



**PHARMALEX**

CONFIDENCE BEYOND COMPLIANCE



## FOREWORD



PharmaLex started over 25 years ago with a vision to be the largest global provider of services handling all health agency requirements. We have the ambition to make a difference to how our industry interacts and works effectively with health authorities, through the provision of our expertise and resources.

Today, our unrivaled global expertise combined with an expert approach to compliance is proven by 1,000+ clients worldwide. Our comprehensive portfolio covers services relevant for all major product categories and therapeutic areas. Each solution is tailored to our customer's needs and is executed to be delivered on time, in budget and with high quality. We work to support our clients to bring specialty products to market and ensure mature products continue to deliver against the desired highest standard.

PharmaLex stands for **PHLEX**ibility! Our trusted, flexible and quickly available local (or global) teams leverage their experience to reduce complexity by using innovative solutions to efficiently manage your products. We are a leader in innovation, for example our technology-enabled solutions provide our clients optimized results and certainty when navigating through all stages of the product life cycle.

In an ever-changing and increasingly complex international healthcare market, we are prepared with industry leading insights to be your partner delivering "confidence beyond compliance".

It has never been a more exciting time to be a part of the life sciences industry and we are honored to play a value-adding role in your success.



**Dr. Thomas Dobmeyer**  
CEO



*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**







# **ABOUT PHARMALEX**

## DELIVERING SUCCESS WITH CONFIDENCE

PharmaLex delivers compliance solutions for pharma, biotech and medtech companies who do not have sufficient expertise or resource. Scalable yet innovative, our high-quality, specialized services go beyond market approval to maintain product portfolios. We have a vast network of trusted global consultants who help clients navigate local regulations. Our diversity provides a distinct advantage in an era when flexibility and efficiency are key to competitiveness. We draw from the combined knowledge of the whole spectrum of life sciences with 25+ years of experience. Compared to some of the large CROs / BPO organizations, we are considered a specialist business organization. What CROs consider a side business, is our core business.

Using technology-enabled solutions, our experts can support you through the entire product life cycle to ensure we deliver exceptional results - going above and beyond the standard to deliver tailor-made solutions worldwide.

► *“Be persistent about your goals and flexible about your methods. It’s something that we at PharmaLex all live by and that this industry demands.”*

## PHARMALEX IN NUMBERS





# GLOBAL REACH & LOCAL PRESENCE

PharmaLex ensures global reach through its network of owned affiliates in Europe, Asia and the US and is proud to operate with more than 1,400 employees. Moreover, PharmaLex works with an established validated network of consultants covering local presence in regions worldwide. This established network leverages over more than 15 years of working together to ensure reliability and trust.



## NORTH AMERICA

Regional hubs

- CANADA
- USA

## LATIN AMERICA

Regional hub

- MEXICO
- PUERTO RICO

## EUROPE

Regional hubs

- BELGIUM
- BULGARIA
- FRANCE
- GERMANY
- IRELAND
- ITALY
- NORDIC REGION
- SPAIN
- SWITZERLAND
- THE NETHERLANDS
- UK

## MIDDLE EAST

Regional hub

- UNITED ARAB EMIRATES

## AFRICA

Regional hub

## ASIA-PACIFIC

Regional hubs

- AUSTRALIA
- CHINA
- GEORGIA
- INDIA
- PHILIPPINES

## WHAT'S IN A NAME?



*“It’s obvious PharmaLex is dedicated to delivering a comprehensive portfolio while their modular approach allows tailor-made solutions. They acknowledge our feedback, modify their approach and adapt accordingly.”*

President, Top 10 Pharmaceutical Company

*“As part of a robust procurement process we met with a number of suppliers offering to meet our needs. PharmaLex really stood out as they had a local language team that quickly delivered results. We’re now entering our fourth year of partnership.”*

Head of Regulatory, Mid-sized Biotech Company

*“What was especially important to me was their ability to get a team, with the right experience, together so quickly.”*

