



GLOBAL CASE STUDY

Full-Service EU MDR Deliverable Update with Consulting and Project Management for a Small Start-Up with New Device Technology

ABOUT THE CLIENT

Client T, a small start-up, has developed several novel Class IIa technologies in a niche market. Like many new companies, Client T faced the challenge of meeting regulatory requirements across multiple geographies and lacked the in-house resources to ensure compliance with EU MDR. With a technical file review looming, Client T required a full remediation of a suite of documents within a tight 5-week timeline. Another CRO proposed a bid of nearly \$500,000, surpassing Client T's financial constraints. GLOBAL's bid to complete the project was around \$100,000.

ABOUT THE PROJECT

Achieving Conformity to EU MDR

Client T needed 6 documents to be remediated and prepared within 5 weeks (CEP, CER, PMCF Plan, PMCF Report, PMS Plan, and PSUR). The templates had gone through some internal updates but were not fully MDR-compliant. GLOBAL's consultants addressed the compliance issues in the templates and improved the formatting and organization to ensure a smooth Notified Body review process.

After the template updates were complete, GLOBAL executed a literature review, state-of-the-art update, vigilance assessment, non-clinical data compilation, and data analysis to demonstrate conformity to the GSPRs. The route to conformity included a complex equivalence argument for which GLOBAL provided strategic consulting.



Manufacturer/ Device Type:

Small, Class IIa Emerging Technology



Services: Template Review and Update, Consulting, Writing



EU MDR Documents: CEP, CER, PMCF Plan, PMCF Report, PMS Plan, PSUR

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



GLOBAL SOLUTIONS

GLOBAL executed the project using the company's values.



Collective Intelligence

GLOBAL's team of consultants, project managers, and writers leveraged their deep experience and expertise to ensure that all project management and EU MDR strategies were well-grounded and effective for Client T's product and goals.



Agility

GLOBAL was able to harness the power of our large team of qualified writers to ensure the entire scope of work was completed within the timeline set by Client T.



Inclusiveness

GLOBAL updated Client T every step of the way and brought them in on our process. During weekly calls, we communicated and collaborated on the evolving strategy and potential roadblocks.



Integrity

GLOBAL executed high quality deliverables with transparency and sound procedures. Questions and concerns were escalated and discussed with Client T immediately.



Curiosity

GLOBAL was excited to work on fast-paced, complex project supporting a new technology that would help save lives.



Sanctuary

GLOBAL understands that EU MDR compliance is complex and evolving; our role is to support our clients and ensure their short- and long-term success

OUTCOMES

- GLOBAL provided 6 total deliverables, while improving and providing updated templates, all within the proposed timeline.
- GLOBAL completed the project within 7% of the proposed budget and we worked with Client T's financial constraints to ensure they received the best deal possible.
- GLOBAL completed drafts of all deliverables within 5 weeks of the project kick-off.
- Client T received top-quality deliverables in the timeline required and within their budget.

CONCLUSIONS

Client T was immensely satisfied with the work GLOBAL executed. They were able to meet their internal deadlines and enter into their technical review with full confidence in the thoroughness and the overall quality of our work.

