



Date: 4 September 2020

**HUMAN RESOURCE CIRCULAR NO: 025/2020**

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**VACANCY: REGULATORY AFFAIRS PHARMACIST**

**Grade: 13**

**Division / Department:** Quality Management & Scientific Affairs

**Position reports to:** Regulatory Affairs Specialist

**Minimum Requirements**

- Bachelor's Degree in Pharmacy
- Medicines registration and CTD/e-CTD training
- 2 years' experience in the SA pharmaceutical industry in a manufacturing/quality assurance/regulatory environment.
- MS Office proficiency (Word, Excel, PowerPoint, Outlook)

**Additional Requirements**

- Regulatory experience and skills in the compilation, preparation, submission and maintenance of dossiers and new drug applications.
- Understanding of a pharmaceutical quality system, cGMP, GPP principles and pharmaceutical legal requirements.
- International regulatory submissions
- Experience in biologicals medicines manufacturing industry.
- e-CTD submissions

**Specific Operational Requirements**

- The successful candidate will be required to work an 8 hour day between 08h00 to 16h00
- The successful candidate may be required to work overtime to meet the business needs
- Local travel may be required to meet business needs

**Key Performance Areas**

- National NBI product regulatory submissions and applications
- International NBI product regulatory submissions and registrations
- Regulatory changes with respect to product licensing conditions, standards and compliance
- Regulatory Affairs Administration
- Internal and external networking and support

**Competencies**

- Technical / Professional knowledge and skills
- Planning and organising
- Attention to detail
- Communication (written and verbal)
- Critical thinking
- Analytical/problem solving skills
- Work standards
- Initiative and self- motivation
- Networking & Liaison
- Inter-personal skills
- Teamwork & Collaboration

**In line with the Employment Equity Act, preference will be given to those applicants whose appointment will address the demographic imbalances in our work force profile.**

**Due to the nature of the business, pre-employment, routine and exit medical examinations are compulsory.**

To apply for this position, please visit this website <https://nbi-sa.jonti2.co.za/>

**Closing Date: 25 September 2020**

***If you have not had a response from us within 30 days after the closing date, kindly accept that your application has been unsuccessful.***