PHARMALEX
CONFIDENCE BEYOND COMPLIANCE

CASE STUDY:
Support with ongoing safety monitoring activities (VigiMon®)

CLIENT SIZE	Medium Pharma	GEOGRAPHY	Germany
THERAPEUTIC AREA	Various		

CLIENT NEED

- The company had identified the need for support regarding regular activities for signal detection
- Since July 2012 the new pharmacovigilance legislation has emphasized the importance of regular ongoing monitoring activities and well documented procedures thereof

PharmaLex offers:

- Support with signal detection from various sources and regarding the validation, prioritization and assessment of detected potential safety signals
- Implement a process for integrating the activities performed by PharmaLex into the clients system
- Using the VigiMon® web application for documentation and all over availability of results to the client

OUR SOLUTION

- Implement a process for detecting potential signals from the medical and scientific literature for approximately 90 active substances on a quarterly basis (process was decided to be supported by the Vigilit® application) resulting in review of about 1600 articles and preparation of 16 SARs per annum
- Exchange of all relevant information between client and PharmaLex (e.g. SPCs and substance list as basis, and all results of PharmaLex activities)
- Provision of Templates by PharmaLex for complete documentation of all relevant steps

PHARMALEX VALUE TO CLIENT

- A continuous service has been established
- Client achieves full compliance with GVP provisions
- The client now has a cost-efficient solution for screening of the medical and scientific literature
- Documentation via the VigiMon® web application provides the client with world-wide secure access to all documents and results of signaling activities

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