A Manufacturing, Pharmaceutical concern in Paarl is looking for a

Regulatory Affairs Pharmacist

Company: Afriplex

Department: Research and Development

Minimum requirements:

- B.Pharm and registration with the SAPC as a Pharmacist.
- Minimum 5 years' experience in the pharmaceutical industry. At least two years in the Regulatory Affairs department.
- Strong knowledge and ability to compile and submit dossiers
- Good relationship with the MCC and other stakeholders.
- 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:-

1. Perform pre-launch stage product submission and registration activities

Completes specific pre-registration activities including receipt, screening, compilation and timeous submission of dossier/s with different dosage forms, e.g. capsules, tablets, etc. to the Medicines Control Council or any other applicable regulatory authority

Ensures that all assigned dossiers are submitted timeously to relevant health authorities and are followed up on regularly in order to enable first to market registrations

Ensures that required standards, protocols and processes around obtaining dossiers and gathering supporting data from suppliers are followed after signing of supply / purchase / financial agreements

2. Performs dossier life cycle management registration activities

Receives, prepares and submits all applicable updates, amendments, resolutions and any other correspondence required by the M.C.C. or any other applicable regulatory authority

Completes dossier audits of Registered Products for the Therapeutic Category Portfolio assigned

Conducts dossier due-diligences, post-registration amendments, pharmaceutical and analytical resolutions for all applicable Regulatory Authorities in compliance with the latest regulatory guidelines and in accordance with specified time-lines in order to support the business and strategic company objectives

Conduct any applicable telephonic communication with M.C.C. or any other regulatory authority

3. Develops and manages stakeholder relationships

Builds and pro-actively maintains critical relationships with the MCC and equivalent bodies in other countries to ensure streamlined submissions, evaluations and registrations

Manages relationships with the MCC's units to ensure more effective streamlining of the company's applications when required

4. Technical and administrative duties with regards to the registration of new Complementary and Alternative Medicines products Administration duties and document maintenance, collection and delivery

Ensures that the Dossier Room and Document Database is kept in good order by completing the required administration activities for appropriate maintenance, co-ordination and accuracy of all dossiers and correspondence

Ensures that photocopying, binding and final preparation of documents for submission to M.C.C. and in-house copies or any other applicable regulatory body are completed and quality checked before final submission

Completion of internal risk reports in line with the above submissions

Delivery and collecting of documents to/from M.C.C. as and when applicable function.

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:

- Keeping pace with regulatory requirements.
- Ensure approval of registration applications of all medicines in applicable countries.
- Ensure the maintenance/ update of registrations in accordance with the relevant
- legislation, regulations and guidelines
- Compilation of registration dossiers for submissions Perform QA on all artwork and approve all printed packaging material
- Ensure compliance with quality requirements on release of medicine for sale in line with GMP and company policies and procedures.
- Prepare and update data for MDR, MIMS or any other external product database for all marketed products in liaison with the Regulatory Affairs Head.
- Establish and maintain effective relationships with all stakeholders

If you meet above requirements, please send your CV and a cover letter to MarethaW@afriplex.co.za on or before the 28th of February 2018.