



PHARMALEX

CONFIDENCE BEYOND COMPLIANCE

FOREWORD



PharmaLex started over 25 years ago with a vision to be the largest specialized global provider of regulated services handling all health agency requirements. Our ambition was 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 600+ clients worldwide. Our key advantage is that we are large enough to scale and manage all client programs, but small enough to be manageable by the client. We work holistically with our clients to combine intelligent global and regional strategies with operational services that deliver effectively. Our comprehensive portfolio covers services relevant for all major product categories and therapeutic areas. 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 Artificial Intelligence (AI) offering provides our clients optimized results and certainty when navigating through all stages of the product lifecycle.

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

- *Using technology-enabled services to empower decision making and driving efficiency gains.*





ABOUT PHARMALEX

DELIVERING SUCCESS WITH CONFIDENCE

PharmaLex is a leading provider of specialized services for the pharma, biotech and medical device industries. 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.



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



9/10

TOP PHARMACEUTICAL
COMPANIES ARE WORKING
WITH US



40+ NATIONALITIES

ON STAFF, INCLUDING FORMER
FDA AND EMA EXPERTS

30,000+

SUCCESSFUL
PROJECTS
COMPLETED

60%

OF OUR CUSTOMER
BASE REPRESENT
SMALL TO MID-SIZED
ENTERPRISES (SMEs)

50+%

OF OUR PROJECTS
ARE GLOBAL

UNDERTAKE

50+

ANNUAL

INDUSTRY

“EXPERTISE”
WORKSHOPS

ON KEY OR NEW INDUSTRY
DEVELOPMENTS
AND REGULATIONS



1000+

EXPERTS WORKING IN
COUNTRIES ACROSS THE GLOBE

**25+
YEARS**

OF INDUSTRY EXPERIENCE



**LEAD 40+
HEALTH AGENCY
MEETINGS
ANNUALLY WITH
EMA/FDA/PMDA**



200+

EXPERIENCED AND CERTIFIED
GLOBAL ALLIANCE PARTNERS
SUPPORTING OUR WORLDWIDE
COVERAGE

GLOBAL REACH & LOCAL PRESENCE

PharmaLex ensures global reach through its network of owned affiliates in Europe, India, China, Latin America and the US. It is also proud to work with an established validated network of Global Alliance Partners 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

- USA
- PUERTO RICO

LATIN AMERICA

Regional hub

- BRAZIL

CIS & RUSSIA

Regional hubs

- GEORGIA

EUROPE

Regional hubs

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

MIDDLE EAST

Regional hubs

- DUBAI

AFRICA

Regional hub

ASIA

Regional hubs

- CHINA
- HONG KONG
- INDIA
- PHILLIPPINES

PHARMALEX OFFERS SUPPORT IN THE FOLLOWING AREAS:

STRATEGY & CONSULTING

- Development Strategy and Gap Analysis
- Integrated Product Development
- Market Access Strategy
- Non-clinical Development Concept and Study Design
- Scientific Due Diligence
- Statistical Services
- Toxicology Assessments
- Clinical Program Development
- Orphan Drug Designation
- Pediatric Investigation Plan (PIP)
- Environmental Risk Assessment

PHARMACOVIGILANCE / MEDICAL AFFAIRS

- Clinical Trial Safety Support
- Pharmacovigilance Consulting
- EU QPPV / National QPPV
- Risk Management Support
- Audit and CAPA Management
- ISCR Management
- Literature Screening
- Pharmacovigilance Systems
- Safety Writing (PSUR, RMP)
- Signal Management
- Medical Information

QUALITY & COMPLIANCE

- GxP Services
- IMP Management
- Interim / Contract QA
- QMS Development and Implementation
- Tech Transfer / Scale-up
- Vendor Audit and Management
- PAI and Commercialization Readiness
- Validation
- Commissioning and Qualification
- Good Distribution Practice (GDP) Compliance

REGULATORY AFFAIRS

- Clinical Trial Applications (CTA)
- Global Procedure Management
- Health Authority / Agency Interaction
- CMC Services
- Marketing and Labeling Activities
- Scientific, Regulatory and Technical Writing
- Global End-to-End Outsourcing
- Mergers and Acquisitions (M&A) Transfers

