PHARMALEX
CONFIDENCE BEYOND COMPLIANCE

CASE STUDY:
Tactical support

CLIENT SIZE	Big Pharma	GEOGRAPHY	Europe
THERAPEUTIC AREA	Animal Healthy	TIME LINE	6 Months

CLIENT NEED

- The client was a global company with several Biosimilars and one NBE in their development pipeline
- The company was in need of support for the preparation of the CMC part of IMPD/IND and CTD

PharmaLex offered support with:

- Creation of templates
- Technical writing (e.g. analytical validation reports, stability reports)
- CMC writing and compilation of Module 3 and 2.3
- Objective: Successful submission of CTA, NDA and BLA

OUR SOLUTION

PharmaLex Project Leader as single point of contact at the customer´s manufacturing site:

- Contact point for all questions
- Overall responsibility for all operational deliverables
- Leads the PharmaLex Expert Team
- Manages timelines and costs
- F2F kick-off and finalization meetings on site at client; mid-term TC for progress review and clarification of questions with all PharmaLex experts

PHARMALEX VALUE TO CLIENT

- Special expertise and know how available on short notice
- PharmaLex experts bridging the gap between Development departments and RA department
- Reduction of work load in the Analytical and Process development departments
- Fastest possible way to create technical and CMC documents out of raw data
- No long-term commitment by client

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