KVK Tech	**Employee Job Description**

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:

Quality assurance ensures that products manufactured by their employers meet industry and federal standards, and to make the entire manufacturing process more efficient.

3. Key Duties & Responsibilities:

- Monitoring and assigning day-to-day activities to the QA inspectors.
- Carry out line clearance activity in Manufacturing/Packaging during batch-to-batch and product-to-product changeover for various dosage forms (e.g. Tablets, Capsules, liquid, powder etc.)
- Sampling and releasing of Raw Materials, Packaging and Labeling Components.
- Review of Primary manufacturing documents like Master Manufacturing record, Master Packaging record, Process Validation/Cleaning Validation protocols.
- In process checking during compression, encapsulation, coating and packaging.
- Online review of the Batch Production record and Batch Packaging records.
- Review and verification of GMP logbooks (equipment, room, DEA activities etc.)
- Collect and submit in-process & finished product samples to Quality Control. Final release of the product to the market. Verify Quality Control testing, and OOS/Investigation/Validations (if applicable) are completed before release of drug products.
- Preparation and Review of SOPs, and protocols.
- Issue Batch Records, Archives all batch records and related documents.
- Supporting deviation closeout, writing investigation reports and initiating/following up on hold notices and corrective & preventive actions.
- Supporting quality related customer complaint investigations and trending activities.
- Support and play key part for Return Drug Product program.
- Train employees on documentation, cGMP and SOPs. Report employees error and Re-train/discipline for error any.
- Supporting annual quality review activities.

- Comply with FDA guidelines/Company Policies of Data Integrity.
- Other duties as assigned.

4. Typical Supervisory Responsibility:

- Serve as an effective member of the Quality team and may serve as a mentor to other Quality employees in the area of expertise.
- Comply to established procedures and identify deficient areas for enhancement through training and revision or implementation or procedures and systems.

5. Education/Technical Competencies/ Certifications/ Licenses:

Technical competencies	• Ability to work with a sense of urgency, prioritize work, meet objective / deadlines with strong organizational capability. • Demonstrated leadership capability (Ex. takes initiative to lead self and others, lead by example and follow through to completion often with minimal direction). • Ability to adjust work schedule based on business requirements ability to manage priorities. • Strong project management skills with the ability to work independently and within a team • Knowledge in all aspects of 21 CFR 210 and 211 • Document all performed analysis as per cGMP, USFDA and 21CFR211.194 guidelines • Follow cGMP (current Good Manufacturing Practices), 21CFR211.22, 21CFR211.28 and 21CFR211.170. • Follow the OSHA (Occupational Safety and Health Administration) and EPA (Environmental Protection Agency) safety regulations • Follow all DEA (Drug Enforcement Agency) guidelines • Strong attention to detail and organizational skills.

	• Effective interpersonal and communication skills
Education/Certifications/Licenses/Other	• Must have BS Chemistry with minimum 10 years in Pharma industry and laboratory setting • Must have MS Chemistry with minimum 5 years in Pharma industry and laboratory setting

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.

b. Work environment:

N/A