

Full PV service outsourcing

Challenge



Lack of capability of handling unpredictable and fluctuating amount of cases

- Client required outsourced PV service.
- QPPV, database set-up and maintenance case management (clinical and post-marketing).
- Case workflow set-up from initial receipt to reporting.
- Listings and query support from database.
- Reporting compliance responsibility.
- PSMF maintenance.

Solution



Highly experienced PV personnel available for signal evaluation, PSUR and RMP writing

- Translated source documentation in local language into English.
- Data entry in client's global database maintained by PharmaLex.
- In-process QC.
- Medical review and assessment.
- Reconciliation with multiple partners.
- Reporting to partners and authorities.
- Monthly meetings for reconciliation and QPPV overview.

Outcome



Established long-term trusted partnership for ongoing support

- One preferred service provider for all PV services.
- One point of contact for partners and authorities.
- Client's need for maintaining PV expertise is reduced.
- Processing of approx. 120 ICSRs per month from partners and worldwide market.