Regulatory & Quality

ASSESSING EU IVDR GAPS JUMP-STARTS COMPLIANCE PROGRAM

A biotechnology company with an innovative cancer-screening tool needed a spark to create urgency. Deadlines were approaching for the European Union's In Vitro Diagnostic Device Regulations (IVDR). But the company didn't have resources to dedicate to the effort. Executives wanted a jump-start to get the compliance program rolling.

IVDR, with its increased scrutiny and stricter requirements, requires notified body review of a company's products and quality management system (QMS). The low number of qualified notified bodies was one of the reasons the EU had already extended deadlines. Notified bodies still have limited time and bandwidth, so medical diagnostic companies must follow their tight timelines or risk getting pushed to the end of a long review queue. This could delay certification for months or even years. Losing access to the European market would have financial and lasting competitive implications.

The biotech company enlisted Integrated Project Management Company, Inc. (IPM) to help it avoid those problems.

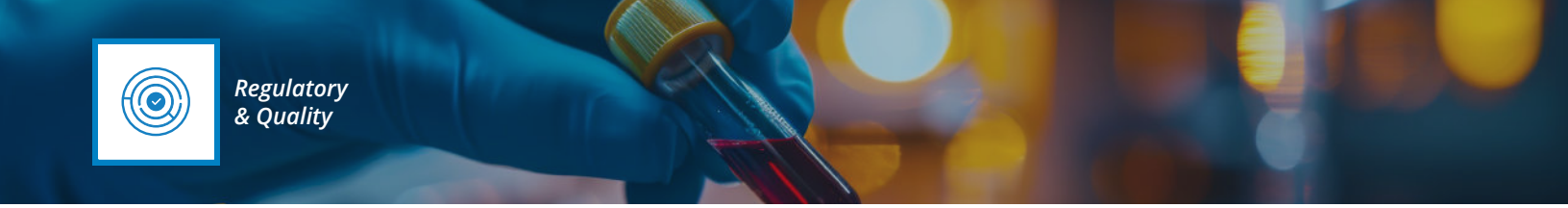
UNDERSTANDING THE CHALLENGES

Despite the organization's ample quality department, staff were stretched thin, handling multiple high-priority tasks. IVDR was considered important but not urgent, so the company didn't have people solely dedicated to the effort. Indeed, they didn't know enough to understand how much they were falling behind.

However, deadlines drew closer. The company had limited resources and budget, but it needed to speed up its IVDR work.

Fortunately, it had a bit of a head start. It had just completed ISO 13485 certification, and many of the requirements overlap. But not all. The IVDR demands additional risk management, technical files, QMS documentation, and more.

IPM's program management consultant had supported their ISO 13485 work. With the background on requirements, quality systems, lessons learned, and team dynamics, she was the right person to identify the gaps the company needed to fill and set up a structure to systematically fill those gaps.



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FIND THE GAPS, FILL THE GAPS

The program manager started by objectively assessing the current QMS and product documentation. She met with the company's notified body to gain clarity and guidance about IVDR requirements. And she collected feedback from past internal and third-party audits. Building a matrix of ISO and IVDR requirements and assets revealed the gaps they needed to fill. The tool then served as a single source of knowledge for tracking status.

Working with the quality and regulatory leads, the program manager outlined the scope of the compliance effort. They developed a high-level roadmap with key milestones to address all the gaps. The largest shortcoming was around risk management documentation, which would also require changes to standard operating procedures.

To help drive a smooth compliance program, they established governance, team structure, and defined roles and responsibilities. They still had to overcome the fact that the teams were already busy with other priorities. To keep people on track, they codified regular short meetings, consistent communication, and persistent follow-ups. Accountability fell to specific individuals, rather than teams or functions, to foster ownership. Even IVDR requirements that didn't apply to their product, such as electronics testing, had an owner, who wrote the rationale for why that data was unnecessary.

Importantly, the effort included writing down assumptions and possible risks to the IVDR compliance program, as well as mitigations. Because the company's budget was tight, IPM's program manager wouldn't be on hand to help execute the work. Her aim was to do everything possible to set the quality and regulatory teams up for success.

THE PATH FORWARD

Although the program was not complete when the IPM consultant transitioned her work to the internal team, the company had made significant progress. IVDR compliance gained greater visibility and priority. Key executive stakeholders, as well as the quality and regulatory departments, became more engaged and understood the need to stay on track.

The program roadmap, accountability, and transparent communication will enable the company to continue to make progress and overcome obstacles until they submit to the notified body and gain access to the EU market.

And, with the experience of preparing the regulatory submission, the company can use the processes and systems IPM implemented for future compliance efforts.

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