



JOB DESCRIPTION

ROLE: Quality Assurance Specialist

SALARY AND BENEFITS: Negotiable

REPORTS TO: Head of Manufacturing

LOCATION: Ruislip

PRIMARY RESPONSIBILITIES

The QA Specialist 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

- Accountable for assisting the Quality Assurance Manager to ensure/follow up/implement corrective actions that are raised by deviations, internal audit or regulatory inspection.
- Responsible for managing quality systems, processes and procedures to assure product quality and safety.
- Responsible for engaging strong intradepartmental and cross-functional/organizational relationships to drive Quality System Requirements (QSRs)
- Owning the development and maintenance of policies and procedures for departmental functions
- Influencing site compliance to Quality policy, Quality Management System procedures, and Quality Star guidelines
- Influencing participation in compliance to internal and external regulations
- Influencing quality system metrics such as Corrective and Preventive Action, training metrics, completion and complain resolution metrics
- Evaluate clinical trial documents to assure their completeness, accuracy and conformance to GCP requirements.
- Define and perform audit of internal systems, investigator sites, CROs, and API manufacturers.
- Provide QA support during regulatory authority inspections, as applicable.
- Update key performance indicators/metrics in a timely manner.
- Inform appropriate internal departments on audit results and work with the necessary staff to achieve GXP compliance.
- 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.
- Respond, at the initiation of the Quality Assurance Manager, to any other special requests that may arise.
- Ad hoc projects
- Any other duties as and when required

ESSENTIAL EXPERIENCE, SKILLS AND ABILITIES

Essential:

- Bachelor's degree, or equivalent
- Proven experience working in a regulated pharmaceutical environment, quality control/assurance, or regulatory assurance
- Proven experience in Quality Management Systems (QMS)
- Analytical & problem-solving skills/root-cause analysis
- Ability to effectively communicate verbally and in writing using the English Language
- Experience using word processing, spreadsheet, and presentation software

Desired Characteristics

- Demonstrated ability to develop & lead process implementation & improvement in a team environment
- Experience with some or all of the following:
 - Production and process controls
 - CAPA, complaints and risk management
 - Understanding of product quality improvement using tools such as Six Sigma, DFR
- Experience performing internal audits
- Demonstrated effective interpersonal and networking skills
- Demonstrated ability to successfully comprehend & carry out/execute actions
- Exceptional conflict-resolution skills
- Ability to interface with top organizational leadership and internal and external customers, responding in a professional manner
- Ability to prioritize and drive multiple programs
- Integrity: Accepting and adhering to high ethical, moral, and personal values in decisions, communications, actions, and when dealing with others
- Accepting constructive criticism and dealing calmly and effectively with high-stress situations. This includes continuing to persevere and remaining calm in challenging or frustrating circumstances
- External Focus: Understanding customer needs, marketplace dynamics, industry trends, and the competitive landscape in the industry/function and considering the external impact of business activities and decisions on the external environment
- Inclusiveness: Energizing others by building a connection with the team through personal involvement and trust and providing feedback and coaching to help develop others
- Clear thinker: Simplifying strategy into specific actions with clear accountability, making decisions with speed and accuracy based on best available information, and communicating priorities clearly and concisely