PHARMALEX
CONFIDENCE BEYOND COMPLIANCE

REGULATORY AFFAIRS APPLICATION SERVICES

A PHARMALEX SOLUTION THAT MEETS YOUR EVOLVING NEEDS

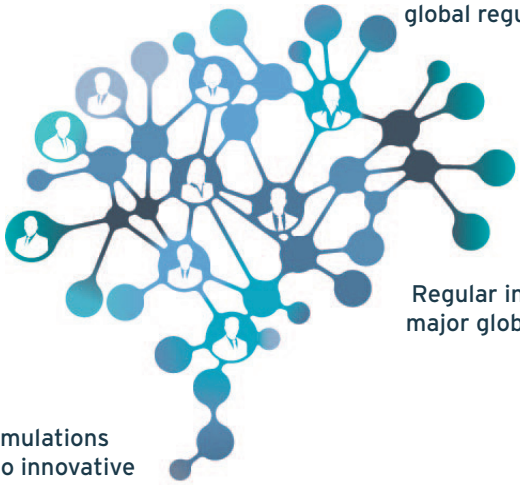
There are strict regulations worldwide that set the framework on how to reach market access. Our regulatory affairs team offers profound knowledge to develop the optimal strategy to obtain marketing authorization.

Numerous opportunities to gain experiences contribute to evolve pragmatic approaches to maintain your product across the lifespan. We provide monitoring of the regulatory environment through various channels and have the capacity and experience to leverage this knowledge to draw conclusions from a cumulated brain tank.

EXPERT KNOWLEDGE COMBINED WITH A GLOBAL FOOTPRINT:

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

20+ years of experience in global regulatory submission



Regular interactions with all major global health agencies

Covering all formulations from generics to innovative release mechanisms

Proven track record with 6,000 successfully completed projects

MARKET & LAUNCH

PRODUCT MAINTENANCE

"Successful strategies call for sound, in-depth experience to create a targeted and effective content submission for your project."

- Global Head of Regulatory Affairs, Large Pharma Company

PHARMALEX CAN OFFER SUPPORT IN THE FOLLOWING AREAS:

- Clincial Trial Applications
  - Clinical trial and ethics dossier requirements
  - Voluntary harmonization procedure
- Marketing Authorization Applications
  - Application format and filing requirements
  - Procedure management and health agency interaction
- Lifecycle Activities
  - Complete implementation procedures
  - Efficient submission strategy
- Product Information Management
  - CCDS/CCSI update management
  - Readability testing and translation services
- Regulatory Intelligence
  - Implications on product development
  - Adherence to regulatory compliance

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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 nonclinical 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