major disruption occurs with global impact on medtech supply chains. When it does, it will be essential to have a robust quality management system (QMS) to solve the accompanying problems and prevent their recurrence. However, attempts to implement such a system can spark paralyzing conversations around how best to achieve digital transformation and return on investment.

For medtech companies, the path to implementing a modern QMS does not need to be complex, as Kareem Elwakil, partner with PwC and Steve C de Baca, executive vice president of quality and regulatory enterprise at Cardinal Health, told attendees of Veeva MedTech Summit.

For most organizations, the best way to influence decision makers to make a necessary technology upgrade is to start the conversation with a strong business use case. Traditionally, compliance was used as the conversation starter, but this is no longer compelling enough. "Compliance isn't necessarily a cost savings issue until it's in front of the organization, when you're dealing with new regulations or potential fines. Otherwise, it's not a driver," C de Baca pointed out.

The CFO and CEO must see the technology as a competitive advantage, a way to improve efficiency and productivity, he said. It also helps to show that the upgrade will help the company respond faster and more easily to customers and demonstrate cost-containment and efficiency to investors and shareholders.

Sell tomorrow's need, not today's process

Making the right business case is challenging, considering economic and business volatility, and regulator demands for evidence of a coherent QMS and risk-based thinking. When choosing QMS technology, C de Baca suggested medtech companies keep the strategic, long-term picture in focus. For example, life science companies whose growth strategy includes acquisitions will frequently onboard systems and people. This will likely introduce intermittent quality issues.

Merging tools and transferring data from one system to another requires agile and flexible systems that may not be used today but will be essential in the future. Being ready for new opportunities requires robust technology that can get everyone up and running quickly. "Sell tomorrow's need, not today's process," advised C de Baca.

Roadmaps for the future

To ensure you address future needs, de Baca suggested, assess your current state fully. Avoid adding a new tool but leaving flawed processes in place and digitizing bad workflows. Your QMS roadmap needs to be specific to your company's unique quality management pipeline. It must take into account the range of users at your company, from R&D to manufacturing operations and beyond.

Identify what the company would do differently if it had unlimited resources. Start by calling out current pain points. Questions that can help get to this answer include the following:

- What is missed during handoffs?
- Are there too many capital processes?
- Where are the gaps in efficiency that lead to lower quality?
- Do we need 20 steps for this procedure, or can it be accomplished in 10?

The best roadmap, the panel agreed, is one that rethinks the setup of a QMS across the enterprise. This is important because most of the people using the system are not specifically involved in quality control. They may work on medical, operations, or commercial teams. In addition, tasks within each area are varied and include workflows for activities like document management, supplier audits, and commercial launch plans.

When these teams are struggling with a workflow, it can result in a sub-par customer experience, even if the technology they employ is new. According to Elwakil, the key to change is focusing on developing new behaviors based on new thinking. "The transformation is about moving toward value, getting your process from your current state of quality management to something else that's significantly better and more impactful," he said.

Partner for change

The rapid pace of change over the past two years has proven that life sciences companies need adaptability in their processes and technology. Supply chains are consistently unpredictable and the new hybrid workforce continues to require more technology to remain connected. Add to that mix the chance that an unexpected regulation will quickly alter how you do business.

For these reasons, life sciences organizations need forward-thinking partners, panelists agreed. Elwakil advises medtech companies to look beyond a potential partner's initial burst of energy and past the implementation of core functionality to consider their track record with innovation. "See what they're doing with AI and [machine learning] and how they're growing their platform to provide future supplier QMS capabilities," he commented.

Financial ROI is generally the beginning and end of a solution discussion. But that conversation should be aligned with the need to achieve long term efficiency improvements. Choosing the right supplier QMS will support that goal and improve efficiencies throughout the organization. Ultimately, it will make your company more competitive while enabling it to bring safer products to market. It will also ensure compliance but, as panelists suggested, you should not make that the focal point of discussions with senior management.

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