PHARMALEX
CONFIDENCE BEYOND COMPLIANCE

CASE STUDY:
PV System & Operations: Taking over of a Complete Pharmacovigilance System

CLIENT SIZE	Large pharma	GEOGRAPHY	Global
THERAPEUTIC AREA	Various	TIME LINE	ongoing

CLIENT NEED

- Set up of a global PV system for a newly established pharmaceutical company, including the transfer of the entire product portfolio from a third party with more than 1,000 marketing authorizations in more than 20 countries. This included all pharmacovigilance (PV) tasks including PV contract management for all PVAs. The client was interested in a single preferred service provider with an international company structure, experienced in provision of PV, RA, Medical Information and Quality services.
- Task / Objective: Set up of PV system including transfer of global safety database and safety relevant data from third party.

OUR SOLUTION

- Set up of a complete new PV system including migration of safety data from third party
- Provision of the PV responsible persons in the EU (QPPV) and local PV responsible persons in several countries
- Preparation and maintenance of the PSMF
- Support of the preparation and maintenance of controlled documents
- PVA management
- Complete ICSR processing: Currently about 2,500 ICSRs/year
- Eudravigilance ICSR Screening
- Literature screening (global and local)
- Ongoing monitoring and signal management
- Audit and inspection support

PHARMALEX VALUE TO CLIENT

- Reduced complexity due to the interaction with only a single service provider for PV, RA, Medical Information and Quality
- High quality PV system is ensured by the broad experience of the service provider
- Gaining a comprehensive package for the handling of PV partners including negotiation of contracts, development of risk evaluation strategies and CAPA follow-ups
- Ad hoc consultation regarding all drug safety related and cross functional topics

DISCOVERY / NON-CLINICAL > CLINICAL DEVELOPMENT > MARKETING AUTHORIZATION / APPROVAL > PRODUCT MAINTENANCE