

KVK Tech	Master Job Description		
	Revision:		

Department	Quality Assurance		
Job Title	Technical Reviewer 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 Technical Reviewer 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 and performing trend analyses and reporting metrics where ever required.

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)

- Daily activities include review of documentation generated during quality control testing, method development, method validation, stability testing, and other analyses.
- Review documentation, results and reports from raw material and finished product analysis for accuracy and completeness.
- Review investigation data using a systematic approach to ensure compliance with procedures and specifications.
- Review and approve the calibration and preventive maintenance activities/documentation for the analytical instruments.
- Assure DEA controlled substances are handled and or reconciled correctly.
- Approve or reject all procedures or specifications impacting on the identity, strength, quality, and purity of drug products.
- Annual Product Reviews.
- Working knowledge with Microsoft Excel, Word, and possibly PowerPoint or any other software that is in use.
- Follow the OSHA (Occupational Safety and Health Administration) and EPA (Environmental Protection Agency) safety regulations.
- Provide feedback from reviews to analysts and supervisor to ensure necessary action are be taken to correct or prevent error.
- Review and approve Analytical Protocols, Analytical Reports and other documents
- Comply with FDA guidelines/Company Policies of Data Integrity.

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- Review and audit projects/analytical data as required and perform other duties assigned by Manager as needed.
- 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.

3. Typical Supervisory Responsibility:

(Identify any responsibilities the role has for supervising others)

Leadership skills which reflect directives for compliance of all pharmaceutical products. Comply to established procedures and identify deficient areas for enhancement through training and revision or implementation of procedures and systems. Train mentor and manage technical reviewer staff.

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)
Bachelor's degree in Chemistry or a related field	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	<ul style="list-style-type: none"> • Minimum of 5 years in pharmaceutical industry with relevant experience preferred • Ability to work effectively in a fast paced, timeline-driven, extremely high-expectation environment • Ability to work independently under the supervision of manager • Taking initiative on assignments on day-to-day responsibilities
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	<ul style="list-style-type: none"> • Proficiency in Microsoft Excel, Word, and possibly PowerPoint or any other software that is in use. • Multi-tasking projects as when necessary to complete on timely manner • Works productively when under pressure. • Takes initiative and exhibits resourcefulness in problem solving; experienced in working in a collaborative team environment. • Experience with FMEA and Risk analysis approaches.
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