PHARMALEX
CONFIDENCE BEYOND COMPLIANCE

CASE STUDY:
Autologous cell product (cartilage defect)

CLIENT SIZE	Small Biotech	GEOGRAPHY	EU
THERAPEUTIC AREA	Cartilage defect	TIME LINE	Over 10 years

CLIENT NEED

- Client was a small biotech company developing an autologous cell product for cartilage defects

Development and regulatory support over 10 years needed for:

- Regulatory strategy
- CMC writing
- Nonclinical writing
- Clinical writing
- eCTD preparation, submission
- Management of EU Centralized Procedure
- Preparations and conduct of Scientific Advices and Oral explanation

OUR SOLUTION

- PharmaLex project leader as single point of contact for the customer:
- Program management
- Contact point for all questions
- Overall responsibility for all deliverables
- Coordination of all PharmaLex experts
- Management of time-lines and costs
- Proposed yearly budgets for specific services and work orders for various deliverables/ services

PHARMALEX VALUE TO CLIENT

- Experts available with ATMP experience in regulatory, quality, nonclinical and clinical
- Access to know-how from many EMA submissions
- No need for implementation of an own state-of-the-art publishing tool
- Access to EU Health Authority opinion leaders via the extensive PharmaLex network
- Flexible contractual framework allowing quick implementation of new work orders

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