SYNER-G BioPharma Group

CASE STUDY

Mobilizing Pharmaceutical Technology Transfers to a Contract Development and Manufacturing Organization (CDMO)

With decades of experience in drug development and manufacturing, Syner-G BioPharma Group is a strategic partner for biopharmaceutical companies to help fast-track their drug development programs.

CHALLENGE

Biopharmaceutical companies face significant challenges when developing new large molecule and small molecule products, with technology transfer being one of the most critical undertakings in their drug development programs. A key component of successful tech transfers is the ability to identify a contract manufacturing partner with the right combination of technical and scientific acumen, customer focus, as well as capacity. That's why an emerging biotech company turned to Syner-G's team of reputable consultants to help with their CDMO partner selection and to facilitate the tech transfer of two oral solid dose (OSD) drug products for Phase II and Phase III clinical trial programs.

SOLUTION

To support this project, Syner-G quickly assembled a cross-functional team of experts with specialized small molecule drug development and manufacturing expertise. The team was comprised of a project manager, analytical scientist, process chemist, and a formulation scientist with deep expertise in chemistry, manufacturing, and controls (CMC).

Syner-G worked closely with their client to identify the right CDMO partner with a strategic fit for their small molecule products. This process included identification of potential CDMO vendors, generation of a request for proposal (RFP) with acceptance criteria for selection, as well as conducting the vendor selection and qualification activities. Following the CDMO selection, Syner-G acted as a liaison between the sponsor and CDMO to establish clear requirements and specifications as well as develop a timeline and communication plan which proved imperative to the project's overall success.

6 MONTHS

2 DRUG PRODUCTS

2 INDs

OUTCOME

Within 6 months of asset acquisition, the team successfully facilitated the tech transfer, method validation, and drug product manufacturing at the selected CDMO and went on to support the writing and filing of two investigational new drug (IND) applications.

The Syner-G team was proud to partner on this project and rise to the challenge of delivering the clinical trial material on time and within budget for both clinical trial programs.