

# BUSINESS CASE

## Case Study: Global portfolio Due Diligence

### CHALLENGE

**A big EU pharmaceutical company engaged in developing, manufacturing and commercializing a broad variety of medicinal products, interested in acquiring a whole set of worldwide brands from a company, but lacking the specific local regulatory knowledge for the audit of dossiers in certain countries.**

The project presented the following challenges:

- Over 125 MAs in **more than 25 countries** in scope of the due diligence (DD)
- Set-up of a **multidisciplinary and integrated team**, together with external local regulatory experts with sound knowledge in dossier quality, as well as regulatory procedures and regulatory intelligence
- **Reduced time** for documentation review, what required of high flexibility and adaptability (time-critical)
- **Strategic consultancy** on MA status for future company investment

### SOLUTION

**The activities performed by Asphalion included:**

- **Dossier quality review in compliance** with national guidelines and regulations and with ICH guidelines
- Regulatory intelligence and clarification on **local requirements** (such as the need of local representation, distributors, manufacturing sites and MA transfer/variations fees and timelines)
- **Executive summary report** of material findings and red flags in current MAs per country
- **Comprehensive product specific reports**

### OUTCOME

**Successful Due Diligence:**

- Assessment of dossier compliance
- In all requested countries
- Within timeline goal
- Within agreed budget

**This allowed the Client to make an informed decision about the portfolio acquisition**