



REGULATORY AFFAIRS APPLICATION SERVICES

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*.



A PHARMALEX SOLUTION THAT MEETS YOUR EVOLVING NEEDS

- **Clinical 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



9 out of 10 top pharma companies are our valued clients



Covering all formulations from generics to innovative release mechanisms



Regular interactions with all major global health agencies



Proven track record with 6,000 successfully completed projects

InnoPHILEX
DISCOVERY /
NON-CLINICAL

CLINICAL
DEVELOPMENT

APPROVAL /
AUTHORIZATION

SourcePHILEX
PRODUCT
MAINTENANCE

DELIVERING SUCCESS WITH CONFIDENCE

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

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 success...

Knowledge. Accelerated.



**KNOWLEDGE.
ACCELERATED.**
confidence beyond compliance

CONTACT US



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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