Head of Outsourcing, Mid-sized Biotech Company

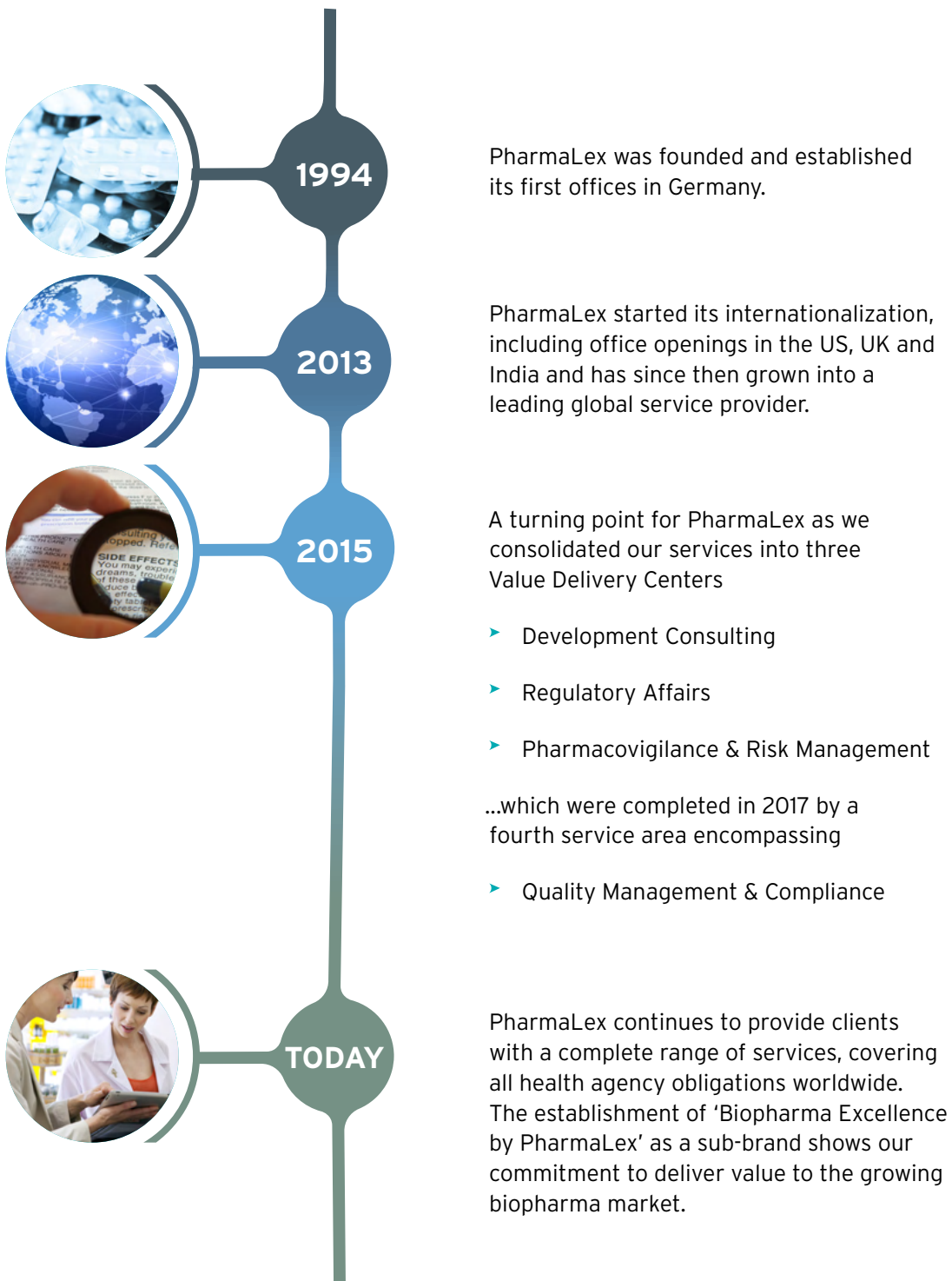
PharmaLex -  
pharmaceutical industry  
experts with flexibility.

These principles form the values and the business approach that PharmaLex was founded on, and are still true today. PharmaLex prides itself on becoming an extension of your team; with the quick turnaround, expertise and flexibility needed to support your goals.

