

Process improvements and in-person monitoring help U.S. pharmaceutical company achieve on time for Phase III clinical trials

Challenge

Syner-G was contracted by a U.S. pharmaceutical company to oversee a 6 month, DS manufacturing as Person-In-Plant (PIP) and assist with preparation of associated submission documents related to Phase III clinical trial batches. The therapeutic agent was for lung fibrosis (Idiopathic pulmonary fibrosis) and the recent pandemic had fast-tracked the program. The CDMO site in India observed inconsistency in batch output with respect to quantity and quality.

Solution

The company partnered with Syner-G to perform onsite technical assessment for DS manufacturing process, identify bottlenecks, suggest solutions/corrective actions for obtaining consistency in batch output (both quality and quantity) and help the CDMO to meet the delivery timelines so that Phase III clinical trials are not affected.

Results

Syner-G experts conducted a gap analysis by reviewing all available data to understand the issues. Based on the findings, an experimental plan for process and quality improvement. The same was executed to identify a more robust process. Subsequently 3 successful kilo lab runs were performed followed by 6 consistently successful scale-up batches. Syner-G experts were onsite to assist the CDMO during the entire campaign. In-person trainings were provided for all stakeholders of the CDMO at appropriate intervals during the campaign. Weekly meetings were conducted with the client and CDMO for updating status and for finetuning of strategies. Client was provided with weekly reports and summary reports on completion of each activity.



Process improvements and in-person monitoring by Syner-G helped the client to get the DS with the right quality and quantity on time for Phase III clinical trials.



6 batches monitored by Syner-G experts were successful with zero OOS/deviation, meeting all the acceptance criteria.



Syner-G provided technical expertise for IND amendment.



Intervention by Syner-G helped the CDMO to improve their overall processes.