PHARMALEX
CONFIDENCE BEYOND COMPLIANCE

CASE STUDY:
Rx-to-OTC Switch Safety Support

CLIENT SIZE Large pharmaceutical

GEOGRAPHY US

THERAPEUTIC AREA Opthamology

CLIENT NEED

- The client was a large pharmaceutical company with offices worldwide
- Client was seeking an OTC indication for established Rx product
- The OTC product has a different indication and is intended for a broader population
- PharmaLex was enlisted to conduct adverse event analyses in five safety databases and a literature review in support of the Rx-to-OTC NDA submission

Timelines:

- Pre-NDA meeting support/attendance (1 month)
- Adverse event analyses and report development for five safety databases (5 months)
- Production of written narratives for 985 case reports (3 months)
- Preparation of relevant portions of the ISS document (2 weeks)
- Conduct of the 120-Day Safety Report follow-up, including safety database analyses, review of literature, and review of clinical safety studies (4 months)

OUR SOLUTION

- Provided strategic support in preparation of and attended the sponsor's pre-NDA meeting with FDA
- Obtained relevant data, conducted adverse event analyses and reported findings for five safety databases
- Searched, reviewed and reported on safety data from published literature
- Obtained Med-watch reports from FDA via FOIA and wrote case report summaries
- Prepared post-marketing safety sections of the ISS document

PHARMALEX VALUE TO CLIENT

- Experience with safety databases commonly used for Rx-to-OTC switches shortens timeframe for analysis and submission
- Expert SAS programmers conducted parallel analyses in five safety databases within five months; and 120-Day follow-up analyses within 4 months
- PharmaLex expertise with FDA procedures informed clients on preparations for face to face FDA meeting

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