## OUR HISTORY:

# Globalizing a personal approach to transforming the health industry

At PharmaLex we strive to expand our services and network in order to deliver personal and innovative solutions for our clients.





# A LEADERSHIP TEAM GROUNDED IN SPECIALIST EXPERTISE

Whatever your challenges, we have the expertise that can help you excel. We take a multidisciplinary approach that draws on a unique blend of knowledge from across the whole spectrum of life sciences.

Headed by world-class industry experts, PharmaLex provides a distinct hands-on advantage.



**Dr. Thomas Dobmeyer**  
Chief Executive Officer

Physician by training, researcher and investigator in immunology, hematology and infectious diseases.

20+ years of experience includes late stage clinical development, medical affairs and pharmacovigilance for a variety of therapeutic areas.



**Christopher Gauglitz**  
Chief Operating Officer

Almost 20 years' experience in management consulting and multiple leadership positions, driving standardization and efficiency across multi-national organizations, to provide superior solutions to clients.



**Dr. Kirsten Jacobs**  
Chief Service Strategy Officer & Executive Vice President Regulatory Affairs Vice President

20+ years of experience in pharmaceutical industry, including various roles in global regulatory affairs and top management consulting.

Leads global team of 350+ academics/regulatory staff, providing a variety of regulatory services worldwide.



**Sébastien Schmitt**  
Chief Commercial Officer

20+ years in sales, marketing and delivery with a solid track record in providing tailored service solutions to multi-national clients.

## LEADERSHIP TEAM CONTINUED



**Ahsan Raza**  
Executive Vice President -  
Quality Management &  
Compliance

Over 25 years of strategic leadership experience. Co-founded a company that focused on compliance area in the life sciences industry, which merged with PharmaLex, bringing harmonization between innovative technologies and client demands.

Leads 250+ global professionals providing a range of QMC services.



**Carolyn Belcher**  
Executive Vice President -  
Development Consulting &  
Scientific Affairs

20+ years experience in R&D, strategic drug development and program management, clinical development and product submission.

Leads over 120 global consultants providing a wide range of product development services.



**Dr. Raphael Troost**  
Executive Vice President -  
Pharmacovigilance

Physician by training with 19+ years of experience including clinical pharmacology, clinical trials, medical informatics and pharmacovigilance.

Leads global team of 150+ academics in the area of pharmacovigilance, epidemiology and risk management.



**Susan Maue**  
Managing Director -  
PharmaLex US  
Corporation

As an industrial engineer, health outcomes researcher and business executive with 20+ years of experience in the pharmaceutical industry, Susan has focused on delivering consulting services that help patients gain access to life-changing medications and improve the delivery of safe, effective clinical care, while building systems that ensure the best customer experience.

# CORPORATE SOCIAL RESPONSIBILITY



## Our Policy

As a company PharmaLex works to support pharma, biotech and medical device companies to remain compliant throughout the product life cycle. Our ethos is to provide flexible and cost-effective solutions that enable companies to bring products intended to diagnose, treat and improve patient wellbeing to market faster. It is this commitment coupled with the acknowledgment of the impact our business model has on the world, that defines our corporate social responsibility strategy. It is of vital importance that we not only take responsibility for our actions as a company but invest in our future as a community. It is for that reason that we have chosen to support a number of causes both globally and locally to ensure we are able to make an impact where it is most needed.

## We are planting trees in conjunction with Treedom.

Treedom is a platform that allows us to plant a tree and follow it online - and a platform that not only benefits the environment but also, combines a social mission. Treedom stands out for financing small agroforestry projects and bringing both environmental and social benefits. They first finance the planting of the trees, nourishing and caring, when they are not yet producing fruits. Then once the trees are productive, their fruits belong to the local community, allowing them to diversify and supplement both their diet and income, further by giving them quality education and training. This collaboration forms part of our Corporate Social Responsibility strategy and reinforces our commitment to sustainability.





