

KVK Tech	Employee Job Description
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1. Employee details:

First Name		Middle Initial		Last Name	
Hire Date		Department	Quality Assurance		
Location	110 Terry 100 Campus	Job Title	QA Group Leader	FLSA Status:	Exempt
Role	N/A				
Sub role (If any)	N/A				

2. Role Purpose:

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

3. Key Duties & Responsibilities:

- 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
- Other duties as required or delegated

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4. Typical Supervisory Responsibility:

- 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.

5. Education/Technical Competencies/ Certifications/ Licenses:

Technical competencies	<ul style="list-style-type: none"> • 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 • Continuous working knowledge of applicable cGMP guidelines • Continuous working knowledge of applicable DEA regulations
Education/Certifications/Licenses/Other	<ul style="list-style-type: none"> • Must have BS Chemistry with minimum 10 years in Pharma industry and laboratory setting preferred • Must have MS Chemistry with minimum 5 years in Pharma industry and laboratory setting preferred

6. Physical Demand and Work Environment:

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.

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b. Work environment:

N/A
