Regulatory and Quality

EU MDR REMEDIATION PRESERVES $300M REVENUE FOR MEDICAL DEVICE COMPANY

Many companies face significant challenges in complying with the European Union's Medical Device Regulation (EU MDR). Difficulties like the pandemic and limited number of notified bodies have prompted the EU to extend compliance deadlines. So, a large U.S. medical device company recognized that there would be struggles ahead.

But the company far underestimated the scale, complexity, and financial investment of the work. Additional and ongoing clinical evaluation and documentation mean EU MDR is not just a regulatory check-off but a new set of business processes. And this product remediation work doesn't drive innovation or new business. Some companies are making a strategic decision to discontinue products or pull them from the European market.

This company, however, had nearly $300 million in revenue at risk. It assigned a dozen people and a few million dollars to the remediation project. But it soon realized that was not enough. Because they lacked the capabilities and capacity in house, executives turned to Integrated Project Management Company, Inc. (IPM) to lead the effort.

ADDRESSING THE CHALLENGES

IPM's strategic project management consultant assessed the organization's needs and progress. Regulatory affairs specialists had been leading the organization of the work, which extended well beyond their area of expertise and influence. Of the 50-some product families that were on market in the EU at the time, only three or four were being remediated. They urgently needed to address the rest.

Some of the products were 20 years old or more, so they would be unlikely to meet current standards. They may need to be updated without altering their fundamental design. Any failures during testing could have serious implications for products already in use.

The company's complicated structure, due to multiple acquisitions over the years, added to the challenges. There were more than 50 quality management systems (QMS) in use, and divisions worked with 11 different notified bodies. The company's global divisions manufacture products that rely on each other. For instance, one country produces a generator that operates another country's surgical devices. So, business decisions often involved myriad stakeholders. The organization hadn't established a governance structure or authority to bridge silos and drive companywide change.

EQUAL PARTS RIGOR AND RELATIONSHIPS

The IPM consultant took a multifaceted approach to the EU MDR compliance efforts based on IPM's remediation service model. He drove the team to build the staffing, budget, governance, and operations procedures necessary to accomplish the cross-functional work. He treated the project not as a mere regulatory exercise, but as a comprehensive program requiring robust project management and strategic oversight across the divisions.

Because he successfully rescued two prior new product development projects for the company, he held some political capital. He collaborated with executives who had seen his business acumen and strategic thinking to justify additional resources. Demonstrating accomplishments, navigating silos, and building relationships enabled him to further increase his influence in order to drive success.

The consultant ultimately organized and oversaw 10 sub-teams of more than 120 people with a budget that was larger than the company's new product development budget.

While the budget was large, it was not bottomless. Working with the business unit leaders, finance, and marketing, the consultant introduced a systematic approach to prioritizing which products to tackle, and in which order, based on revenue and strategic objectives. Often the leaders needed to make tough decisions. Would future revenue pay for the investment in testing and remediating each product? And when standards and deadlines changed, they had to make decisions again, even for products that had already been submitted to notified bodies.

Processes were established for responding to notified body inquiries. And when products gained approval, the consultant guided the team to establish production readiness for the changes needed in labeling and instructions for use.

FOUNDATION FOR THE FUTURE

At press time, one product family has achieved compliance and a handful of families are waiting for notified body review. The EU MDR remediation continues at the medical device company. And the governance and processes that IPM's consultant established still drives product rationalization and other strategic decision-making. In fact, the work has grown, as the company has asked him to frame post market surveillance and documentation procedures.

Importantly, the EU MDR efforts are preserving most of the company's $300 million in EU revenue and its competitive position in the market. They have also laid the foundation for effective product portfolio rationalization and readiness for large regulatory changes in the future.

In the meantime, because of IPM's expertise and strategic leadership, company executives have been able to focus on new product development and other critical projects.