How the Role of Regulatory Operations Professionals Will Evolve

By Terri Howard

This article highlights the shift taking shape in the medical device and diagnostics industry and defines regulatory professionals' increased impact on business decision-making as a result of new global regulations that require a complete regulatory transformation. This is the second in a two-part series on the evolving role of regulatory operations professionals.

Introduction

Regulatory operations professionals in the medical device industry have reached a crossroads. Mounting challenges due to globalization, increased supply chain complexity and patient safety have made regulatory teams far more strategic to their organizations. Where they used to be considered foot soldiers fighting in the trenches to satisfy health authority demands, regulatory professionals now have seats at the table with senior leadership because of their importance in helping organizations navigate a complicated compliance landscape.

Device companies have experienced more regulatory changes in the last two years than in the last 20, with major updates to ISO 13485:2019, the Medical Device Single Audit Program and the European Union *Medical Devices Regulation* (*MDR*), which goes into effect on May 26, 2021. Some

health authorities are pressing organizations for detailed supply-chain tracking and in-depth monitoring of both raw materials and contract manufacturers. Now, companies are counting on regulatory professionals to find ways to be more efficient and effective in a more heavily regulated world.

Despite their newfound importance and greater responsibilities, regulatory teams struggle with the same resource constraints that have held them back for years. For instance, two-thirds of regulatory affairs departments remain small with fewer than 25 full-time employees.[1] Many also still rely on manually intensive and time-consuming processes, including spreadsheet collaboration, file sharing and email to perform key aspects of their jobs. With *EU MDR* on the horizon, the role of the regulatory professional will expand and forever change. Rather than focusing primarily on new discoveries in the approval stage, regulatory teams also will need to stay on top of the intricate network of laws and guidelines globally. To succeed, they will look to transform regulatory operations based on the following four key pillars so they can continue to evolve and adapt to business, market and regulatory changes:

1. people
2. operations
3. product portfolios
4. technology

"…Four pillars elevate the stature of regulatory teams in the medical device industry and enable regulatory transformation on a global scale…"

People: Find the Change Agents

Hiring the right people or re-allocating staff where they can best leverage skillsets that align with a medical device company's new operating model is key to assuring teams are staffed to meet emerging challenges. Once on board, arming these regulatory operations professionals with the time, tools and training to perform their jobs is critical.

However, many companies struggle to find and attract enough quality talent. In fact, even as the *EU MDR* deadline is less than six months away, two-thirds of medical device organizations have not yet started preparing,[2] citing lack of internal resources as one of the top reasons for the delay.

Increasing headcount is a top priority for companies in addressing the long-term challenges of *EU MDR*. Forward-looking medical device companies understand the importance of having teams with the appropriate regulatory knowledge that can add strategic value to help the company keep pace with regulatory changes.

One of high-demand skills sought in regulatory professionals today is strong communications skills to effectively collaborate across functions, especially

clinical, quality and safety. In order to ensure compliance with the *EU MDR* and other new guidelines, regulatory professionals must work more closely with clinical, quality, safety, commercial and manufacturing teams.

Operations: Prepare for Change

In order to efficiently handle regulatory change, companies need to establish an operating model that connects end-to-end processes across teams and regional affiliates. Regulatory professionals, with a stronger voice in the executive suite, can be instrumental in breaking down longstanding siloes that inhibit collaboration.

For example, *EU MDR* will increase the requirements associated with a clinical, evidence-based approach to compliance. Device companies will need to demonstrate the safety of an increased number of devices in their portfolios, regardless of when they were introduced. *EU MDR* also will require a shift from passive postapproval management of the product based on specific milestones, such as renewal or audit dates, to active and ongoing management, monitoring and renewal of all documentation required by health authorities.

Ramping up an organization to deal with these changes seems overwhelming, but an operating model that brings together different functional units enables a collaborative approach to change. Regulatory professionals who consider their available resources and establish the right processes ahead of this change will connect the right people, internally and among partners, to form strong project teams with minimal time, effort or stress.

Product Portfolio: Address Compliance Early

Medical device companies channel research and development dollars to specific therapeutic areas or patient groups where the company can make a significant impact. Regulatory operations professionals can provide crucial spending advice throughout the process, flagging potential challenges early and providing suggested solutions for achieving and maintaining compliance.

