

KVK Tech	Master Job Description		
	Revision:		

Department	Quality Assurance		
Job Title	Document Control Associate	FLSA Status	Non-Exempt
Role	N/A		
Sub Role (If any)	N/A		
Reports To	Associate Director of Quality Management Systems		

1. Role Purpose:

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

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 spreadsheet and Empower calculations in a timely manner, while maintaining compliance with cGMP requirements, FDA, OSHA, EPA, and DEA.

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)

- 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.
- Track and assist with implementation of compendial changes
- Process change control requests as required.
- Prepare documents for Regulatory submission as required.
- Maintenance of Departmental Training Manuals
- Prepare and issue maintenance/calibration schedule for 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

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- 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)
Associates degree in science or related field from an accredited college or university 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
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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.)

Technical competencies	<ul style="list-style-type: none"> • 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
Certifications	N/A
Licenses	N/A

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Other	<i>N/A</i>
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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:

N/A