



## OPERATE A FUNCTIONAL AND EFFICIENT PHARMACEUTICAL QUALITY SYSTEM

A **functional pharmaceutical quality system** is not only a regulatory requirement, but also an integral element in pharmaceutical organizations to assure **products' pharmaceutical quality** and **patients' safety**. A well-designed and **efficient quality system** will serve as a safe and sound basis for your business. It documents and verifies your approach for high quality products towards health agencies.

We have a broad spectrum of competencies in **GxP quality management** as well as in adjoining regulatory areas. This approach allows us to manage interfaces even in complex situations and provide additional value especially for **small- and medium-sized organizations**.



### A PHARMALEX SOLUTION THAT MEETS YOUR EVOLVING NEEDS

- Providing consultancy, gap analyses and operational support on GxP topics
- Designing, implementing and optimizing your GxP quality system
- Preparing applications for manufacturing and wholesale distribution authorizations
- Designing and documenting processes as SOPs
- Implementing risk management approaches / FMEA analyses
- Planning and performing GxP audits and self-inspections (incl. CAPA management)
- Preparing and supporting health agency inspections
- Supporting remediation activities



*GxP experts with 20+ years of experience*



*Strategic consultancy & operational support*



*Experienced GMP / GDP-auditors*



*External know-how & building in-house capabilities*

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