Today, successful product development must take regulatory compliance into consideration throughout the process of designing, developing and delivering new devices. When organizations view compliance as a footnote to the process, something that can be handled *after* a new product strategy has been defined, issues typically arise. However, forward-looking regulatory teams prepare for regulations and alert organizations to transparency and records traceability requirements, i.e., clinical evidence, post-market studies and risk management plans across the device lifecycle and entire supply chain.

The next-generation regulatory operations professional will need to have comprehensive regulatory intelligence globally so they can, for instance,

avoid a costly decision to develop a product for a new indication for China if the additional compliance requirements call for time-consuming, expensive testing. As device companies are forced to be more discerning with product development strategies, regulatory teams offer valuable information concerning the cost of compliance that can impact global go-to market plans.

Technology: Unify Regulatory Information Management

Most device companies are instead using disparate, manually based systems that limit visibility and agility. Regulatory processes span both documents and data; however, device companies are often using point solutions designed for an entirely different process or generic office solutions to manage either documents or data. Additional solutions for project management, calendaring and communications add to the number of disconnected, inefficient solutions often found in regulatory departments. One global company had more than 150 separate systems managing various parts of the regulatory process.

Deploying a unified platform for Regulatory Information Management (RIM) can better connect business processes and people while providing real-time data and insights. Advanced technology will enable regulatory operations professionals to keep up with a growing amount of global information, the quickening pace of regulatory change and the need to collaborate with more people. Unified RIM platforms facilitate better access, visibility and control over regulatory document and data processes.

A recent spinoff of Novartis, Alcon Laboratories, a leading manufacturer of ophthalmology medical devices, had been relying on manual processes, spreadsheets and file shares to track and share submission information. The company, with operations in more than 70 countries, modernized its approach by standardizing on a unified cloud platform to streamline management of clinical, commercial and regulatory content and data for a single source of truth across its operations.

Lori Holder, director of global regulatory operations at Alcon and a 25-year medical device industry veteran, discussed Alcon's journey to transformation recently during a RAPS webinar. She noted that her team is fortunate enough to be larger than most. This has enabled the company to get ahead of pending regulations, which has been a huge priority for Alcon. Even so, Alcon has faced many of the same challenges confronting smaller organizations, especially trying to do more with less.

"As our systems grew older, it grew harder to get things done," Holder said. "Managing submissions was largely manual and handled by spreadsheet submission trackers that had to be constantly maintained and updated. With our unified approach, all that data is contained in one system. We can take that information and upload templates, request funding and completely manage submissions without emailing back and forth. We are

also able to collaborate on final drafts of submissions and submit them for approval electronically, so the corporate team doesn't have to chase down approvals. I think this unified system will allow us to streamline our process and work smarter."

Holder acknowledged, however, that the implementation of RIM technology and full regulatory transformation will take time and stressed the fact that such rollouts should be supplemented with solid data, quality procedures, strict policies, and best practices.

"Technology isn't a magic wand," she said. "It doesn't resolve everything. You must still make sure you understand where the data in your system came from and how it will be used. Otherwise, you end up collecting similar data multiple times and lose your single source of truth."

Figure 1. Six Criteria for RIM System Evaluation

Eyeing the Future

Tomorrow's regulatory operations professionals will empower their organizations to thrive in a heavily regulated world. This will require professionals to step outside of the more familiar "reg-ops" role of the past to focus on the four key pillars of transformation: people, operations, product portfolio and technology. And, while technology can be a great enabler, it's the bright minds putting it into action that will ensure success. Regulatory transformation will not only help device companies succeed and get safe treatments to patients faster, but it will also yield professional success. As an instrumental agent to transformation, regulatory operations

professionals will garner greater influence on product development, go-to-market planning and overall business strategy.
No matter the approach, though, every medical device company should be looking toward the future and establishing their new business model for operating in this new regulatory landscape. The increased complexity of regulations such as *EU MDR* requires a new approach.

Organizations that embrace change and modern approaches now will significantly improve compliance and efficiency in how they go to market and compete.

References

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About the Author

Terri Howard has more than 20 years of experience in life sciences, with the last decade focused on regulated content management technology for the medical device industry. She has worked with industry leadership teams to form and influence change in regulatory business practices, most recently at CareFusion, now BD. Howard joined Veeva Systems in 2015 as director of strategy to help medical device companies leverage cloud technology to bring products to market faster and more efficiently. She can be reached at terri.howard@veeva.com.

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