

# Head of Quality Assurance

## Job Description:

### 1. Quality Management System (QMS) Development & Compliance

- Establish, maintain, and continuously improve the QMS in accordance with **ISO 15189:2022**, **ISO 9001:2015**, and **PIC/S GMP**.
- Ensure compliance with national and international regulatory and certification standards.
- Lead quality audits (internal and external) and coordinate necessary corrective and preventive actions (CAPA).
- Develop and implement policies, standard operating procedures (SOPs), and quality manuals.
- Oversee batch disposition and ensure that only safe and effective products are released.

### 2. Regulatory & Certification Compliance

- Ensure compliance with laboratory certification requirements under **ISO 15189:2022**.
- Oversee adherence to quality management principles outlined in **ISO 9001:2015**.
- Ensure manufacturing processes align with **PIC/S GMP** standards.
- Serve as the primary liaison with NPRA, certification bodies, and regulatory authorities as the **Quality Management Representative (QMR)**.
- Ensure all-time readiness of the site for regulatory agency inspections and internal audits.

### 3. Risk Management & Continuous Improvement

- Identify, assess, and mitigate quality-related risks in laboratory and manufacturing processes.
- Implement continual improvement strategies using **Quality Risk Management (QRM)** principles.
- Oversee non-conformance investigations and implement corrective and preventive measures.
- Monitor industry trends and identify opportunities for improving quality assurance management.

### 4. Audit Management & Training

- Plan and conduct internal audits to assess compliance with standards and regulations.
- Lead preparation for external audits by NPRA, certification bodies, and other regulatory agencies.
- Develop and deliver training programs to enhance quality awareness and compliance across the organization.
- Ensure staff competency through regular assessments, training, and continuous education.

### 5. Document Control, Data Integrity & Change Control

- Maintain document control systems in compliance with quality standards.
- Ensure the integrity, security, and confidentiality of data in laboratory and manufacturing operations.
- Implement quality metrics and data-driven decision-making processes to enhance performance monitoring.
- Manage change control processes, ensuring adherence to all regulatory and internal requirements.

## 6. Supplier & Customer Quality Assurance

- Manage supplier qualification, audits, and performance evaluations.
- Ensure that customer complaints and feedback are addressed effectively and in a timely manner.
- Collaborate with cross-functional teams to resolve quality issues and enhance customer satisfaction.

## 7. Leadership & Resource Management

- Define operational strategy and roadmap for Quality Assurance management at the site.
- Ensure the availability of adequate resources, including manpower, to maintain compliance with **GXP requirements**.
- Provide strong leadership and expertise to ensure the achievement of all **quality assurance, compliance, and operational excellence goals**.
- Coach and develop direct and indirect reports through **training, mentorship, and performance management**.
- Execute Quality Management Reviews and set performance improvement areas.