SYNER-G BioPharma Group

CASE STUDY

U.S. Pharmaceutical company improved quality of overall documentation saving time and filing delays

Challenge

Syner-G was contracted by a US Pharmaceutical Company to help improve the quality of submission documentation generated during the manufacture of a Drug Substance intended for Phase II trials. Client was outsourcing the manufacturing at a CDMO site in India and the quality documentation called for multiple revisions on Client's end, resulting in significant additional efforts and delays.

Solution

Syner-G was tasked to review and bring in the right perspective of a variety of GMP documentation – executed BMRs, validation reports, analytical reports, investigation reports related to OOS, deviations, etc. with an objective of improving the documents to be ready for filing.

Results

Syner-G reviewed each documentation and provided suggestions/comments/guidance to the CDMO to bridge the gaps observed. This enabled the CDMO to provide acceptable explanation and clarity to each gap identified in the documentation including investigation reports of incidents, OOS, and deviations. Appropriate training by Syner-G experts were provided to the stakeholders at the CDMO along with on-site visits. A tracker was maintained listing observations of each document and reconciliations were recorded. As the assignment progressed, the number of observations per document decreased to a minimal, providing documented evidence of improvement in quality of documentation. The progress of the assignment was communicated to the client through weekly reports and regular virtual meetings.

- Client was able to receive technically sound and ready to file documentations from the CDMO, thereby saving time, efforts and delays for filing.
- Overall quality of documentation was improved at CDMO site.