KVK Tech	**Employee Job Description**

1. Employee details:

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

2. Role Purpose:

Lead, train, and direct the daily activities of the Packaging/Manufacturing Departments by following all applicable Standard Operating Procedures/cGMP's as well as maintain a safe work environment.

3. Key Duties & Responsibilities:

- Supervise day to day operations of Manufacturing/Packaging.
- Assist with daily planning and scheduling to ensure proper workflow.
- Monitor, organize, and execute all functions associated with packaging of pharmaceutical commercial products and assuring compliance with cGMP, SOP, FDA, DEA, and OSHA rules and regulations.
- Work directly with management and group leaders to ensure appropriate follow through of the weekly planning schedule.
- Prepare and review packaging documentation.
- Create/ Revise SOP's where necessary, revise batch records.
- Work closely with Quality Assurance, Shipping, and Sales.
- Coordinate with Quality Assurance and warehouse personnel to ensure availability of required materials.
- Report shift completions and weekly planning schedule.
- Responsible for accuracy and completion of packaging batch records and all paperwork in a timely manner.
- Motivate a diverse workforce of all employees to exceed department goals, which include safety, compliance, quality, and productivity.
- Knowledge of principles, policies, practices, procedures, and strategies required to properly supervise and perform the operations of packaging lines.
- Technical background in the fields of packaging equipment installation operations (IQ/OQ/PQ) and preventative maintenance.

- Ability to communicate effectively both orally and in writing as pertains to planning, assigning and supervising the work of staff and providing status reports to management to increase efficiencies across department
- Ability to interact effectively with employees
- Communicate changes in schedule to the staff
- Train on SOP's, new methods, safety, and cGMP's on a continuum
- Communicate to H.R. staffing issues
- Responsible to access staffing levels and approve increases and decreases
- Attend Packaging and Production meetings in a timely fashion
- Other duties as assigned
- Comply with FDA guidelines and Company Policies

4. Typical Supervisory Responsibility:

Supervise the day-to-day activities of packaging operators, group leaders, material handlers and mechanics on one shift in a pharmaceutical packaging environment to ensure that packaging lines are run in an efficient manner, company packaging and shipping schedules are met and waste and downtime are minimized.

5. Education/Technical Competencies/ Certifications/ Licenses:

Technical competencies	• Computer literate with basic knowledge of Microsoft Office • Basic knowledge of an Inventory reporting system, e.g., SYSPRO, JDE, SAP, Vantage • Must have good communication skills • Must be able to read, write, and communicate in English • Missing productivity tracking and improvements • Training mechanics to minimize downtime • Train group leaders and employees to set up packaging equipment • Monitor Production losses and overall • Productivity, suggest enhancements to increase productivity • Must have leadership skills • Accuracy reporting to ERP System (SYSPRO). • Accuracy reporting to batch records

	• Entering information in log books for DEA, and FDA purposes • Must be a critical thinker with a "can do" attitude, and be able to think "outside the box". • Process troubleshooting • Ability to maintain good housekeeping across various Suites in a GMP environment • Thorough understanding of IQ, OQ, and PQ • Handle and complete special projects as required • Other duties as required or delegated • Document all information as per cGMP, USFDA and 21CFR211.194 guidelines. • Follow cGMP (current Good Manufacturing Practices), GLP (Good Laboratory 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
Education/Certifications/Licenses/Other	• College degree or equivalent or technical school certificate • 1-3 years previous experience working in a regulated environment (GMP or FDA) or a combination of work experience and college or technical school education.

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