BoMRA VACANCIES

The Botswana Medicines Regulatory Authority (BoMRA) is an organisation set up under the Medicines and Related Substances Act (MRSA) of 2013 and was established by the Botswana Government to regulate the supply chain of medicines and related substances, cosmetics and medical devices in order to ensure their quality, safety and efficacy. The Authority is looking for Talent to occupy the following positions and become a part of a vibrant High performing team.

CHIEF REGULATORY OFFICER (X1)

Reporting directly to the Chief Executive Officer
Job Purpose
The purpose of this role is mainly to ensure that the Medicines and Related Substances Act is adhered to and that medicines are registered, narcotics controlled, medicines and medical devices tested and assessed for conformity to specifications.

Main duties
- Reporting to the CEO, you will be responsible for providing technical and operational strategic direction to ensure implementation and coordination of various technical functions related to the regulation of medicines and medical devices. While working with mostly the CEO and management team, you will advise on technical and operational matters and make recommendations on the overall regulatory strategy of the organization.

-The incumbent will provide regular reports to the CEO and Board of BoMRA on the functioning and regulatory performance of the Authority. You will contribute to reviews of MRSA and regulations and work with stakeholder organizations to ensure mainstreaming of emerging fields in medicines regulatory science. The post is suited to a determined, upwardly mobile professional ready for the top technical job to enhance full functional development of existing and new functions including veterinary medicines registration and medical devices. The incumbent will adapt to and demonstrate management ability and leadership in leveraging the values of the Authority to drive technical strategy implementation.

Qualifications and Experience
A Bachelor's Degree in Medicine, Veterinary, Pharmaceutical or Scientific Degree with 08 years appropriate experience in health products regulation or experience in corporate health products and services regulatory environment, of which at least five (5) years must be at a senior management level supporting business operations. An MBA or similar management qualification will be an advantage.

REGULATORY OFFICER – EXEMPTIONS & RENEWALS (X2)

Reporting directly to Manager Complementary Medicines & Cosmetics
Main Purpose of Job
Assessing information in dossiers submitted by applicants seeking exemptions from going through the normal marketing authorisation or post registration variations against relevant applicable legal and scientific regulatory standards to ensure speedy processing of authorizations so that medicines, medical products and cosmetics of acceptable quality are accessible in the market.

Main Duties
- Process applications for exemptions from going through the normal registration process for new medicines, medical products and cosmetics or exemptions to the normal variation process of existing authorizations by assessing and evaluating dossiers submitted against regulatory quality, safety and efficacy standards to protect the health and wellbeing of the public and of animals.

- Assist manufacturers and distributors with scientific and legal information, guidelines, and clarifications on the compliance requirements for market authorization in response to enquiries or proactively as part of educational interventions initiated by the Authority to promote high levels of compliance.

- Conducting scientific evaluation of data in dossiers or additional information provided by applicants for exemptions in response to formal requests for further information to determine accuracy and adequacy for consideration for marketing authorization.

- Assist internal audit activities by providing required information to in accordance with the audit policy, procedures and plans of the Authority to ensure a work-class internal quality management system.

- Write product exemptions evaluation or post assessment reports in accordance with BOMRA guidelines for review by peers and submission to the Registration Committee of the Authority to support effective market authorization decision making

- Write letters communicating the decision of the Authority to applicants in accordance with BOMRA guidelines to ensure understanding and customer satisfaction

- Maintain data bases of applicants and local representatives of applicants and of market authorization decisions in accordance with BOMRA guidelines to ensure easy and timely access for reference or any other relevant subsequent intervention.

- Seek to achieve personal and team performance targets in accordance with performance plans and business plans to ensure high level of productivity and customer satisfaction.

- Contribute to the development and maintenance of quality management documentation to ensure an efficient and effective system of capturing, storing and sharing information with relevant stakeholders.
- Maintain continuous professional development by engaging in self-study and membership of professional institutes to ensure personal professional growth and increased value to BOMRA.

Qualifications:
- Degree in Pharmacy or related field
- Post graduate training in regulatory affairs

Experience and skills:
- Successful completion of the post-graduation government internship
- Medicines, health products and cosmetics regulatory affairs
- Technical Report Writing
- Information technology

DOSSIER ASSESSMENT SPECIALIST – HUMAN MEDICINES (X1)

Reporting directly to the Manager of Human Medicines
Main Purpose of Job
Your main responsibility is to ensure that human medicines that are authorized to be in the market comply with legal and regulatory requirements in Botswana with respect to quality, safety, and efficacy.

Main Duties:
Your duties include,
- administrative and technical review of the quality, non-clinical and clinical data submitted in support of applications for registration and post approval variations of medicines,

- preparation of technical reports for submission to the relevant committee for regulatory decisions and,

- ensure that the necessary guidelines, standard operation procedures and reference materials are in place for medicines registration.

Qualifications
You will need to possess a Degree in Pharmacy with a minimum of three (3) years' experience working in pharmaceutical sectors, Government, national or international NGOs.

