PHARMALEX

CONFIDENCE BEYOND COMPLIANCE

FOREWORD

PHARMALEX
CONFIDENCE BEYOND COMPLIANCE

PharmaLex started 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

"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."

ABOUT PHARMALEX

DELIVERING SUCCESS WITH CONFIDENCE

PharmaLex is one of the largest specialized providers of Development Consulting, Regulatory Affairs, Quality Management & Compliance and Pharmacovigilance, Epidemiology & Risk Management worldwide. Our GLOCAL (GLObal reach and loCAL presence) 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

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 ENTERPRIZESs (SMEs)

50+%
OF OUR PROJECTS ARE GLOBAL

UNDERTAKE
50+
ANNUAL INDUSTRY "EXPERTISE" WORKSHOPS
ON KEY OR NEW INDUSTRY DEVELOPMENTS AND REGULATIONS

850+
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

LATIN AMERICA

Regional hub

- BRAZIL
- PUERTO RICO

CIS & RUSSIA

Regional hubs

EUROPE

Regional hubs

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

MIDDLE EAST

Regional hub

AFRICA

Regional hub

ASIA

Regional hubs

- CHINA
- INDIA

PHARMALEX OFFERS SUPPORT IN THE FOLLOWING AREAS:

DEVELOPMENT CONSULTING

- Regulatory and scientific consultancy services
- Integrated product development and project management
- Regulatory strategy (incl. health agency interactions), gap analysis and due diligence
- Scientific, regulatory and medical writing
- Development CMC, consulting and manufacturing strategy
- Statistical services across non-clinical and clinical development
- Health economics / market access / pricing / strategic advice
- Labeling services
- Medical affairs & marketing strategy
- Medical information services 24/7

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

QUALITY MANAGEMENT & COMPLIANCE

- Develop phase appropriate quality system
- Gap analysis, remediation and implementation
- Pre-approval inspection readiness (Mock PAI audit)
- Warning letter and consent decree remediation
- External and internal audits
- Routine compliance support (Document control, CAPA, batch release)
- EDMS and CSV (21 CFR part 11 compliance)
- Microbiology and analytical quality control support

PHARMACOVIGILANCE, EPIDEMIOLOGY & RISK MANAGEMENT

- 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

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 – **pharma**ceutical industry **ex**perts with **flex**ibility.

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.

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.

Monika Rese

Vice President – Finance

15+ years leadership experience as an internationally qualified finance executive, gaining skills in strategic and financial management as well as experience in setting up and developing professional finance teams.

Monika has worked with companies around the globe and has developed strong intercultural perspective and leadership skills with an international focus.

Claudia Hinrichs

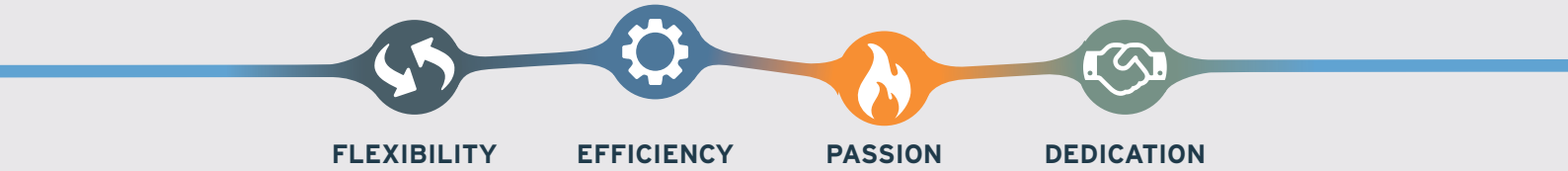
Vice President – Human Resources

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

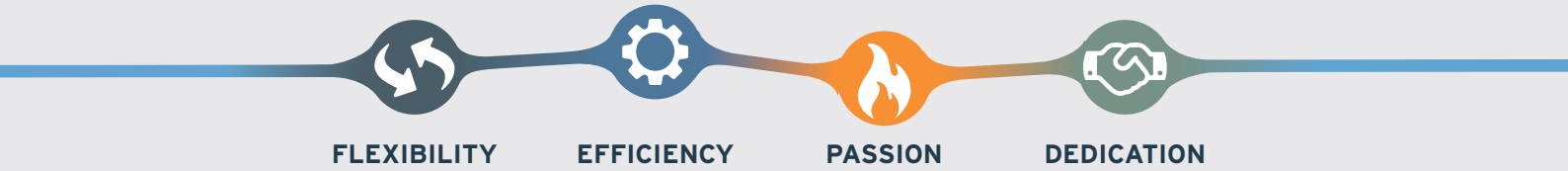
EFFICIENCY

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).

