KVK Tech	Employee Job Description

1. Employee details:

First Name		Middle Initial		Last Name			
Hire Date		Department	Quality Assurance				
Location	110 Terry, 100 Campus, 38 Cabot	Job Title	Compliance Officer (QA Associate)		FLSA Status:	Exempt	
Role	N/A						
Sub role (If any)	N/A						

2. Role Purpose:

The QA Associate ensures quality and compliance of the materials and components entering the facility with applicable regulatory requirements and internal specifications. Primary activities will include process development and optimization, specification development, material and component sampling, inspection and disposition and supplier auditing. Additional activities may include reviewing documents and data, conducting process-focused audits, maintaining quality databases, performing trend analyses and reporting metrics where required, as well as performing quality and compliance training, as needed. Provide support during regulatory inspections. Assists with the development of SOPs, specifications, or other quality documents as needed.

3. Key Duties & Responsibilities:

Key Job Responsibilities:

- Inspect and disposition GMP raw materials, components and manufactured products.
- Perform both paper and on-site audits of vendors / suppliers.
- Review and approve method qualification and associated summary reports.
- Initiate and support the performance of investigations associated with GMP materials.
- Conduct walk-throughs of all manufacturing areas for adherence with SOPs and good documentation practices including but not limited to sample management and accountability, data integrity (manufacturing, calibration and maintenance logbooks, batch record documentation) and adherence with applicable safety requirements.
- Review SOPs, specifications, batch record documentation.
- Support implementation of Quality Management Systems (change control, deviation, CAPA, root cause investigations, market complaints, product recall, OOS and outliers).
- Review validation reports for aseptic manufacturing, filling and support processes and utilities for compliance against approved protocols.
- Ensure manufacturing compliance for adherence with process validations, hold time studies, and media fill simulation studies.

- Preparation of standard operating procedures.
- Maintain training need matrices.
- Perform quality review of documents for adherence with batch record requirements, SOPs and approved protocols.
- Support quality floor audits and/or floor inspections.
- Assists with quality improvement initiatives as needed.
- Assists with development/ writing of SOPs or other quality documents and/or reports as needed.
- Provides consultation on quality and compliance topics in areas of expertise.
- Effectively performs a variety of duties, on schedule, with accuracy and competency.
- Serves as an effective member of the Quality team and may serve as a mentor to other Quality employees in the area of expertise.
- Performs other duties as assigned.
- Complies with company polices and SOPs.

4. Typical Supervisory Responsibility:

N/A

5. Education/Technical Competencies/ Certifications/ Licenses:

Technical competencies	• Minimum of 5 years of experience in the Aseptic Manufacturing Pharmaceutical industry • Good written and oral communication skills • Strong knowledge of US FDA guidelines, 21 CFR Part 210 and 211 requirements, ISO 14644-1(Clean room standards) ICH and EU requirements. • Working knowledge of Aseptic techniques. • Experience in statistical analysis, process capability reviews with software is a plus • Ability to act independently • Excellent interpersonal, verbal and written communication skills .

Education/Certifications/Licenses/Other	• Must have a BS in Microbiology (preferred), Chemistry or related science field • ASQ (Quality Manager/Quality auditor) is a plus. • Six-Sigma certification is a plus.

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 grasp 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:

Sterile and office work environments