MedTech Experts Share Drivers & Best Practices for Modernizing Quality

Alcon, Epredia, Johnson and Johnson, and PwC

Antiquated systems, disconnected processes, and limited data visibility can leave medtech organizations struggling to execute with the speed and agility needed to efficiently manage quality assurance. With additional regulatory requirements and increasing mergers, acquisitions, and divestitures, organizations feel pressure to improve efficiency and reduce complexity with end-to-end connected processes.

Fortunately, several organizations have already overhauled their quality processes and are seeing increased efficiency and reduced complexity. Four quality leaders from Alcon, Epredia, Johnson & Johnson, and PwC shared their expertise in a recent panel discussion covering everything from the changing landscape of medtech to implementation best practices.

The Current Landscape

The industry has broadly accepted the move to cloud-based solutions but is still fragmented, filled with disparate systems that can only perform some aspects of quality management. This can lead to data management and oversight issues, as Tracy McKinney, head of quality information systems at Alcon explained. “There’s a lot of data cleaning that has to happen because you’re not using the same data sets. Being able to extract that data to use it for predictive analysis is limited, so as we move forward it makes a big difference to have data in a centralized cloud system.”

Kareen Elwakil, a partner at PwC added, “We’ve discovered over time that it makes more sense to have a single, best in breed, eQMS platform tailored to the specific use cases and applications that are necessary and required of quality professionals.”

Factors Impacting Transition

Mergers, acquisitions, and divestitures are prevalent in the medtech industry, forcing organizations to evaluate systems and business processes. Beyond these events, regulatory pressures, new post-pandemic norms, and internal improvement initiatives push organizations to examine and update systems.

Epredia’s recent divestiture is a prime example. With more than six systems to manage quality processes (two of which were paper-based), Epredia’s divestiture compelled them to streamline across the organization. This catalyst pushed them to find an interconnected system that would allow processes to flow smoothly between regulatory and quality.

Mergers, acquisitions, and divestitures like Epredia's are becoming commonplace, adding another layer to the pressures spurring digital transformation across the medtech industry.

Kareen Elwakil presented the new regulations affecting the medtech industry as an opportunity to "take a critical eye to our portfolio and evaluate how we move information and manage data." He went on to pose the question, "What are the roles and responsibilities that will set us up for success in the long term?" With outside pressure forcing organizations to appraise current solutions, this can be a good time to redefine processes.

Easy to use systems that connect data across the organization are not just preferred; they are expected from users. And with the data visibility provided by cloud systems, quality and regulatory teams see improved speed and agility, especially in processes that cross departments such as adverse event reporting and post-market surveillance.

How Others are Modernizing

"Now we have a fully integrated system," said Mark Ramser of Epredia. After a rigorous selection process, Epredia chose Veeva because its cloud-based system ensures uptime, and its interconnectivity enabled them to increase efficiency cross-departmentally. Customer complaints, investigation, product change, and change control are tied together to provide open communication and quick feedback globally. This integration enables Epredia to standardize its risk management approach across campuses to ensure consistency.

Similarly, Kareem Elwakil from PwC emphasized the importance of utilizing a fit-for-purpose quality solution. After struggling to repurpose solutions outside of their core competencies, PwC took the time to identify the things they needed in each system and combined those requirements to find a system that elevates quality beyond compliance.

Strategies for Successful Change Management

With experience working through their organizations' implementation processes, our panel of quality experts shared a few key strategies for successful change management. They all agreed that consistent, effective communication and a clear vision from leadership helped get everyone on board faster and preempt surprises for end users.

Phased Roll-Out

Dr. Alon Ben Jacob of Johnson & Johnson recommends a phased roll-out to ensure the pace of change does not overwhelm the team. "Gradual implementation is key, especially if you are transitioning from a paper-based system to multi-layer software." said Jacob. He also shared the importance of investing time in communication and feedback loops to ensure you're progressing in the right direction and can adjust course as needed.

Lastly, Jacob warns that push-back should be carefully considered as stakeholders may discover issues with new processes that need to be addressed. He recommends developing an interdependency map to identify interactions of complex functions company wide.

Mark Ramser reinforced the phased approach as a best practice. As Epredia saw success with the initial roll-out of QualityDocs they saw increased buy-in across the organization for digital change. Now, other functional teams are eager to use the system and modernize their systems because they have experienced the benefits.

Involve Stakeholders Early

"Start early and do your due diligence," said Tracy McKinney of Alcon. She proposed that organizations involve the right people while minimizing the number of decision-makers to ensure the group can be agile and effective during the implementation. Alcon started with an exploratory process to evaluate existing processes before creating an implementation plan. "It's important to understand your processes before you start because you can end up automating a bad process if not," Tracy warned. Alcon created an implementation plan that tacked the manual processes first to gain immediate efficiency gains from evaluation.

Mark Ramser. Epredia, echoed the sentiment that stakeholder buy-in and understanding is essential early. "Our goal was to have a fully integrated system," explained Ramser, "so we need to have a fully integrated change control system to communicate issues and get feedback." Epredia communicated that vision to the team and maintained continual communication and company-wide visibility into the roll-out. The approach got people on board and supportive of the changes.

The Future of MedTech Quality

"Many times, we're spending too much effort keeping score and not playing the game," said Mark Ramser of Epredia. However, with improved systems and processes in place, "we can focus on actually making decisions and moving forward," he added.

While infusing organizations with more streamlined workflows, digital transformations like Epredia, Alcon, and Johnson & Johnson allow key stakeholders to appraise the overall processes. Tracy McKinney of Alcon found herself asking, “What happens when we’re able to connect [quality] to registration information and things we haven’t been able to do easily in the past?”

For example, Alcon is currently exploring the possibility of having suppliers work through the documentation directly in their system to improve security and audit tracking. Epredia is already streamlining workflows by allowing external service organizations to work through their specific documentation within Veeva Vault. This approach not only drives efficiency and optimizes resource time, it ultimately speeds time to get products to patients.

Kareem Elwakil of PwC encourages medtech organizations to evaluate AI for potential efficiencies such as leveraging complaint data to understand and identify potential causes. Organizations in the pharmaceutical space already see value in high-volume transactions as AI has evolved, and medtech can achieve the same benefits.

Additionally, as manufacturing operations have been divested, the dynamic has changed to emphasize supplier management oversight control communication. Kareem Elwakil encourages organizations to ensure their communications are cleaner, more simplified, and integrated within the organization.

Throughout the changes affecting the medtech industry, unified, fit-for-purpose solutions will continue to enable organizations to maintain the speed and efficiency needed to get higher quality products to patients faster.