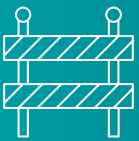# CASE STUDY
EFFICIENCY GAINS WITH STRATEGIC OUTSOURCING OF MATURE PRODUCT PORTFOLIO

THE CHALLENGE

Top 20 global biopharmaceutical and life sciences company, with robust portfolio of more than 70 products in various therapeutic areas. Looking to outsource regulatory affairs support for mature product portfolio (430+ Marketing Authorizations (MAs) across Europe and 1,900+ MAs in other regions, including Canada, Australia and China).
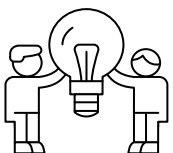
THE SOLUTION

PharmaLex successfully delivered global HQ and local (E-2-E) regulatory maintenance services, by taking over core responsibilities and providing holistic support for strategic and operational CMC, publishing and submission activities, as well as pharmacovigilance and medical affairs support.

As part of the engagement, the team:
- Implemented a lean governance structure
- Implemented process improvement efforts
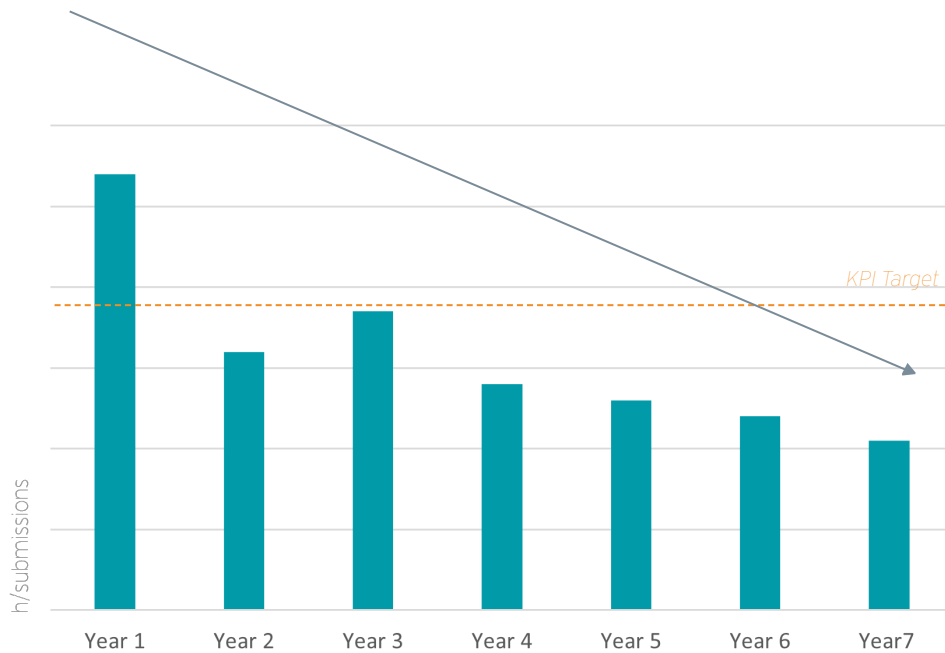- Established and tracked KPIs to deliver on efficiency gains

THE OUTCOME

- Client was able to refocus internal resources on core strategic activities
- Overall reduction of workload due to efficiency gains by up to 20%
- Reduced process complexity
- Scalable and flexible resource model ensured long-term stable partnership. Currently program is running in its 8th year continuing to bring efficiency gains.

➤ PHARMALEX

CASE STUDY

TOP 20 BIOPHARMACEUTICAL COMPANY WAS ABLE TO SAVE TIME AND BOOST EFFICIENCY, WHILE SIGNIFICANTLY REDUCING COSTS

Efficiency KPI Development

KPI Target

h/submissions

Year 1   Year 2   Year 3   Year 4   Year 5   Year 6   Year7

Source: PharmaLex

Efficiency Gains

Time savings
Proven track record showing significant decreased time invested per submission

Higher volumes
During the seven years of partnership, the number of products outsourced to PharmaLex has doubled. Today, we maintain 60% of client established portfolio.

Cost savings
Smart allocation of staff and distribution of tasks led to significant cost savings

Quality enhancement
Stable senior team with high focus on quality delivery
(Quality KPI met), a technology-based approach was involved

Flexibility
Ad hoc/Expert support in numerous other projects with qualified trained and onboarded staff

➤ **PHARMA**LEX