

Syner-G Helps Biotech Firm Successfully Advance Life-Saving Drug Through Manufacturing Startup and Clinical Trials

About

The client is a clinical-stage biotechnology company focused on the phase III development of an anti-interleukin-6 monoclonal antibody therapeutic for the potential treatment of chronic active antibody-mediated rejection, the leading cause of long-term rejection in kidney transplant recipients.

Challenge

The client had successfully advanced their drug asset to the end of Phase II clinical studies, and while they had an internal CMC (Chemistry, Manufacturing and Controls) specialist, they felt they needed a more robust, experienced team to move the drug through Phase III for manufacturing.

Solution

The client chose to partner with Syner-G based on the company's deep expertise in CMC and project management and its reputation in the industry. Syner-G helps its clients design and implement science and risk-based, phase-appropriate solutions to expeditiously advance drugs during development. 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.

Results

The client was highly impressed with the Syner-G team, not just with their depth of CMC expertise but also their professionalism, honesty, and friendliness, which helped them immediately integrate into the client company's culture. They also appreciated Syner-G's ability to manage every detail seamlessly, which helped relieve a great deal of pressure from the client's team. The client also appreciated Syner-G's openness about technical and budget issues, which was instrumental in keeping the project moving forward and meeting their goals.

The client's drug candidate is currently in multi-national clinical studies, which is a testament to the success of the Syner-G partnership.

"The Syner-G team was professional, transparent, honest, and had a very objective view of the project—in addition to just being good people."