



Date: 30 April 2018

HUMAN RESOURCE CIRCULAR NO: 015/2018

VACANCY: REGULATORY AFFAIRS SPECIALIST

Grade: 14

Division / Department: Quality Management & Scientific Affairs

Position reports to: Manager: Regulatory & Clinical Affairs

Minimum Requirements

- Bachelor's Degree in Pharmaceutical Sciences or related Science discipline
- e-CTD dossier format training and submissions
- At least 6 years in the pharmaceutical regulatory environment.
- Regulatory experience with preparation, submission and maintenance of dossiers.
- National and international new drug application submissions
- Understanding of a pharmaceutical quality system, cGMP principles and pharmaceutical legal requirements.
- General supervisory experience.
- MS Office proficiency (Word, Excel, PowerPoint, Outlook)

Specific Operational Requirements

- May be required to work additional hours where critical submission deadlines need to be met.
- The successful candidate may be required to travel and work overtime to meet the business needs.

Key Performance Areas

- National NBI product registrations and regulatory submissions.
- International NBI product registrations and regulatory submissions.
- Regulatory guidance with respect to product licensing conditions, standards and compliance.
- Trace-ability of regulatory documents and decisions.
- Internal and external networking and support.
- Performance management of staff.

Competencies

- Technical / Professional knowledge and skills
- Planning and organising
- Attention to detail
- Verbal and Written Communication
- Analytical / problem solving skills
- Work standards
- Initiative and self-motivation
- Self –management
- Networking & Liaison
- Interpersonal 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.

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

Closing Date: 25 May 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.