# OUR APPROACH



## KNOWLEDGE. ACCELERATED.

confidence *beyond* compliance

PharmaLex can quickly supply the widest range of **highly-skilled market leading experts** to our clients. We work with you to identify and overcome any challenges, but remain sufficiently flexible to respond and adapt to your evolving needs. Our **experienced team** spans all geographies, helping you to **accelerate your products or accelerate access to much needed resources**, and to stay one step ahead of essential requirements needed by health agencies worldwide. Our **knowledge accelerates** your business success.

Put simply, our approach transcends all of our work, providing you with our expertise and ability to achieve quicker timelines, or...

***Knowledge. Accelerated.***

# WE COMBINE OPERATIONAL EXCELLENCE WITH TECHNOLOGY TO REALIZE IMMEDIATE AND SUSTAINED BENEFITS FOR OUR CUSTOMERS

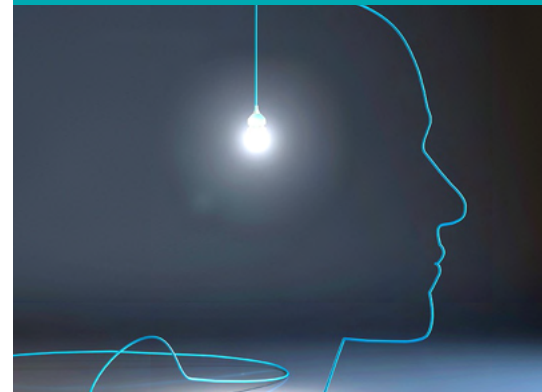
Our solutions enhance our clients processes. They are coordinated by designated Program Managers to ensure smooth delivery. All programs can be tracked and measured via KPIs to ensure defined timelines and agreed budgets are being met.

Not matter what solutions we provide, we work with our clients to design the underlying **Strategy**, advise and implement the necessary **Processes and Systems**, take ownership to ensure delivery with **Operational Excellence** via our global network of subject matter experts. No matter which solution we lead, we manage teams successfully to excel.

**Critical Success Factor - Installation of the Program Manager as the architect.**

The assignment of a responsible Program Manager with direct access to PharmaLex delivery and decision makers across all services and countries.

Responsibilities include: implementing strategies, leading expert teams, measuring ROI & KPI and taking overall ownership from the very start of program start.



## Brain - PharmaLex Employees

- World-class industry experts providing knowledge across the whole spectrum of life sciences
- Multidisciplinary approach to services
- Local insights at global reach

## Heart - Committed to Excellence

- Strive to deliver exceptional results with operational excellence
- Our values are the core foundation by which we perform our business: Flexibility / Passion / Efficiency / Dedication

## Muscle - Technology Enabled Services

- Automatic and intelligent compilation of content and drafting of documentation
- Leverage deep machine learning
- Utilize modern analytics + smart search technologies

### Comprehensive Service Portfolio

Services that ensure market access and product compliance worldwide

### Functional Orientation

Cross-functional set-up to deliver integrated services from various departments

### Subject Matter Expertise

Focusing on Pharma, Biopharma, MedTech and Diagnostics

### Access Worldwide Resources

Global reach with local market knowledge via our near-, off- and in-country delivery units



### Program Management

Installation of a Program Manager as solution architect and responsible during delivery

### Delivery Programs

From single services to complete business process outsourcing programs

### Business Transformation

Value-adding business outcomes across the entire organization

### Technological Innovation

Enabled service solutions driving efficiency gains and decision-making

**OUR SOLUTIONS ARE FOUNDED ON 8 KEY PILLARS WHICH FUEL KNOWLEDGE AND OPERATIONAL EXCELLENCE**



**50+%**  
OF OUR  
PARTNERSHIPS  
ARE GLOBAL

## PHARMALEX SOLUTIONS THAT EXCEED YOUR EVOLVING NEEDS

Our one-stop solutions help global pharma companies to manage their health authority obligations, in order to focus your own resource on the most strategic assets. Our trusted, flexible and quickly available teams deliver expertise to reduce complexity by using innovative approaches to efficiently develop, commercialize and maintain your products. Our success is proven by long-term partnerships. We offer a simplified business solution that is modular and flexible, wrapping all of our stand-alone services into bundles.



