

Local lifecycle Regulatory Affairs management

Challenge



Local affiliates require support for mature product portfolio in DE / FR / IT

- ▶ Global life science company.
- ▶ Required regulatory support on local level (LRAM) required for DE / FR / IT:
 - Responsible for product portfolio needed.
 - Handling of local tasks and procedure management handled by one person on client site.
 - Contact person for HA requests needed.
 - Ability to correspond fluently in local language is crucial.

Solution



Local Lifecycle Regulatory Affairs management

- ▶ Established program governance structure with clear responsibilities and common decision board and implementation plan.
- ▶ Provided early definition of product portfolio (already in PharmaLex responsibility on headquarter level).
- ▶ Handled local peculiarities by implementing Senior / Junior roles for most effective workload distribution.
- ▶ Provided early definition of activities in scope / out of scope and tracking of KPIs and budget.

Outcome



Successful local end-to-end concept

- ▶ Clear ownership and responsibilities for defined product portfolio and countries with PharmaLex covering procedure management and local requirements.
- ▶ Generated synergies by true end-2-end outsourcing.
- ▶ Controlled performance measurements via budget and KPIs.
- ▶ Processed consultancy and operative innovations as part of the program.