EXECUTIVE - REGULATORY & QUALITY / PHARMACIST

Aceto is a leading global chemical distributor and manufacturer providing specialty chemicals, intermediates, and reagents to the life science and advanced technology end markets. With business operations in nine countries, Aceto distributes over 1,100 chemical compounds used principally by the pharmaceutical, nutraceutical, agricultural, and specialty chemicals industries. Aceto's global operations, including a significant staff on the ground in China and India, are distinctive in the industry and enable its worldwide sourcing and regulatory capabilities.

Founded in 1947, customers leverage Aceto as a chemical supplier for niche, difficult to source materials, at a price that provides real solutions. We match customer needs with our broad inventory of qualified suppliers to identify best fit for Quality and performance.

We serve customers in the following business segments:

- Active Pharmaceutical Ingredients
- Pharmaceutical Intermediates
- Nutritionals
- Agricultural Protection Products
- Specialty Chemicals
- Cosmetic Ingredients

The Regulatory & Quality (RA) Executive is responsible for filing, follow up necessary applications and handling all government interactions pertaining to the regulation process for products requiring governmental approval. Assist to develop procedures to ensure regulatory, sales and customer compliance as and where required for Singapore Region

The position will be full time and should be based in Singapore and will report to the managing Director.

Responsibilities will include:

- Provide directions for developing, implementing, and maintaining the regulatory permit/license to comply with the Medicines & Poison Acts and meet Health Science Authority (HSA) requirements
- Handle regulatory documentation of pharmaceutical products, including facilitate internal & external audits at site level
- Ensure third party warehouse follows strictly requirements for storage of Controlled Drugs
- Review and supervise Customer Service personnel on issues with poisons and controlled drugs in relation to shipments of goods
- Apply for Import/Export licenses for Psychotropic Substances / Controlled Drugs to Central Narcotic Bureau (CNB) /HSA
- Approve the sales of controlled drugs to customers
- Ensure proper maintenance of controlled drugs records for CNB/HSA inspection
- Provide advice on any regulatory or quality issue and assist on other relevant issues in the capacity of a pharmacist

- Keep track of changes in country's regulatory requirements and provide regulatory intelligence to Management, Business Development and Sales team.
- Support in the maintenance of the Quality Management System to comply with GDP requirements and international regulatory requirements.
- Maintenance of HAS importer license, wholesale license and other licenses for business operation.
- Any other ad-hoc duties as and when assigned by immediate Reporting Officer
- Explaining and Ensuring regulations, policies, or procedures compliance with regulations
- Advising others on matters that are related to regulatory processes and compliance
- Overseeing the planning, coordination, and management of regulatory documentation activities. Examining, identifying, and interpreting relevant regulatory guidelines
- Analyzing and evaluating laws and regulations that apply to the process of determining the impact on company activities
- Compiling and overseeing the maintenance of regulatory documentation databases & systems, coordinating efforts that are related to the preparation of regulatory documents
- Developing and maintaining healthy communication with regulatory agencies regarding pre-submission strategies, compliance test requirements, potential regulatory pathways, or clarification, and follow-up on submissions still under review.
- Develop, follow up and closing sales of Regulated products, documentation and filling for Singapore.

Required Experience:

- Degree in Pharmacy, Medical Science or equivalent.
- At least 3 years of regulatory affairs experience in a pharmaceutical company.
- Registered Pharmacist with Singapore Pharmacy Council

Other Specific Knowledge and Skills:

- Good time management skills, as a regulatory affairs specialist, must be able to work effectively in a demanding environment where strict timelines and protocols must be met
- Proficiency and familiarity with databases or other information management tools, since regulatory affairs specialists frequently work on managing and documenting information
- Excellent organizational and project management skills to frequently coordinate complex activities, often with competing priorities
- Well-developed analytical skills and the ability to pay particular attention to details
- Well-developed written and oral communication and interpersonal skills to frequently work with other employees and team members, and also advise others on compliance and regulatory matters
- Fluent English

To apply for this position, please send your resume and cover letter to Ms Pauline Sng - email : psng@aceto.com

Thank you.