# Our Solutions

Today's ever-changing market requires expertise and innovative solutions to overcome the challenges of tomorrow. Based on the feedback of more than 1,000+ clients we have tailored our unrivaled services, because we know that whether you are a large or small pharmaceutical company, a biotech or a medtech company, your requirements vary. Extensive experience fuels our service portfolio to deliver activities across the span of your product lifecycle - both pre- and post launch - always ensuring compliance to regulations.

- 1** Provide you access to **global resources**, allowing you to complement, supplement, or fulfill your resource needs.
- 2** Be a **one-stop-solution** to help you manage your health agency obligations.
- 3** Be a **long term partner** you can count on while you utilize our strategic thinking and industry understanding.
- 4** Provide guidance to **efficiently manage your products**.
- 5** **Reduce complexity** and streamline processes with innovative approaches.

PharmaLex can support clients throughout the product lifecycle. Our service portfolio is modular, enabling us to provide a completely customized solution for every client. Working along the entire product lifecycle, we successfully bring innovations to commercialization, as well as maintaining and expanding products globally!

## CROSS-FUNCTIONAL ADVISORY SERVICES FROM TARGET TO IMPLEMENTATION

**INTEGRATED PRODUCT DEVELOPMENT**  
FROM DISCOVERY TO PRODUCT

**BRINGING INNOVATIONS TO MARKET**  
FROM SUBMISSION TO  
COMMERCIALIZATION

**END-TO-END OUTSOURCING PLATFORMS**  
OPTIMIZING EFFICIENCY, PRODUCT  
COMPLIANCE AND MARKET COVERAGE  
GLOBALLY TO LOCALLY

DISCOVERY /  
NON-CLINICAL

CLINICAL  
DEVELOPMENT

APPROVAL /  
AUTHORIZATION

POST-APPROVAL /  
MAINTENANCE

**MERGERS & ACQUISITIONS**  
GUIDING THROUGH BUSINESS  
TRANSFORMATION

## 98%

SUCCESS RATE IN STAFFING HIGHLY  
QUALIFIED EXPERTS WITHIN THE  
AGREED TIMEFRAME.

## 9 OUT OF THE TOP 10

PHARMACEUTICAL COMPANIES ARE  
OUR VALUED LONG-TERM CLIENTS.



## CROSS-FUNCTIONAL ADVISORY SERVICES

Request our services worldwide and we can provide support from our pool of 1,400 on or off-site experts.



## INTEGRATED PRODUCT DEVELOPMENT

Today's ever-changing regulatory environment requires expertise and innovative solutions to overcome the current and future challenges that all companies face. Our aim is to help our clients achieve marketing approval and commercial excellence.



## BRINGING INNOVATIONS TO MARKET

We are experts at navigating the ever-changing regulatory landscape and equipped to guide our clients to reach authorization approval in time and in budget. We determine the best application route for your product. We manage every step of the procedure, and ensure all documentation is 100% accurate and compliant before submission.



## END-TO-END OUTSOURCING PLATFORMS

The regulatory maintenance of approved products is essential and critically important for pharma compliance. PharmaLex is able to support Pharma companies to refocus their workload on core strategic competencies, and alleviate the challenges caused by constant demands for pre- and post-approval activities for complete product portfolios.



## MERGERS & ACQUISITIONS

PharmaLex is able to leverage their extensive experience working on M&A related RA activities on a global and local level across multiple client programs to overcome challenges and allow clients to achieve their corporate goals in a compliant and timely manner while ensuring business continuity.

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## WEB BASED PLATFORM

WHICH ENAbLES EFFICIENT ONLINE LITERATURE SCREENING LOCALLY AND GLOBALLY – THIS HAS BEEN IMPLEMENTED BY MOST OF OUR CLIENTS.

## UP TO 20%

TIME SAVED THROUGH BUNDLING SERVICES WITH ONE ESTABLISHED PARTNER DEALING WITH ALL HEALTH AGENCY OBLIGATIONS.

