PHARMALEX
CONFIDENCE BEYOND COMPLIANCE

CASE STUDY:
Full service post-marketing and clinical trial PV activities for mid- sized pharma company

CLIENT SIZE Smart & medium Pharma

GEOGRAPHY EU & US

THERAPEUTIC AREA Various

CLIENT NEED

- The US company developing modified release formulations for existing active ingredients was in need of appointing an EU-QPPV.
- Client gradually transferred PV tasks to PharmaLex resulting in full responsibility of all their PV activities with PharmaLex.
- PharmaLex up-scaled resources accordingly.
- Client currently has two products, one with a MA for the US other with a MA for both US and EU.
- Needs support for introduction of new products into the EU as well as further expansion in the US.

OUR SOLUTION

- Training of PharmaLex staff on the client's safety database.
- Close cooperation between PLx and client to ensure quality.
- Complete case processing including expedited reporting: Average 250+ cases per year for 2 products.
- Global literature screening for 2 products.
- Safety report writing (RMP, PSUR).
- Participation in MHRA / CHMP health authority inspections.
- Preparation and maintenance of the PSMF, PV SOPs and WIs.

PHARMALEX VALUE TO CLIENT

- Via PLX the client has a local presence in the EU to liaise with their marketing partner without the need to set up their own infrastructure.
- Flexible up scaling and down scaling of resources upon request.
- Access to PV experts with many years of hands-on experience.
- Through global reach PharmaLex is able to cover PV support on a multinational scale.
- Extensive PharmaLex portfolio allows client to outsource various task to one solution provider.

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