APEX PHARMA MARKETING PTE LTD

POSITION TITLE : REGULATORY AFFAIRS MANAGER

DATE : 4 OCTOBER 2019

A) ABOUT APEX

Apex Pharma Marketing Pte Ltd is an established distributor for pharmaceuticals and consumer healthcare products to hospitals, medical specialists, general practitioners, pharmacies and healthcare stores.

At Apex Pharma Marketing Pte Ltd, our people are our greatest assets. We are always looking for dynamic and talented people to join us. Be part of a vibrant, energetic and dedicated Apex family.

B) OVERALL PURPOSE OF JOB

The Regulatory Affairs Manager has the primary responsibility of working first hand with suppliers and Principals, and together with assigned personnel, towards achieving common strategic regulatory goals. He/she needs to provide training, guidance and direction to assigned personnel to achieve the said goals and ensure consistency with the policies and procedures of the company.

B) PRINCIPAL DUTIES AND RESPONSIBILITIES

- Identifies, evaluates and recommends regulatory strategies to secure earliest possible registration and marketing approval for new products and maintain or improve the status of existing ones.
- Stay current with regulatory trends so as to help propose and formulate appropriate regulatory strategy.
- Supervise the Regulatory Affairs team by planning, assigning and directing work within team, and appraising team's performance against set regulatory goals.
- Reviews and ensures accurate completion and timely submission of governmental, company and other reports as required in respect of assigned areas of responsibilities.
- To assess and provide direction to the Regulatory Affairs team in product registration submission. Ensure adherence of pre- and post-product registration commitment to regulatory authorities.
- To develop and maintain positive relationships with regulatory authorities. Bridging and narrowing the regulatory gap of enforcements and company practices.
- Perform regulatory submissions, track and provide status updates for Therapeutic Products, Chinese Proprietary Medicine, Medical Devices, Product Enquiries and Medical Advertisements and Permits.
- Maintain timely submissions and implementations of post approval variations for therapeutic products and medical devices
- Handle permit applications related to controlled drugs, psychotropic drugs and unregistered products and medical devices
- Handle import, distribution and record-keeping of controlled drugs.
- Provide regulatory advice and consultation to principals on the changes and updates within the local regulatory infrastructure and guidelines
- Support regulatory compliance activities for post market vigilance reporting (ADR), and product recalls.

- Designs, establishes and maintains an organisational structure and staffing to effectively accomplish the division's goals and objectives.
- Directs and oversees the supervision of assigned personnel, which includes work allocation, training and problem resolution, evaluates performance and makes recommendations for personnel actions.
- Ensures that work production in the assigned division meets established objectives, specifications, and standards, and that all-applicable operating policies and procedures are adhered to.
- Recommends and participates in the development of company policies and procedures to ensure efficient and safe operation of the division.
- Establishes rapport and maintains an amicable and fruitful business relationship with existing as well as potential clients and Principals.
- Participates in the development and management of annual operating budgets for the assigned division and regularly monitors expenditure.
- Performs miscellaneous job-related duties as assigned.

INTERESTED PARTY, PLEASE EMAIL CV TO apexhr@apexpharma.com.sg