Competencies
The key competencies for the role include proficiency in written and spoken English; an ability to plan and work independently; interpersonal skills; presentation skills; attention to detail; good knowledge of pharmaceutical regulatory issues; knowledge of aspects of Botswana and regional medicines policies, and legislative system governing pharmaceuticals; and good knowledge of ICT applications as well as an ability to write clear and comprehensive technical reports; teamwork.

DOSSIER ASSESSMENT SPECIALIST – VETERINARY MEDICINES (X3)

Reporting directly to the Manager Veterinary Medicines
Main Purpose of Job
Your main responsibility is to ensure that Veterinary medicines that are authorized to be in the market comply with legal and regulatory requirements in Botswana with respect to quality, safety, and efficacy.

Main Duties:
Your duties include,
- administrative and technical review of the quality, non-clinical and clinical data submitted in support of applications for registration and post approval variations of medicines.
- preparation of technical reports for submission to the relevant committee for regulatory decisions and,
- ensure that the necessary guidelines, standard operation procedures and reference materials are in place for medicines registration.
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Qualifications
You will need to possess a Degree in Pharmacy/Veterinary Science/ Human Medicines with a minimum of three (3) years' experience working in pharmaceutical sectors, Government, national or international NGOs.

Competencies
The key competencies for the role include proficiency in written and spoken English; an ability to plan and work independently; interpersonal skills; presentation skills; attention to detail; good knowledge of pharmaceutical regulatory issues; knowledge of aspects of Botswana and regional medicines policies, and legislative system governing pharmaceuticals; and good knowledge of ICT applications as well as an ability to write clear and comprehensive technical reports; teamwork.

QUALITY OFFICER (X1)
Reporting Directly to the Manager Quality Management
Main Purpose of the job
To provide support to the Authority, in the development, implementation and monitoring of the Quality Management System (QMS) in order to ensure conformance to set standards.

Main Duties
- Review of QMS documentation within the Authority to ensure alignment to QMS requirements.

- Conduct internal QMS audits within the Authority in order to monitor the effectiveness of the QMS.

- Liaise with the Certification Body, Accreditation Body and any other relevant assessment body on behalf of the Authority to ensure effective implementation of the audit and/or assessment plans.

- Conduct root cause analysis for identified non-conformities within the Authority to prevent their recurrence in the system.

- Receive internal and external complaints and address them to improve customer satisfaction.

- Use analytics to evaluate process performance by functions to monitor the effectiveness of the QMS.

- Plan and prepare logistics for management review meetings within the Authority in order to ensure continued suitability and adequacy of the QMS.

- Identify risks within the unit and implement risk action plans to treat the risks to acceptable risk level.

- Conduct periodic induction and trainings within the Authority in order to enhance the effectiveness of the QMS.

- Maintain and retain QMS documented information within the Authority to support QMS operations.

Qualifications
Academic qualifications:
Preferably Bachelor of Science Degree or Bachelor Degree in a field related to business or
Associate degree in Quality Assurance from a recognized institution.

Work experience: At least 3 years' experience in quality management of a reputable organization, preferably a medicines regulation.

Competencies: Certificate of ISO 9001 Lead Auditor Training, good understanding of ISO 9001, proven record of QMS effectiveness monitoring using analytics, experience in using continual improvement tools. Training including internal auditing on ISO/IEC/17020 and/ or ISO/IEC/17025 will be an added advantage

Essential skills: Ability to write clear and comprehensive technical reports; attention to relevant detail; excellent communication skills; time management; collaboration & team work.

REGULATORY OFFICER – RESEARCH (X1)

Reporting to: Manager, Clinical Trials and Research
Main Purpose of the Job:
Working under the Manager, Clinical trials and Research, the officer will collaborate with different strategic business units to assess research needs and develop and implement research plans in accordance with leading practices aimed at the advancement of regulatory science to ensure quality health care for people and animals.

Main Duties:
- To contribute to the planning and implementation of the research strategy for BoMRA to ensure that the regulatory system increasingly fosters accessibility to new medicines, health products and cosmetics to improve public health and animal care.

- Implements programmes and projects to gather new information and make discoveries that add value to enabling regulation to enhance the accessibility, quality, safety and efficacy of medicines, medical products and cosmetics.

- Assist in the establishment of a centre of excellence for regulatory science knowledge to enable the Authority to foster a culture of innovation to developing regulatory tools, systems, processes and technologies to enhance the durability of regulated products to protect public health and the health of animals.

- Contribute to the establishment of a Knowledge Resources Centre and the building of knowledge management capacity to ensure stakeholders such as health care providers, manufacturers, distributors, patients, public and scholars have access to cutting edge information on medicines, medical products and cosmetics.

- Assist in the forging of partnership with research institutions and universities in Botswana and outside to ensure a coordinated and holistic approach to research on the regulation of medicines, medical products and cosmetics to enhance the positive impact of research of public and animal health.

- Engage in continuous professional development to stay up to date with cutting edge technology and knowledge to ensure that BOMRA achieves evidence-based world-class regulatory excellence.

