PHARMALEX

REGULATORY CMC COMPLIANCE
IMPLEMENTING A SUSTAINABLE APPROACH TO THE CMC COMPLIANCE PROCESS

CMC (Chemistry, Manufacturing and Control) compliance is an important component in the lifecycle of a medicinal product, but is one that is continually challenged by many factors, including: Mergers & Acquisitions, increasingly complex networks of internal / external manufacturing sites and insufficiently robust internal processes to manage complexity and cross- functional interfaces.
These factors often 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.

A PHARMALEX SOLUTION THAT MEETS YOUR EVOLVING NEEDS

- Our team of CMC and Quality experts will help you make your compliance proactive and in line with health agencies' requirements , supporting the uninterrupted supply of medicines to patients.
- Besides broad experience, we bring a standardized approach and ready-to-use templates for compliance gap analysis and remediation to the table.
- We can provide the necessary resources to manage such projects even under high time constraints.

OUR SERVICES OFFERINGS INCLUDE

- CMC Due Diligence (e.g. in-licensing activities) / Gap Analysis
- Product / Patient Impact Assessment
- Development & implementation of risk-based gap remediation plan
- CMC Technical Writing
- Root Cause Analysis of gaps in CMC information
- Preparation of regulatory health authority inspection (including CAPA - Management)
- CMC maintenance support: change control and quality variations
- Design, development and optimization of your GxP-Quality System
- Product scope includes human and veterinary medicinal products comprising all types of APIs (chemicals, biologicals, herbals & homeopathic)

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

125+ CMC experts Worldwide

750+ quality overall summary expert reports prepared

Proven track record with 7,500 successfully completed projects

InnoPHLEX

DISCOVERY / NON-CLINICAL

CLINICAL DEVELOPMENT

AUTHORIZATION / APPROVAL

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