GLOBAL
REGULATORY WRITING & CONSULTING

CASE STUDY

CMC Authoring and Regulatory Strategy for an Investigational New Drug Application

Project Type: CMC Dossier for an Initial IND Submission

Product Type: Antibody-Drug Conjugate

Product Lifecycle Stage: Phase 1

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 REGULATORY CMC CAPABILITIES

Regulatory CMC Strategists to help navigate the complex regulatory landscape

CMC Technical Experts to guide process, formulation, and analytical development

Quality Experts to support phase-aligned cGMP compliance

Writers & Document Specialists to author submission-ready regulatory and technical documents

ABOUT THE CLIENT

The client was a clinical-stage biopharmaceutical innovator company focused on treating solid tumors with antibody-drug conjugates (ADCs).

ABOUT THE PROJECT

ADC development programs are inherently complex because they combine the technical challenges of small molecule and large molecule development into a single program. Additionally, this client had a small team of subject matter experts supporting the entire ADC pipeline. Due to the resulting resource constraints and an aggressive timeline, the client engaged with GLOBAL regulatory and CMC experts to author Module 3 for the initial IND and to provide strategic regulatory support for the program.

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GLOBAL SOLUTIONS

- Create an end-to-end project plan based on the client's current state and planned submission timeline.
- Perform a gap assessment of available source documents to proactively identify potential deficiencies in an initial IND.
- Develop a risk-based strategic remediation plan prioritizing potential clinical hold deficiencies.
- Author Module 3 with a complete data package and an appropriate level of detail by leveraging relevant CMC regulatory and writing expertise.
- Manage efficient document development throughout the process, including client reviews, copyediting, formatting, and eCTD publishing.
- Prepare recommended responses to potential Information Requests prior to submission.

OUTCOME

Our partnership yielded:

- A right-first-time IND that was submitted on time and received a Safe to Proceed letter with no Agency questions requiring immediate responses.
- A high-quality submission facilitated by collaborative project management that overcame the client's resources challenges and complex network of third-party development sites.
- Integration of Agency feedback into ongoing development activities and alignment to phase-appropriate milestones.

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