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Regulatory Affairs and Clinical Affairs Manager

Hiring organization
MJM Recruitment & Care Givers

Employment Type
Full-time

Beginning of employment
Immediately

Duration of employment
Full Time

Pharmaceutical
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Job Location
KZN

Date posted
July 1, 2021

Valid through
31.07.2021

Description

About the role

Directing and managing the Regulatory and Clinical Affairs (RCA) department to ensure provision of and adherence to best practices relating to regulatory compliance and clinical information with respect to the manufacture, sale and appropriate clinical use of safe, quality, efficacious products in accordance with registration commitments, operational and strategic requirements and internationally accepted regulatory standards and those accepted by the South African Health Products Regulatory Authority (SAHPRA) and other regulatory agencies.

Minimum Requirements

1. Pharm degree

M.Sc. Clinical Pharmacy or equivalent postgraduate degree

Registered with the South Africa Pharmacy Council (SAPC)

5 years' experience in the SA pharmaceutical regulatory environment

3 years' experience with Medicines Information Services

A minimum of 3 years' experience at senior management level including leading, mentoring and coaching teams.

A thorough understanding of the requirements of a pharmaceutical quality system and cGMP principles.

Fully proficient in MS Office (Word, Excel, PowerPoint, Outlook)

Good working knowledge of bibliographic management software Fully proficient in databases such as MS Access, Lotus Notes, InforMED, PCV Manager or similar.

Clinical Trials Knowledge & Experience.

SAP experience will be an added advantage.

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

Key Performance Areas

Providing regulatory and clinical inputs into the companies strategic planning and review process

Review of regulatory and clinical impact of strategic and business planning processes.

Participate in specific and relevant strategic review teams to provide strategic regulatory intelligence throughout the product life-cycle, including guidance and support for product development from pre-clinical through to registration and product optimisation.

Support the companies high level business objectives by finding the optimal regulatory approaches in the context of the specific markets, GMP and other regulatory requirements through

strategic, expedient and efficient preparation of key regulatory and clinical affairs deliverables.

Regulatory compliance with national and international legislation

Taking overall responsibility for the regulatory function at the company

Ensuring that the regulatory framework at the company is clearly defined and effectively communicated within the business to ensure compliance and adherence to current local, regional and ICH regulatory and technical requirements, as appropriate.

Conducting dossier due diligence to ensure that all gaps are addressed in preparation for submissions of variations or new registration applications.

Ensuring the companies product and company licenses and legal documents are maintained in terms of the Medicines- and Pharmacy Acts of South Africa.

Defining the regulatory strategy with regard to changes in legislation affecting our products, or alignment with business and strategic objectives.

Keeping abreast of all national and international regulatory developments in order to anticipate changes and proactively integrate these into the companies business practices.

Providing regulatory support to the company

Pharmacist (RP) with respect to:

Regulatory aspects such as the implications of variations from the dossier and product registration conditions to facilitate decision-making.

RP’s compliance initiatives in ensuring that regulatory changes/impact are duly and diligently considered and communicated.

Performing regulatory and clinical risk analysis and advising on risk mitigation strategies.

Managing the companies promotional and advertising activities in line with the Medicines Act and Marketing Code Authority.

Pharmacovigilance compliance with national and international legislation

Keeping abreast of local and international pharmacovigilance regulations and practices in order to anticipate changes and proactively integrate these into the companies business practices.

Monitoring and reporting new evidence and published information of suspected adverse events related to NBI products for evaluation of risk, preventative or corrective action.

Identifying requirements for amendments to safety statements in the Professional Information (PI's) and Patient Information Leaflets (PIL's) of the companies products for further consideration and implementation.

Evaluating and updating the companies pharmacovigilance policies and procedures in compliance with local and international Good Pharmacovigilance Practice requirements.

Supervising and approving compilation of all pharmacovigilance reports (PSURs, etc), clinical study reports and post marketing evaluations for the companies products to meet statutory requirements.

Reviewing and approving adverse event procedures, communications and reports with relevant internal and external individuals as well as organisations such as SAHPRA.

Analysing adverse event reports and product complaints to identify trends and initiate the necessary changes to product safety statements or processes, in consultation with other relevant companies staff.

Convening and chairing Safety Committee meetings for discussions required in terms of adverse event reports, as appropriate.

Liaising with external consultants in terms of adverse event investigations, when required.

Overseeing training in pharmacovigilance for relevant companies staff.

Provision of regulatory guidance with respect to product licensing conditions

Participating at various meetings and project forums which require regulatory input.

Assisting internal company departments by providing regulatory guidance and information supporting and complementing their activities.

Approving new or amended master documentation that could impact on the company registration commitments.

Evaluating all company change requests from a regulatory perspective, and monitoring of the implementation of these changes within company

Identifying practises which would impact on companies licensing conditions and advising on appropriate corrective action.

Convening and chairing meetings to address issues that impact on regulatory submissions.

