SYNER-G BioPharma Group

CASE STUDY

From CDMO to In-House cGMP Manufacturing: Scaling Success in Cell Therapy Technology Transfer

BACKGROUND

A clinical-stage company developing innovative cell therapies for cancer and immune-mediated diseases partnered with Syner-G BioPharma Group to scale and transfer their manual manufacturing process from a Contract Development and Manufacturing Organization (CDMO) to a newly established Good Manufacturing Practice (GMP) suite at their existing facility. This critical transfer was pivotal in supporting the company's growth, enhancing operational efficiency, and preparing for upcoming clinical and commercial milestones. The primary objective was to successfully scale and transition the manual manufacturing process to the internal GMP facility while ensuring operational readiness and full compliance with both EU and FDA regulatory standards.

PROJECT SCOPE

The project scope encompassed several key activities focused on improving operational efficiency and optimizing the client's manufacturing process for their cell therapy products. It started with the development of a strategic plan to manage the process development and technical transfer from the CDMO to the internal cell therapy suite. A vital aspect of this initiative was implementing an automated cell processing platform to enable scalable GMP compliant manufacturing while optimizing formulation strategies for successful GMP runs in the new facility. Throughout this implementation, the Syner-G team managed the vendor relationship and facilitated data collection to inform user requirements and specifications for the automation platform.

Additionally, the project included extensive support for manufacturing, facility, and operational readiness. This involved establishing an Aseptic Operator Qualification (AOQ)/Media fill program, providing environmental monitoring support, developing a thorough operator training program, designing effective room layouts, ensuring material and equipment readiness, implementing cleaning protocols, and offering guidance on packaging, labeling, and software validation, among other key initiatives.

The project also addressed analytical development needs, including assay validation and clinical preparation to meet stringent quality standards. A comprehensive review of development and qualification documents was conducted, along with careful planning and management of process comparability studies to ensure consistency and compliance. Additionally, the project provided support for IND submissions, with particular focus on the Chemistry, Manufacturing, and Controls (CMC) sections.

OUTCOME

Syner-G's expert team effectively managed and supported process validation and comparability studies, ensuring the consistency and reliability of the manufacturing process. They developed comprehensive analytical qualification protocols and reports that identified key parameters for method validation. The team also conducted thorough process and equipment risk assessments to enhance operational performance and ensure regulatory compliance. Over 180 critical documents were reviewed and managed to confirm GMP readiness. The project also included the successful completion of Environmental Monitoring (EM) and Aseptic Operator Qualifications (AOQ) and Aseptic Process Simulation (APS) programs, with strategic execution of activities to support GMP batching. In the final phase, the team completed three consecutive batches in the GMP suite, including one GMP run, demonstrating robustness of the process and its readiness for scale-up.

OVERALL TIMELINE: 6 MONTHS

Syner-G's team of experts, recognized for their agility, expertise in cell therapy manufacturing, and dedication to operational excellence, was instrumental in completing this critical technology transfer for their client within just six months. Through careful planning, oversight, and execution, Syner-G helped the client establish an internal GMP cell therapy suite, setting the stage for both clinical and commercial success. This initiative not only improved operational performance but also enabled the client to foster innovation within their cell therapy manufacturing processes, ensuring scalable and high-quality production to meet future demands.