BoMRA VACANCIES

The Botswana Medicines Regulatory Authority (BoMRA) is a body that was established through the Medicines and Related Substances Act of 2013, to regulate the supply chain of Human and Veterinary medicines, Medical Devices and Cosmetics. The Authority is looking for professionals to join their growing team.

Job Title: Director - Pharmacovigilance & Clinical Trials

Job summary

We are looking for a dynamic strategic leader for the role of Director Pharmacovigilance & Clinical Trials to oversee and drive strategic and operational functions of Pharmacovigilance (PV) & Clinical Trials at BoMRA.

The job reports directly to the Chief Regulatory Officer and its primary role is to oversee the implementation of a national post market surveillance & pharmacovigilance programmes. The incumbent is expected to ensure that all stakeholders, pharmaceutical service providers, and the general public, receive appropriate information on medicines safety. The role is also responsible for adverse drug reactions reporting, clinical trials monitoring, risk management for investigational and marketed products, regulation of promotional materials and advertising. The Director is to further ensure compliance with the relevant legislation, company policies and procedures.

Key Responsibilities

1. Actively participates in and coordinates the development of regulations and procedures and standard operating procedures for Pharmacovigilance, Post-Marketing Surveillance and Clinical Trials.
2. Assessment of Clinical Trial applications and inspections of Clinical Trials sites.
3. Ensures that Adverse Drug Reactions (ADRs) are assessed timely and according to approved guidelines and regulations to monitor safety signals to marketed products and investigational medicinal products.
4. To establish a system for reporting of Product Quality defects and technical non-compliance to control Substandard and Falsified medical products (SFs) and cosmetics in the market.
5. Manages the development, implementation and maintenance of computerised software and database for PV and Clinical Trials.
6. Assess and evaluates the reports of recommendations to the Product Registration and PV Committees.
7. Works closely with the other department heads to implement quality management system in the department.
8. Coach, motivate, and manage employees' performance through regular communication and timely feedback of performance appraisals, and making provision for appropriate training and development.
9. Prepare, implement, and monitor departmental budget and annual work plans to achieve the organisational strategic goals and objectives.
10. To foster cooperation with regional and international bodies on matters pertaining to the department.
11. Collaborate with Public Health Program Managers to build safety monitoring in public health programs and integrate with National PV program.
12. Organise workshops, seminars, continuing education programs to build capacity amongst all stakeholders responsible for PV and clinical trials.
13. To train future healthcare professionals in PV through liaison with universities/colleges to integrate PV in the pre-service curriculum.
14. Collaborate with academic and research institutions to execute research projects in PV and generate data that is relevant for the country for further characterization of an identified safety issue.
15. To communicate and collaborate with other stakeholders subscribing to alternative medicines to help their activities contribute to and enhance the nation's goals of an effective PV system.
16. To develop projects attracting donor funds to strengthen regulatory functions and build capacity.

Knowledge and experience

The role requires a Masters degree (MSc) or its equivalent in Pharmacy, Medicine or related field from a recognized institution and with at least at least ten (10) years' regulatory experience in the area of pharmacovigilance, clinical trials oversight as well as the implementation of both structured and unstructured post market surveillance. Six (6) years of this experience must be in a senior managerial position. A Doctor of Philosophy degree in the relevant field is an added advantage.

Competencies

The role requires a pragmatic and collaborative leader with a deep understanding of the medicine safety landscape. The incumbent should have the ability to work independently, with good interpersonal skills, strong communication skills, initiative, as well as tact and discretion in handling of confidential information. The position holder should also demonstrate good working knowledge of ICT Applications, a high level of diplomacy and good judgement, a high degree of integrity and probity, excellent organizational skills, strong ability to follow detailed processes and procedures, and precision in execution of work with attention to detail. A creative problem solver, with an entrepreneurial mindset and a strong leadership skill with a demonstrated track record of successfully managing and leading a diverse team, is preferred.

Kindly forward your applications to **recruitment@bomra.co.bw**

Closing date: 04 July 2024

Only shortlisted candidates will be contacted.

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