



# PHARMACEUTICAL PRODUCTS & MEDICAL DEVICES

## REGISTRATION & REGULATORY SERVICE SUPPORT

Hong Kong & Macau / Greater Bay Area



A member of



# KLN PHARMA

assists manufacturers to navigate the Pharmaceutical Regulatory road map and to help to standardise procedures, centralise systems, streamline regulatory submissions, manage the entire registration process with cost-effective solutions.



## COMPANY PROFILE

KLN PHARMA (HONG KONG) LIMITED is one of Asia's biggest pharmaceutical and healthcare third party (3PL) and fourth party (4PL) logistics companies. Our regulatory advice team brings diverse expertise across therapeutic areas and functional disciplines to provide regulatory services throughout product development and lifecycle.

We share our expertise in pharmaceuticals, biologicals, healthcare products, medical devices, health supplements and veterinary products, and are committed to helping our clients and partners to deliver safe and effective therapeutics.

## OUR SERVICES

Product  
Registration

Regulatory  
Service  
Support

Trade &  
Distribution

Sales &  
Marketing

Pharmacovigilance  
Management  
Support

Training &  
Consultancy



## Product Registration

We can assist in developing a regulatory strategy to capture or grow your market share, increase productivity and maintain competitive position.

Our services include:

- Acting as your independent regulatory representative for registration of imported **Pharmaceutical Products and Medical Devices** in HK
- Evaluation of documentation and supervision of related tasks
- **Pharmaceutical Products and Medical Devices** regulatory consulting
- Product lifecycle maintenance (e.g. variations, renewals, etc.)
- Marketing Authorisation holder maintenance, renewal & transfer



## Trade & Distribution

We provide an extensive coverage to various sales channels and outlets, as well as regular deliveries to outlying islands and remote areas.

- Key Accounts & General Trade
- Ethical Segments
- Home Delivery
- Public & Private Hospitals
- Rehabilitation centres & NGOs



## Guidelines

## Regulations

## Regulatory Service Support

- Facilitate interactions with the Department of Health Drug Office on regulatory issues and respond to their questions
- Regulatory consulting on advertising and marketing
- Regulatory translations (SPC, PIL, labelling)
- Translations of Instruction For Use (IFU)
- Artwork and mock-up support
- Product classification

