PHARMALEX
CONFIDENCE BEYOND COMPLIANCE

CASE STUDY:
M&A Regulatory Support – Initial Situation

CLIENT SIZE Top 20 Pharma company

GEOGRAPHY Global

THERAPEUTIC AREA Various

CLIENT NEED

- Deal covered 3,500 marketing authorizations (MA) in >120 countries
- Country dossiers need to be transferred as well as global dossiers
- Processes for MA transfer need to be designed (globally & locally)
- MA transfer need to be supported operationally as of Day 0 (closing)

OUR SOLUTION

- Preparation and support of MAH transfer submission packages including authority contacts
- Clarification of any open items with local sites during MAH transfer
- Regulatory strategies and corresponding activities for selected countries, for which a MAH transfer application is not possible but requires a new marketing authorization application
- Risk assessment/management to contribute to a smooth MAH transfer process while supporting ongoing variations, timing of further variation submissions

PHARMALEX VALUE TO CLIENT

- Flexible contractual framework allows quick implementation of new work orders
- Attractive pricing model for customer with dual system (lump sum and extra hours)
- Assured resources and additional support as required
- Access to additional knowledge base as per PharmaLex pool as opposed to single freelancers

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