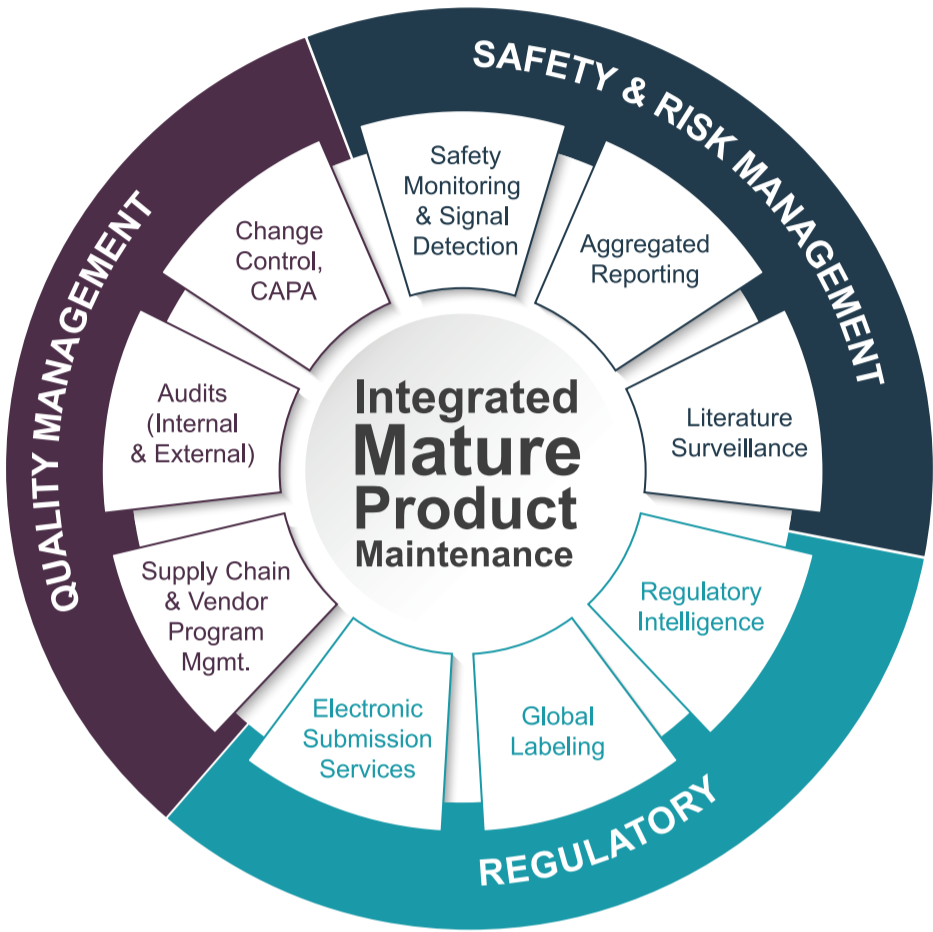**PHARMA**LEX

POST-LAUNCH GLOBAL OUTSOURCING

"Communication - the human connection - is the key to success: One of my goals at PharmaLex is to foster a program environment with open and transparent communication"

Constanze Burkhardt
Vice President Global Program Management

The new outsourcing paradigm is built on a tailored, blended model of in-country, near-shore, and offshore resources, ensuring that partner domain experts are seamlessly integrated into the biopharma company and oversight of the portfolio is centrally managed. We build our synergies on the foundation of expertise, knowledge, and innovation – which ultimately leads to efficiency and cost reduction for clients

SAFETY & RISK MANAGEMENT
QUALITY MANAGEMENT
REGULATORY

Safety Monitoring & Signal Detection
Change Control, CAPA
Aggregated Reporting
Audits (Internal & External)
Literature Surveillance
Supply Chain & Vendor Program Mgmt.
Regulatory Intelligence
Electronic Submission Services
Global Labeling

Integrated Mature Product Maintenance

HOW CAN PHARMALEX HELP?

- PharmaLex deilvers a **comprehensive solution** for all services, from **global to local**
- **Ownership and responsibility** leads to minimum oversight by client
- **20% Overall reduction of workload** due to efficiency gains by year 2-3
- **Global Program Management** as PharmaLex´ core competency will stir and run programs efficiently with no decrease in quality
- High degree of **flexibility to ramp-up resources** to cover all required functional areas
- **Innovation and technology** sharing on possible improvements

PharmaLex takes ownership of assigned portfolio with a dedicated program management function
Our philosophy: engage the right expert for the right task, irrespective of location

POST APPROVAL / MAINTENANCE PHASE

POST-LAUNCH OUTSOURCING
Optimizing efficiency, product compliance and market coverage globally to locally

REGULATORY	PHARMACOVIGILANCE	QMC	DEVELOPMENT CONSULTING
• CMC • LCM • Labelling • Publishing	• Risk Management • Database / Systems • Global Analysis	• Quality and Compliance Services	• Risk Management • Medical Analysis • Medical Writing • Ad Promo • Medical Compliance

REGIONAL HUB MODELS (if applicable)

REGIONAL HUB	PHARMACOVIGILANCE HUB
• All local activities which do not require local presence • Language skills	• Coordination of Pharmacovigilance request from the region

LOCAL (IN-COUNTRY)

• Local RA Manager / MAH • Submissions to HA • Translation • Local intelligence	• QPPV • Case reporting	• Medical advice • Ad promo services • Medical compliance	• Local QA tasks