

JOB DESCRIPTION

ROLE: Quality Assurance Manager SALARY AND BENEFITS: Negotiable REPORTS TO: Head of Quality LOCATION: Ruislip

PRIMARY RESPONSIBILITIES

The QA Manager will manage quality systems, processes, and procedures to assure product safety and quality by driving business alignment to correct industry requirements and business objectives by managing quality system design, controls, and continuous improvement.

SECONDARY RESPONSIBILITIES

- Lead the site in GXP compliance
- Manage day-to-day activities of QA staff
- To manage and approve OOS/OOT process for site
- To review, collate data and write PQRs for Pharmaceutical products
- To review batches and support QP product release
- To manage the site equipment validation and calibration annual planner
- 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
- Lead in compliance to internal and external regulations
- Lead 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

Role holder qualifications

- Degree in scientific discipline
- Minimum 3 yrs hands on pharma QA experience
- Supervisory/management experience