PHARMALEX
CONFIDENCE BEYOND COMPLIANCE

VALUE ADDED MEDICINES

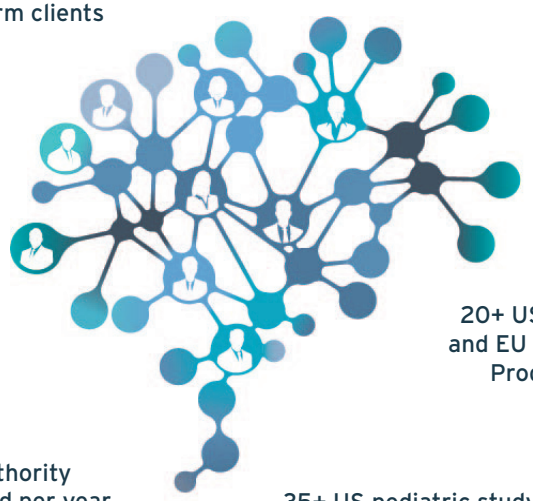
A PHARMALEX SOLUTION THAT MEETS YOUR EVOLVING NEEDS

Value Added Medicines developments aim at enhancing well-established, off-patent molecules by optimizing their efficacy, tolerability, or ease of use or even exploring them in new indications. Despite the obvious benefits these products offer to the patient, the lack of adequate incentives, pricing and reimbursement for these products, call for time- and cost optimized development and regulatory strategies.
PharmaLex can leverage decades of international drug development & registration experience to help move your development idea into action. We have successfully managed development efforts from the lead compound/idea through to market approval and life-cycle management worldwide. Let our experts design a strategic solution that is tailored to your development goals.

EXPERT KNOWLEDGE COMBINED WITH A GLOBAL FOOTPRINT:

9 out of the top 10 pharmaceutical companies are valued long-term clients

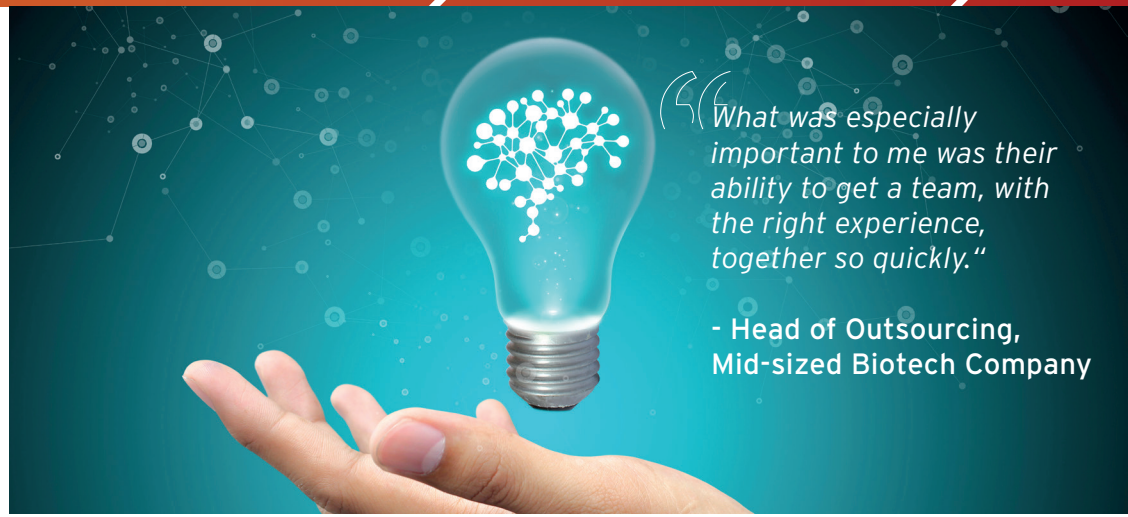
6+ Adaptive Pathway and PRIME eligibility applications, Breakthrough designations



20+ US Orphan Product and EU Orphan Medicinal Product designations

40+ health authority interactions led per year

35+ US pediatric study plans / EU paediatric investigation plans



PHARMALEX CAN OFFER SUPPORT IN THE FOLLOWING AREAS:

- **Development Strategy and Gap Analysis**
  - Creation of development plans and target product profiles
  - Managing health authority interactions (meetings, written advice)
- **CMC, Non-clinical and Clinical Development Consultancy**
  - Study design & protocol development incl. biostatistics & data management
  - Regulatory writing (e.g. eCTD Module 2 documents, ISS / ISE)
- **Quality Program Development and Review**
  - Developing fit-to-purpose QA and QC programs
  - Due Diligence evaluation of QA Systems
- **Submission Management**
  - Marketing applications and regulatory procedure management worldwide (including MAA, NDA / BLA)
  - Clinical Trial Applications (e.g. IND / IMPD)
- **Leveraging special regulatory provisions to optimize development & approval time and price negotiations**
  - Orphan drug designations (EU, US)
  - Pediatric development plans / waivers (PIP / PSP)

contact@pharmalex.com
www.pharmalex.com

Caren Martini
Senior Director, Head of Development Consulting & Scientific Affairs
caren.martini@pharmalex.com

Dr. Martina Steiper
Senior Director, Principal Consultant Development & Regulatory Strategy
martina.steiper@pharmalex.com

DELIVERING SUCCESS WITH CONFIDENCE

PharmaLex is one of the largest providers for Development Consulting, Regulatory Affairs, Quality Management & Compliance and Pharmacovigilance, Epidemiology, & 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 Dobmeyer, CEO

PHARMALEX IN NUMBERS

PHARMALEX