PHARMALEX

CONTENT AND REVIEW OF CHEMISTRY, MANUFACTURING AND CONTROL (CMC)

Our Chemistry, Manufacturing and Controls (CMC) group provides regulatory guidance in setting specifications, method development and validation of documentation. We can help you build a positive relationship with EMA, FDA or your local health agencies.

Whether it is a case of first-time submission, change control or maintenance throughout the lifecycle, our multi-disciplinary teams take care of GxP, technical writing, regulatory strategy, change control and submissions on a global basis. We have a great record of success in supporting your CMC needs – both chemicals and biologicals.

A PHARMALEX SOLUTION THAT MEETS YOUR EVOLVING NEEDS

- Product scope includes human and veterinary medicinal products comprising all types of APIs (chemicals, biologicals, biosimilars, herbals & homeopathics)
- Strategic consultancy during pharmaceutical development and lifecycle management
- Compilation of quality dossiers (ICH and non-ICH)
  - CTD modules 3 and 2.3
  - IMPD, IND
  - ASMF / DMF, CEP
  - Normative document
- CMC and technical writing
- CMC maintenance support: change control and quality variations
- Gap analysis / due diligence (e.g. in-licensing activities)
- CMC and GMP compliance
- Optimization of the supply chain
- GxP services (GMP, GACP, GDP) including audits

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