Job title:

Regulatory Affairs Pharmacist

Company: Afriplex

Department: Regulatory Department

Minimum requirements:

- Pharmacist degree & registered with the SAPC - non-negotiable.
- Minimum 3 years' experience as a Regulatory Pharmacist - Non-Negotiable
- Proficiency in Afrikaans is essential .
- Experience with complimentary medicines and Botanical extracts as well as knowledge of CAMs, homeopathic and herbal medicines will be advantageous.
- Excellent written and verbal communication skills.
- Ability to manage multiple and varied tasks with enthusiasm and prioritizing of workload with attention to detail.
- Computer literate with good numeracy skills.
- A flexible attitude with respect to work assignments and new learning.
- Self-motivated with a willingness to accept responsibility and challenges.

Job purpose:

The incumbent's role will be to provide technical and administrative assistance to the Regulatory Department managers and pharmacists with regards to the registration of new Complementary and Alternative Medicines products. To provide technical and administrative assistance to the Responsible Pharmacists and the Regulatory Department managers and pharmacists with regards to all GxP activities as per the legal requirements for applicants.

Key responsibilities and accountabilities:

GENERAL

- Gather information and data from multiple business partners and internal systems.
- Compiling a summary of technical documentation files
- Evaluate interim results and compile reports as required.
- Work efficiently with other regulatory personnel.

- Organising and managing of information and record keeping.
- Ensuring GxP is maintained.
- Expertise regarding pharmacovigilance, quality systems in pharmaceutical industry or CAMS sector
- Create and cultivate alignment on new regulatory pathways for current and new product development in South Africa
- Responsible for Regulatory Affairs functions across the board
- Responsible to obtain and maintain regulatory licenses
- Review, maintain, update, compile and submit dossiers for current and new products in South Africa
- Ensure to update and advise department and stakeholders on regulatory matters
- Responsible to represent the Regulatory Function Matters at various meetings, internal and external.
- Ensure good relations with the Regulatory Authorities and build upon network of regulatory contacts
- Ensure guidelines and regulations compliance is adhered
- Responsible for eCTD compilation, submission and follow up (non-negotiable requirement)
- Perform audits on existing and new product dossiers
- Manage and ensure audit readiness at all times
- Implementing guidelines to support Quality Assurance's processes
- import permits management

ADVERTISING AND PROMOTIONAL MATERIAL

- Review and approve all promotional material and training material relating to the advertising and promotion of medicines and related products for the SA and SADC markets in compliance with legislation, the SA Code of Marketing Practice and any other applicable regulations/guidelines and corporate requirement. This includes products marketed by other companies or licensors
- Liaise with marketing divisions and third parties where necessary regarding advice, queries, and timelines with regard to the above
- Liaise with the Third-Party companies regarding appropriate promotional claims, clinical reviews etc. where necessary
- Assist with the review of information relevant to each product

- Attend promotional campaign concept presentations by the brand managers and/or advertising agencies to provide regulatory support and input to the marketing teams at their request

PRINTED PACKAGING / ARTWORK

- Review and approve concept of new or updated artwork/printed packaging material for medicines and related products for the SA and SADC markets in compliance with applicable legislation and corporate requirements
- Undertake the Afrikaans translation and / or validation of Professional Information and Patient Information Leaflets for the SA market for new products and for existing products requiring updates to their safety information

MEDICINE REGISTRATION/PRODUCT LAUNCHES

- Assist with the sourcing of information and compilation of documentation required for new product launches, line extensions, marketing authorisation transfers, tender applications and the like, such as Product Launch Briefs.
- Liaise with Third-Party companies and the New Product Launch team for information related to the completion of these documents where necessary

PROJECT MANAGEMENT

- Assist with the management of specific projects to ensure the continued marketability of SA and SADC products when necessary
- Provide any other support required for the continued commercialisation of products in SA and other SADC countries
- Participate in internal audits of the RA-SA team and of other internal Regulatory/QA teams in accordance with the Self-Inspection schedule