

GLOBAL CASE STUDY

Long-Term Partnership with Large Multinational Corporation for EU MDR Remediation of an Entire Project Portfolio



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



Services: Writing, Consulting, Project Management



EU MDR Documents: CEPs, CERs, PMCF Plans, PMCF Reports, 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 M is a large medical device manufacturer with a large portfolio comprising numerous Class IIb and III devices. Client M reached out to GLOBAL shortly after EU MDR's entry into force. Client M was looking for support remediating their Peripheral Intervention device portfolio to help with the transition to EU MDR.

ABOUT THE PROJECT

- Large Device Manufacturer (Client M) required full-service EU-MDR remediation for an entire portfolio of high-risk devices. Client M had recently acquired another company and needed help bringing all of their documentation, including CEPs, CERs, PMCF Plans, and PMCF Reports up to MDR compliance.
- Client M had a strong internal writing team, but the team was too small to meet the demand of an approaching EU MDR deadline. Client M's expanded portfolio also offered new challenges in terms of developing an appropriate cadence and transferring these devices into their internal QMS System.



GLOBAL SOLUTIONS

As part of our full-service commitment to Client M, we provided over-arching Project Management services that integrated our team directly into the scoping, planning, and execution of an entire portfolio of deliverables.

- GLOBAL writers integrated themselves into Client M's team to take part in template development, process improvements, project oversight, and cross-functional meetings.
- Weekly meetings between Team Leads allow teams to work in lockstep to provide high-quality deliverables on-time, on-budget, and in alignment with internal writing strategies.
- Integration with project-management tools enabled GLOBAL to accurately and consistently anticipate Client M's internal writing team's needs so that we provided support and assistance quickly.
- Our team approach allowed GLOBAL to take on a higher number of assignments than could be executed by single writers. GLOBAL's high output and efficiency made our services an excellent value.
- Trips to visit Client M's campus cemented the close relationship between our GLOBAL team leads and Client M.
- GLOBAL's project management tools and long-term and close relationship allowed us to gain a deep familiarity with Client M's portfolio. GLOBAL's writers updated the same documents multiple years in a row; this experience results in better strategy decisions, effective incorporation of NB feedback, and highly efficient execution of top-quality deliverables.

OUTCOME

GLOBAL has maintained a long-term successful relationship with Client M thanks to high-quality deliverables, open lines of communication, team integration, and a commitment to supporting Client M's success. Our integration with Client M's team has instilled a sense of shared goals and accomplishment which strengthens our bond with our client group.

CONCLUSIONS

GLOBAL's commitment to our clients leads to long-standing relationships that yield years of high-quality deliverables and a familiarity with the portfolio. These strong relationships lead to increased effectiveness, efficiency, and higher quality of the deliverables. Partnering with GLOBAL can improve project management, project processes, and reduce stress and workload for your valuable internal team.

