KVK Tech	Employee Job Description

1. Employee details:

First Name		Middle Initial		Last Name			
Hire Date		Department	Quality Assurance				
Location	110 Campus 110 Terry	Job Title	Document Control Associate			FLSA Status:	Non-Exempt
Role	N/A						
Sub role (If any)	N/A						

2. Role Purpose:

The primary responsibility is to track compendial changes, implementation plans and deadlines; prepare, update and maintain methods and specifications; process change control requests; prepare documents for submission and maintain/validate spreadsheet and Empower calculations in a timely manner, while maintaining compliance with cGMP requirements, FDA, OSHA, EPA, and DEA.

3. Key Duties & Responsibilities:

- 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) regulations per laboratory SOPs.
- Prepare, maintain and revise analytical methods and specifications as required
- Track and assist with implementation of compendial changes
- Process change control requests as required.
- Prepare documents for Regulatory submission as required.
- Validate and maintain calculations in controlled Excel spreadsheets and Empower. Revalidate as required.
- Maintenance of all electronic and hard copies of Standard Operating Procedures for all departments and their distribution including companywide on-line portal
- Maintenance of Departmental Training Manuals
- Maintenance of approved and executed Annual/Monthly Maintenance/Calibration Schedules for all the Manufacturing/Packaging Equipment and Quality Control Instruments
- Perform other duties as required
- Periodic purge of documents
- Document retrieval and Support for FDA and any other customer inspections

- Documents to be issued or retrieved within the expected timelines
- Work with Microsoft Excel, Word and Adobe Acrobat
- Research and gather information in a timely manner.
- Prepare, label, organize and maintain files.
- Follow all SOPs.
- Comply with FDA guidelines/Company Policies of Data Integrity
- Other duties as assigned

4. Typical Supervisory Responsibility:

N/A

5. Education/Technical Competencies/ Certifications/ Licenses:

Technical competencies	• Pharmaceutical industry experience is preferred • Applicable knowledge of DEA regulations • Good Math and computer skills including working knowledge of Word and Excel • Good verbal and written English • Good interpersonal and communication skills
Education/Certifications/Licenses/Other	• Associates degree in Science or related field from an accredited college or university

6. Physical Demand and Work Environment:

a. Physical demands:

While performing the duties of this job, the employee is frequently required to stand, walk, use hands to finger, handle or feel, and talk or 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