GLOBAL

REGULATORY WRITING & CONSULTING

CASE STUDY

Developing Efficient Solutions to Client Needs

Therapeutic Area: Oncology

Product Type: IgG1 antibody

Document: Investigational Medicinal Product Dossier (IMPD)

We support Medtech and Biopharma innovators with strong, collaborative partnerships, tailored regulatory consulting and writing services, and deep strategic expertise.

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GLOBAL'S DOCUMENT PRODUCTION CAPABILITIES

- Expert support for formatting, compilation, and publishing
- Tailored workflows that adapt to client needs
- Reliable, submission-ready deliverables every time
- Emphasis on efficiency through streamlined processes
- Integrative partnership versus provider-client relationship

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ABOUT THE CLIENT

The sponsor - a clinical-stage biopharmaceutical company with programs spanning rare disease and oncology - was supported by a lean but highly-skilled team. While experienced in development, the group faced the technical and coordination challenges that often arise with complex submission documents such as IMPDs.

ABOUT THE PROJECT

The sponsor requested a fully compiled Word version of an IMPD that included a comprehensive, linked Table of Contents, List of Tables, and List of Figures, along with a PDF of the full document. Our document production lead quickly recognized that such an approach would introduce significant risks: large, heavily formatted Word files are prone to corruption when numerous section breaks are used, and table/figure numbering inconsistencies could create discrepancies between the compiled document and the source files.

Although technically possible, the instability and effort required made this approach inefficient for meeting the sponsor's underlying needs.

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GLOBAL SOLUTIONS

Our first step was to clarify the client's desired final product. Through discussion, it became clear that the client's true need was a compiled PDF that was easy for reviewers to navigate.

GLOBAL's document production specialists designed an alternative process and developed a prototype file for review. Instead of compiling the entire IMPD in Word, individual sections were converted to PDF and then assembled into a single, functional document. Using advanced PDF settings, our team created a visible bookmark pane that served as a dynamic Table of Contents, ensuring the final product was both comprehensive and stable.

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OUTCOME

GLOBAL helped the sponsor refine their request and delivered a solution that avoided the risks of Word file corruption while achieving the desired functionality. The approach was less labor-intensive than the original plan, saving the client both time and budget.

CONCLUSIONS

This project underscores the value of collaboration and open discussion. It's always helpful to talk through any client requests that differ from a standard way of doing things. In this case, one short meeting with the client helped identify their actual need. By clarifying requests and pinpointing issues, we can better help our clients achieve the desired outcome, often in a more efficient and technically sound manner. The result was a practical solution that gave the sponsor confidence in both the process and the final deliverable.

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