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Quality Manager – Active Raw Materials (ARM) – Pharma

Hiring organization
MJM Recruitment & Care Givers

Employment Type
Full-time

Beginning of employment
Immediately

Duration of employment
Full Time

Industry
Pharmaceutical

Job Location
Durban

Base Salary
R 1 600 000million

Date posted
September 2, 2026

Description

PURPOSE OF THE POSITION:

Guided by its purpose to provide products for patients to alleviate pain and suffering and improve their quality of life, the companies vision is to be the leading African manufacturer and supplier of quality therapeutic proteins and diagnostic products.

Contributing to the quality, safety, and efficacy of the companies products through:

Rigorous evaluation and approval of new plasma suppliers in line with the companies specifications and local and international guidelines, and

- Review of epidemiological data and other data from plasma suppliers and updating of companies plasma master file on an annual basis, and
- Testing and release of human plasma and its derivatives (active raw materials) procured from plasma suppliers, adhering to sound scientific principles and complying with current good manufacturing practice (cGMP).
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Further, the Plasma Quality manager is responsible for the smooth, efficient day to day operation of the Quality Active Raw Material (QARM) laboratory, providing operational assurance in support of business and strategic requirements. Lastly, the Plasma Quality manager is responsible for the companies formal environmental monitoring program, through monitoring production environments, including the companies aseptic filling suite, to ensure the environments comply with regulations.

KEY PERFORMANCE AREAS:

Ensuring on-going safety and quality of plasma and its derivatives through compliance to company specifications

Keep abreast of new and emerging developments/changes in guidelines on the production, control and regulations of human plasma derived medicinal products.

- Keep appraised of national and international trends and regulatory standards.
- Review and maintain specifications for plasma in accordance with the European Pharmacopoeia monograph and the companies Plasma specifications.
- Participate in appropriate industry forums, congresses and meetings on viral safety, GMP in blood establishments and plasma fractionation in low and middle income countries.
- Communicate to plasma and intermediate suppliers all criteria set out in the companies specifications to ensure suppliers meet the companies requirements.
- Maintain strong relationships with plasma suppliers and other external stakeholders to ensure plasma quality standards are achieved.

Review of new and existing plasma suppliers and updating of the plasma master file (PMF)

- Assess potential plasma suppliers for producing high quality plasma suitable for fractionation and ensuring compliance with GMP in blood establishments. These include verification that suppliers adhere to GMP standards and relevant regulatory requirements.
- Audit new and existing plasma suppliers to ensure their compliance to safety, quality, GMP, companies requirements.
- Evaluate collection, testing, storage and transportation of plasma from suppliers
- Communicate plasma quality and safety problems/issues to suppliers.
- Research information and analyse annually, the possible risk of virus and other transmissible agents by the companies plasma products using documented risk models.
- Collate epidemiological data and other data from the donor population to continuously survey prevalence, incidence and trends of infectious or quality markers relevant to the safety and quality of the companies medicinal products and propose counter measures.
- Promote support for the implementation of new testing regimes.
- Compile Plasma Master File annual updates for submission to SAHPRA to obtain approval for plasma suppliers under a contract fractionation agreement or to other regulatory bodies for plasma suppliers that are under a toll fractionation agreement.
- Assist with any queries by SAHPRA on new plasma suppliers and the plasma master file.

QARM laboratory management

Plan and coordinate plasma, intermediate and final product testing based on formal specifications and production needs.

- Manage QARM laboratory staff for timely analysis and reporting of active raw materials.
- Propose and implement effective strategies for the optimal testing and processing of plasma and its derivatives
- Ensure prompt release of raw materials and intermediate products for production.
- Manage the construction and testing of plasma pools
- Ensure test kit providers are approved by SAHPRA and testing is performed in accordance to the companies regulatory product dossiers.
- Collaborate closely with Plasma Stores to identify reconciliation challenges and develop solutions to address them
- Manage non-compliant plasma between the companies Plasma Stores and QARM
- Manage lookbacks systems at the company.
- Implement and maintain an external proficiency testing program.
- Maintain in-house controls and reference standards.

SAP and LIMS

Ensure all SAP and LIMS transactions are completed as required for the release of active raw materials, and intermediates.

- Perform SAP tasks as required by the quality management system and

other business processes.

Ensure LIMS and SAP is optimally set up and utilised to support effective, productive and efficient QARM laboratory operations, and identify opportunities for further improvement to maximise LIMS functionality.

Analytical methods and laboratory equipment

- Assess the feasibility and benefits of new analytical methods, preparing justifications and CAPEX requests.
- Develop user requirement specifications for new QARM facilities, equipment, and contract testing.
- Assist the Validation Team in preparing IQ, OQ, and PQ documents for qualification.
- Coordinate equipment qualifications and method validations, providing necessary documents to Regulatory Affairs for SAHPRA submissions.
- Oversee the implementation of new analytical methods and equipment post-SAHPRA approval, following chang the compaines management procedures.
- Maintain a program for calibrating, servicing, and maintaining analytical equipment to ensure accuracy and prevent breakdowns.

