JOB DESCRIPTION

ROLE: Quality Assurance Specialist
SALARY AND BENEFITS: Negotiable
REPORTS TO: Quality Control Manager
LOCATION: Baroda, India

PRIMARY RESPONSIBILITIES

- To manage quality systems, processes and procedures to assure product quality and safety
- To engage strong intradepartmental and cross-functional/organizational relationships to drive Quality System Requirements (QSRs)
- Own the development and maintenance of policies and procedures for departmental functions
- Influence site compliance to Quality policy, Quality Management System procedures and guidelines

SECONDARY RESPONSIBILITIES

- Influence participation in compliance to internal and external regulations
- Influence quality system metrics such as Corrective and Preventive Action, training metrics, completion and complaint resolution metrics
- Define and perform audit of internal systems and external suppliers and manufacturers
- Inform appropriate internal departments on audit results and work with the necessary staff to achieve GXP compliance
- Provide QA support during regulatory authority inspections, as applicable
- Update key performance indicators/metrics in a timely manner
- Develop and maintain GxP standard operating procedures in accordance with regulatory and company requirements
- Contribute to the development of the annual Audit Plan to assure compliance and provide ongoing updates to adjust the Audit Plan, as necessary
- Provide oversight to external partners and vendors, which would require regular on-site visits
- Manage day-to-day activities of quality staff
- Any other duties as required

KNOWLEDGE, SKILLS AND EXPERIENCE

- Should have sound knowledge of ICH and other regulatory guidelines and Good Laboratory Practices.
- Well versed in operation with different analytical instruments like HPLC, UV and GC
- Have experience in Documentation for Validation, Stability study, Specification and SOPs.
- M. Pharm. or M. Sc. With minimum 1 or 2 Experience in Analytical Research and Development.