PHARMALEX
CONFIDENCE BEYOND COMPLIANCE

ADVANCED THERAPIES
NAVIGATING THROUGH THE REGULATORY FRAMEWORK

A PHARMALEX SOLUTION THAT MEETS YOUR EVOLVING NEEDS

DISCOVERY / NONCLINICAL

CLINICAL DEVELOPMENT

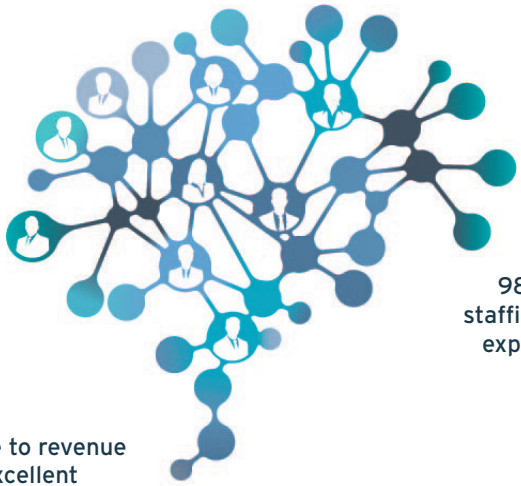
Since the introduction of the Tissue and the Advanced Therapy Medicinal Products (ATMP) regulatory framework in the EU and the corresponding US framework programs for cell-based or gene therapy products, we support clients in navigating through this highly challenging environment.

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.

EXPERT KNOWLEDGE COMBINED WITH A GLOBAL FOOTPRINT:

60% of our customer base represent small and mid-sized enterprises

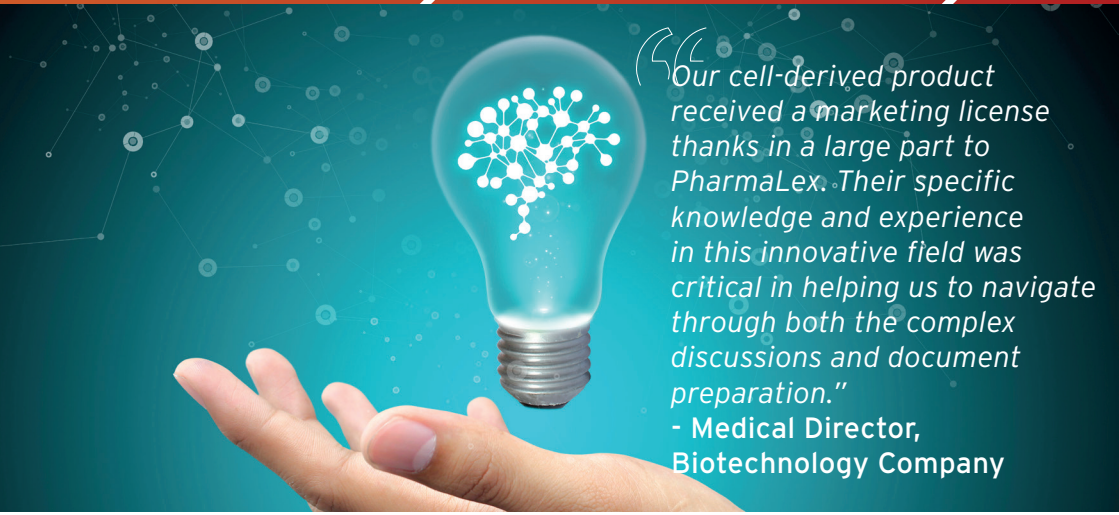
Navigate EU and US development in parallel



98% success rate in staffing highly qualified experts within agreed timeframe

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

10+ years of experience in regulatory ATMP development



"Our cell-derived product received a marketing license thanks in a large part to PharmaLex. Their specific knowledge and experience in this innovative field was critical in helping us to navigate through both the complex discussions and document preparation."
- Medical Director, Biotechnology Company

PHARMALEX CAN OFFER SUPPORT IN THE FOLLOWING AREAS:

- Full regulatory support for development, authorization and life-cycle 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

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DELIVERING SUCCESS WITH CONFIDENCE

PharmaLex is one of the largest providers for 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 nonclinical requirements to clinical development, through regulatory submission processes and finally guide you to market approval and product maintenance post-launch activities.

> *"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 IN NUMBERS

200+
EXPERIENCED AND CERTIFIED LOCAL REPRESENTATIVES SUPPORTING OUR GLOBAL COVERAGE

25+ YEARS
OF INDUSTRY EXPERIENCE

9/10
TOP PHARMACEUTICAL COMPANIES ARE OUR SATISFIED CLIENTS

40+ NATIONALITIES
ON STAFF, INCLUDING FORMER FDA AND EMA EXPERTS

60% OF OUR CUSTOMER BASE REPRESENT SMALL AND MID-SIZED ENTERPRISES