

CASE STUDY: Strategic Outsourcing - Transfer of Global Maintenance Activities

 **CLIENT SIZE** 45000+ employees

 **GEOGRAPHY** Europe

 **THERAPEUTIC AREA** Veterinary Products

 **TIME LINE** 15 months

CLIENT NEED

- ▶ Multinational EU-based innovator company
- ▶ Transfer all global maintenance activities for a portfolio of mature products
- ▶ Within transfer the full product responsibility has been handed over to PharmaLex
Scope of PharmaLex responsibilities:
- ▶ Support of regulatory relevant initiatives and business projects of the client as well as new applications for roll-out extension of the transferred products
- ▶ GRA Manager responsibility for CMC and Safety and Efficacy
- ▶ Substantial updates of specific documentation (e.g. DACS, Product Design Reviews)

OUR SOLUTION

- ▶ Program governance structure with clear responsibilities and common decision board
- ▶ Commonly agreed implementation plan with responsibility handover in 4 waves
- ▶ Early definition of interfaces and in scope / out of scope activities
- ▶ Pragmatic modifications of customers processes where applicable
- ▶ Definition and tracking of KPIs and budget

PHARMALEX VALUE TO CLIENT

- ▶ Access to additional regulatory knowledge and benchmarking data of peer companies
- ▶ Temporary fluctuations in workload handled by PharmaLex staff
- ▶ Performance measurement via KPIs
- ▶ Long term budget control
- ▶ Process consultancy and operative innovations as part of the program

DISCOVERY /
NON-CLINICAL

CLINICAL
DEVELOPMENT

APPROVAL /
AUTHORIZATION

PRODUCT
MAINTENANCE