SYNER-G BioPharma Group

CASE STUDY

Strategic CMC Development Partnership Enabling Timely Approval and Launch of a Breakthrough Product

The client is a global precision therapy biotechnology company focused on oncology.

Challenge

The client lacked the internal resources to review and validate its strategy and approach to its first commercial program. They needed CMC support for their first drug which has "breakthrough" designation. The client embraced the outsourced model and knew it could achieve its goals faster and more efficiently by partnering with experts instead of hiring internal people.

Solution

The client initially chose Syner-G because of the company's expertise in regulatory CMC. However, the client expanded the relationship and Syner-G provided CMC/Regulatory/Quality/PM consulting and contract services for various activities such as Technology transfer, process validation, CMC regulatory strategy, QA and QC. The client specifically chose to expand the relationship beause of Syner-G's demonstrated technical expertise, collaborative approach, and willingness to do whatever it takes to achieve the client's goals.

Results

The client was delighted at the "quality, experience, knowledge, and expertise" of the Syner-G team and how well they fit into the client's culture. The client's Head of Pharmaceutical Sciences says, "They were always available when needed and problem-solved immediately."

Because of the quality of the entire Syner-G team, the client knew it was going to receive the same caliber of service and expertise from everyone they worked with.

Due to the support and dedication of Syner-G over the 5-year relationship, the client was able to achieve the following:

- Successful first cycle approval
- On-time product launch
- Developed programs under very tight timelines
- Patient benefits
- Continued support for post-approval activities and more support for their subsequent drugs