SYNER-G BioPharma Group

CASE STUDY

Partnership helped to reduce time to market by ensuring for U.S. based virtual Biopharmaceutical company

Challenge

Syner-G was contracted by a U.S. based virtual biopharmaceutical company, who develops drug candidates for neurological diseases, to oversee the Quality and Compliance aspects for the Drug Substances and Drug Products in various phases of Product Development. The development batches were outsourced from multiple vendors in India.

Solution

Syner-G provided the QA resource (Person-in-Plant) to review and approve DS and DP in early phase development and Phase III clinical. The responsibility included review, assessment of impact and approval of mGMP documents generated for the Drug Substance and Drug Product by the Client and the related Vendor CDMO. QA resource must ensure phase appropriate GMP compliance and QMS activities related to the project have to be tracked. Support of QP/ Regulatory audits and Supplier Qualification audits are also expected.

Results

Syner-G provided services as an extended QA team for the client. The QA Consultant supported the product development program by review and approval of documents such as Quality Agreements, Master and Executed Batch Manufacturing records, batch related Change Controls, Deviations, Investigations, analytical data, Validation reports and Stability protocols. Additionally, Syner-G experts provided suggestions on improvements in procedures to meet the quality and regulatory expectations, notified the deficiencies in documentation to vendor CDMO, lead the subsequent discussions and onsite visits which were held to address the identified concern and remedial measures were suggested. The release of the Drug substance or Drug product for formulation or clinical supplies, as appropriate, was an essential step in the process. It was thoroughly examined during the Supplier and QP audit at the Vendor CDMO sites. Furthermore, a comprehensive review of the relevant sections of the IND related to both the Drug Substance and Drug Product was conducted. Syner-G experts ensured effective communication with the client by providing regular updates and conducting virtual meetings to keep them informed about the status and progress. In addition to this, as part of the interaction with CDMOs, Syner-G engaged in weekly or biweekly discussions with the teams, including brainstorming sessions, to align efforts with the proposed product development timeline.

- Procedures were harmonised, procedures vs practises were streamlined.
- Helped to reduce time to market by ensuring Quality is built into the process in the early phases of product development.
- Helped the CDMOs to improve overall Quality Culture thereby reducing Supplier risk.