> *"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**

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.

Inno*PHLEX*

PHARMALEX SOLUTIONS THAT MEET YOUR EVOLVING NEEDS

Inno*PHLEX* is the comprehensive end-to-end solution for specialized pharma and biotech companies to drive successful product development. We accelerate your product's time-to-market and help mitigate risk by engaging our range of subject matter experts. Benefit from our extensive local network of health authority connections to help navigate you through the regulatory process. We offer a simplified business solution that is modular and flexible, wrapping all of our stand-alone services into bundles.

Inno*PHLEX*

Today's ever-changing regulatory environment requires expertise and innovative solutions to overcome the current and future challenges that companies face. Based on the feedback of more than 600 clients we have tailored our unrivaled services to address your needs regardless of company size. Our Inno*PHLEX* portfolio bundles all of our extensive development consulting, regulatory, quality management and pharmacovigilance expertise together to support you in bringing your new drug or device to market, as well as maximizing its value through lifecycle developments.

Inno*PHLEX* helps companies to:

1	2	3	4	5
Accelerate your product's **time-to-market**.	Drive successful product development, with our **one-stop solution**.	Utilize our **extensive local network** of health agency connections.	Reduce risk by engaging our range of **subject matter experts**.	Navigate through the regulatory process, **mitigating the risks**.

The services within this bundle include anything from scientific advice (FDA/EMA), orphan drug designation, ATMPs support and biosimilar development.

1. TIME-TO-MARKET

We offer increased productivity, reducing time-to-market or even getting there first.

"We were 6 months behind our competitor for MA when we hired PharmaLex; they integrated into our team to close the gap resulting in approval 6 months ahead – a total gain of 12 months!"

VP, Biotechnology Company

SAVED 2-3 YEARS
BY AGREEING AN ACCELERATED DEVELOPMENT PATHWAY WITH HEALTH AUTHORITIES FOR SPECIALIZED PHARMA COMPANY.

SUCCESSFULLY CONDUCTED SEVERAL
'FIRST-IN-CLASS'
SWITCHES TO OTC FOR DIFFERENT PHARMA COMPANIES.

2. ONE-STOP SOLUTION

This model relies on the successful partnership with your PharmaLex account manager, someone who is on hand when you need them, operates in your time zone, and who provides the innovative solution you need.

"PharmaLex advised, built and managed our lead investigational molecule. They helped us globalize the molecule from the ground up and take it international, to both US and European markets."

Head of Scientific Affairs, Biotechnology Company

DELIVERED INTERNATIONAL PRODUCT ROLL-OUT ACROSS MULTIPLE COUNTRIES FOR INDEPENDENT PHARMA COMPANY WITH SINGLE POINT OF CONTACT.
RESPONSIVE WITHIN 24H.

COORDINATED ALL REQUIRED DRUG DEVELOPMENT SERVICES (INCLUDING DRUG SAFETY) AS
SOLE PROVIDER
FOR A BIOTECHNOLOGY COMPANY.

3. EXTENSIVE HEALTH AUTHORITY NETWORK

Our team including former employees of regulatory authorities offers in depth insights and knowledge of health agencies' current thinkingfirst-hand know-how of the health agencies.

"We recently had some tricky FDA meetings and the PharmaLex team was at hand to guide us through the process. They acted as an extension of our team and because they anticipated the needs, were pro-active to advise us on the best path forward before we were in a serious situation. It's been so important to tap into that insider knowledge to put us one step ahead of the curve."

Specialist, Pharmaceutical Company

LEAD 40+
HEALTH AGENCY INTERACTIONS ANNUALLY WITH EMA/FDA.

20+ YEARS
OF EXPERIENCE IN PRE-AUTHORIZATION SUBMISSIONS, INCLUDING REGULAR INTERACTIONS WITH FDA, EMA AND ALL OTHER RELEVANT REGULATORY HEALTH AGENCIES.

WORKED WITH A
RANGE OF BODIES
ACROSS THE EMA (CAT, PDCO, COMP); PMDA (JAPAN) AND FDA (CDER, CBER, SFDA).

4. SUBJECT MATTER EXPERTS

Our extensive and highly qualified team of subject matter experts, deal with regulatory agencies worldwide; we helped bring one of the first ATMPs to market. Our expert knowledge includes New Chemical and Biological Entities (NCEs, NBEs), Biosimilars, Generics and Value Added Medicines.

