Kohne Pharma GmbH

European Marketing Authorisations & Regulatory Affairs

OUR OUTSOURCING OFFER

Selectable Modules

Within the European and German legislation high demands are permanently made on drug safety.

Pharmaceutical enterprises are confronted with a multiplicity of laws and regulations and have to cope with an increasing request of information from patients, health care professionals and regulatory authorities.

The current market environment asks for flexibility and cost efficiency. Outsourcing enables you to reallocate your resources and to focus on your core business.

You can choose any level of complexity, either from a single module or assign us with a number of tasks within a project or transfer the entire venture to us.

Choose from the following modules:

+ **EU-QPPV**
+ **Pharmacovigilance System**
+ **Literature Research**
+ **Adverse Drug Reactions Reports**
+ **Periodic Safty Update Reports (PSUR)**
+ **Signal Management**
+ **Risk Management System**
+ **Environmental Risk Assessment (ERA)**
+ **CCDS/CCSI**
+ **Clincial and Non-Clinical Overview**
+ **EVMPD**

Please have a look inside for the detailed description of our services.

About Kohne Pharma

Kohne Pharma is your reliable partner who possesses almost 40 years of experience in the field of regulatory affairs and pharmacovigilance services.

We, at Kohne Pharma, are always driven by our philosophy to provide an outstanding service characterised by expertise, quality and flexibility.

Our well-trained team of specialists provides the latest pharmaceutical and regulatory knowledge and manages interdisciplinary regulatory projects.

We understand our customer's needs and are able to translate difficult regulatory requirements into your daily business.

As a service provider for the international pharmaceutical industry we serve our customers not only in Europe but also in the Rest of the World (ROW).

Kohne Pharma is your Regulatory Affairs and Pharmacovigilance expert!

www.kohne-pharma.de

MODULAR OUTSOURCING

Kohne Pharma GmbH
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PHARMACOVIGILANCE

EU-QPPV

+ We take over the duties and the responsibility of the Qualified Person for Pharmacovigilance (QPPV) in accordance with §63a German drug law/directive 2001/83/EU on behalf of pharmaceutical enterprises.

PHARMACOVIGILANCE SYSTEM

+ Planning and establishment of your pharmacovigilance system (at your location)
+ Compilation of a Pharmacovigilance System Master File (PSMF) according to GVP module II and its maintenance
+ Preparation and maintenance of SOPs incl. employee training

LITERATURE RESEARCH

+ Weekly worldwide scientific literature search
+ Regular screening of authority websites

ADVERSE DRUG REACTIONS REPORTS

+ Collection, identification and assessment of Adverse Drug Reactions (ADR)
+ MedDRA coding and data base entry
+ Notification of suspected serious ADRs to authorities

PERIODIC SAFTY UPDATE REPORT (PSUR)

+ Conduction of the necessary literature search
+ Preparation of PSURs according to GVP module VII
+ Compilation of Line Listings
+ Adaptation to formats required outside EU/EEA

SIGNAL MANAGEMENT

+ Screening of relevant authority websites
+ Screening of active surveillance systems and EMA and WHO-UMC data bases
+ Signal detection according to GVP module IX
+ Permanent Benefit Risk Assessment (BRA)
+ Taking necessary measures

RISK MANAGEMENT SYSTEM

+ Preparation of Risk Management Plans (RMP) according to GVP module V
+ Maintenance of RMPs
+ Preparation of educational material

ENVIRONMENTAL RISK ASSESSMENT (ERA)

+ Preparation of ERA Phase I

CCDS/CCSI

+ Preparation and update of Company Core Data Sheets and Company Core Safety Information (CCDS/CCSI)
+ Development of strategy and customized system for international operating MAHs for implementation of safety relevant information into CCDS/CCSI, SmPC and their maintenance

CLINCIAL AND NON-CLINICAL OVERVIEW

+ Preparation of module 2.4 of CTD (NCO) and module 2.5 of CTD (CO) and addendum reports

EVMPD

+ Appropiate submission software available
+ „3rd party provider" or „virtual affiliate"
+ Data coding, entry and submission as x-EVMPD to EMA

Prices and terms:
We offer all our services for an attractive individual price subject to a service agreement with your company.

For further services, scan me or browse:
www.kohne-pharma.de

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