Attending and participating at external meetings and training forums to keep abreast with changes and developments in the industry.

Provision of Clinical Information Services related to company products

Guiding the formal responses to enquiries and literature requests from internal and external stakeholders on various aspects related to company products.

Evaluating, reviewing and approving the clinical and medicines information supplied within the required time frame, in the appropriate format.

Ensuring appropriate and up to date resources and systems are provided for accessing, retrieving and filing current clinical and medicines information to meet service objectives.

Updating the database and documentation appropriate to record, track and report on enquiries. Managing and organising the functions of the specialist library (E.K. Dunning Library) in terms of service provision to company departments and individuals.

Engaging in continuous updating of clinical knowledge by attendance and participation at conferences, seminars and workshops.

Provision of external and internal education and training services

Monitoring the requirements and delivery of lectures, and Continuing Medical Education (CME) to pharmacy students and healthcare professionals on the clinical indications of plasma-derivatives, fundamentals of plasma fractionation and quality and safety aspects of plasma-derivatives.

Directing the induction training and on-going learning of product consultants and other relevant staff relating to the clinical and pharmacovigilance aspects of company products, customer complaints mechanisms and medicine information services.

Providing guidance in the compilation of the education and training presentations, hand-outs and detailing aids.

Ensuring records and documentation related to education and training sessions are adequately maintained.

Conducting clinical trials and post-marketing studies

Managing companies compliance with regulatory requirements for conducting clinical trials and post-marketing surveillance studies

Evaluating the strategic value and appropriateness of NBI participation in independent clinical trials using company products for recommendations to SMT.

Chairing the review committee for financing and sponsorship of post-marketing studies and clinical trials.

Reviewing the clinical validity of trial/study protocols in line with regulatory requirements and obtaining approval of verified protocols through the internal process for conducting post marketing studies and clinical trials.

Liaising with contract organisations and principal investigator with regard to site selection, set-up and monitoring of all post-marketing studies and clinical trials.

Ensuring conformity of all the components of the trial/study with applicable

guidelines, legislation and regulations. Appointing a monitor for overseeing the progress of the study or clinical trial to ensure it is conducted, recorded and reported in accordance with the protocol, SOP's and other applicable guidelines, legislation and regulations.

Keeping abreast of local and international post-marketing surveillance and clinical trial guidance and regulations.

Internal and external networking, relationship-building and support

Contributing to the regulatory strategy and knowledge to assist stakeholders navigate the challenging regulatory environment

Providing internal stakeholders with up-to-date legislation and guidance, as it becomes available.

Collaborating with internal staff to facilitate expedited internal procedures, processes, reviews, and communication of information.

Supervising appropriate and timely dissemination of business related, regulatory and clinical information to relevant departments and individuals concerned.

Addressing and resolving interdepartmental conflict that may arise as a result of prioritisation problems.

Representing the department on interdepartmental projects, committees and meetings.

Establishing and maintaining professional and productive working relationships, underpinned by regular and effective communication with key SAHPRA representative.

Establishing and maintaining professional and productive working relationships with key representatives of regulatory authorities in export markets where companies products are registered or anticipated to be registered.

Attending and providing meaningful input into relevant Pharmaceutical Industry and Medical Advisory forums and groups

Consulting with Medical experts or other key opinion leaders on clinical and pharmacovigilance issues, when required.

Networking and liaison with clinical groups and patient organizations to enhance the companies relationships with external stakeholders.

Administration of the RCA department

Setting the strategic direction for the department in line with companies mission, vision and strategic objectives.

Establishing goals and objectives for optimal performance of the department in line with divisional objectives.

Compiling budgets for annual expenditure and training needs in the department.

Monitoring and controlling monthly departmental expenses to ensure compliance to budget provision. Investigates and accounts for budget variances with corrective

action, as needed.

Identifying requirements for upgrading or procurement of new equipment and resources, and motivates for purchase.

Compiling and presentation of operational and financial departmental reports as required.

Reviewing, editing and compiling SOPS and related documents in the QA Document Management System (DMS) as necessary.

Management and development of departmental staff in support of the companies People Management agenda

Influencing and inspiring staff to uphold and embody the companies core values.

 Motivating and guiding staff to set individual objectives and workplans with timelines that are aligned to NBI's vision, mission, objectives and core values.

Communicating with staff professionally and respectfully.

Utilising effective staff management practices in supervising and leading staff, and managing staff expectations.

Objectively tracking and documenting performance of staff through the use of performance plans, review meetings and regular feedback.

Instituting remedial and corrective action (performance counselling), where appropriate, to optimise performance.

Dealing appropriately with conflict, employee issues, concerns and problems in line with NBI's internal channels and disciplinary procedure.

Identifying and planning of individual development and training needs in collaboration with staff.

Providing developmental and job enrichment opportunities, as appropriate, that maximize employees' potential and enhance employee motivation and morale.

Effective monitoring and management of departmental leave, overtime, resources and capacity.