



GLOBAL 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 CMC CAPABILITIES



Our **Regulatory CMC Strategists** develop sound and defensible 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.

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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 the Module 3 (Chemistry, Manufacturing and Controls [CMC]) section 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 the IND Module 3 section. This particular product contained 100+ bacterial strains, and thus provided a significant challenge to gather and organize the required information into Module 3 for both the client's subject matter experts (SMEs) and the GLOBAL authors. Typically, most INDs have only one or two cell banks that need to be described.



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.

OUTCOME

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
- Simplifying the 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

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, and provided a valuable source of knowledge for the client's current and future product development programs.

