

# BUSINESS CASE

## Case Study: Global Regulatory Support for a Multiregional Medicinal Product Program



### CHALLENGE

A major pharmaceutical company requested support to **register a medicinal product** with two distinct regulatory strategies **in Europe and the US** based on separate phase III trials in each region, starting from an approved EU dossier in a therapeutic indication 1 while in the US it is not authorised.

- The company needed to prepare separate **dossiers** reflecting **regional clinical data** and **regulatory requirements**.
- The European submission involved multiple **decentralized procedures (DCPs)** for a new **therapeutic indication 2**.
- The US dossier had to align with **FDA expectations** for therapeutic indications 1 and 2, requiring careful **regulatory strategy alignment** across jurisdictions.
- **Complex dossier adaptation** was therefore required.



### SOLUTION

#### Global Dossier Development and Adaptation

- **End-to-end dossier preparation** for both the EU and US, leveraging the existing EU dossier but updating Modules 1, 2, 4, and 5.
- Delivered **advice** for regulatory strategies, including inputs to paediatric waiver requests and national requirements.
- In the EU, Asphalion **adapted and compiled the entire CTD/eCTD dossier for the new therapeutic indication 2** in line with decentralized procedure (DCP) requirements, managed readability user testing, and provided critical regulatory support from validation to approval including responses to authority queries.
- In the US, tailored **medical writing for therapeutic indications 1 and 2 and eCTD submission activities** covered all required modules, including support for the NDA pathway and maintenance activities.
- **Cross-functional project management** ensured streamlined coordination, optimized timelines, and efficient resource allocation.



### OUTCOME



#### Regulatory Clarity and Confidence

Achieved **timely submission** of new regulatory dossiers in both EU and US, including documentation updates for new indications and requirements.

Enabled **simultaneous dossier submissions** across several EU states, minimizing project delays and bottlenecks.



#### Achievement of Key Milestones

Achieved accelerated and **synchronized submissions**, supporting **faster approvals** and maximizing **commercial opportunities worldwide**.



#### Accelerated Development Pathway

Established a global project model and strengthened the client's ability to manage future submissions for other indications or regions, establishing workflows adaptable to diverse global regulatory strategies.