PHARMALEX

REGULATORY CMC COMPLIANCE

ASSESS YOUR RISK PROFILE AND STRENGTHEN YOUR REGULATORY COMPLIANCE

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.

A PHARMALEX SOLUTION THAT MEETS YOUR EVOLVING NEEDS

- 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)

20+ years of experience in global regulatory maintenance support and CMC

100+ CMC experts Worldwide

500+ quality overall summary expert reports prepared

Proven track record with 6,000 successfully completed projects

InnoPHLEX

DISCOVERY / NON-CLINICAL

CLINICAL DEVELOPMENT

APPROVAL / AUTHORIZATION

PRODUCT MAINTENANCE

SourcePHLEX

DELIVERING SUCCESS WITH CONFIDENCE

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

KNOWLEDGE.
ACCELERATED.
confidence *beyond* compliance

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 sucess...

Knowledge. Accelerated.

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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