



## PORTFOLIO MAINTENANCE OUTSOURCING

 A PHARMALEX SOLUTION THAT  
EXCEEDS YOUR EVOLVING NEEDS

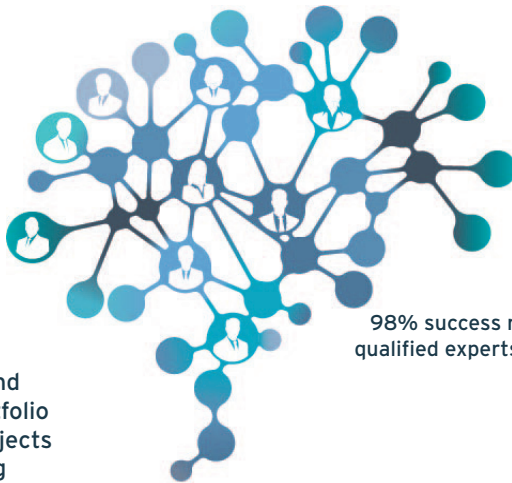
Today's ever-changing market requires expertise and innovative solutions to overcome the challenges of tomorrow. PharmaLex combines global reach and many years of experiences, to provide a **viable Strategic Outsourcing** solution, capable of maintaining your products throughout the life cycle while ensuring the **highest quality and compliance**.

The maintenance of approved products is essential and critically important for compliance. PharmaLex is able to support companies to refocus their workload on **core strategic competencies**, and alleviate the challenges caused by **constant demands** for pre- and post-approval activities.

## EXPERT KNOWLEDGE COMBINED WITH A GLOBAL FOOTPRINT:

All activities handled under agreed budget - no change orders necessary

Projects with 400+MAs across 40+ countries (ICH & non-ICH regions)



4 major global and 10+ regional portfolio maintenance projects currently running



98% success rate in staffing highly qualified experts within agreed time-frame

All operational activities handled by PLX - minimal client oversight necessary



MARKET &  
LAUNCH

PRODUCT  
MAINTENANCE



“What was especially important to me was their ability to get a team, with the right experience, together so quickly.”

- Head of Outsourcing,  
Mid-sized Biotech Company

## PHARMALEX CAN OFFER SUPPORT IN THE FOLLOWING AREAS:

- ▶ Provision of full regulatory responsibilities including global labeling
- ▶ Establishment of clear program governance structures
- ▶ Controlling and performance measurement via budget & KPIs
- ▶ Guiding process consultancy and operative innovations
- ▶ Supporting large globally acting customers with small or large number of established products

Submissions successfully  
passing internal review

**QUALITY**

**Regulatory  
Project  
Success**

**BUDGET**

Resource investment per  
submission

**TIME**

Submissions  
delivered in time

[contact@pharmalex.com](mailto:contact@pharmalex.com)  
[www.pharmalex.com](http://www.pharmalex.com)



**Dr. Constanze Burkhardt**  
 Senior Director,  
 Strategic Outsourcing  
[constanze.burkhardt@pharmalex.com](mailto:constanze.burkhardt@pharmalex.com)



**Dr. Katharina Schroeder**  
 Director, Principal Consultant  
 Regulatory Affairs  
[katharina.schroeder@pharmalex.com](mailto:katharina.schroeder@pharmalex.com)

## DELIVERING SUCCESS WITH CONFIDENCE

PharmaLex is one of the largest providers for Development Consulting, Regulatory Affairs, Quality Management & Compliance and Pharmacovigilance, Epidemiology, and Risk Management worldwide. Our global teams of experts can take you through early strategic planning activities and non-clinical requirements to clinical development, through regulatory submission processes and finally guide you to market approval and product maintenance post-launch activities.



*“Since our founding in 1994, every single one of our clients is our top priority! We lead where others follow. We help clients to go beyond compliance, to capitalize on greater efficiencies, streamline complexity and to deliver true business value.*

*Ask us how we can make your job easier - over 600 customers are glad they did.”*

Dr. Thomas Dombeyer, CEO

## PHARMALEX IN NUMBERS

