Regulatory Transformation Demands New Business Cases and KPIs

As the number and complexity of medical device regulations increase around the world, more companies have found that dependence on legacy IT, manual processes, and disconnected data is no longer sustainable. Change is needed if their regulatory affairs departments are to keep pace with increased workloads and regulator expectations.

More medtech companies are approaching competitive and regulatory challenges by laying the foundation for digitization, and streamlining processes to improve data quality and visibility. Along the way, some have learned that successful change requires a strong business case and clear expectations, as well as new KPIs to measure improvement.

At the Veeva MedTech Summit, regulatory affairs leaders — including Ram Iyer, director of global regulatory Science with Cook Medical, and Exact Sciences' IT project manager, Jaya Vaishnav and senior regulatory affairs specialist Kelly Barbeau — discussed industry challenges and shared best practices in a panel discussion.

A four-stage journey

Panelists agreed that regulatory transformation requires organizational commitment and meticulous planning. It is also crucial to begin the project with the end in mind, and to make ease of use a priority. At most med tech companies, preparing for regulatory transformation generally involves going through the following four stages:

Preparing the business case

First, existing pain points and key reasons for change must be clearly defined, and all stakeholders affected must be brought in to consider solutions. The benefits of removing pain points must then be assessed quantitatively and qualitatively to determine what the organization must gain from change. At this stage, panelists agreed, it is important to remain focused on the most critical issues to prevent scope creep.

Identifying the solution

A cross-functional team is essential to assessing potential solutions and selecting the technology that best addresses the company's unique pain points and accommodates user needs while supporting strategic vision for its regulatory affairs infrastructure.

Implementing the new application

Implementation success is reliant on team members being laser-focused on initial project drivers and parameters. To be successful, companies should create a team and designate representatives from each function to steer the project towards completion. And keep in mind that it is always possible to add incremental improvements later on.

Monitoring the system after implementation

As the old saying goes, 'what we measure, we improve,' and the implementation stage should not end when the new application goes live. Post-implementation monitoring offers significant opportunities to realize the most benefit from regulatory transformation.

Establishing robust adoption KPIs, for example, can improve employee's adoption of new technology. These should measure technology uptake within the organization with problem areas prompting discussion and development of strategies to improve.

In addition, sharing quantitative data with employees on how the implementation will benefit them and the overall business is key to winning over hearts and minds. Establishing a strong communication program in which the benefits are emphasized not only gets employees to adapt to change, but it can open the door to additional improvement in the future.

Addressing pain points and enabling innovation

Exact Sciences and Cook Medical experienced similar pain points as they began to drive their business cases and communicate the need for change. For Exact Sciences, the business case arose primarily from corporate growth and acquisitions resulting in a diversity of practices and challenges with data accessibility between locations. The company needed to harmonize activities in order to achieve its goals for regulatory affairs, and staying with disparate, inaccessible systems became untenable. It needed a "single source of truth," as Barbeau put it.

For Cook Medical, twin burdens of legacy systems and siloed data operations provided the impetus for change, especially in light of changes brought by EU MDR. "It was a scramble," Iyer said, to try to identify which product registrations applied in different regions. Ultimately, adopting new approaches enabled Cook to build a strong case for change by emphasizing how it would enable the company to make better decisions for its portfolio of products.

Beyond the immediate benefits from eliminating operational pain points and unifying disconnected data systems, transformation allows forward-thinking organizations to consider where they want to go next, and enables innovation to take place more efficiently, Vaishnav pointed out.

Best practices for implementation

Panel host Ayesha Shah, strategy director at Veeva MedTech, emphasized that regulatory transformation involves a large-scale implementation that must often be accomplished with existing team members and resources. Best practices are crucial to ensure efficiency and avoid overburdening core team members.

Pre-planning and frequent communication are critical. Panelists offered the following tips, which helped them before, during, and after implementation:

- Invest significantly in pre-implementation work, and understand how the new system fits within the existing IT architecture
- Fully evaluate capabilities and user needs across the organization
- Consider both direct and indirect stakeholders who will be affected by the system's implementation, from end-users to senior corporate leaders
- Build strong partnerships, both internally and with the vendor team
- Establish parallel work streams to save time and utilize resources more efficiently
- Secure executive sponsorship for the effort before it begins, and ask for support from leadership in terms of project timelines and resourcing
- Appoint an appropriately resourced core cross-functional implementation team whose members share passion for the project
- Nurture open communication on timelines, expectations, and responsibilities

Empowering the team to make its own decision was crucial to Exact Science's successful implementation, Barbeau said. For projects of this scope and scale, she said, there are so many decisions to make that "you're often configuring on the fly."

Beginning with the end in mind

When the panel took place, Cook Medical was still at a relatively early stage in its implementation, but was already considering the most suitable business process metrics to use, which included on-time submissions, submission timelines, hand-offs, and additional information requests.

Ease of use is imperative if staff are to accept a new technology. "The best solution is the worst solution if no one is using it," Shah said. For Cook, establishing ease-of-use criteria at the outset of the project was crucial to ensure that users derived the most benefit from the program. "If it's a clunky system," Iyer said, "people are not going to use it."

Beginning with the end in mind by considering the core metrics most important to the organization helps ensure that the project is aligned with real business drivers. After all, the rewards of getting the process right are substantial.

Successful regulatory transformation has already unlocked a host of benefits for medtech companies, including faster time-to-market, global compliance, and harmonized global processes.

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>
> **–Ayesha Shah, strategy director at Veeva MedTech**

To learn more about RIM implementation, click here to watch the on-demand sessions.