

BUSINESS CASE

Case Study Analysis: Preparation of an EU IMPD for a biologic product



CHALLENGE

A biopharmaceutical company that had recently licensed a biological product from an Asian developer, starting Phase I of a clinical trial in the European Union, needing support to continue with the CMC development.

The project presented the following challenges:

- Identifying the main gaps in the source documentation and Asian IND dossier available to comply with EU quality guidelines and achieving a smooth evaluation in the EU.
- Limited time to perform the gap analysis and the writing of the CMC IMPD part.
- Defining the schedule and allocating resources for writing the CMC IMPD section.
- Support during all clinical phases, identifying key CMC data to be generated.
- Managing and planning milestones to achieve and regulatory interactions.



SOLUTION

CMC activities performed by Asphalion included:

- Gap analysis of existing source documentation and the Asian IND dossier to propose a mitigation strategy.
- Development of a CMC strategy to comply with the defined schedule.
- Acting as the contact point with relevant stakeholders for coordination and data gathering.
- Writing the CMC IMPD section in a coherent and consistent manner to support the clinical trial application within the agreed timeline.
- Further support after IMPD approval, including evaluation of CMC changes during the clinical trial and assessing the need for quality amendments.

Other non-CMC specific activities performed:

- Management of all regulatory activities for the clinical trial.
- Writing of the investigator's brochure (IB) and the pre-clinical and clinical IMPD sections.
- Well-planned and carefully executed project management to ensure a successful application.



OUTCOME

Successful Clinical Trial Authorization:

- No questions raised on the CMC IMPD section.
- Within the planned clinical trial start date.
- Optimized writing strategy for planned changes during the clinical trial.
- Within the agreed budget.



CLIENT TESTIMONIAL

“Thanks to the Asphalion Team for your **expertise, reliability** and **capacity** to prepare **quality** documents, thus getting us the **approval without any issues**”.