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

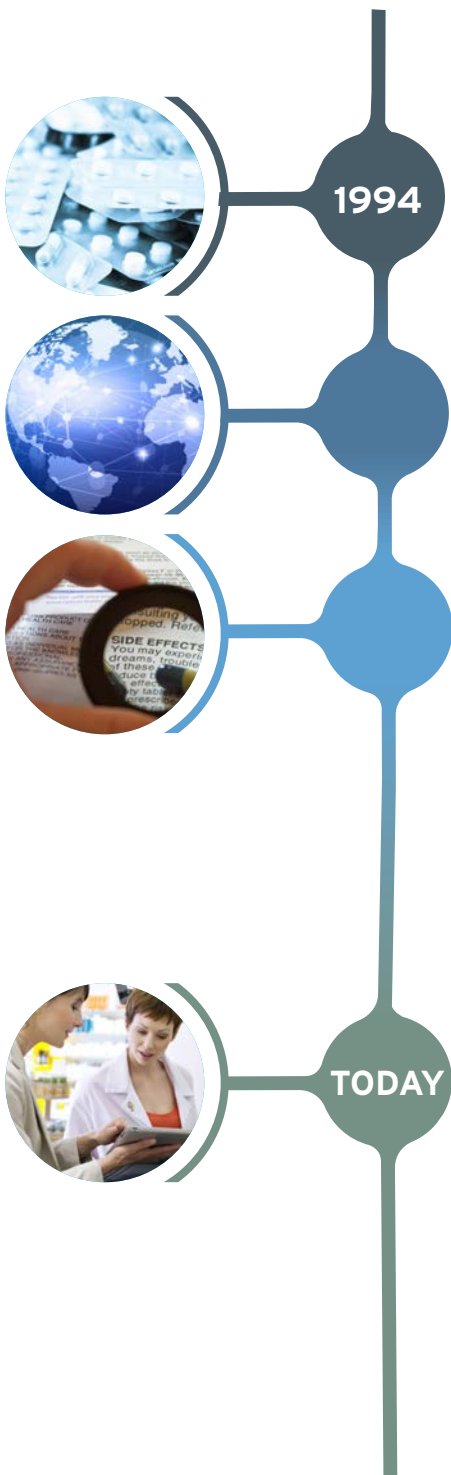
PharmaLex -
pharmaceutical industry
experts with flexibility.

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.



1994

PharmaLex was founded and established its first offices in Germany.

PharmaLex started its internationalization, including office openings in the US, UK and India and has since then grown into a leading global service provider.

A turning point for PharmaLex as we consolidated our services into four Value Delivery Centers...

- ▶ Development Consulting
- ▶ Regulatory Affairs
- ▶ Pharmacovigilance, Epidemiology & Risk Management
- ▶ Quality Management & Compliance

TODAY

PharmaLex has evolved into the largest global specialized provider for (biopharmaceutical and medical device) regulated services.

Our core delivery model is our ability to provide clients with a complete range of services, covering all health agency obligations worldwide.

OUR GROWTH OBJECTIVES - THE MASTER PLAN

In line with our motto 'Confidence *Beyond* Compliance', our strategy is to build a global provider in regulated services. We believe that in order to deliver a truly competitive solution for our clients, we need to be able to compete both in terms of size and service.

Using a mixture of organic and inorganic growth, we are in a strong position. We can bolster our existing resources by drawing on the experience gained through merging with established companies, as well as building new teams in new locations to develop our local knowledge.

The driving factors behind our strategy are as follows:



GLOBAL REACH

Regulations are harmonized on a global level driven by multinational cooperation. However, those who work within the Emerging Markets know that there are still a significant number of country-specific regulations and that achieving the "last mile" can become tricky. In addition, many pharma companies are not only required to maintain products outside of their own reach but also have to explore new markets where growth opportunities have been saturated, therefore are increasingly

requesting support for global end-to-end submission projects. We will support our clients in their aspirations to explore new markets and get their products approved and marketed and maintained in these countries. We will add new offices in countries and regions where most of the gross pharmaceutical value is generated or which are of particular interest to our clients. Through the proximity to our clients, we can help them by providing the right resources at the right time, in the right place.



OPERATIONAL EXCELLENCE

Regulations are constantly updated and new regulations are released. The medical device area has recently come under the spot light and the demarcation between medicinal products and medical devices is breaking up companion diagnostic, drug device combinations and personalised medicine. Market Access is a new area. Companies are giving up their traditional functional silos to work in matrix organizations, in an attempt

to better leverage existing resources thereby reducing time-to-market, maintenance efforts and risk. We are merging with companies to broaden our service portfolio to areas which are closely linked to regulatory work. This has included areas which complement our traditional service offerings, e.g. health economy, statistical services, medical devices, quality management.



