GLOBAL
REGULATORY WRITING & CONSULTING

CASE STUDY

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

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

We build and train teams to maximize efficiency and quality.

WORK WITH US

@GLOBALRWC
WWW.GLOBALRWC.COM

GLOBAL'S MEDICAL DEVICE CAPABILITIES

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

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

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

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

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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

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.

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CASE STUDY

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

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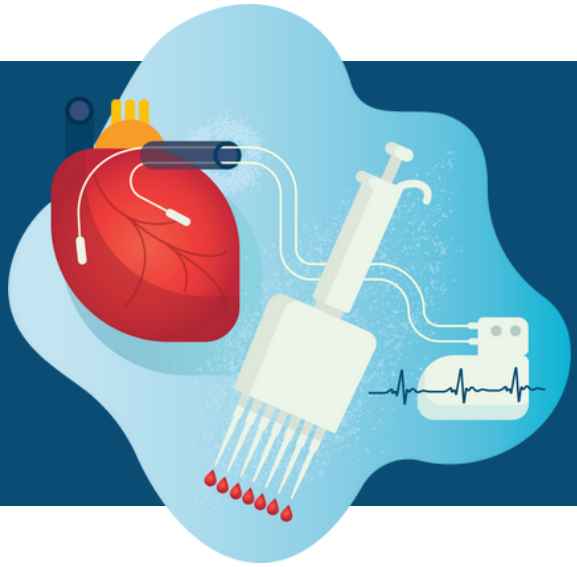
OUTCOMES

- GLOBAL provided 6 total deliverables, while improving and providing updated templates, all within the proposed timeline.
- GLOBAL 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.



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Achieving Conformity to EU MDR

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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.
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