SYNER-G BioPharma Group

CASE STUDY

Successful Partnership Improved Efficiencies and Reduced Overall Spend

About

The client is a small, clinical-stage oncology company focused on developing novel medicines for metastatic breast cancer patients.

Challenge

Advancing a new registration-ready drug from discovery and phase 1 clinical trials to phase 3 clinical trials is challenging. Managing the manufacturing, quality, and regulatory side of the processes (collectively called CMC – Chemistry, Manufacturing and Controls) takes a unique team with multiple areas of expertise. As a small company, the client did not have in-house team members with the skills necessary to manage all aspects of CMC effectively. Neither did they have the financial resources with which to hire such a highly qualified, specialized team.

Solution

The client chose to partner with Syner-G BioPharma Group to manage all of its CMC activities. They made the decision based on Syner-G's expertise in peptide manufacturing and because one of its founders had worked with the FDA to create accelerated guidelines for review and approval. This is a very unique expertise in the marketplace.

"Syner-G took ownership of the project as if it belonged to them, making themselves available 24/7 for real-time manufacturing concerns and engaging closely with the FDA on our behalf to satisfy regulatory and quality requirements. They are a TREMENDOUS asset to have. They feel like part of our team; they are a true stakeholder in the success of our programs."

Results

The client was impressed with Syner-G's ability to deliver value from the very first day by building highly effective communication channels across functional teams, including leadership and management. This included hosting regular meetings and maintaining project timelines and Gantt charts. Syner-G also created alignment on goals and set expectations on timing and outputs, ensuring everyone was represented on the Gantt and that they stayed on schedule. Other results included the following:

- Engaged directly with our manufacturing partners to ensure technical success and high-quality deliverables
- Reduced multiple quarters of drug development through improved efficiencies
- Reduced overall spend as a result of a phase-appropriate comprehensive CMC strategy
- Enabled registration-ready drug for late-phase clinical trials

The FDA puts as much emphasis on manufacturing capabilities as it does on safety and efficacy to ensure the manufacturer can scale with high-quality processes to meet demand. Syner-G provided that assurance.