PHARMALEX

VALUE ADDED MEDICINES

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 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 lifecycle management worldwide. Let our experts design a strategic solution that is tailored to your development goals.

A PHARMALEX SOLUTION THAT MEETS YOUR EVOLVING NEEDS

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 (MAA, NDA / BLA) e.g. 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)

9 out of 10 top pharma companies are our valued clients

20+ Adaptive Pathway, PRIME, Fast Track and Breakthrough designation Therapy requests

30+ US Orphan Product and EU Orphan Medicinal Product designations

50+ US pediatric study plans / EU paediatric Investigational plans

InnoPHLEX

DISCOVERY / NON-CLINICAL

CLINICAL DEVELOPMENT

APPROVAL / AUTHORIZATION

PRODUCT MAINTENANCE

SourcePHLEX

DELIVERING SUCCESS WITH CONFIDENCE

PHARMALEX IS A LEADING PROVIDER OF SPECIALIZED SERVICES FOR THE PHARMA, BIOTECH AND MEDICAL DEVICE INDUSTRIES

KNOWLEDGE.
ACCELERATED.
confidence *beyond* compliance

We guide you from early strategic planning activities and non-clinical requirements through clinical development, regulatory submission processes and post-approval / maintenance post-launch activities.

Our experts use **technology-enabled solutions** to support you through the entire product lifecycle. We deliver exceptional results – going above and beyond the standard to deliver tailor-made solutions worldwide.

The PharmaLex Group now has over **1000** employees, with **33** offices in **21** countries and more than **600** satisfied clients worldwide.

Stay **one step ahead** of essentials requirements needed by health agencies. Our knowledge accelerates your business sucess...

Knowledge. Accelerated.

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STRATEGY & CONSULTING REGULATORY AFFAIRS PHARMACOVIGILANCE QUALITY MEDICAL AFFAIRS

1000+
SUBJECT MATTER EXPERTS WORLDWIDE

25+ YEARS
OF INDUSTRY EXPERIENCE

9/10
TOP PHARMACEUTICAL COMPANIES ARE OUR SATISFIED CLIENTS

40+ NATIONALITIES
ON STAFF, INCLUDING FORMER FDA AND EMA EXPERTS

50+%
OF OUR PROJECTS ARE GLOBAL