KVK Tech	Master Job Description
	Revision:

Department	Quality Assurance		
Job Title	Investigations System 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)

Primary responsibility is for the effective administration and operation of the KVK-Tech Investigations System as part of the Quality Management System. The KVK Tech Investigations System encompasses the management of Deviations, Complaints and Corrective Actions/Preventive Actions (CAPA) System. Implement operational procedures to ensure that the investigations and CAPAs are aligned with and incorporate the current Good Manufacturing Practices (cGMPs) and Food and Drug Administration (FDA) guidance requirements as well as applicable company policies, standards and procedures. In addition, ensures that investigation reports and corrective and preventive actions are thorough and completed on a timely basis.

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)

- Responsible for implementing a Quality focused system incorporating a science-based approach to evaluate events reported to and by QA, to ensure that all events are thoroughly investigated as per cGMPs and FDA pharmaceutical industry guidance and that the final reports and associated CAPAs are accurate, adequately issued and timely completed.
- Provides leadership and direction to KVK Tech employees to develop and effective Investigations System in compliance with both the company's and the regulatory agency's requirements.
- Reviews and approves investigation reports and monitors its progress to ensure these are completed in a timely manner, consistent with cGMPs, Good Documentation Practices, site's SOPs and policies and site operation's needs.
- Ensures resources have been adequately assigned and anticipates the need to provide or request additional assistance in accomplishing the completion of investigation process and reporting.
- Monitors, trends and evaluates the root causes identified in investigations in order to

review the effectiveness of previously implemented actions or if additional actions are deemed required, such as recommending improvements to Quality Systems in light of gaps identified during the root cause analysis.

- Develops and maintains updated procedures that outline the investigation system to consistently and effectively meet the applicable cGMPs.
- Keeps current in new or revised GMP related regulations, the site products, controls, projects and processes to warrant that investigation reports are consistent with the existing operating environment.
- Ensures that the assigned site's Investigators are adequately and consistently trained in the procedures applicable to the position as well as up to date in the corresponding procedure revisions and in the technical and regulatory fields required to effectively perform the duties assigned.
- Identifies and promptly notifies KVK Tech's management of deviations or events where the quality standards of a product/material compromise marketed products and recommends action plans to remediate or to prevent such events. Ensures that Field Alert Reports and market actions related to events requiring investigations are submitted/taken as per defined timeframe.
- Liaise and effectively interacts with applicable functional areas to assure due date commitments that may affect system's compliance and/or material/product release are discussed or alternative actions can be implemented.
- Maintains communication with applicable functional areas and external services providers to ensure that, as applicable, extended investigations and/or CAPAs are understood, timely completed and followed up.
- Provides technical assistance to assigned Investigators and site functional area management and participates in the review and evaluation of GMP related issues that involve manufacturing, packaging, storage and laboratory processes (e.g., from investigations, CAPAs, APRs, management of change or audits).
- Participates, leads and/or assists Cross Functional Investigations, as required.
- Establishes an effective follow up mechanism or system to monitor that investigation activities are adequately and consistently addressed, reports issued and timely completed.
- Communicates periodically with functional areas to review and inform the result of the

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monitoring and trending evaluations to provide feedback on the effectiveness of the appropriate actions or demand commitments/accountability to further prevent recurrence.

- In charge of documenting, monitoring and presenting Investigation System and CAPA System metrics and activities.

3. Typical Supervisory Responsibility:

(Identify any responsibilities the role has for supervising others)

Assistant Managers in charge of complaints, investigations and CAPAs.

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)
College Degree, i.e., BS, in Natural Sciences, Pharmacy, Engineering or related field preferred. Master degree is desirable but not a must.	*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.)

Technical competencies	▪ At least ten years-experience in the pharmaceutical industry including manufacturing processes and QA/QC control systems. ▪ At least 5 years of experience in a leadership position within a Quality function.

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	▪ Thorough and proven knowledge of cGMP investigation requirements and FDA Industry Guidelines for investigations. ▪ Direct or indirect previous experience with FDA inspections, is desirable. ▪ Experience and/or knowledgeable in product and test method transfers, validation and qualification activities of product, computer systems, equipment and facilities. ▪ Thorough knowledge of cGMP's, FDA regulations, validation and qualification requirements, and Computer system validation basics. ▪ Computer knowledge, including word processing, presentation, worksheets and electronic mail. ▪ Proven and proficient technical writing skills for the evaluation of pharmaceutical industry investigation reports. ▪ Knowledge and practical use of mathematics, graphics and statistical analysis skills to evaluate process related controls and/or data. ▪ Self-starter, creative, teamwork and results oriented, proficient in negotiation skills. ▪ Technical knowledge in pharmaceutical manufacturing processes and technologies and processing equipment. ▪ Proficiency in the evaluation of events to assess and investigate the cause utilizing analytical and problem-solving skills. ▪ Demonstrated ability to maintain confidentiality. ▪ Proven strong leadership skills and consistently a key contributor to the organization. ▪ Proficient people skills and focused on development of supervised colleagues/resources. ▪ Proven ability to work under pressure and availability to

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	work at any time needed. ▪ Effective in managing priorities and ability to assist colleagues directly working in assigned tasks in handling stress. ▪ Proficiency in time management, planning and organization capabilities. ▪ Proficiency in handling concurrently and effectively multiple high priority initiatives maintaining in focus the sense of urgency and sound quality and business judgement. ▪ Position requires reading professional literature and technical manuals; speaking to groups of employees, other public and private groups. ▪ Writing technical documents and complex reports in English.
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.

b. Work environment:

N/A