PHARMALEX

ADVANCED THERAPIES

NAVIGATING THROUGH THE REGULATORY FRAMEWORK

Since the introduction of the Tissue and the Advanced Therapy Medicinal Products (ATMP) regulatory framework in the EU and the corresponding US framework programs for cell-based or gene therapy products, we support clients in navigating through this highly challenging environment.

Due to the rapidly evolving ATMP landscape it's key to have up-to-date knowledge and expertise to successfully develop a product and gain a centralized market authorization (MA) in Europe and / or a Biologic License Authorization (BLA) in the US. ATMP development requires experts and specific experience in regulatory strategy, CMC and clinical development a unique management of various aspects throughout the overall development pathway.

A PHARMALEX SOLUTION THAT MEETS YOUR EVOLVING NEEDS

- Full regulatory support for development, authorization and lifecycle management
- Consulting on appropriate development strategies (e.g. biodistribution, tumorigenicity, orphan designation)
- Support for specific procedures like classifications, certifications, Orphan designations, SME application, GMO application etc.
- Preparing and participating at ITF, SA at EMA or national authorities and FDA
- Facilitating the communication with scientific committees of EMA (e.g. CAT, PDCO, COMP) and FDA (e.g. Advisory Board meetings)
- Writing of documents for clinical trials in EU or US (i.e. IMPD, IND, IB)
- Development of PRIME, hospital exemption, compassionate use for patients and early access programs
- Developing and writing of paediatric investigation plans
- Writing or review of all CTD documents for MA applications

Navigate EU and US development in parallel

Accelerate time to revenue by using our excellent network with competent authorities

10+ years of experience in regulatory ATMP development

98% success rate in staffing highly qualified experts within agreed time frame

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.

CONTACT US

contact@pharmalex.com

/company/pharmalexglobal

www.pharmalex.com

@PharmaLexGLOBAL

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