

KVK Tech	Master Job Description		
	Revision:		

Department	Quality Assurance		
Job Title	Group Leader	FLSA Status	Exempt
Role	N/A		
Sub Role (If any)	N/A		
Reports To	Quality Assurance Supervisor		

1. Role Purpose:

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

Primary responsibility is to complete assignments in a timely manner while maintaining compliance with cGMP requirements, FDA, OSHA, EPA, and DEA. Complete Laboratory investigations or other assignments in a timely manner. Testing and documentation will be delegated through the Manager/Head of the Department.

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)

- Reviews all lab data to ensure no deviations in execution against pre-approved methods and procedures.
- Checks data integrity
- Trends data
- Analyzes data
- Organizes laboratory notebooks and data
- OOT investigations
- OOS investigations
- Coordinates with QC laboratory personnel
- Handles and completes special projects as required
- Identifies compliance issues
- Checks data integrity
- Trends data
- Thoroughly Analyzes data
- Formulate pertinent hypothesis and confirms hypothesis
- Identify possible and verifiable root cause to complete investigation (LIR, OOT, OOS) in timely manner
- Establish corrective/preventive action (CAPA)
- Conduct appropriate follow -up actions undertaken
- Coordinates and assist QC laboratory personnel
- Other duties as required or delegated

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3. Typical Supervisory Responsibility:

(Identify any responsibilities the role has for supervising others)

<ul style="list-style-type: none"> • Through oversight of laboratory review including calibration and qualification of instruments, testing data for various raw and packaging materials, In-process and Finished product along with stability testing management. • Comply to established procedures and identify deficient areas for enhancement through training and revision or implementation of procedures and systems.

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 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.)

Technical competencies	<ul style="list-style-type: none"> • 10 years in Pharma industry and laboratory setting preferred • Working knowledge of HPLC, UPLC, GC Dissolution, AA, UV spectrophotometer • Aptitude for application of analytical methods • Proficiently skilled in laboratory techniques • Ability to work independently under the supervision of a group leader • Takes initiative on assignments and day to day responsibilities • Proficient in personal computers • Excellent interpersonal and communication skills • Organization
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	<ul style="list-style-type: none"> • Continuous working knowledge of applicable cGMP guidelines • Continuous working knowledge of applicable DEA regulations
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