**5 New Ways to Challenge the MedTech Status Quo and Speed the Total Product Lifecycle**

If 2020 taught us anything, it was that challenges bring innovation. We experienced resilience as MedTech companies changed how they operate and began leveraging digital ways of working to accelerate the development and delivery of medical devices and diagnostics, while ensuring patient safety.

These innovations have given way to long-lasting opportunities for medtech companies to address multiple changes within the industry. Modernizing systems and processes will enable companies to swap manual, paper-based processes for digital solutions that will speed the total product lifecycle and shape the future of healthcare.

Here are 5 critical focus areas for MedTech to speed the product lifecycle:

**1. Unify QA/RA Processes to Increase Efficiency**

New and changing regulations, like EU MDR and IVDR, now require companies to know every detail about a product at all times. These new requirements are making it more difficult to manage the product lifecycle with manual, siloed systems. MedTech companies need to update processes and connect systems to drive greater efficiency and visibility throughout the total product lifecycle.

Connecting quality and regulatory systems is one crucial component. With connected QA/RA, updates in the quality management system can automatically trigger regulatory activities, ensuring a single source of truth and compliance. By harmonizing with modern cloud solutions, regulatory and quality processes can be streamlined so teams have visibility across data and operations, speeding how products are brought to market.

**2. Modernize Regulatory Systems to Keep Pace with Dynamic Regulations**

Regulatory requirements for medtech products are getting more complex, leading to data collection and analysis on a much larger scale. Organizations are managing growing volumes of data and new requirements that place greater scrutiny on data management throughout the total product lifecycle. Relying on paper-based and siloed systems and processes is no longer an option and the industry is rapidly adapting to keep up.

MedTech companies need to look at all parts of the organization including processes, documentation, and systems to ensure compliance readiness. Having global visibility and one source of truth has become crucial as products now have to be pre-approved, not to mention increased requirements for pre-market clinical evidence, UDI, and post market surveillance.

Leading medtech companies are moving toward cloud-based regulatory information management systems (RIM) that are connected to other systems, bringing together cross-functional teams for a holistic view across the total product lifecycle. For example, paper and email approvals can now be streamlined via automated workflows and include a digital record and timestamp of each person who reviewed and approved documents, a stark contrast to providing wet signatures, hard copies, faxes, and hand deliveries.

**3. Modernize Clinical Data Management to Support Growing Evidence Needs**

MedTech studies have grown increasingly complex in recent years, requiring data collection and analysis on a scale much larger than ever before. Companies are not only having to deal with growing volumes of data, but also new requirements that place greater scrutiny on data management throughout clinical studies.

Companies need to shift toward solutions that provide a single source for clinical data management that is connected to clinical operations. The modernized approach and systems will be crucial for tracking, analyzing, and sharing diverse data across the organization and sites to improve trial performance and speed. They’ll also allow companies to better integrate real-world data from mobile devices and wearables with the data they’re collecting in controlled settings.

**4. Transform Quality Management for Remote Audit Readiness**

In 2019, the FDA issued 49 Class I recalls—the most the industry’s seen in the last four years. Meanwhile, non-routine external quality events, such as FDA 483s, warning letters, and consent decrees, have cost the industry an average $7.5 billion to $9.5 billion per year\*.

Improving quality processes while continuing to innovate requires medtech companies to implement more advanced quality management systems (QMS) that enable greater collaboration between internal teams, external partners, and regulators. With new requirements for product quality using real-time data collected during post-market surveillance, fully automated electronic health authority submissions and non-electronic submission outputs will help ensure timely adverse event reporting and more proactive complaints handling.

While remote auditing was initiated due to necessity during the pandemic, auditing groups and MedTech companies are increasingly finding remote audits to be a much more efficient alternative to the traditional, in-person audits.

As a result, remote auditing will become a permanent component of the quality workflow, even once travel and onsite restrictions are lifted. Not only will auditors be able to access required files more easily, collaboration across regulatory, quality, and clinical teams will also improve. Longer term, the shift to remote auditing will drive companies to digitize quality processes and improve supply chain continuity.

The companies that invest in modern cloud quality systems will be in a much better position to reap the benefits of remote auditing. With content and data stored and accessed in one central application, they won’t have to worry about updating multiple files in different systems, making information sharing much faster and easier. As teams get used to these new ways of working, we’ll eventually see less reliance on paper, fewer onsite audits, and a much more sustainable model for the future.

**5. Evolve Commercial Models for Greater Importance on Claims Management**

The industry’s move toward digital has caused a proliferation in content—marketing teams are churning out 10 times more content than only five years ago. Current processes and technologies are fragmented and are no longer sufficient to manage content creation, medical and legal approval, and distribution. In addition, as device companies expand geographically, sharing content becomes cumbersome.

This year we will see companies make a concerted effort to better manage the creation and distribution of marketing and product claims across the organization. Transitioning to an end-to-end digital asset management platform is enabling marketing teams streamline the processes for creating, sharing, and reviewing content. This digital, cloud approach addresses a range of inefficiencies stemming from disconnected, manual ways of doing business, including increasing visibility and control to quickly move content through the supply chain in a central system.

The modernization efforts will ensure regulatory compliance, reduce risk, and help companies gain greater insight into the effectiveness of their claims in relation to the performance of their marketing campaigns. Moving forward, integrated claims management will create compelling upstream and downstream effects that can accelerate time to market and strengthen brand perception.

As the medtech industry continues to modernize, successful companies will keep innovating to meet rigorous requirements with new, digital ways of managing the total product lifecycle and help shape the future of healthcare. If you would like to learn more, please contact us to connect with one of our industry experts.

\*McKinsey & Co, Capturing the value of good quality in medical devices, 2017