Regulatory and Quality

CONTINUITY, STRUCTURE ENABLE EU MDR REMEDIATION IN AN EVOLVING ORGANIZATION

Preparing for the European Union's Medical Device Regulation (EU MDR) has been a disruptive, resource-intensive effort. The European Commission refined guidelines, a global pandemic struck, and deadlines changed. Notified bodies evolved, as did their direction. Testing, documenting, and applying for certification has taken years longer than most companies expected.

In the meantime, medical device companies still had products to develop and businesses to run. Many experienced changes in leadership, organizational structure, and/or strategic priorities. All of these complicated ongoing EU MDR remediation efforts. Consistent and adaptive leadership was required to maintain focus and momentum over the years.

An ophthalmic product manufacturer recognized early on that it didn't have the resources or processes to remediate the hundreds of products it sold in Europe. It tapped its long-time program management guide, Integrated Project Management Company, Inc. (IPM), to lead the effort.

SETTING DIRECTION

What started as a compliance project soon turned into something much larger.

First, IPM worked with the regulatory, R&D, and quality teams to understand the new guidelines and standards while they were still being refined by EU regulators. As with most companies, they learned that they had to test products that had been on the market for 10 or even 20 years. Staff responsible for—and excited about—new product development had to give time and attention to "old" products.

A structured approach was critical. IPM led a comprehensive assessment of the product portfolio, identifying gaps and helping stakeholders prioritize high-risk and high-value products. Through workshops and governance board engagement, IPM helped business leaders face a tough truth: not everything could be a top priority. By leading systematic prioritization efforts, IPM enabled different functions to allocate resources realistically and avoid the burnout of constant firefighting.

FORMING THE BACKBONE

To navigate shifting deadlines and resource constraints, IPM introduced a stage-gate process, tech file dashboards indicating needs and status, and a decision log. The latter was a critical tool for preserving institutional knowledge and avoiding repetitive debates. When questions resurfaced years later—such as why a product had been sunsetted—the log showed who made the call, when, and why.

The thorough historical information became the backbone of the six-year program. It was the consistent source of truth through sponsor changes (MDR ownership moved from the R&D project management office to regulatory to quality over the years), staff layoffs, a company reorganization, and new C-suite executives.

IPM consultants adjusted to each new sponsor's style and needs, whether that meant communicating through their preferred channels or bridging gaps with disconnected functional groups. They maintained a "one team, one goal" mindset to build accountability, even when R&D teams were more interested in innovation than remediating legacy products. They ensured contract manufacturing organizations stayed aligned and addressed resource conflicts head-on.

For example, the company culture discouraged teams from saying no to additional work. So when a leader decided their project couldn't wait, MDR efforts suffered. IPM worked with the governance board to reaffirm that MDR was a top priority and to communicate the consequences of delaying testing, documentation, and responding to notified bodies.

IPM program leaders applied lessons from early submissions to later submissions. For instance, when two groups were trying to submit tech files at the same time, it overtaxed supporting teams. So they staggered milestones to smooth resourcing needs. Similarly, they used the decision log to search for solutions on past submissions. In one case, a product contained a heavy metal element, which must be called out. But what if it's used only within stainless steel? The company had to respond consistently or risk queries from the notified body. Once the decision was made how to report about the possible contaminant, all the tech files followed suit.

REACHING THE FINISH LINE

Ultimately, IPM led the program for six years, guiding more than 200 SKUs worth over $140 million annually through EU MDR remediation.

Perhaps more importantly than handing off ownership of the decision log, tech file summary, and a refined process, IPM left behind a culture of accountability and realistic planning and goal setting. The organization is better prepared to gain MDR certification for new products and to tackle the next large, complicated remediation program.

Through the ups and downs of a complex, multiyear effort, IPM provided a steady hand, bringing consistency, enabling decisions, and helping the company move forward with confidence.