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:

- Merger and Acquisition (M&A) programs - where significant numbers of product licenses are transferred,
- Increasingly complicated networks of internal / external CMOs, and
- Insufficiently robust internal processes in place within an organization 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. 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.

A PHARMALEX SOLUTION THAT MEETS YOUR EVOLVING NEEDS

- CMC due diligence (e.g. in-licensing activities) / gap analysis
- Product / patient impact assessment
- Development and implementation of risk-based gap remediation plan
- CMC and technical writing
- Root Cause Analysis of gaps in CMC information
- Preparation for regulatory health authority inspection (incl. 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, biosimilars, herbals & homeopathic)

25+ 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

MARKETING AUTHORIZATION / APPROVAL

PRODUCT MAINTENANCE

SourcePHLEX

DELIVERING SUCCESS WITH CONFIDENCE

CONTACT US

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"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 Dobmeyer, CEO

PharmaLex is one of the largest specialized providers of **Development Consulting, Regulatory Affairs, Quality Management & Compliance and Pharmacovigilance, Epidemiology & 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.

PharmaLex supplies the widest range of **highly-skilled leading experts**. Our experienced teams span **all geographies** to expedite product developments and provide **access to much needed resources**.

Stay **one step ahead** of essential requirements needed by health agencies worldwide. Our knowledge accelerates your business success...

Knowledge. Accelerated.

KNOWLEDGE.
ACCELERATED.
confidence *beyond* compliance

900+
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