SYNER-G BioPharma Group

CASE STUDY

Advancing Biotech Drug Development: Syner-G BioPharma's Collaborative Approach to Chemistry, Manufacturing, and Controls

About

The client is a U.S.-based clinical-stage biotechnology company using artificial intelligence (AI) and human data to transform drug discovery and development The company uses machine learning to map the complex causes of diseases to develop proprietary drug candidates on their biology and chemistry platforms.

Challenge

The client needed a partner with extensive Chemistry, Manufacturing and Controls (CMC) experience that would take a team approach to help them achieve their goals.

Solution

The client partnered with Syner-G BioPharma Group to provide expertise and guidance on CMC, drug substance, drug product, and regulatory compliance. Syner-G helps its clients design and implement science and risk-based, phase-appropriate solutions to advance drugs during development expeditiously. Syner-G's CMC 360 and Regulatory Affairs business units operate in an integrated fashion to ensure full compliance with scientific standards and regulatory requirements.

"The Syner-G team is incredibly flexible. They've done everything possible to accommodate necessary changes, even when the requests were reasonable. They provide reasonable guidance, and they deliver on it."

Results

The client experienced significant improvements and advancements in its CMC efforts and meeting project management deadlines. As part of its work for the client, Syner-G wrote and produced regulatory documents and facilitated communication and navigation with regulatory offices in multiple countries, including capturing and submitting documentation for approval to various governing bodies, all of which was an "enormous help."

Other results included the following:

Helped develop a robust synthetic process for a chemical compound with stability challenges. The results included:

- Increased yields of drug substance and reproducible polymorph solid states
- Enabled scalability for future batches
- Increased stability of the compound

Developed a process to deliver granulated compound into sachets so the drug can be administered to the targeted patient population

Developed in-use stability studies to enable a smooth transition to clinical trials.

Designed and implemented liquid and food compatibility studies to support clinical trials

"It was great to work with Syner-G both personally and professionally," said the client's [Head of Chemistry]. "Having a partner that provided all our needs has made a huge difference in our productivity and production."

The [Head of Chemistry] also appreciated how the Syner-G team had many one-on-ones and molded themselves into the client's team and how well the team worked with CROs. Syner-G helped alleviate a great deal of burden from the client's team.

With Syner-G, the client achieved significant advances in its manufacturing processes for drug substance, drug product, and regulatory compliance.