



**OPERATE A FUNCTIONAL AND EFFICIENT  
PHARMACEUTICAL QUALITY SYSTEM**

 **A PHARMALEX SOLUTION THAT  
MEETS YOUR EVOLVING NEEDS**

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**.

## EXPERT KNOWLEDGE COMBINED WITH A GLOBAL FOOTPRINT:

Experienced  
GMP / GDP-auditors



GxP experts with  
20+ years of experience



Strategic consultancy &  
operative support



Successful interactions with  
various health agencies



External know-how & building  
in-house capabilities



MARKET &  
LAUNCH

PRODUCT  
MAINTENANCE



*We provide comprehensive and tailor-made consultancy and operative GxP support."*

- Dr. Jörg Strähle  
Senior Director, CMC Services,  
Head of Regulatory CMC

## PHARMALEX CAN OFFER SUPPORT IN THE FOLLOWING AREAS:

- ▶ Providing consultancy, gap analyses and operative support on GxP topics
- ▶ Designing, implementing and optimizing your GxP quality system
- ▶ Preparing applications for manufacturing and wholesaling 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

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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 Dombeyer, CEO

## PHARMALEX IN NUMBERS

