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REGULATORY WRITING & CONSULTING

CASE STUDY

Navigating the Complexities of a Microbiome Product Filing

Project Type: Initial IND Submission

Product Type: Live Biotherapeutic Product (Microbiome)

Product Life Cycle Stage: Phase 1

GLOBAL'S REGULATORY CMC CAPABILITIES

Our **Regulatory CMC Strategists** develop sound and defendable strategies to help clients navigate the complex regulatory landscape.

Our **CMC Technical Team** provides process and analytical support and program development guidance.

Our **Quality Professionals** can help maintain compliance with phase-appropriate cGMPs from early development through commercialization.

Our experienced **Authoring Teams** produce high-quality submission and technical documents.

We build and train teams to maximize efficiency and quality.

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ABOUT THE CLIENT

Our client was a small, start-up biotechnology company working on a live biotherapeutic product with 100+ live bacterial strains. The client was seeking to initiate clinical trials and engaged GLOBAL to author Module 3 (Chemistry, Manufacturing and Controls [CMC]) of their Investigational New Drug Application (IND).

ABOUT THE PROJECT

The history, manufacture, and testing of all cell banks used in biologics manufacturing must be provided in IND Module 3. This particular product contained 100+ bacterial strains, which created significant challenges to gathering and organizing the required IND information. Typically, most INDs have only one or two cell banks that need to be described.

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GLOBAL SOLUTIONS

GLOBAL proposed a cell bank report template, which organized the required information common to all the cell banks, with placeholders in tables to present the unique cell bank information, such as the species name/strain number, origin of strain, media used, testing results, etc.

Organizing the reports in this way resulted in a comprehensive report for each cell bank, with minimal effort from the SMEs. These reports were attached to the 3.2.S.2.3 Control of Materials section, rather than embedding a large amount of information in the Module 3 text.

OUTCOMES

The client was very pleased with the templates, and their IND was reviewed favorably.

The cell bank report templates provided many solutions and benefits to the client, namely:

- A standardized reporting format, which ensures the same information is captured for each cell bank and facilitates health authority review
- Simplified Module 3 content, making authoring and review easier for all parties
- Reports that could be easily used for other INDs, as the client was considering using some of the same cell banks in other investigational products
- Records that could be used for intellectual property documentation or due diligence review purposes

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CONCLUSIONS

When presented with a challenge unique to the growing microbiome field, GLOBAL authors used their expertise in cell banks for complex biologics to provide a creative solution that increased efficiency for the client SMEs and regulatory affairs staff, for GLOBAL authors, and regulatory reviewers, in addition to providing a valuable source of knowledge for the client's current and future product development programs.

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