

<b>KVK Tech</b>	<b>Employee Job Description</b>
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**1. Employee details:**

First Name		Middle Initial	N/A	Last Name	
Hire Date		Department	Operations		
Location	110 Terry, 100 Campus	Job Title	Technical Writer	FLSA Status:	Exempt
Role	N/A				
Sub role (If any)	N/A				

**2. Role Purpose:**

Primary responsibility is to investigate and document all deviations and customer related complaints related to the Manufacturing, Packaging and Shipping/Receiving departments by reviewing all related documents, and interviewing relevant personnel so as to identify the root cause and corrective actions required. Also, to change or correct any related documents pertinent to the conclusion of the investigation (i.e., SOP's) while maintaining compliance with cGMP requirements, FDA, OSHA, EPA, and DEA.

**3. Key Duties & Responsibilities:**

- Prepare Quality Event Records (including deviation, incident reports, planned deviation and product complaint investigations)
- Prepare and Review Out of Specification (OOS) investigations for internal and external analyses.
- Prepare and Review Risk Assessments, CAPAs, Change Control documents and Standard Operating Procedures (SOPs)
- Prepare and review Master production and packaging batch records
- Prepare and review Qualification Protocols and reports
- Handles and completes special projects as required
- Other duties as assigned or delegated

**4. Typical Supervisory Responsibility:**

N/A

**5. Education/Technical Competencies/ Certifications/ Licenses:**

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Technical competencies	<ul style="list-style-type: none"> <li>• Practical working knowledge of Pharmaceutical Manufacturing Operations</li> <li>• Excellent English writing, spelling, punctuation, and grammar skills</li> <li>• Ability to interpret complex data and draw valid conclusions</li> <li>• Proficient in the use of spreadsheets, databases, presentation, and word processing software. Basic Microsoft Office proficiency is expected.</li> <li>• Strong interpersonal skills and the ability to effectively work and communicate with cross-functional teams</li> <li>• Strong organizational and multi-tasking abilities</li> <li>• Self-motivated, work well independently and as a team player and re-prioritize workload as required</li> <li>• Continuous working knowledge of applicable cGMP guidelines and DEA regulations</li> </ul>
Education/Certifications/Licenses/Other	<ul style="list-style-type: none"> <li>• B.S. or higher degree from an accredited college/university in a scientific discipline or English, OR at least 0-5 years of job-related experience or equivalent</li> </ul>

**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