WE MANAGED PROJECTS WITH

## 400+ MAs ACROSS 40+ COUNTRIES

(ICH & NON-ICH REGIONS) ALLOWING

## COST REDUCTIONS OF UP TO 70%

THROUGH THE IMPLEMENTATION OF A HYBRID LOCAL & OFF-SHORING MODEL.

OUR COLLABORATION WITH VOLV USES

## ARTIFICIAL INTELLIGENCE PARADIGMS

TO REDUCE COMPLEXITY IN PRODUCT DEVELOPMENT AND SERVICES.





# OUR SERVICES



## DRIVEN BY EXPERTISE - COVERING KEY DEPARTMENTS

We can cover all key departments of your business with our experts responsible for providing all of our service offerings, ensuring our clients have the best expertise and skills available for every single job.

Within each department, we offer a full range of services which are either strategic consulting, support or processing.

Our solution bundles consist of core services from all departments, relevant to the product's lifecycle and offers our clients a one-stop solution ensuring the best value for money. Every client need will be assessed and discussed so a single service or package of services can be developed and provided to address each client's unique requirements.

Our experienced staff span more than 40 countries worldwide, giving us unrivaled reach to provide the whole spectrum of regulated services.



## CONFIDENCE BEYOND COMPLIANCE

PharmaLex offers end-to-end regulated services that provide real value to our clients.

We differ from other contract service providers by focusing on specialized regulatory services (rather than clinical ops, manufacturing or sales support) to deliver and comply with all health agency obligations. Our global team has more than 1,400 local knowledge experts.

PharmaLex supports pharma companies throughout the entire product life cycle, ensuring compliance with pharmaceutical regulations and providing vital scientific and strategic advice on drug development. Our services include product maintenance post launch activities.

## PHARMALEX KEY AREAS OF EXPERTISE:

### Development Consulting

- ▶ Integrated product development and project management
- ▶ Regulatory and scientific consultancy services
- ▶ Regulatory strategy (incl. health agency interactions), gap analysis and due diligence
- ▶ Scientific, regulatory and medical writing
- ▶ Development CMC, consulting and manufacturing strategy
- ▶ Non-clinical and clinical development services
- ▶ Health economics, market access, pricing, strategic advice
- ▶ Labeling services
- ▶ Medical affairs & marketing strategy
- ▶ Biostatistics & data management services

### Regulatory Affairs

- ▶ Initial marketing authorization applications, line extensions and referrals in 80+ countries worldwide
- ▶ Full portfolio maintenance service (e.g. variations, renewals) across all regions
- ▶ Global roll-out strategy for new submissions including due diligence activities
- ▶ Consultancy and regulatory operations during M&A activities
- ▶ Change control procedures, CMC writing for chemicals and biologicals
- ▶ Electronic submission services in all formats
- ▶ CCDS development & worldwide roll-out
- ▶ Procedure management and health agency contacts

*"We have been working with PharmaLex for over 10 years because they are a valued and trusted partner. This is not something you can buy; it is something you build and requires the expertise PharmaLex can provide."*

*- SVP, Global Pharmaceutical Company*



KNOWLEDGE.  
ACCELERATED.  
confidence beyond compliance

## Quality Management & Compliance

- ▶ Design, development and implementation of GxP & ISO Quality Management Systems
- ▶ Audit program management
- ▶ Pre-Approval Inspection (PAI) readiness
- ▶ Distribution / GDP compliance
- ▶ GxP facility design
- ▶ Commissioning, Qualification and Validation (CQV)
- ▶ Contamination control strategy development
- ▶ E-DMS and E-QMS implementation
- ▶ Computer Systems Validation (CSV)
- ▶ Virtual QA, including vendor and CAPA / deviation management
- ▶ Contract QA / staff augmentation

## Pharmacovigilance & Risk Management

- ▶ Pharmacovigilance & Clinical Safety
- ▶ ICSR management, including collection, evaluation, processing, distribution and reporting (incl. validated safety database)
- ▶ Signal management
- ▶ Risk management
- ▶ Periodic safety reports
- ▶ Pharmacovigilance system and compliance
- ▶ EU-QPPV, local QPPV
- ▶ Quality system, audit and inspection support
- ▶ Safety data exchange agreements
- ▶ Pharmacoepidemiology
- ▶ Literature Surveillance (VigiLit)



 Our role varies depending on the client's need.

