

# Post-M&A PharmaLex program governance

## Challenge



Start-up Pharma company with no REG, PV, Quality infrastructure with urgent need for Programme Governance to be established

- Major pharma portfolio asset purchase (approx. 20 products and 450 MAs, across 47 markets) .
- No ability to support program governance of multi-functional Regulatory Affairs (RA), Pharmacovigilance (PV) and Quality Management (QM) operational activities
- Required urgent support to provide operational activities and oversight, with the ability to establish an appropriate program governance model as required for a Pharmaceutical company.

## Solution



PharmaLex delivery of tiered global Programme Governance model through to client

- Provided a one-stop solution for client to serve all requested services and undertake program governance.
- Developed and implemented a tiered program governance model with provision of:
  - Steering Committee to oversee strategic and budget / financial reporting elements
  - Mirrored structure between client and PharmaLex to ensure close collaboration and partnership at program manager, functional and operational levels
  - Communication plan and structured meetings.

## Outcome



Programme Governance successfully established to address client needs and model 'blueprint' for the future

- Program governance model successfully delivered to client.
- Robust, yet flexible governance approach accommodated changes in client personnel, strategies and operational priorities.
- Risk mitigation strategies, issue escalation pathways and structured meetings.
- A blueprint for future large-scale outsourcing programs.