

KVK Tech	Master Job Description		
	Revision:		

Department	Quality Assurance		
Job Title	Quality Engineer	FLSA Status	Exempt
Role	N/A		
Sub Role (If any)	N/A		
Reports To	Associate Director of Corporate Quality Assurance		

1. Role Purpose:

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

The Quality Engineer provides technical support to the entire facility, specifically related to maintenance of facilities, maintenance of equipment, equipment installation, calibration and services. This position will also provide support for process improvement and optimization, by evaluating existing processes and configuring manufacturing systems to reduce cost, improve sustainability and develop best practices within the production process to ensure cGMP with all operating equipment.

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)

- Responsible for the planning and undertaking of scheduled maintenance on all manufacturing, packaging, and utility equipment.
- Prepare, review and execute the engineering work tickets and complete with timely manner.
- Prepare, review and execute Preventive Maintenance and calibration schedules.
- Design facilities and equipment layouts for installation/relocation. Install equipment and support equipment qualifications.
- Coordinate Validation and IQ/OQ/PQ activities with Production, Quality Control Laboratories and outside contractors providing leadership, training and guidance.
- Oversee and execute commissioning/qualification/validation documents following established standards and templates for process equipment/utilities.
- Investigate deviations (both minor and major), with responsibility to interface with Operations, Automation, and Quality approvers.
- Lead in the identification and implementation of process improvement projects, productivity initiatives and corrective actions while focusing on equipment uptime, minimizing cost and maintaining process consistency
- Foster a collaborative relationship with manufacturing floor personnel focused on high quality investigations, meaningful corrective actions, and reducing the deviation generation rate. Determine appropriate corrective actions to prevent reoccurrence of the deviation. Ensure corrective actions are effective and improve right first time (RFT).
- Must have strong problem-solving skills and a hands-on approach to problem solving. Perform mechanical and electrical troubleshooting of equipment breakdown. Initiate repair work orders and ensure successful return to operation.
- Oversee mechanical maintenance of all laboratory, manufacturing and packaging equipment.
- Support deviation investigations (both minor and major) for assigned operational area.

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- Work alongside Operations to develop reliable, consistent manufacturing processes that meet cGMP requirements.
- Evaluate operational metrics and performance indicators for their assigned area to continuously improve the capabilities of the organization.
- Participates in audits, inspections, and training programs in the area of responsibility.
- Manage control subsisting systems for fire detection and protection of facilities.
- Communicates frequently with operation, technical, and quality representatives within area of support through the process.
- Oversee the interviewing, hiring, training, and development of all department personnel, ensuring they can function effectively in a team environment.
- Ensure department personnel are properly trained on cGMP SOPs.
- Ensure department personnel are properly trained in Safety Procedures.
- Comply with FDA guidelines/Company Policies of Data Integrity.
- Other duties as assigned.

3. Typical Supervisory Responsibility:

(Identify any responsibilities the role has for supervising others)

N/A

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/MS in engineering preferred in chemical, mechanical or industrial engineering 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.)

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Technical competencies	<ul style="list-style-type: none"> • 5 years relevant experience preferred • Follow cGMP (current Good Manufacturing Practices), 21 Code of Federal Regulations, Parts 210, 211 and 1304. • Follow the OSHA (Occupational Safety and Health Administration) and EPA (Environmental Protection Agency) safety regulations. • Follow all DEA (Drug Enforcement Agency) guidelines • Experience in problem solving and troubleshooting • Technical writing and deviation investigation experience • Pharmaceutical product manufacturing process improvement and optimization experience • Experience with formal problem-solving techniques, such as root cause analysis (RCA). • Experience in equipment automation. • Experience in deviation management, troubleshooting and resolving manufacturing anomalies. <p>Experience and proficiency in the following areas:</p> <ul style="list-style-type: none"> • Managing engineers and maintenance staff. • Automated control for equipment operation. • Blueprint and electrical schematic reading. • Knowledge of manufacturing and packaging operations. • Knowledge of CMMS programs. • Preventative maintenance procedures and scheduling. • PLC programs. • Industrial PC literacy. • Knowledge of Fire Prevention Systems and Maintenance
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:

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N/A