"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 needed for meetings with the regulatory authorities as well as licensing applications."

Medical Director, Biotechnology Company

OVER 850
EXPERTS WORKING IN COUNTRIES ACROSS THE GLOBE.

WE HOST NUMEROUS INTERNATIONAL FACE-TO-FACE AND VIRTUAL
LECTURES
LED BY OUR SUBJECT MATTER EXPERTS.

5. MITIGATE RISK

To navigate through the complexities of development activities we provide guidance and strategic insights to determine the optimal path right from the start.

"The PharmaLex team stepped in at a critical time when we were applying for a new chemical entity status for an established product. Their quick thinking and forward-looking approach flagged a missing protection document which saved us thousands of Euros and of course time we didn't have!"

Head of Product Development, Biotechnology Company

75%
OF PROJECTS PASSED SUCCESSFULLY THROUGH DEVELOPMENT PHASE
WITHOUT MAJOR FINDINGS.

Inno*PHLEX* : Service Overview

PharmaLex can support clients throughout the product lifecycle. Our service portfolio is modular, enabling us to provide a completely customized solution for every client. The following services are delivered via Inno*PHLEX:*

DISCOVERY / NON-CLINICAL → CLINICAL DEVELOPMENT → AUTHORIZATION / APPROVAL

Integrated Program & Project Management: coordination of development projects & submissions, product development plan regeneration.

CMC Development: product characterization, support of formulation & analytical method development, process validation, QBD, continued process verification & accelerated development strategies, definition of critical quality attributes & specifications, release & stability testing strategies.

Regulatory Strategy & Development Services: health authority meetings, gap analyses of regulatory & scientific documents, assessment of special designation opportunities, due diligence evaluations.

Non-clinical Development Services: program design / protocol development & review, vendor selection & oversight.

Clinical Development Services: clinical development plan, study design/protocol development & review, CRO selection and oversight, study management, CSR writing.

Biostatistics & Data Management Services: CMC/QBD, non-clinical & clinical studies: e.g. SAPs, meta-analyses, ISS/ISE support, PK/PD modelling, CDISC compliance, focus expertise in adaptive & Bayesian designs.

Pharmacovigilance Services: clinical study safety surveillance, SAE reporting, individual case report processing & follow up, authoring of risk management plans (USA/EU), provision of PV system including QPPV, DSUR report preparation.

Regulatory & Medical Writing: pediatric development plans, orphan designation applications, briefing books for health authority interactions, applications for special consideration (e.g. PRIME, adaptive pathways) Investigator brochures, non-clinical overviews & summaries, environmental risk assessments.

Quality Assurance & Compliance Services: QMS development & maintenance, GXP vendor qualification, GXP audits, inspection support & remediation, pre-approval inspection readiness (PAI).

Regulatory Operations: technical dossier compilation, publishing & validation, eCTD consultancy & electronic submissions; document templates & document formatting support.

Procedure Management: filling of registration documentation, procedural advice & management for US, EU and growth markets, liaison with regulatory agencies globally, delivery of local and global intelligence.

Labeling: Company Core Data Sheet and US & EU regional product information creation.

Market Access Services

Customer On-site Support: a convenient, tailor-made and cost effective solution for companies looking for short-, medium- and long-term resource.

60%

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

Source*PHLEX*

A PHARMALEX SOLUTION THAT EXCEEDS YOUR EVOLVING NEEDS

Source*PHLEX* is the one-stop solution helping 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 local teams leverage their experience to reduce complexity by using innovative approaches to efficiently maintain your products. Our success is proven by long-term cooperation with our clients. We offer a simplified business solution that is modular and flexible, wrapping all of our stand-alone services into bundles.

Source*PHLEX*

Today's ever-changing market requires expertise and innovative solutions to overcome the challenges of tomorrow. Based on the feedback of more than 600 clients we have tailored our unrivaled services, because we know that whether you are a large or small pharmaceutical company, a biotech or a medical device company, your requirements vary. Our Source*PHLEX* portfolio bundles all of our extensive experience to provide on-going maintenance activities to ensure your legacy products remain compliant.

Source*PHLEX* is designed to:

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 for support.

4
Provide guidance to **efficiently maintain your products**.

5
Reduce complexity and streamline processes with innovative approaches.

Our full service bundle provides the most value and at the same time offers flexibility to those in need of a condensed service solution for outsourcing, whether it is required to meet an immediate resourcing demand or to manage mature products, we can help.

1. GLOBAL RESOURCE

Request our services worldwide and we can provide support from our pool of 650+ on or off-site experts.

