Kohne Pharma GmbH

European Marketing Authorisations & Regulatory Affairs

OUR OUTSOURCING OFFER

A broad variety of services

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 assign us with a number of tasks within a complex project or you can transfer the entire venture to us.

Our services cover three mayor fields:

+ **Application Procedures**
+ **Life Cycle Management**
+ **Pharmacovigilance**

COVERAGE OF SERVICES

We offer an all-inclusive package which considers and consists of the following elements:

+ We work in accordance with your SOPs.
+ We comply with all local specific requirements in your territory.
+ We cooperate with your affiliates or agents.
+ We can handle all documents electronically.

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 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 expert!

www.kohne-pharma.de

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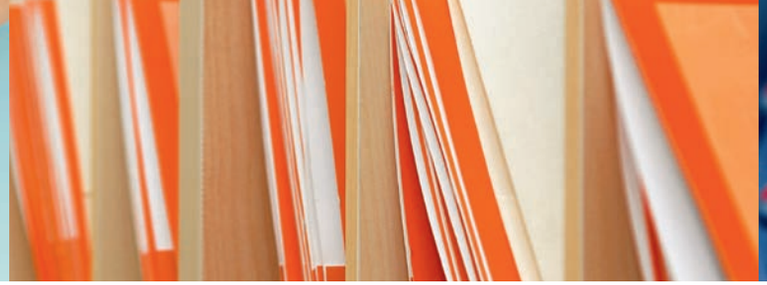
OUTSOURCING

APPLICATION PROCEDURES

LIFE CYCLE MANAGEMENT

PHARMACOVIGILANCE


APPLICATION PROCEDURES

+ Strategic advice on and planning of application procedures
+ Preparation and compilation of dossiers
+ Preparation of Clinical and Non-Clinical Overviews
+ Filing of the application including shipment
+ Accomplishment of national and European application procedures for medicinal products (MRP, DCP and CP)
+ Creation of package leaflets, SmPCs and labelling of finished pharmaceutical products
+ Organisation of Readability Testing
+ eCTD – electronic application and maintenance of eCTD submissions
+ Handling and answering of deficiency letters
+ Communication with the regulatory authorities

VARIATIONS

+ Planning of variation procedures including compilation of all necessary documents and information
+ Filing of the application and execution of variation procedures (IA, IB, II)
+ Handling of deficiency letters during the procedure
+ Execution of the necessary Change Control Management

LIFE CYCLE MANAGEMENT

+ Monitoring of applicable terms
+ Allocation and compilation of all necessary documents and information
+ Accomplishment of dossier updates
+ Communication with the regulatory authorities
+ Filing of the renewal and execution of the procedure
+ Answering of questions by the regulatory authorities
+ Consideration of all local requirements

PHARMACOVIGILANCE

+ Compilation of a Pharmacovigilance System Master File (PSMF) or Risk Management Plans (RMP) including necessary maintenance and updates
+ Provision of Qualified Person for Pharmacovigilance (EU-QPPV)
+ Execution of worldwide scientific literature research
+ Collection, assessment and notification of Adverse Drug Reactions (ADR)
+ Creation of Periodic Safty Update Reports (PSURs). Benefit from the pooling of PSURs for different customers!
+ Permanent Benefit Risk Assessment (BRA)

Project management:
All our services are accompanied by a state-of-the-art project management irrespective if you choose a single module or a broad range of services.

Your advantages:

+ We fix the desired results of the project.
+ We create a project plan and set up the milestones during the project.
+ We provide you with a fixed project manager as your personal contact.
+ We take over the entire project management of the assigned task.
+ We can assume the entire communication with internal and external stakeholders (Authorities, Agents, Drug Safety, Global Regulatory Affairs and Global Labelling).
+ We keep you updated during the entire process.
+ We report critical events and propose solutions.
+ We conclude the project successfully.

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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