

BUSINESS CASE

Case Study: EU registration of a Biosimilar

CHALLENGE

A biopharmaceutical company located in East Asia engaged in discovering and developing biosimilar medicines, interested in entering the EU market for the first time

The project presented the following challenges:

- Setup of a multidisciplinary and integrated scientific writing team
- Definition of calendar and allocation of resources for **CTD modules writing**
- **Bridging relevant reference medicinal product data** from third-countries with EU, as well as planning and adjusting characterization studies and comparability protocols
- **Reviewing biosimilarity exercise in line with EU framework**
- Due to the complexity of biosimilar dossier writing, an **end-to-end and fully integrated project lead was required**
- Managing and **planning of Centralized Procedure** regulatory interactions and milestones

SOLUTION

The CMC activities performed by Asphalion included:

- **Gap analysis** of existing manufacturing documentation
- Development of **CMC strategy**, including comparability and biosimilarity exercise protocols
- **Pre-Submission Meeting with EMA:** agreement on critical issues, such as comparability, immunogenicity data, justification of indications and extrapolation of safety/efficacy data from different indications
- Writing of all **CMC DS and DP sections** in a coherent and consistent manner to support central claims, such as safety, comparability and biosimilarity

Other non-CMC specific activities:

- Management of the **entire MAA procedure** with all administrative, operational and eCTD publishing activities until approval
- Management of **translations** from pre-opinion until linguistic review and opinion by agencies
- Well-planned and carefully executed project management to ensure a **successful application**

OUTCOME

Successful Marketing Authorization:

- **Approved indications**, as desired by client
- **Prescription interchangeability** was granted
- Within **time-to-market** set goal
- Within **agreed budget**