

BUSINESS CASE

Case Study Analysis: Global regulatory procedures



CHALLENGE



SOLUTION



OUTCOME



- **Expand local business**
- No regulatory knowledge in complex EU procedures

- Global registration strategy and role of MAH
- **5-year** plan to register **7 products** in **20 EU** countries through DCPs, RUPs, and NPs
- Strategic reports, gap analysis, coordination with HA, dossier preparation and submission, follow-up until authorization, dossier maintenance activities

- **+65 MAs obtained** in 12 European markets



- **Launch in the US as new market with an innovative product**
- No regulatory knowledge

- Bridging EU with the US
- Pre-submission activities
- Dossier adaptation and update from EU dossier for DDA for a NDA submission
- M1 preparation
- ISS and ISE
- US Agent services

- **Successful NDA approval in a pioneer timeline**



- **Expand to the UK market post-Brexit**
- No experience nor capability

- Comprehensive services from RA to publishing and submission, including pharmacovigilance
- **Adapting to post-Brexit regulation**, optimizing time to market and ensuring continuous compliance in the UK

- **5 products registered post-Brexit via NPs and new IRPs**



- **Expand the business worldwide in record time**
- Not enough internal resources

- **2,5 FTEs** for the **global registration strategy and operational support** during procedure and up to approval
- Preparation, compilation and submission of dossiers
- Coordination with HA (and with local partners)
- Follow-up and project management during all the procedure
- Implementation of a KPI reporting

- **180 MAA in +32 different RoW countries in one year** (GCC, Africa, Asia and CIS)

BUSINESS CASE

Case Study Analysis: Support during Life-Cycle Management



CHALLENGE



SOLUTION

The activities performed by Asphalion included:



OUTCOME

Search for an external provider to **outsource the life-cycle maintenance** of legacy products worldwide

- **6 FTEs** dedicated on the full life-cycle maintenance
- **New drug applications, variations, renewals, MAH transfers and pre/post-approval activities**
- Publishing
- Global Strategic labelling support
- RIMS management

+4 year's maintaining outsourced portfolio of **3 products** with over **360 MAs** worldwide

Search for an external provider to **outsource the life-cycle maintenance** of legacy products in RoW

- **2 FTEs** dedicated on the full life-cycle maintenance
- **Renewals, variations, transfers of ownership, new roll-outs, RIMS update and publishing**
- **Dossiers Submission** service in each country, and **CTD/eCTD publishing** tailored for **the GCC region**.
- Partner management
- Coordination of multi-language mock-ups and their implementation across countries

+10 year's maintaining outsourced portfolio of **15 products**

An increased workload exceeded internal capacity, necessitating **quick and flexible resource allocation**

- **2 FTEs**, ensuring optimal resource utilization and efficiency across projects
- **Flexible service** modality based on the real monthly dedication of time.
- Adaptation to client's workflows and internal systems
- Coordination with internal departments and stakeholders

- Maintenance activities for **+130 procedures**
- **Rescued + 20 MAs** from sunset clause
- +10 new MAs and +7 MATs