

CASE STUDY: Consultancy and support for IDMP Implementation

 CLIENT SIZE	Medium Pharma	 GEOGRAPHY	Europe
 THERAPEUTIC AREA	Aesthetic medicine & Neurology	 TIME LINE	6 months

CLIENT NEED

- ▶ Client intends to prepare for upcoming IDMP implementation in Europe
- ▶ Focus lies on compliance and optimizing the usage of related information within the company
PharmaLex offered support with:
- ▶ Awareness meetings
- ▶ Gap analysis
- ▶ Proposal for implementation covering systems, processes and data

OUR SOLUTION

- ▶ Performance of gap analysis incl. report involving several departments (e.g. regulatory, pharmacovigilance, manufacturing, QA, IT etc.)
- ▶ Definition of process need and landscape with stakeholders
- ▶ Preparation of an Action Plan and reporting into executive management teams on different levels
- ▶ Setup of project organization and governance team

PHARMALEX VALUE TO CLIENT

- ▶ Kick-Off trainings and awareness meetings performed
- ▶ Proposals for processes and future landscape defined
- ▶ Topic embedded into related programs (global IT infrastructure updates; track & trace project etc.)
- ▶ Latest information from agencies and working groups
- ▶ All results delivered within defined time frame

DISCOVERY /
NON-CLINICAL

CLINICAL
DEVELOPMENT

MARKETING AUTHORIZATION
/ APPROVAL

PRODUCT
MAINTENANCE