

Strategic outsourcing of mature product portfolio



Challenge

Client needed to take over RA product responsibility in a timely manner according to client's standards and processes

- Global innovator company.
- Wanted to outsource parts of their mature product portfolio.
 - > 60 products in different therapeutic areas
 - 430 MAs in Europe, 1,900 MAs international (incl. CN, AUS, CAN).
- Scope of PharmaLex support:
 - Full regulatory product responsibility
 - GRA CMC Manager
 - All publishing and submission activities
 - Piloting of PV and Medical Affairs interface.



Solution

Implementation of lean governance structure with timely takeover of product responsibility

- Program governance structure with clear responsibilities and common decision board.
- Commonly agreed implementation plan with ambitious ramping up of staff.
- Provision of early definition of interfaces and in scope / out of scope activities .
- Recommended pragmatic modifications of clients processes where applicable.
- Defined and tracked KPIs and budget.



Outcome

Establishment of strategic partnership with common strategic goals

- Strategic partnership as win-win situations for clients and PharmaLex.
- Fluctuations in workload fully handled by PharmaLex staff.
- Controlling and performance measurement via budget and KPIs.
- Process consultancy and operative innovations as part of the program.
- Generation of dedicated efficiency gains whilst maintaining complete product portfolio to client's standards.