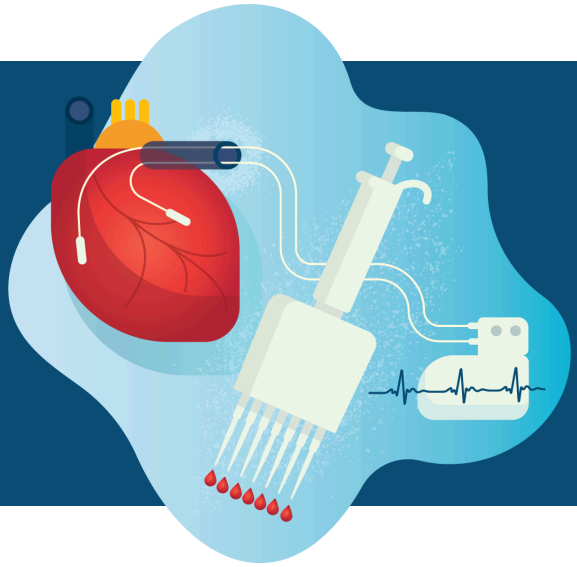

GLOBAL CASE STUDY

Periodic Safety Update Report (PSUR) Vigilance Data Reporting

Manufacturer/Device Type: Large, Class I - III Devices

Services: Writing, Consulting, & SOP and Template Updates

EU MDR Documents: PSURs

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

Client C, a large multinational medical device company with products spanning multiple diagnostic and therapeutic areas, has maintained a long-standing relationship with GLOBAL. Having previously collaborated on CERs, Client C enlisted GLOBAL to support writing PSURs for multiple business units.

ABOUT THE PROJECT

Client C got an early start with the transition to MDR and were ahead of schedule after the transition timeline was extended. Client C began writing PSURs prior to the publication of the MDCG 2022-21 PSUR guidance document.

After MDCG 2022-21 became available, Client C required changes to their general PSUR procedures, template, and vigilance data reporting.

GLOBAL SOLUTIONS

SOP and Template Alignment

GLOBAL's consultants assisted with updating SOPs and template revisions to align with MDCG 2022-21. GLOBAL's consultants and writers also updated completed PSURs to comply with current requirements and guidance.

GLOBAL SOLUTIONS (CONTINUED)

Key Changes

GLOBAL and Client C collaborated to improve vigilance data reporting across all PSURs, with emphasis on the following:

- Vigilance data reporting periods were clearly defined.
- Setting expectations around analysis of historical vigilance data.
- For legacy devices that will not be certified under the MDR, the PSUR must be maintained until the end of the shelf life and/or intended lifetime of the last individual device placed on the market.
- Serious incidents should be characterized by the device problem, root cause, and health effects and categorized using IMDRF Adverse Event Terminology.
- Serious incident data will be grouped both by region and worldwide.
- Non-serious incidents will also be reported by IMDRF Annex A (Medical Device Problem) terms/codes.

By implementing these changes, Client C's cross-functional team was able to collect and assess complaints data in the needed format.

OUTCOMES

- SOP and template improvements ensuring compliance with regulations and guidance
- Consistent approach for organizing and categorizing incident data
- Detailed strategy for maintaining PSURs for legacy devices
- Remediation of previously completed PSURs, allowing for smoother annual updates
- Improved cross-functional collaboration with complaints-handling team, leading to greater overall efficiency

CONCLUSIONS

Process, template, and vigilance data reporting improvements allowed Client C to maintain their regular cadence of PSUR submissions with minimal Notified Body findings and need for remediation.