

Global PV Outsourcing

Challenge



Efficient global literature surveillance according to GVP

- Globally operating pharma company requested support concerning quality management and operative PV activities with the focus on case processing
- Client was thus looking for one preferred service provider with an international company structure
- Responsibilities included all workflows and activities relevant for case processing and quality management

Solution



Establishment of automated weekly database search

- Training of PharmaLex staff on the client's safety database
- Close cooperation between PharmaLex and client to ensure quality
- Complete single case processing including expedited reporting: Average 18,000+ cases per year for 272 active substances
- Global literature screening for 272 active substances
- Safety report writing (RMP, PSUR, AtCO)
- Participation in BfArM / MHRA / SUKL / ANSM inspections.
- Preparation and maintenance of the PSMF, PV SOPs and WIs

Outcome



272 active substances screened weekly
130,000 screened abstracts and 18000+ ICSRs per year

- PV compliance in all requested fields achieved
- Ability to manage fluctuating case volumes including seasonal spikes in report numbers while maintaining quality metrics
- No need to increase the client's internal resources during peak times of workload
- The client was able to refocus existing staff to the customer and business sides of the process