Qualifications:
- Degree in Toxicology, Pharmacy, Pharmacology, Microbiology; Medicine or related health sciences field
- Master's in health Science or related Sciences is desirable

Experience:
- 5 years' experience, 2 years in an applied research position in a scientific research environment

Competencies:
- Judgment and objectivity
- Evidence based decision making
- Governance and ethics sensitivity
- Relationship management
- Teamwork and collaboration
- Facilitation and negotiation
- Managing change

PROJECT OFFICER – Botswana Clinical Trials Regulation Project (X1)
Reporting to the Director- Pharmacovigilance & Clinical Trials
Main Purpose of Job
The purpose of this role entails planning, organizing, and directing the completion of the BoCTRe project sponsored by European and Developing Countries Clinical Trials Partnerships, by ensuring the project work packages are completed on time, on budget, and within scope. You will be employed on a full-time basis for a period of 24 months.

Main Duties:
- You will analyze the current regulatory procedures for clinical trials in Botswana and identify gaps to be addressed and also assist in developing and implementing standardized SOPs, guidelines, and training programs for Institutional Review Board members. You will facilitate and participate in the conduct of training for the personnel involved in conduct of clinical research to follow the SOPs and guidelines.
- You will also participate in conducting of Good Clinical Practice (GCP) inspections at different clinical research sites and work with IT department in the development and implementation of technological platform for submission and review of Clinical Trials (CT) protocols.
- Facilitate Steering Committee and provide logistics for training, travel, procurement, provide publicity for the project through relevant social media platforms and grant administrative support.

Qualifications
You will need to have degree in health sciences with 3 years' experience in working in the area of conduct of clinical trials.

Competencies
The key competencies for the role include understanding of ICH – GCP guidelines, ethical conduct of clinical trials, clinical trial regulations– national and international. Proficiency in project management operating procedures, oversight and monitoring is desirable.

ENFORCEMENT MANAGER (X1)

Reporting directly to the Director, Licensing & Enforcement.
Main Purpose of Job
Your role will be to ensure compliance to the Medicines and Related Substances Act of 2013. You will be responsible for providing effective planning and coordination of enforcement and investigations; assist in ensuring compliance with statutory frameworks.

Main Duties:
- To oversee and conduct investigations & enforcement activities.

- To carry out investigations of possible infringements of the Medicines and Related Substances Act and other relevant legislations.

- To recommend appropriate criminal and administrative sanctions and ensure the necessary investigations and information is compiled to ensure enforcement of decisions.

- To plan & collaborate with other local and international institutions and regulatory bodies, to ensure enforcement of relevant legislation & regulations.

- To partner & work with relevant stakeholders to build intelligence on illegal activities in the pharmaceutical sector.

- To provide reports & advise the Director on all matters pertaining to enforcement.

- To work & partner with the Manager Public Relations & Communications to sensitize the pharmaceutical sector & general public on matters of pharmaceutical regulation & compliance respectively.

- To work with other Directorates to develop an online database for educating & informing the general public on all illicit, falsified & counterfeit medicines & products.

- To develop and implement guidelines, manuals & standard operating procedures (SOPs) for the department.

- Provide leadership to staff in the unit by ensuring effective support, capacity building, performance management & motivation strategies are applied to enable delivery of effective services & results.

- Undertake any other responsibilities, tasks or activities as may be assigned from time to time.

Qualifications:
- Minimum of a Bachelor's Degree in Pharmacy, Pharmaceutical Sciences, Veterinary, Medicine, Law and related field with appropriate experience. A Master's degree is an added advantage. Registration with a professional body is essential.
- **Work experience:** A Minimum of 5 years work experience in enforcement, regulatory and/or investigative environments. The individual must have served in a supervisory role for a minimum of 3 years working with electronic platforms monitoring and people management.

- **Essential skills:** Strong understanding of Criminal and Administrative Law.; strong understanding of the Botswana context of pharmaceutical supply & distribution channels, and legislative system governing pharmaceuticals; and good knowledge of ICT applications;

- **Competencies:** High level of Integrity; Keen attention to detail; excellent communication and interpersonal skills; ability to write clear and comprehensive technical reports; team work.

RECORDS ASSISTANT (X1)
Reporting directly to the Records Coordinator
Main Purpose of the Job
To maintain and monitor both manual and electronic records, carry out records management activities and facilitate ease of retrieval and availability of information for the effective administration and operations of the Authority.

Main duties:
- Mail management, receives sorts and dispatches mail
- Maintains both physical and electronic Records
- Arranges files according to the Classification Scheme
- Accessions semi current Records
- Uploads records into the EDRMS
- Retrieves files for action
- Ensures compliance with records management policies and procedures

Qualifications:
Diploma in Records Management from a recognised institution. A valid driver's license with more than 2 years' experience.

Experience
- A minimum of 2 years' experience in Records Management
- A valid driver's license with more than 2 years' experience.

If you have the above capabilities kindly send your application, detailed CV and certified copies of certificates and national Id to recruitment@bomra.co.bw
Please ensure that you specify the job title in the subject of the email

NB: The Authority will only respond to the shortlisted

Closing date:
9TH December 2021

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ISO 9001:2015 Quality Management

BoMRA MEDICINES REGULATORY AUTHORITY