

KVK Tech	Employee Job Description
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1. Employee details:

First Name		Middle Initial		Last Name	
Hire Date		Department	Regulatory Affairs		
Location	110 Terry, 100 Campus	Job Title	Regulatory Affairs Associate	FLSA Status:	Non-Exempt
Role	N/A				
Sub role (If any)	N/A				

2. Role Purpose:

Primary responsibility is writing regulatory submissions by successfully coordinating with the Manager for priorities; while maintaining compliance with cGMP requirements, FDA, OSHA, EPA, and DEA.

3. Key Duties & Responsibilities:

- Interact with cross functional teams for procurement of documentation required for regulatory submissions.
- Review technical documents for accuracy and with supervision, determines acceptability for use in regulatory submissions (i.e. ANDA and NDA)
- Create documents in accordance with eCTD specifications.
- Update and maintain the internal database as needed
- Comply with FDA guidelines/Company Policies of Data Integrity
- Other duties as required or delegated

4. Typical Supervisory Responsibility:

N/A

5. Education/Technical Competencies/ Certifications/ Licenses:

Technical competencies	<ul style="list-style-type: none"> • At least 1 year experience with technical writing • Minimum 3 years Pharma experience • Proficient with Adobe PDF, Illustrator/In Design, Microsoft Office and advanced computer skills
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	<ul style="list-style-type: none"> • Continuous working knowledge of applicable FDA/ICH/DEA regulations • Continuous working knowledge of applicable cGMP guidelines
Education/Certifications/Licenses/Other	<ul style="list-style-type: none"> • Bachelor’s Degree in Pharmacy, Chemistry or Scientific Discipline preferred

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