PHARMALEX
CONFIDENCE BEYOND COMPLIANCE

BIOPHARMA - CMC

A PHARMALEX SOLUTION THAT MEETS YOUR EVOLVING NEEDS

DISCOVERY / NON-CLINICAL

CLINICAL DEVELOPMENT

Biopharmaceuticals are an unprecedented success story. Due to their outstanding efficacy and safety and their high potential to address unmet medical needs, biopharmaceuticals are by far the fastest-growing part of the industry and are already making up 20 percent of the global pharma market.

But the effort and amount of technological skills required for the development and production of these complex molecules are both challenging and evolving rapidly, and so are the associated expectations of the regulators. Therefore it is essential to account for regulatory requirements early on in development and to carve out the most efficient path to approval to ensure commercial success.

Based on a broad global project experience, we at PharmaLex recommend an integrated solution combining our scientific, technological and regulatory expertise to meet your specific support needs, both for specific aspects or for the complete development process.

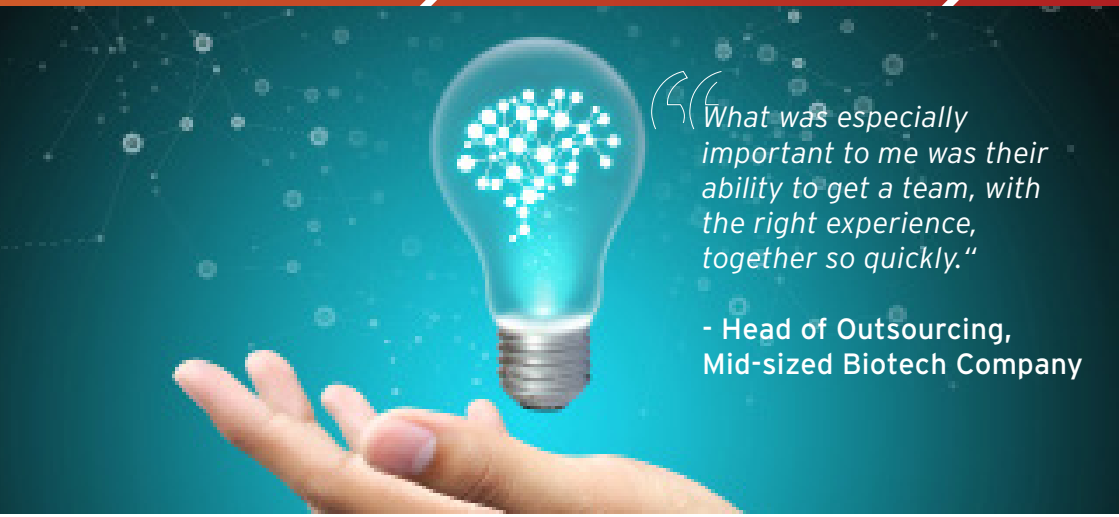
EXPERT KNOWLEDGE COMBINED WITH A GLOBAL FOOTPRINT:

The product types we support include:

- Recombinant proteins (e.g. mAbs (and derivatives), hormones, enzymes, fusion proteins)
- Tissue, cell and gene therapy products / ATMPs
- Biosimilars
- (Non-recombinant) biologicals isolated from living sources
- Peptides
- Antibody drug conjugates (ADC)
- Vaccines (recombinant proteins, live attenuates and recombinant vector vaccines)

9 out of the top 10 pharmaceutical companies are valued long-term clients

Up to 20% time saved by bundling services dealing with all health agency obligations



PHARMALEX CAN OFFER SUPPORT IN THE FOLLOWING AREAS:

- Development and regulatory strategy considering regional requirements (e.g. US, EU, Canada, Japan, Emerging Markets)
- Gap Analysis / Due diligence
- Technical writing and compilation of regulatory documents
- Scientific advice and other health agency meetings
- Risk assessment
- Preparation of TPP
- Comparability exercises
- General ‘troubleshooting’, including investigations and root cause analysis and support for CAPA
- Deviation and change control preparation / review
- Method / process validation
- Process characterization
- Project management

contact@pharmalex.com
www.pharmalex.com

Zeb Younes
Director,
Regulatory Affairs CMC
zeb.younes@pharmalex.com

Swen Grein
Director,
Head of Regulatory CMC
swen.grein@pharmalex.com

DELIVERING SUCCESS WITH CONFIDENCE

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

"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

PHARMALEX