GLOBAL CASE STUDY

Consulting and Authoring an Investigational New Drug Application

Project Type: Initial IND Submission

Product Type: Antibody Drug Conjugate

Product Life Cycle Stage: Phase 1

GLOBAL'S CMC CAPABILITIES

Our **Regulatory CMC Strategists** develop sound and defendable strategies to help clients navigate through 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.

Want to learn more about our services? Visit **globalrwc.com/cmc** or email **info@globalrwc.com**.

ABOUT THE CLIENT

A clinical-stage, innovative biopharmaceutical company focused on treating cancer by targeting the tumor microenvironment.

ABOUT THE PROJECT

- The client had a clinical stage antibody-drug conjugate (ADC) product in development.
- ADC projects are technically complex because they combine the challenges of small molecule and large molecule development into a single program.
- The client had a small team of subject matter experts supporting multiple ADC development programs progressing in parallel at a network of contract manufacturing and testing sites across multiple regions.
- Due to an aggressive timeline and resource constraints, the client asked GLOBAL to author the CMC modules of the initial Phase 1 IND and to provide strategic regulatory support for the program.

GLOBAL SOLUTIONS

GLOBAL had prior experience supporting ADC programs at all stages of the clinical development timeline. Using our proven matrix-team approach, GLOBAL's team of regulatory and technical experts reviewed the product development package while our team of experienced technical writers authored the IND submission.

- The GLOBAL team performed a first-pass assessment and worked collaboratively with the client to devise a project plan to address critical deficiencies and enable submission with minimal impact to overall project timeline.
- GLOBAL's regulatory strategists leveraged experience supporting similar programs to provide guidance to the client to ensure that the correct level of detail was provided in the filing to facilitate Agency review.
- GLOBAL's experienced technical writing team authored high quality draft submission documents and effective program management expedited client review.
- The GLOBAL technical team provided a critical review of development documents generated by the client's contract manufacturing and testing laboratories and provided feedback to ensure that development gaps were addressed and that future program development activities were aligned with phase appropriate submission requirements.
- The GLOBAL team performed a holistic review of the complete CMC Module to ensure consistency and continuity across all submission modules and compiled a list of potential Agency review questions and pre-positioned draft responses.
- GLOBAL's Regulatory Operations team performed submission-enabling copy editing and publishing activities. The GLOBAL in-house publishing team can expedite the turnaround from pencils down to publishing. In this case, the turnaround was 2 days.

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.
- GLOBAL produced a high-quality submission facilitated by collaborative project management that overcame the client's resource challenges and complex network of third-party development sites.
- GLOBAL helped the client align the ongoing program development activities to phase-appropriate milestones.
- GLOBAL provided submission documents that the client can leverage to drive future development and submission efficiencies.