PHARMALEX
CONFIDENCE BEYOND COMPLIANCE

OUR WRITING CAPABILITES

A PHARMALEX SOLUTION THAT MEETS YOUR EVOLVING NEEDS

DISCOVERY / NON-CLINICAL

CLINICAL DEVELOPMENT

9 OUT OF THE TOP 10
pharmaceutical companies are valued long-term clients

UP TO 20% TIME SAVED
by bundling services dealing with all health agency obligations

TECHNICAL WRITING

CMC / quality writing for regulatory submissions

- Global market applications (e.g. MAA / BLA / NDA)
- Life-cycle activities (CMC variations, changes, annual reports, MA renewals)
- Clinical trial applications (e.g. IMPD / IND)
- Briefing documents for regulatory authority meetings / scientific advice
- Chemical & biological pharmaceuticals, e.g. biotechnology-derived molecules (e.g. mABs, fusion proteins, biosimilars), ATMPs, ADCs, herbals

REGULATORY WRITING

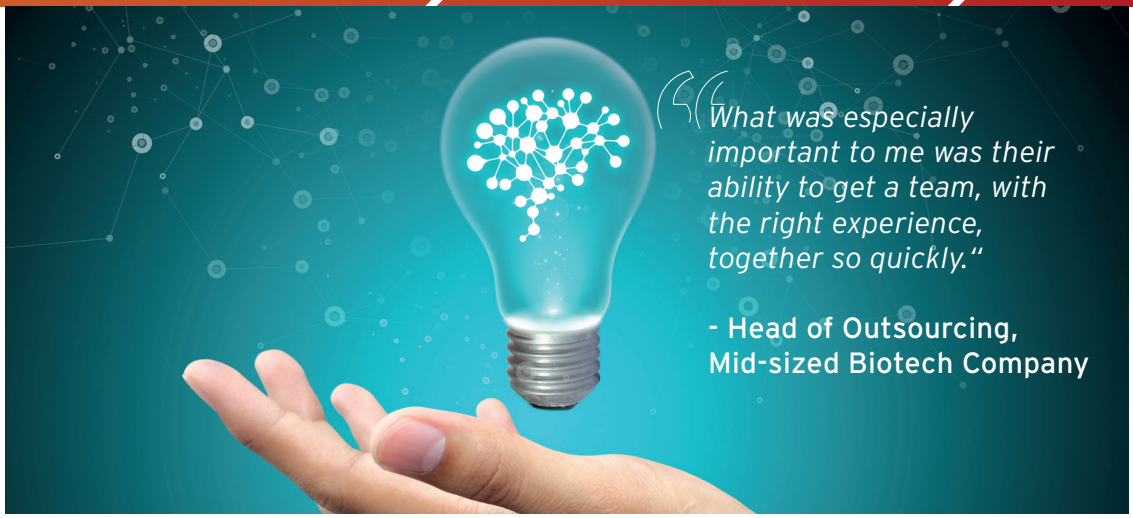
Regulatory/non-/clinical writing for regulatory submissions (early new drug developments & LCM)

- Toxicological impurity evaluations
- Orphan applications (EU / US)
- Pediatric development plans (EU PIP / USA PSP)
- Investigator's brochures
- Briefing documents for regulatory authority meetings / scientific advice
- Clinical trial applications (e.g. IMPD / IND)
- Non-clinical and clinical reviews & summaries (e.g. MAA / BLA / NDA)
- Integrated summaries of safety and efficacy (ISS / ISE)
- Environmental risk assessments (EU / USA)
- Labeling / CCDS preparation

PHARMALEX

MARKET & LAUNCH

PRODUCT MAINTENANCE



MEDICAL WRITING

Documents related to the conduct of clinical studies

- Clinical study concepts & outlines
- Clinical study synopses
- Clinical study protocols
- Clinical study reports
- Amendments to study protocols and study reports

SCIENTIFIC WRITING

Non-/clinical writing for non-regulatory purposes

- Scientific publications
- Abstracts
- Promotional material
- Product brochures
- Product monographs

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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 Dobmeyer, CEO

PHARMALEX IN NUMBERS

PHARMALEX