Management of external / contract laboratories

- Coordinate with outsourced laboratories to ensure testing, results are completed within companies timelines and any changes to testing is reported to company immediately
- Ensure contract laboratories use suitable and validated analytical methods.
- Audit relevant contract laboratories per as companes vendor management program, to ensure that test procedures are in line with the companies requirements.

Manage and oversee environmental monitoring program

- Define the companies environmental monitoring and contamination control strategy to comply with the relevant guidelines such as PIC/s Annex 1.
- Draft, review, approve and implement SOP’s and other controlled documents related to environmental monitoring.
- Define critical control points for environmental monitoring and sampling sites based on risk assessments.
- Define action and alert limits of the various microbiological sample areas (Grades A to D, raw materials, intermediates and final products).
- Ensure adequate resources are available for sampling, testing, and the oversight of the aseptic filling processes by the Production Microbiologists and Microbiology Technician and that the Aseptic Filling room is released prior final product filling
- Perform trend analysis of bioburden results and environmental results to

allow for corrective actions to be implemented promptly.
- Assist with compiling reports and the evaluation of aseptic process simulations.
- Perform investigations and identify root causes in case of sterility failures and other Microbiological data deviations, viral contamination, aseptic process simulations and related risk assessments to products.

COMPANIES STRATEGY:

- Contribute to company strategic plans and their implementation.
- Participate in strategic initiatives and continuity in leadership.
- Ensure alignment of the QARM department with company-wide strategic initiatives.

Review and reporting of trends

- Monitor, analyse and report on trends of key QARM performance indicators as part of monthly, quarterly and annual reviews and reports, including annual product quality reviews, or APQRs.
- Coordinate with applicable QARM laboratory staff to ensure the monthly review of reference standards and inhouse controls is performed, including statistical analysis and reporting of the trends.
- Ensure the appropriate use of sound statistical analysis of results.
- Prepare quarterly and annual reports on analytical results of raw materials, in-process and final product testing, as well as utilities.
- Attend quarterly and annual review meetings and provide input into the meetings as required.

Health, safety and the environment

- Ensure compliance to all relevant legislation e.g. Occupational Health and Safety Act.
- Coordinate the investigation of SHE incidents in the department, and identify and implement effective CAPA’s to prevent recurrence.
- Ensure that companies procedure on waste management is being followed in the laboratory.
- Ensure safety protocols are adhered to by all staff.

Maintain the quality system to ensure GMP compliance

- Ensure compliance to the companies quality management system, GMP principles and SAHPRA guidelines in the QARM department.
- Establish, review, and enforce SOPs for processes and analytical methods.
- Communicate QMS requirements to staff.
- Prepare for and participate in GMP audits by third parties and regulatory authorities.
- Conduct internal audits and implement corrective actions for continual improvement.
- Coordinate with QARM staff to identify, document and implement CAPAs

for non-conformances from audits and inspections.
- Collaborate with Quality Division managers to foster a culture of quality and uphold the companes Quality Policy.
- Identify and implement continuous improvement initiatives, including annual Quality Objectives for the QARM department and monitor progress.
- Coordinate out-of-specification root cause investigations per the companies SOP and distribute reports to stakeholders.
- Coordinate customer complaint investigations, and prepare reports in compliance with the companies SOP.
- **General Administration**
    - Accurate and timely compilation of all annual QARM cost centre budgets, and submission of the budgets ahead of the deadlines.
    - Effective controlling of the expenses against budget.
    - Compiling monthly report for the QARM cost centres and Head: QM as required.
    - Authorise all payments to suppliers to the department and control all departmental expenditure in accordance with budget.
    - Identify and motivate for capital equipment required to optimise the operations and in line with requirements of the QARM department.
    - Assist the Head of Quality Management and Scientific Affairs as and when required.

QUALIFICATIONS AND EXPERIENCE:

Minimum Requirements

- M.Sc in Microbiological Science, Molecular Biology, Biochemistry or related field (PhD degree preferred)
- Computer literacy: MS Office, SAP, LIMS

- 5 to 10 years as a senior staff manager in a quality or pharmaceutical environment.

- At least 5 years of Quality Control or Microbiology laboratory experience

- Working knowledge of GMP in blood establishments, transfusion transmittable infections, plasma quality and safety, as well as related regulatory requirements preferred.

- Thorough understanding of cGMP, GLP and international pharmaceutical standards preferred.

- Hands-on experience with internal and supplier audits will be an advantage.

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