SYNER-G BioPharma Group

CASE STUDY

Partnership with a Canadian Pharma Organization resulted in savings in effort and material cost for time-critical clinical program

Challenge

Syner-G was contracted by a Canadian Pharma Company to perform an emergency Investigation Audit triggered by an OOS of a time-critical Phase II supply at a CDMO site in India.

Solution

Syner-G experts visited the CDMO site within 3 days of the partnership agreement to investigate the incident. Syner-G experts were expected to find the root cause of the incident and recommend remedial measures to save time and material critical for the Phase II trials. During the visit, Syner-G was also tasked to perform an audit of the CDMO's Quality System.

Results

Syner-G mobilized two of its experts (locally available in India) quickly and performed the tasks at the CDMO site and the investigation of the incident was completed along with the root cause identified. Syner-G experts assisted the CDMO in preparing a technically sound investigation report with appropriate CAPA. Subsequently, a QMS audit was performed. Based on the reports provided by Syner-G and remedial measures from CDMO, the batch of DS in question was re-worked to meet acceptance criteria for clinical trials.

- Client was able to save time and expensive material for time-critical clinical program.
- Personnel at CDMO were educated to handle incidents and compliance documentation in a scientific and acceptable manner.