GLOBAL
REGULATORY WRITING & CONSULTING

CASE STUDY

Clinical Investigational Reports for Medical Devices: Supporting Compliance with a Cross-Functional Team

Manufacturer / Device Type: Small, Class III Devices

Services: Writing, Project Management, Consulting

PMA Submission: Templates, SOPs

We build and train teams to maximize efficiency and quality.

WORK WITH US

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GLOBAL'S MEDICAL DEVICE CAPABILITIES

Project Management including schedule creation and full-service project management for PMA 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, CSRs, and Literature Reviews

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ABOUT THE CLIENT

A small medical device firm (Client X) was struggling with the structure and format of their clinical investigation report for their upcoming PMA submission. They reached out to GLOBAL for advice and after discussions decided to employ GLOBAL to revamp and restructure their report.

ABOUT THE PROJECT

Their medical device report had been written according to International Council for Harmonization (ICH) E3 Structure and Content of Clinical Study Reports. Consequently, it read more like a study report for a pharmaceutical product rather than a report for a medical device. In addition, Client X requested that their tables, listings, and figures (TLFs) be incorporated into the report and hyperlinks added. Deadlines were tight.

GLOBAL SOLUTIONS

The Medical Device Team at GLOBAL recommended Client X switch from an ICH E3 format to a format consistent with Appendix D of International Standard Organization (ISO) 14155:2020 Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practice and that they use GLOBAL's Regulatory Operations team to incorporate the TLFs into the report and add hyperlinks. To make it easier to navigate the 6000-page compilation, our expert publishing team added PDF bookmarks of all the TLFs .

OUTCOME

- The structure and format of the report was revised from ICH E3 to ISO 14155:2020.
- TLFs and their respective hyperlinks were fully incorporated into the report.
- The 6000-page compilation was fully QC'd by GLOBAL.
- Client X was satisfied with the outcome and Client X reached out to us for another CSR project.

CONCLUSIONS

Through cross-functional teamwork, GLOBAL successfully converted Client X's clinical investigation report to the ISO 14155:2020 format with full incorporation of all TLFs and in-report hyperlinks.

GLOBAL is one community that lives by 6 core values: agility, collective intelligence, curiosity, inclusiveness, integrity, and sanctuary. This project saw the interplay of all of these values. Client X's timelines were tight, so we shifted our priorities (**agility**), we leveraged expertise from our clinical team, our medical device writing team, and our regulatory operations team (**collective intelligence**), we expanded our skillsets (**curiosity**), we worked outside of our traditional silos (**inclusiveness**), we were transparent with the client (**integrity**), and we embraced their needs as our own and shepherded the project to success (**sanctuary**).

WORK WITH US

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