PHARMALEX

SIGNAL MANAGEMENT ACTIVITIES CUSTOMIZATION

Ensuring reliable, high quality, trackable and compliant data

PharmaLex customizes the signal management activities, assisting with continuous monitoring of the safety data to **detect, validate, prioritize, author signal assessment report,** and **recommend actions** for signals through quantitative and qualitative reviews.

Our experts are experienced and well versed in providing responses to **safety questions** from the health authorities; evaluating and critically appraising ICSRs, aggregate data, and literature and thereby providing a comprehensive evaluation report.

On November 22nd, 2017 the EMA launched the new EudraVigilance database (EVDAS) and gave Marketing Authorization Holders (MAHs) access to the system. MAHs are required to inform the EMA and national competent authorities of validated signals detected for their products.

We at PharmaLex, have a team of experts who perform the EVDAS review for the products in the EVDAS pilot list by monitoring the Signals of Disproportionate Reporting (SDR) and significant Reporting Odds Ratio (ROR) as defined in the EVDAS manual.

Our proprietary **Macro Based Tool** which **reduces the efforts** for EVDAS eRMR reports evalutation by around 50% by auto-populating the dispositions for drug-event pairs

- Preparation and implementation of signal monitoring plan
- Routine review of various sources for signals
- Validation and evaluation of signals
- Propose appropriate actions and assist in communicating and implementing these through PharmaLex regulatory experts
- Strategic advice on responding to health authority queries on safety issues
- Review of EVDAS eRMR reports through proprietary tool

9 out of 10 top pharma companies are our valued clients

Over 1000 eCTD submissions annually

Regular interactions with all major global health agencies

Proven track record with 6,000 successfully completed projects

InnoPHLEX

DISCOVERY / NON-CLINICAL

CLINICAL DEVELOPMENT

APPROVAL / AUTHORIZATION

PRODUCT MAINTENANCE

SourcePHLEX

DELIVERING SUCCESS WITH CONFIDENCE

PHARMALEX IS A LEADING PROVIDER OF SPECIALIZED SERVICES FOR THE PHARMA, BIOTECH AND MEDICAL DEVICE INDUSTRIES

KNOWLEDGE.
ACCELERATED.
confidence *beyond* compliance

We guide you from early strategic planning activities and non-clinical requirements through clinical development, regulatory submission processes and post-approval / maintenance post-launch activities.

Our experts use **technology-enabled solutions** to support you through the entire product lifecycle. We deliver exceptional results - going above and beyond the standard to deliver tailor-made solutions worldwide.

Stay **one step ahead** of essentials required by health agencies.

Our knowledge accelerates your business success...

Knowledge. Accelerated.

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GLOBAL COVERAGE
WITH SUBJECT MATTER EXPERTS WORLDWIDE INCLUDING FORMER HEALTH AUTHORITY / AGENCY EXPERTS

25+ YEARS
OF INDUSTRY EXPERIENCE

9/10
TOP PHARMACEUTICAL COMPANIES ARE OUR SATISFIED CLIENTS

COMMITTED TO
ENVIRONMENTAL CHANGE

50+%
OF OUR PROJECTS ARE GLOBAL