# OPERATIONAL MODELS

Level of involvement

## PharmaLex Role

Fully Outsourced Program

Departmental Expertise

Resource Supplement

One-off Deliverables

## Example / Client Type

- PharmaLex manages entire program, with direction from client
- “Acting as Department”
- First or only proprietary product
- Large or Small-mid size or startups (HQ or local affiliates)
- Requires an experienced program manager

- Client lacks regulatory, PV, QMC or preclinical expertise and needs guidance through the process
- PharmaLex coordinates with client's existing departments to seamlessly manage the development process

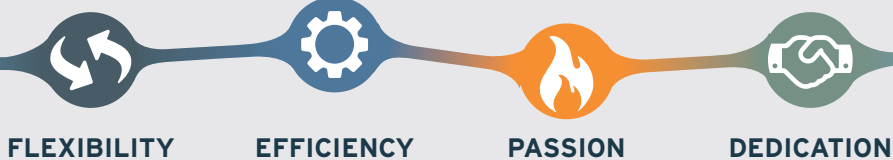
- Client has full DD capabilities, but resource constrained for specific project
- Client may lack expertise in specific area
- Often larger companies or smaller companies expanding their portfolios

- Companies with specific, typically shorter-term issues
- PharmaLex delivers “white papers”, regulatory documents, plans of action, due diligence analyses, QA/Monitoring services



**OUR VALUES**

# OUR VALUES



We strive to deliver exceptional results – going above and beyond the standard to exceed your expectations. Our values aren't just words, they are the core foundation by which we do our business.

Listen to what our clients say:



## FLEXIBILITY

We deliver subject matter experts and tailored solutions, whether working on-site or remotely. We offer innovative solutions that help manage risks and optimize processes.



*PharmaLex has been our strategic outsourcing partner for over 10 years. As our needs have evolved over time, so has PharmaLex. They have always delivered the right experts who can advise and guide our teams at different sites."*

**VP, Multinational Company**



## EFFICIENCY

Our staff – 80% of whom have over 20 years of industry experience – collaborate on world class NCE, NBE, OTC, biopharmaceuticals, and more. We quantify our efficiencies with KPIs installed for each project. Deliverables are tracked to be on time, in budget and to successfully pass clients' internal review.



*The PharmaLex team are trained on our SOPs and know our company. They provide recommendations for improvements and suggestions in a very constructive partner-like, and most importantly, pro-active manner. We have very unique and strict SOPs, and PharmaLex always finds quick solutions and make them happen. Most importantly, they provide savings without jeopardizing the quality of the output."*

**Senior VP, Global Pharmaceutical Company**



# OUR VALUES



FLEXIBILITY



EFFICIENCY



PASSION



DEDICATION



## PASSION

We thrive on navigating a highly regulated environment utilizing some of the most experienced professionals in the field. We have worked on strategic products of world class medications in areas including anti-infectives, biosimilars and regenerative medicines.

Our staff are passionate about their field and the majority have been in the industry for more than 20 years, including former government health agency employees (FDA and EMA).



*Having PharmaLex dedicated experts on hand, who know my business inside and out has been truly game changing. I am always happy to recommend them to my colleagues."*

**Medical Director, Biopharmaceutical Company**



## DEDICATION

We are built on local teams that are committed to excellence and delivering the highest standards of service. We have a 95+% continuation rate. Once clients have worked with us, they stay with us - understanding the value-adding role we bring to their success.



*It's really important for us to have local language experts that can easily slot into the existing team. PharmaLex has been integral to the success of our business."*

**Managing Director, Global Biopharmaceutical Company**



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## ● CONTACT US

We look forward to discussing how we can help you!

To find out more about any of our solutions, contact us today at:  
[contact@pharmalex.com](mailto:contact@pharmalex.com) or visit our website  
[www.pharmalex.com](http://www.pharmalex.com)