CASE STUDY

RQM+ Partners With Global IVD Manufacturer to Remediate Over 150 IVDR Technical Files

Background

A client that ranks among the leading global IVD manufacturers was transitioning a portfolio of more than 150 legacy devices to the IVDR. With a spectrum of diagnostic test assays, reagents, controls and calibrators across multiple classes, the company needed a systematic approach to creating compliant technical documentation under the IVDR. When it learned that its initial IVDR submissions would not pass muster with the notified body, the client turned to RQM+ for support.

Challenge

NB identifies several findings in first submissions.

A global in vitro diagnostic company had submitted its first technical files to the notified body under the IVDR only to receive pushback on various aspects of clinical evidence. Several findings were identified, including nonsystematic literature searches, lack of support for clinical performance claims and poor demonstration of state of the art — among other major issues. The notified body also pointed out the lack of coherence across the entirety of the technical documentation, showing misalignment between clinical, R&D, regulatory and post-market teams.

The manufacturer was planning its first 10 submissions to the notified body, including immunoassay and molecular-based IVDs from Classes B to D, but had to stop those based on the major gaps identified in the first files selected for notified body review. The company had spent the previous two years transitioning its products to the IVDR for a portfolio of more than 150 devices just to realize that most of its efforts had been wasted because it did not have the appropriate direction and expertise in-house. Client costs dedicated to IVDR transition to date, including labor, were estimated to be more than $3.5 million.

Solution

RQM+ completes IVDR remediation project.

Due to the significance of the issues encountered and in the absence of helpful feedback from its notified body, the client turned to RQM+ for help. RQM+ remediation efforts were targeted on key areas of noncompliance using our unique knowledge of notified body expectations and led by ex-notified body reviewers.

Our project team worked on a complete business integration solution, streamlining procedures and improving overall business integration from design and risk management to performance evaluation and post-market surveillance. This resulted in notified body findings being overturned in record time. Very minimal feedback was received by the notified body once RQM+ got involved and the first products were CE marked in a single round of notified body questions, reducing time to market by several months.

Approach

RQM+ started with a mock assessment of one of the files, which was led by ex-notified body IVDR experts and a team of IVD consultants with regulatory and product-specific knowledge. The file was scrutinized from beginning to end, and no stone was left unturned.

A comprehensive report was delivered one month after the start of the project, which outlined all areas of noncompliance, and a risk assessment on each finding was conducted. The report formed the basis of the new IVDR remediation project led by RQM+ and allowed our team to focus on common themes of noncompliance across the portfolio.

A project lead was assigned, and a multidisciplinary team of medical writers and clinical subject matter experts (SMEs) was put together to remediate all 10 files that were going to be submitted to the notified body. The team consulted with our IVDR SMEs throughout the entire project to ensure all remediation activities would meet notified body expectations.

RQM+ was able to quickly deploy around 15 staff members to the project, which took just over six months to complete. The remediated files were resubmitted to the notified body. The first four files have already been certified, and only minor clarifications were requested throughout the rounds of questions with the notified body.

Results

Client saves money and wins key contracts.

The success of these first deliverables has led to an extension of scope for RQM+ to remediate all of the more than 150 files in the portfolio and a multiyear agreement for our clinical and post-market practices to support ongoing PMS and PER reviews over the lifecycle of the devices.

Impact Factors

Cost savings estimated with outsourcing were an average of $40,000 per technical file based on the following factors:

There was a decrease in notified body approval costs with fewer rounds of questions being asked and less time spent on the review. Originally, the company got pushback of more than 40 questions from the NB. After our work with the client, it resubmitted the files, and the NB had zero questions on all items that were remediated by RQM+.

On average, it could take a year from application to certificate issue for one product to be approved. It may take even longer if a device depends on external consultations, such as high-risk Class D devices without common specifications or companion diagnostics. If the client hadn't spent valuable time with a complete in-house remediation approach, it would have avoided wasting 6-8 months dealing with unnecessary NB questions on clinical evidence. RQM+ was able to reduce the time frame for approval from the moment we were involved.

Early market access with the IVDR enabled the client to win key contracts with health institutions through tendering processes that were giving preference to IVDR-certified products. Under an IVDR legislative framework, it is not uncommon to see procurement processes in Europe and authorized representatives asking for evidence of a manufacturer's IVDR transition and/or its progress.

The client is expected to see total cost savings of more than $6 million for more than 150 products in its portfolio by outsourcing remediation to RQM+ instead of handling it internally due to RQM+'s expertise, efficiency gains and in-depth knowledge of notified body expectations.

The client restructured several divisions — particularly in R&D, QARA and clinical teams — based on RQM+'s assessment and recommendations toward efficiency, better integration and compliance.

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for more than 150 products across its portfolio.

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The number of questions the notified body had after technical file remediation with RQM+.

6-8 months

The time saved on rounds of notified body questions and approval.

> **"I still can't believe how much work has gone into this project. We could not have done it without the support of your team. I have only one regret: That we did not come across RQM+ two years ago when we first started our IVDR journey!"**

Vice President Regulatory Affairs
at a global diagnostics firm

Contact us for a Consultation

RQM+