

Local pharmacovigilance services (LPVS)

Case Study

Customer profile

Mid-sized biopharmaceutical company with a presence across the Americas, Europe, and Asia-Pacific, Africa, and the Middle East.

Broad portfolio of marketed products and a robust pipeline encompassing oncology, respiratory, CNS, ophthalmology, pain management, and biosimilars.

Customer challenge

The company was looking for an experienced single global vendor to meet its extensive requirements for local affiliate pharmacovigilance support. Extremely tight timelines for onboarding new countries plus licensing limitations in its legacy pharmacovigilance IT system meant that the organization needed a completely new model for processing ICSRs that it could standardize internationally across all local PV activities.

Key requirements for its new model included:



Improve cross-functional communication, processes, and business intelligence prior to engaging new countries and entering new markets



Implement a validated training platform



Perform automated compliance tracking



Solution: PharmaLex local affiliate PV services

After reviewing multiple bids, the company chose PharmaLex as having the capabilities and expertise that best matched its requirements. Working closely with each country in the customer's network to understand each local situation, practices, and environment, our local PV experts mapped all regional activities to develop a deep gap analysis of local requirements and status.

Drawing on our extensive network of local PV professionals, we then rapidly fielded an 81-strong team of local PV staff to meet the identified capacity needs – including a complete crew of experienced Regional Leads.

We also established a brand-new Oracle Argus LAM Hub model to globally coordinate the customer's ICSR processing, overcoming the existing license limitations. This included the creation of a robust and standardized process for countries to send cases to the hub for database entry, increasing efficiency, accuracy, and timeliness.

Finally, our expert team created and implemented a new collaborative workspace and program management methodology to provide training and track compliance during initiation. We incorporated best practices to optimize local pharmacovigilance processes and help maintain consistency across the customer's quality management system (QMS).



Customer outcome

Today, the customer benefits from a streamlined and standardized approach to its local PV processes, driving significant improvements in cross-functional interaction, quality, compliance, efficiency, and cost control. Their team can now effectively monitor performance of local affiliates across the 94 countries in scope, with comprehensive oversight and clear, consistent communication principles.



Customer feedback

"Collaborating with PharmaLex is one of our greatest successes."

"What we have achieved thus far is incredible...huge step toward harmonization of local PV processes with centralized oversight."

Disclaimer

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