



Date: 15 October 2018

HUMAN RESOURCE CIRCULAR NO: 036/2018

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
- 3 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: 29 October 2018

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