

Vacancy



| | |
|-------------------------|----------------------------|
| Job Title | Regulatory Affairs Manager |
| Department | Regulatory Affairs |
| Location | Midrand |
| Upward Reporting | Head of Quality/RP |

| PURPOSE OF JOB | |
|--|---|
| <p>The role is responsible for developing strategies to ensure regulation compliance of the organization and also to ensure that necessary documentation is completed and submitted to relevant regulatory statutory bodies.</p> | |
| KEY RESPONSIBILITIES (KPA'S) | ACTIVITIES |
| Product registrations | <ul style="list-style-type: none"> • Management of all product registrations, new products and variations in local and ZA export market • Contribution to monthly meeting with region regarding registration status of all products • Ensure that all legal requirements regarding product registrations are implemented and legislation changes are clearly communicated as required. • Close liaison with all Manufacturing facilities to ensure that any anticipated regulatory changes that will affect product supply are communicated to marketing to anticipate the effect on the market. • Ensure packaging material related to SAHPRA changes are implemented as needed • Ensure marketing code compliance with all promotional material • Participate in the senior management team as a Regulatory Affairs lead and share best practices with peers |
| Stakeholder Relationship Management | <ul style="list-style-type: none"> • Build relationships with SAHPRA and other stakeholders both internal and external thus continuously ensuring good working relationships and continued compliance • Ensure all required fees are paid as required (Annual retention and New Product Registration fees) • Foster good working relationship with local plant |
| People Management and Training | <ul style="list-style-type: none"> • Draft or update job profiles of staff as the needs of the department and the organization changes • Draft performance contracts with staff by setting clear key performance indicators (KPI's) annually or as required • Draft and communicate training needs of staff by analyzing previous employee performance and identifying performance gaps on an ongoing basis • Manage and provide ongoing performance feedback to staff as required |

| | |
|------------------------|--|
| | <ul style="list-style-type: none"> • Implement the performance evaluation process by scheduling performance reviews with staff, leading the performance discussion and completing the performance reviews annually • Manage the department's recruitment needs by liaising with HR to ensure that recruitment is reflective of Employment Equity targets as required • Manage the department's leave by making sure all staff leave has been applied for on ESS and approved as discussed and as required. • Manage the compliance of policies and procedures within the department by ensuring policies and procedures are effectively communicated to the team as required. • Ensure appropriate disciplinary action is taken as required |
| Budget management | <ul style="list-style-type: none"> • Setting annual cost centre budget and CAPEX budget • Monitoring adherence to budget monthly making quarterly adjustments as needed during forecast meetings • Predicting spending in advance especially at month and year end ensuring accrual is made as needed |
| Quality and Compliance | <ul style="list-style-type: none"> • Draft and initiate SOP's required for the Regulatory Affairs (RA) Department to ensure that all RA function related processes within FKSA are compliant on an ongoing basis • Ensures that RA function related activities are in compliant with legislated requirements i.e. Medicines Act, Pharmacy Act and Good Manufacturing Practice as well as corporate guidelines • Approval of promotional material in line with company and industry standards. Ensure adherence to Marketing Code • Implement corrective action from any internal or external audits • Assist in the resolution of all RA function related CAPA's and deviations • Ensure that contracts and SLA's relevant to the department are in place and liaise with the line manager or Managing Director. • Manage the collection of B-BBEE related evidence and record keeping on an ongoing basis. • Ensure adherence to health and safety procedures as required by legislation. • Act and participate as a Health, Safety and Environment appointee delegated by the Head of Marketing and Regulatory Affairs. |

| Education: Formal Qualifications | |
|---|--|
| Required Level of Education | <p>B. Pharm or Dip Pharm qualification</p> <p>Registration with the South African Pharmacy Council</p> |
| Skills & Experience | |
| <ul style="list-style-type: none"> • 6 – 10 years of regulatory affairs experience and experience in Pharma regulatory management • People management skills, as well as with deep international & local regulatory knowledge • Highly skilled in establishing partnerships and collaboration with business partners, as well as internal and external stakeholders • Strategic thinking and ability to partner and influence at all levels • Established and existing relationships in the industry and with key stakeholders | |
| Competencies: | |
| <p>1. Business Competency: The ability to recognize opportunities for new services and products and to act accordingly, taking measured risks into account.</p> <ul style="list-style-type: none"> • Customer orientation • Ability to meet deadlines & attention to detail • Goal & result orientation • Problem solving • Continuous improvement • Assertiveness <p>2. Strategic Competency: Transforms the Fresenius Kabi SA vision and strategy into specific business plans, concepts and priorities based on broad strategic knowledge and business understanding of our core competences</p> <ul style="list-style-type: none"> • Strategic Orientation • Cross Departmental thinking approach • Sense of Market and future trends • Management of Complexity <p>3. Leadership Competency:</p> <ul style="list-style-type: none"> • Management by Objective • Coaching • Delegating / Delegation • Planning & Organizing • Communication and negotiation • Teamwork • Empowers People <p>4. Professional Competency:</p> <ul style="list-style-type: none"> • Expert Know-how • Passion for success • Innovative • Adaptability/Flexibility • Change fit <p>5. Social and Intercultural Competency:</p> <ul style="list-style-type: none"> • Authentic (Integrity) | |

- Trustworthy, reliable & respected
- Quality & Safety
- Values
- Conflict Management
- Diversity
- Networking (Cooperation)

The Affirmative Action principles as set out in the Company's Employment Equity targets and Policy shall apply. In addition, selection of the successful candidate will be dependant on the operational requirements of the Company.

All staff interested in applying for this position should hand deliver their applications to **Tsebishi Mohuba personally or email tsebishi.mohuba@fresenius-kabi.com**

Closing date: 20th October 2023