



REGULATORY COMPLIANCE
ASSESS YOUR RISK PROFILE AND STRENGTHEN
YOUR REGULATORY COMPLIANCE

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

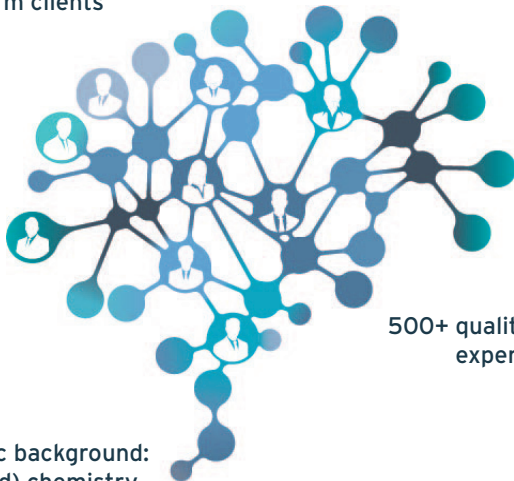
Pharmaceutical companies are marked by factors such as external changes in the regulatory environment and internal **Merger & Acquisition programs**, entry into new markets (especially non-ICH regions) or changes in the product portfolio. Strategic decisions are often done by senior management without prior **consultation of regulatory teams and QPPVs**. These actions sometimes lead to compliance issues, which may have serious consequences from a delay in product approval requiring corrective actions up to product recalls and the loss of marketing authorizations. Our team of CMC and GxP experts will help you make your **compliance proactive** and in line with health agencies' requirements.

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 maintenance support and CMC



500+ quality overall summary expert reports prepared



Broad scientific background: pharmacy, (food) chemistry, biology, biochemistry, biotechnology

Proven track record with 6,000 successfully completed projects



MARKET &
LAUNCH

PRODUCT
MAINTENANCE



PharmaLex provides recommendations for improvements and suggestions in a very constructive way. We have very unique needs with strict SOPs, but they support us to identify new solutions and make it happen."

- Head of Compliance, Global Pharmaceutical Company

PHARMALEX CAN OFFER SUPPORT IN THE FOLLOWING AREAS:

- ▶ Preparation audit inspection (incl. CAPA-management) compliance check
- ▶ Gap analysis / due diligence (e.g. in-licensing activities)
- ▶ CMC maintenance support: change control and quality variations
- ▶ GxP services (GMP, GACP, GDP, GCP)
- ▶ Implementing risk management approaches / FMEA analyses designing, implementing and optimizing your GxP-quality system
- ▶ CMC and technical writing
- ▶ Optimization of the supply chain
- ▶ Product scope includes human and veterinary medicinal products comprising all types of APIs (chemicals, biologicals, biosimilars, herbals & homeopathic)

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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

