Post–M&A pharma infrastructure development

Challenge

Start-up Pharma company with no REG, PV, Quality systems infrastructure, processes and limited personnel

- Client start-up with major pharma portfolio asset purchase (approx. 20 products and 450 MAs, across 47 markets).
- Client has no Regulatory Affairs (RA), Pharmacovigilance (PV) and Quality Management (QM) capacities in-house (neither globally nor locally) to take care of the acquired portfolio and no established systems, tools or processes.
- Needed support to handle all MAH transfers and subsequent maintenance activities for RA, PV and QM on global and local level.

Solution

System and process infrastructure development for PV and QMS, prior to client undertaking MAH responsibilities

- PharmaLex provided one-stop solution for client to serve all requested services.
- PharmaLex developed and implemented:
  - MAH transfer plan aligned with client commercial priorities and incorporating timeframe for infrastructure development.
  - A global PV System together with local PV infrastructure.
  - Commercial operating model, Quality Management System (QMS) and attainment of a WDA license.
  - Global processes.
  - Definition of interfaces for client and selling company (e.g. supply chain, artwork, PV…) .

Outcome

Client successfully able to take full MAH responsibilities on time using the system infrastructure delivered by PharmaLex

- Fully compliant Pharmaceutical infrastructure with global and local PV services and QMS established within four (4) months.
- MAH compliant Regulatory Affairs structure to maintain MAs in all requested countries.
- Full coverage of local and global RA, PV and QM activities for our client across global markets in scope.
- Platform established for future lifecycle maintenance activities.