"The 'soft things' make PharmaLex stand out - they're on the same time-zone and don't over-promise."

Global VP, Top 10 Pharmaceutical Company

98%
SUCCESS RATE IN STAFFING HIGHLY QUALIFIED EXPERTS WITHIN THE AGREED TIMEFRAME.

2. ONE-STOP SOLUTION

We provide dedicated account managers as a single point of contact.

Maintaining PV case management, labeling, CMC, submissions and achieving GxP compliance require insights and capabilities that you may not have in-house and seldom find support by one service provider. We have the one-stop solution for a whole host of outsourcing possibilities.

"We had a very short time frame to ramp up and migrate to a completely new PV system for our 210 mature products; this could only be done through the resource and expertise that PharmaLex provides."

Head of Pharmacovigilance, Global Pharmaceutical Company

UP TO 20%
TIME SAVED THROUGH BUNDLING SERVICES WITH ONE ESTABLISHED PARTNER DEALING WITH ALL HEALTH AGENCY OBLIGATIONS.

3. LONG-TERM PARTNER

The long-term relationships provides trust, stability and the opportunity for ongoing feedback to continually improve.

"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 flexibility PharmaLex can provide."

SVP, Global Pharmaceutical Company

9 OUT OF THE TOP 10

PHARMACEUTICAL COMPANIES ARE OUR VALUED LONG-TERM CLIENTS.

4. EFFICIENTLY MAINTAIN YOUR PRODUCTS

Integrated global program management allows synergies across services and geographic regions, while ensuring standardization of essential data sets and dossiers worldwide.

"PharmaLex provides recommendations for improvements and suggestions in a very constructive way. We have very strict SOPs, but they support us to identify new solutions and make it happen."

Head of Compliance, Global Pharmaceutical Company

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.

5. REDUCE COMPLEXITY

Very often it takes an outsider looking in to help uncover areas for improvement and reduce the complexity. With subtle changes we have uncovered under-utilized resources in existing teams and revised processes and systems leading to significant cost savings.

"Vigilit, automated PharmaLex software, has changed the way our Manager of Literature Monitoring teams work, saving hours of manual time which can now be done efficiently through this single online program."

Senior Manager Pharmacovigilance, Mid-sized Pharmaceutical Company

WE DEVISED A

WEB BASED PLATFORM

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

OUR COLLABORATION WITH VOLV USES

ARTIFICIAL INTELLIGENCE PARADIGMS

TO REDUCE COMPLEXITY IN PRODUCT DEVELOPMENT AND SERVICES.

Source*PHLEX* : Service Overview

PharmaLex can support clients throughout the product lifecycle. Our service portfolio is modular, enabling us to provide a completely customized solution for every client. The following services are delivered via Source*PHLEX:*

Product Maintenance

CORE ACTIVITIES

- Technical / medical writing & dossier updates
- Classification of changes
- Dossier preparation, submissions & approvals
- 2nd wave submissions / global roll-outs
- Authority communication
- Labeling / PI / CCDS management globally
- Publishing all formats
- VigiLit: literature surveillance
- ICSR, signaling and risk management
- Medical information services
- Inspection support including mock regulatory audits to ensure MA Holder compliance
- Design, implementation and remediation of your Quality Management System (QMS), in accordance with ICH Q9
- Customer On-site Support: a convenient, tailor-made and cost effective solution for companies looking for short-, medium- and long-term resource.

PORTFOLIO MAINTENANCE OUTSOURCING

- All RA, PV and compliance activities on a global / local level for a given portfolio included
- Direct interfaces to manufacturing, marketing & other, limited oversight by client
- Program governance structures with clear responsibilities
- Performance measured via KPIs
- PV systems outsourcing
- Process innovation and regulatory / PV intelligence

M&A ACTIVITIES

- Due diligence activities (REG, PV, Compliance)
- Strategic advice on M&A project set-up
- Handling of operational activities during M&A
- Database mergers
- Site rationalization activities
- SDEA contract management
- Quality system, audit and inspection support

CMC SITE TRANSFERS & COMPLIANCE PROJECTS

- Gap analysis of existing dossiers
- Strategy consulting on manufacturing sites portfolio and second supplier options
- Planning of site transfer variation timing (avoid out of stock situations) according to legislation in respective countries
- Realization of CMC change control requirements
- Operational QA work

50+%
OF OUR PROJECTS ARE GLOBAL

CONTACT US

We look forward to discussing how we can help you!

To find out more about any of our *PHLEX* solutions, contact us today at: contact@pharmalex.com or visit our website **www.pharmalex.com**