

# End-2-end portfolio maintenance (outsourcing) program



## Challenge

Large unstructured source repository and limited timeframe

- Diverse stakeholders within M&A activity.
- Short preparation timelines.
- Regulatory activities across the world (EU, CIS, APAC, MENA, Africa, LATAM).
- Part integration into client Quality systems.



## Solution

PharmaLex owned ready to use QMS and worldwide RI know-how

- Fast handover and take up of regulatory activities.
- Worldwide set-up based on client needs (end-2-end).
- Utilization of PharmaLex existing regulatory processes and systems.



## Outcome

Fully compliant Portfolio Maintenance activities which met program milestones and timelines

- Autonomous compliant management of all MAs.
- Established interfaces and governance structure (KPIs, budget reporting).
- Proactive project and stakeholder management according milestones.