

Local pharmacovigilance services (LPVS)

Expert affiliate PV support for market maintenance and growth

Trusted partner for scalable success

Our Affiliate PV solutions help biopharmaceutical companies of all sizes navigate complex regional and local PV regulatory requirements - driving growth in existing as well as new markets worldwide.

Navigating local affiliate pharmacovigilance

PharmaLex is a trusted safety support partner for biopharmaceutical organizations worldwide, delivering expert Local Pharmacovigilance Services (LPVS) to help streamline entry and expansion across international markets.

Our comprehensive global pharmacovigilance expertise and extensive local presence provides flexibility to scale quickly across markets, without compromising quality - helping to avoid common safety-related delays in product submissions, authorizations, and marketing.

Whether you are a small biopharmaceutical organization launching its first product in a new market or a large life sciences business with established global reach, our Affiliate PV

solutions provide access to highly specialized pharmacovigilance staff that meet your need for reliable local expertise and mandated on-the-ground PV presence in key markets.

Gain a competitive edge by tapping into more than 1000 subject matter experts and native pharmacovigilance resources in over 150 countries - available when and where you need them.



Drive expansion, M&A or first entry to new markets



Facilitate growth in existing markets

Local PV consulting, key staff and operational best practices

Our LPVS solutions add critical PV expertise, reduce workloads for local teams and help meet the requirements of relevant health authorities.



Streamline

market expansion and achieve business targets



Facilitate

current market growth and reduce revenue risk



Gain

workload flexibility without compromising quality



Specialists across the safety lifecycle



Planning

Consulting services; audits and analysis; Risk Management planning



PV systems

Creation and maintenance of local PV systems, local PSMF, and SOPs



PV requirements

LPPV/Local QPPV/LSR; local ICSR management; literature screening



PV due diligence

Customized due diligence to help optimize marketing applications



Global/local safety reporting

Domestic and foreign ICSRs to regional and local competent authorities; PSURs and risk management plans

LPVS: global reach, local presence

Comprehensive Affiliate PV solutions

PharmaLex can support your team with pharmacovigilance expertise to navigate the continually evolving complexities of global, regional and local PV requirements. Our comprehensive Affiliate PV solutions help to avoid common regulatory mistakes that can constrain business growth - freeing your own team to focus on strategic safety priorities.

From providing local Qualified Persons for Pharmacovigilance (QPPV) – such as those mandated by the EU and many national health authorities – to implementing safety quality systems to delivering full-service PV management, our Affiliate PV solutions can help you:

- Reduce the risk of marketing application delays or rejections
- Gain expert guidance on regional marketing authorization pathways
- Scale quickly by filling critical gaps in regional and local knowledge or capabilities with experienced pharmacovigilance staff
- Streamline and optimize local and regional PV processes based on our proven best practices, automation, and innovative technologies
- Leverage a global partner to standardize regional and localized services to improve consistency, save costs, streamline comms and KPI reporting, and meet your stringent SOPs

Affiliate PV full scope of services

Provision of LPPV/Local QPPV/LSR and deputies	✓
24/7 availability where required plus multiple language coverage	✓
National point of contact with local health authorities (+ requests)	✓
Creation and maintenance of local PV systems (+ local PSMF/SOPs)	✓
Local literature screening, where required	✓
Local ICSR management (intake/processing/reporting/tracking)	✓
Submission of domestic/foreign ICSRs to competent authorities	✓
Preparation and submission of PSURs and risk management plans	✓
Training in medicinal product SmPC content & HCP interaction	✓
Risk management plans and local implementation of RM material	✓
Educational materials	✓
DHCP communications	✓

Local PV legislation monitoring and proactive customer updates	✓
Support and participation in PV inspections and audits	✓
Local PV quality management support and training for local affiliates	✓
E2E management of patient support programs & market research	✓
Local signal detection, where required	✓
Medical Information services (first level)	✓

Solving complex product lifecycle safety challenges to help you:



Boost resources

with expert support for in-house safety teams



Meet regulatory requirements

Mandated by regional and country-level health authorities



Improve efficiency

and accuracy of safety management and reporting



Reduce opex costs

while maintaining quality and risk management

PharmaLex advantage

25+
years of experience

50+%
of projects global

1000+
subject matter
experts worldwide

150+ countries
has local PV native
resources

85+
global PV systems

300+
PV clients

40+
nationalities on staff,
including former FDA
and EMA experts

190+
local PV systems





Add critical PV expertise, reduce local workloads and meet safety requirements worldwide

PharmaLex is a proven partner for global and local pharmacovigilance support across the safety lifecycle. Bringing consulting expertise and PV best practices built over thousands of customer engagements - spanning regulatory, medical, scientific affairs, clinical development and quality (GCP/ GMP) programs - PharmaLex Local Pharmacovigilance Services (LPVS) empower your team to make better informed market decisions based on superior safety intelligence and deeper executive insights. Our Affiliate PV solutions add critical expertise, reduce workloads for local teams and help meet safety requirements mandated by health authorities.

Streamline

market expansion and achieve business targets

Facilitate

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Gain

workload flexibility, optimize quality and compliance

[**Request a discovery meeting today!**](#)