COSTS

Our clients are very cost sensitive, so are we. We can be more efficient by using scope and scale effects. By working together across functions (scope effects) we can make better

use of shared functions, thereby reducing full costs. Increasing the size of our organization will help us to realise scale effects.

CORPORATE SOCIAL RESPONSIBILITY

As a company, PharmaLex recognizes the role it can play in supporting worthy causes across the world. Having the ability to invest in environmental and social wellbeing is an important part of our attitude to business as well as helping to reinforce our values. In line with our company approach, Knowledge Accelerated, we are focusing our efforts on initiatives that revolve around education. These complement our existing internal strategy which aims to provide flexibility, training and equal opportunities for our staff and external contacts.

We will extend our Corporate Social Responsibility obligations in the future, ensuring we use the influence we have to enrich the lives of others.



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.



Dr. Kirsten Jacobs
Executive Vice President -
Regulatory Affairs

17+ years of experience with previous roles in regulatory operations and international regulatory affairs.

Leads global team of 250+ academics/regulatory staff, providing a variety of regulatory services worldwide.



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 submissions.

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



LEADERSHIP TEAM CONTINUED



Dr. Raphael Troost

Executive Vice President -
Pharmacovigilance,
Epidemiology &
Risk Management

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.



Ann McGee

Global Partner -
Quality Management &
Compliance

Over 30 years work experience within the pharmaceutical industry, as both a regulator and a consultant. Her experience spans quality and regulatory compliance (GxP) across the product lifecycle.

Has inspected nationally and internationally on behalf of the EMEA for GxP compliance and has advised on best practice guidance for the pharmaceutical industry.



Christina S. Rebel-Otterbach

Managing Director,
PharmaLex US Corporation

20+ years accomplished in Finance and Business Leadership; focusing on Financial and Business Management, Organization, Global Expansion, Turnaround and Strategy with US- and Europe-based companies operating globally.

Christina has worked with companies operating globally, focusing on operational excellence and scalability while driving profitability and shareholder value.



LEADERSHIP TEAM CONTINUED

**Marta Vila Ramos**

Vice President -
Corporate Development,
Business Innovation &
Strategy

Has had leading roles during 20 years in international and challenging environments, such as Accenture, PWC, Sandoz and INSUD Pharma Group. These experiences have given her a deep knowledge in strategy, business development, innovation and regulatory affairs areas.

Her outstanding entrepreneurial attitude has allowed her to launch innovative and efficient initiatives specially related to new operational models.

**Hermann Frings**

Group Chief Finance
Officer

25+ years experience as a qualified finance executive, with very broad experience in Finance, Accounting and Controlling, Taxation and Transfer Pricing, IT (SAP implementations and roll-outs); experience also in Supply Chain Management, Key Account Management and Procurement

Hermann has developed strong international teams and has experience of working for an international service provider in the healthcare sector.

**Claudia Hinrichs**

Vice President -
Human Resources

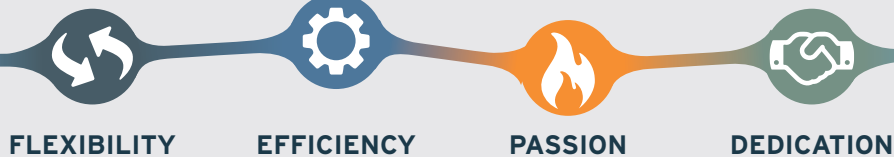
Organizational Psychologist by training with more than 20 years of experience in HR and more than 15 years' experience in international HR management roles.

Claudia has worked for healthcare and consulting companies and is leading the Global HR team within PharmaLex.



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

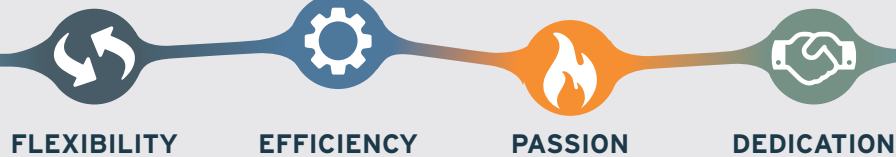
Our staff – 80% of whom have over 20 years of industry experience – collaborate on world class NCE, NBE, OTC, biopharmaceuticals, and more. We quantify our efficiencies with KPIs installed for each project. Deliverables are tracked to be on time, in budget and to successfully pass clients' internal review.



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



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).



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



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

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.



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 or visit our website
www.pharmalex.com