PHARMALEX
CONFIDENCE BEYOND COMPLIANCE

CASE STUDY:
Preparation, submission and coordination of a Centralized Procedure (CP) for PUMA formulation

CLIENT SIZE	Small company	GEOGRAPHY	EU
THERAPEUTIC AREA	Neurology	TIME LINE	14 - 15 Months

CLIENT NEED:

- A small European pharmaceutical company has identified the need for support from service provider due to lack of capacities and capabilities to process a centralized procedure for a PUMA formulation
- PharmaLex offered support for various regulatory activities in relation to the preparation, submission and coordination of the centralized procedure
- Project Management
- Definition and tracking of KPIs and budget

OUR SOLUTION

- Support of regulatory relevant initiatives and business projects of the client including EMA interactions of all regulatory activities for PUMA formulation
- Coordination with EMA (e.g. letter of eligibility, name review application, pre-submission meeting, etc.)
- Preparation, compilation and submission of the corresponding complete dossier format to EMA and obtaining Commission Decision (CD) within the time lines
- Coordination and support during validation, response phase and post CP phase until CD

PHARMALEX VALUE TO CLIENT

- Commission decision obtained 14 months after start of the procedure
- The successful marketing authorization for the fourth human medicinal product PUMA in the EU was granted
- Performance measurement via KPIs

DISCOVERY / NON-CLINICAL > CLINICAL DEVELOPMENT > MARKETING AUTHORIZATION / APPROVAL > PRODUCT MAINTENANCE