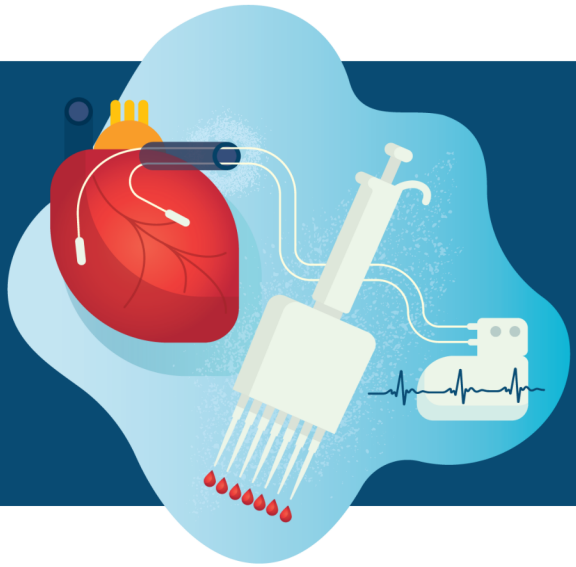

GLOBAL CASE STUDY

Full-Service EU MDR Regulatory Writing, Consulting, Project Management, and Training for a Sustainable Future

Manufacturer / Device Type: Mid-Size, Class I - III Devices

Services: Writing, Project Management, Consulting, Training

EU MDR Documents: CEP/CER, PMS, PMCF

GLOBAL'S MEDICAL DEVICE CAPABILITIES

Medical & Regulatory Writing including CEP/CERs, PMCF & PMS Plans/Reports, PSURs, SSCPs, and Literature Reviews

Project Management including schedule creation and full-service project management of EU MDR deliverables

Regulatory & Technical Consulting including CER strategy, PMCF strategy, SOP review, and template review

Training including our regulatory writing internship program, CER essentials course, and custom training programs

ABOUT THE CLIENT

A mid-size medical device company, Client X boasts a large and diverse portfolio of products, including many Class I accessories in addition to several high-risk Class IIb and III devices. With the new EU MDR requirements, Client X recognized the need to act soon to ensure conformity. Like most manufacturers, Client X's documents and processes were not immediately MDR-ready, nor was there clear direction within the industry for how to achieve MDR compliance. Furthermore, Client X did not have an established writing team prior to MDR.

GLOBAL SOLUTIONS

Project Management and Training

GLOBAL began with a week-long EU MDR training to teach Client X's cross-functional team about the new EU MDR regulatory requirements and how the regulations would affect each department.

GLOBAL's consultants evaluated the portfolio and current certification status of all products and developed a schedule. Considering the timeline for meeting MDR compliance, GLOBAL's team developed an initial strategy of focusing on remediation for MDR-readiness while still maintaining certification under MDD. This approach would allow time for additional data collection and minimize efforts needed for MDR certification.

GLOBAL SOLUTIONS (CONTINUED)

Update Templates and Procedures

GLOBAL's consultants reviewed and updated templates for clinical evaluation and post-market surveillance documents to align with EU MDR requirements. SOP updates and revisions were also provided.

Writing, Consulting, and Ongoing Training

A team of dedicated writers from GLOBAL helped Client X's internal team with the first round of remediated documents. Advice on product-specific strategy and post-market clinical follow-up activity was provided as needed. GLOBAL's writers also provided training and guidance to Client X's growing internal team. This model ensured that all new team members were trained to the latest standards without adding to the workload of established team members.

OUTCOMES

- EU MDR-compliant templates for CEP/CERs, PMCF Plans/Reports, PMS Plan/Reports/PSURs and related SOPs have been successfully implemented
- GLOBAL wrote the first revision of EU MDR-compliant documents while providing consulting on the regulatory strategy and clinical data collection
- The portfolio project schedule continues to be leveraged for determining timelines and resourcing
- GLOBAL's team has trained several new internal team members to execute regular updates
- GLOBAL continues to support with consulting needs, including Notified Body responses

CONCLUSIONS

As a result of their partnership with GLOBAL, Client X was able to remediate their entire portfolio to EU MDR compliance. With GLOBAL providing the heavy lifting for writing and strategy, the team was able to navigate this difficult transition without becoming overwhelmed and risking regulatory non-compliance.

Today, Client X continues to work with GLOBAL regularly as we provide consulting and support with Notified Body feedback. We are also on standby for unexpected surges in work related to maintaining their current project schedule.