Syner·G

Case Study

From Data to Dossier:

Smart Scale-Up Solutions in Biopharmaceutical Manufacturing

Background

A leading biopharmaceutical company focused on developing innovative solutions in drug development and delivery faced a significant challenge: they needed to accelerate critical scale-up initiatives under tight timelines with limited resources. To overcome this hurdle, they partnered with Syner-G, leveraging our expertise to develop an intermediate batch size and conduct essential process development studies and characterization reports in line with their Validation Master Plan. Additionally, our team created a comprehensive Dossier for Module 3 Sections S.2.2, S.2.3, S.2.4, and S.2.5. This partnership not only addressed the client's immediate scale-up needs but also enhanced their overall agility, positioning them for long-term success in a rapidly evolving market.

Project Scope

The project scope encompassed several key activities designed to ensure compliance and a successful outcome. First, a thorough data review was conducted to achieve 100% compliance for all process validation and characterization studies, as well as Process Performance Qualification (PPQ) campaigns. Throughout this process, the team worked closely with operational and scientific staff in process development to address any challenges that arose, ensuring that the data was presented clearly and effectively. In the report generation phase, eCTD-approved templates and regulatory guidelines were utilized to create all necessary reports. This included the creation, routing, review, adjudication, and approval of supporting reports for the Dossier. Additionally, the project involved the creation and review of the Dossier itself, using the approved reports and data to generate the required sections. Collaboration with internal staff and partner organizations was essential for the thorough review and approval of all sections, facilitating a comprehensive approach to compliance and documentation.

Outcome

All requested process development, characterization, and PPQ reports were generated and approved on time, demonstrating Sequoia's commitment to efficiency and quality. The approved reports and data were effectively leveraged to generate the necessary Dossier sections. The project was successfully completed within the scheduled timeline, fully meeting the company's objective of scaling up with an intermediate batch size within 9 months.

Timeline: <9 Months

Conclusion

Syner-G's team of experts, known for exceptional planning, timely execution, and proficiency in process engineering and quality compliance, serves as a trusted partner for biopharmaceutical companies looking to scale their manufacturing operations. We specialize in process validation and the generation of essential documentation that enhances process efficiency while ensuring compliance with GMP standards. Understanding that project success depends largely on the commitment of the people involved, we prioritize consistent communication and cross-functional collaboration.

Our people-centric approach empowers our clients' teams to navigate challenges effectively and their operational objectives with confidence