JOB VACANCY: Regulatory Affairs and Compliance Officer (1)

Company Overview:
Abacus is the leading distributor and manufacturer of pharmaceutical products in the East Africa region with a presence in 5 countries (Uganda, Kenya, Tanzania, Rwanda, and Burundi). Over the last 25 years, Abacus has grown from a small trading company to the leading pharmaceutical manufacturer and distributor in East Africa.

About the Role:
Abacus Pharma (A) Ltd – Rwanda is looking for a skilled and experienced Regulatory Affairs and Compliance Officer to join our dynamic team. As a Regulatory Affairs and Compliance Officer, you will play a pivotal role in ensuring adherence to regulatory standards and compliance with quality assurance systems. Key responsibilities include overseeing product pre-registration, registration, and post-registration processes, providing effective and efficient quality assurance systems support to the Abacus Rwanda including supporting the implementation and maintenance of the quality management system, and performing the day-to-day work to meet the compliance standards of the QMS and the local Regulator as applicable to global and local standards

Position: Regulatory Affairs and Compliance Officer
Location: Kigali, Rwanda

Job Roles and Responsibilities:

Pre-registration:

Dossier review

- Review and evaluate documentation of drugs, medical devices and cosmetics before submission of dossier to RFDA for registration.
- Communicate with applicant/ manufacturer on the requirements/ deficiency of the dossier before submission of the application for registration of the products to RFDA.
- Compilation of dossier after submission of information from applicant/ manufacturer and approve submission of dossier to RFDA for application of registration of product.

Registration Process

- Cooperate with the company finance department to ensure that all fees relating to drug registration are payable to RDFA.

- Submission of dossier, samples and other requirements to RFDA for application of registration of products.
- Submission of GMP documents i.e. SMF to the Authority for the site audit and coordinating with the Authority for the audit plans.
- Make a close follow-up on the application of registration of the product and facilitate the registration process by responding to queries addressed by RFDA on time.
- Collection and confirm the registration certificate granted by RFDA after registration approval.

Registration

Importation of product

- Importation process of the product by applying permit for importation of the product (RFDA online application system).
- Monitor storage of products under respective storage conditions at the premises.

Post Registration.

Post Marketing surveillance and Pharmacovigilance

- Take measures by reporting to RFDA on any issue relating to counterfeit drugs and substandard drugs identified on the market.
- Collection of information relating to adverse drug reactions and report to RFDA.
- Coordination of the recall process of any product complaints from customers and take necessary measures.

Post Approval regulatory issues.

- Application of post-approval regulatory issues such as variation/ alteration, promotional materials approval and renewal of the registered product.
- Coordinating the payment of the annual retention fees for the principal companies
- Renewal application of product registered after expiration of registration time
- Apply for any variation as per company and market interest.
- Appling for the approval of the promotional material

Destruction Process

- Coordinating of the destruction process for expired/damaged/recalled products.

Quality Systems (in all technical operations):

- Ensure that all SOPs are in place, in use and updated
- Support the APL Rwanda to ensure that all internal procedures and systems in use are compliant with QMS, and local regulatory requirements, including but not limited to good storage and distribution practices (GSDP).

Key Performance Indicators:

1. New product registrations
2. Implementation of ISO standards
3. SOP training and adherence
4. Timely registration of drugs
5. Timely report submission

Competencies:

1. Technical Knowledge/ Skills:
2. Excellent written and verbal communication skills
3. Analytical mindset and problem-solving skills
4. Ability to work independently and in cross-functional teams
5. Proficiency in Microsoft Word, Excel, PowerPoint, and Outlook

Behavioral / Attitude Competencies:

1. Respect for others
2. Sociability
3. Result-oriented
4. Openness and decisiveness
5. Teamwork

Minimum Qualifications / Requirements:

1. Bachelor's degree in Pharmacy
2. 2-5 years of experience in the pharmaceutical or healthcare industry

How to Apply:

If you are a motivated professional with a passion for regulatory affairs and compliance and meet the qualifications outlined above, we invite you to submit your Resume and a cover letter detailing your relevant experience and why you would be a great fit for the role. Please send your application to aplrw.rwanda@abacuspharma.com by **30th April 2024**.

Abacus Pharma (A) Ltd is dedicated to promoting diversity and inclusivity in the workplace. We are an equal opportunity employer and welcome applications from all qualified candidates. We appreciate your interest in joining our team, but please note that only shortlisted candidates will be contacted for further consideration. It's important to note that we will be reviewing applications on a rolling basis and the best candidates may be selected before the application deadline. Therefore, we encourage interested candidates to submit their applications as soon as possible.

End.