

KVK Tech	Master Job Description		
	Revision:		

Department	Quality Assurance		
Job Title	Quality Assurance Manager	FLSA Status	Exempt
Role	N/A		
Sub Role (If any)	N/A		
Reports To	Senior Director of Quality Assurance		

1. Role Purpose:

(Provide a brief summary of the primary purpose of this role)

The Quality Assurance Manager ensures quality and compliance of the facility with applicable regulatory requirements. These activities may include reviewing documents and data, conducting process-focused audits and inspections, consulting on quality and compliance issues, maintaining quality databases and performing trend analyses and reporting metrics where required, as well as performing quality and compliance training, as needed. May serve as quality host for client audits and inspections and provide support during regulatory inspections as well as conducting and/or coordinating auditing for vendor quality. Assists with the development of SOPs, specifications, policies or other quality documents as needed.

2. Key Duties & Responsibilities:

(Briefly describe the essential activities that are performed by this role including key duties/responsibilities. Each statement should start with a verb. Additionally, indicate how frequently it is performed)

- Design, implement and manage the installation and use of Master Control to handle the electronic documentation of Market Complaint, Deviation, OOS, Outliers, Root Cause Investigation, CAPAs, Recall, Change Controls, SOP and training.
- Chair the Investigations review Board (IRB) meetings, issue minutes and follow up on corrective and preventative actions.
- Manage and trend the deviation process while ensuring that a thorough investigation report is completed in a timely manner using proven root cause analysis tools.
- Manage the review, tracking, GMP compliance and approval of Change Controls for Production Processes, Facilities and Equipment.
- Manage all CAPA commitments to ensure timely completion of the outlined tasks and effectiveness.
- Manage the Customer Complaint system for both product and adverse event complaints; ensuring investigations are performed on time and any notifications meet regulatory reporting requirements (i.e. Field Alert Reports (FARs), 3 day and 15 day alerts, etc.).

KVK Tech	Master Job Description
	Revision:

- Manage the collation and generation of Annual Product Reviews (APRs); ensuring the timely approval of all APR's and the continued improvement of the generation process and the effectiveness of the utilization of report contents and data.
- Set and support company goals for the Quality Systems group as well as monitor the results and employee performance.
- Oversee the interviewing, hiring, training and development of all quality systems personnel, ensuring employees can function effectively in a team-base culture.
- Develop and maintain site quality metrics in accordance with new FDA guidance.
- Act as the SME for Deviations, CAPAs, Change Controls, Complaints and Site Quality Metrics during regulatory or FDA cGMP inspections.
- Maintain KPIs related to laboratory accuracy and conformance with SOPs, regulations and Guidelines and present to the Quality Council.
- Develop and maintain monthly Site Quality Council meeting, as well as coordinate and handle weekly Investigation Review Board meetings.

3. Typical Supervisory Responsibility:

(Identify any responsibilities the role has for supervising others)

Serves as an effective member of the Quality team and may serve as a mentor to other Quality employees in the area of expertise.

4. Education & Experience:

(Describe the education required for this role, including specifications, if any. If equivalent experience or knowledge can be substituted for the educational requirements, A combination of Education and experience shall be taken into account.)

Education Requirement	Specialization (If any)
BS Chemistry or related science field, MS preferred	N/A
N/A	N/A

Experience Requirement

(Describe the experience required for this role. Identify the type of experience, number of years, and any additional comments on the experience and education requirements for the role. Also, include any geography specific requirement that differs from the experience.)

N/A	
Number of Years (Minimum to Maximum)	N/A

5. Technical competencies/ Certifications/ Licenses:

(Briefly describe the required competencies such as, skill, ability, knowledge an individual must possess to perform the role. Also, identify any certification or licenses required to perform the role.)

KVK Tech	Master Job Description
	Revision:

Technical competencies	<ul style="list-style-type: none"> • Review of Annual product quality reviews. • Preparation, approval of Standard Operating Procedures. • Preparation and review Quality Risk Management for process, area and equipment. • Assist with quality improvement initiatives as needed. • Assist with development/writing of SOPs or other quality documents and/or reports as needed. • Provides consultation on quality and compliance topics in the area of expertise. • May serve as client quality liaison and/or quality host of client audits; coordinates responses to client audits. • Effectively performs a variety of duties, on schedule, with accuracy and competency. • Performs other duties as assigned. • Complies with company policies and SOPs. • 10 years of experience in the pharmaceutical industry preferred • Good written and oral communication skills • Experience in statistical analysis, process capability reviews with software preferred • Ability to act independently • Excellent interpersonal, verbal and written communication skills
Certifications	N/A
Licenses	N/A
Other	N/A

6. Physical demand and Work environment:

(Provide details regarding the physical demands and work environment that are essential to the role)

a. Physical demands:

While performing the duties of this job, the employee is required to walk, sit, and use hands to finger, handle or feel tools or controls, reach with hands and arms, balance, stoop, crouch, bend, talk and hear. The employee must lift and/or move up to 20 pounds. Specific vision abilities required by the job include close vision, distance vision, color vision, peripheral vision, and depth perception.

KVK Tech	Master Job Description
	Revision:

b. Work environment:

N/A