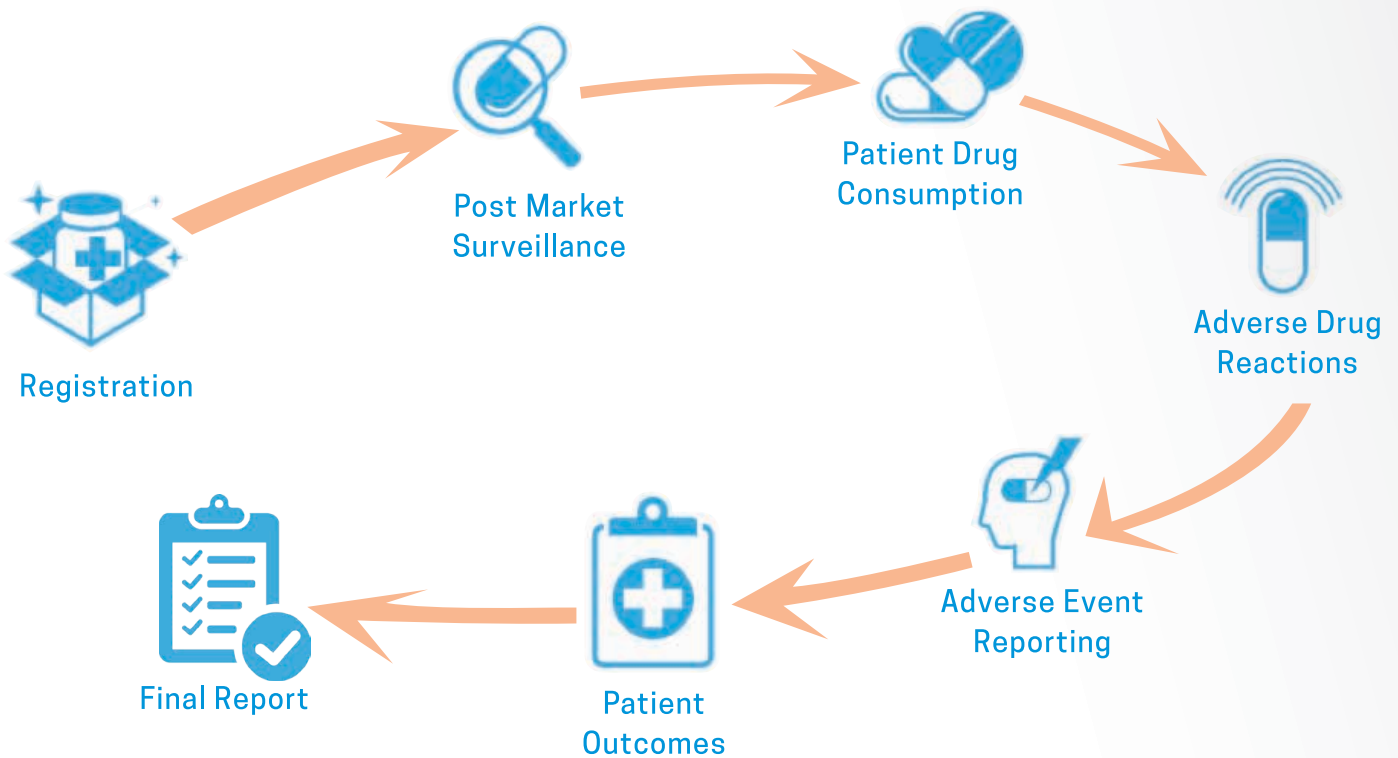


## Sales & Marketing

- Capture the market & develop strategies
- Large sales & marketing team
- Expand market share and minimise selling costs
- Plan and execute promotions
- Support events, exhibitions and booths
- Produce marketing collaterals
- Provide stock management services

# Pharmacovigilance Management Support

- Adverse event tracking
- Local literature screening
- Periodic safety update reports submissions
- Adherence to regulatory compliance/ maintenance



## Training & Consultancy

We also customise solutions to meet specific technical needs and financial capabilities. Our expert team has more than 10 years of experience in the pharmaceutical industry and can offer the following services:

- Identification of necessary skills, competencies and qualifications needed to perform given roles and understanding of business requirements
- Guidance on functional behavior and the implementation of Quality Management System (QMS)





# FOR MAINLAND & OVERSEAS MANUFACTURES/ SUPPLIERS

We offer the following services:

- Preparing, reviewing and submitting drug product dossier
- Tracking legislative changes in relevant regions
- Advising on legal and scientific restraints and requirements
- Presenting registration documents and carrying out any subsequent negotiations to obtain or maintain marketing authorisation
- Giving strategic and technical advice at the highest level, making an important contribution both commercially and scientifically to the success of the company
- Helping to avoid badly kept records or poor presentation of data
- Providing comprehensive pharmacovigilance services for post-marketing surveillance



# EXPAND BUSINESS IN THE GREATER BAY AREA



With the announcement of the Work Plan for Regulatory Innovation and Development and Medical Device, issued by The National Medical Products Administration, a new opportunity has opened up for the pharmaceutical industry in Greater Bay Area (GBA).

Drugs and medical devices registered and used in Hong Kong public hospitals will be permitted to use in designated healthcare institutions in GBA region, under urgent clinical use and advanced clinical applications.

We are striving to provide the most effective registration service to our clients. If your company is interested in expanding into the GBA, KLN PHARMA is your ideal partner for your needs.



**CONTACT US NOW**



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