

<b>KVK Tech</b>	<b>Master Job Description</b>		
	<b>Revision:</b>		

<b>Department</b>			
<b>Job Title</b>	Validation Associate	<b>FLSA Status</b>	Exempt
<b>Role</b>	N/A		
<b>Sub Role (If any)</b>	N/A		
<b>Reports To</b>			

### 1. Role Purpose:

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

Support site commissioning and qualification, equipment qualification, and process and assay validation by ensuring the timely development, execution and coordination of all validation activities pertaining to facility, equipment and process in compliance with Quality System requirements, site procedures and regulatory requirements. This role will develop validation and Quality System documentation (e.g. IQ/OQ/PQ/SOP/Change Controls/Deviations/CAPAs etc.). This role will organize all validation activities ensuring project completion per schedule requirements. Additionally, the Validation and Calibration Specialist will be required perform and support GMP instrument calibration activities and completion of the corresponding documentation.

### 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)*

- Maintain the Company's compliance with established KVK Standard Operating Procedures and specifications and Current Good Manufacturing Practices.
- Write, execute and coordinate commissioning, qualification and validation protocol testing.
- Compile relevant commissioning/qualification/validation study data and generate summary reports to document the results of the studies.
- Aid in troubleshooting/impact assessment for atypical conditions during studies/ validations.
- Assist in the maintenance and development of any existing validation programs to ensure continued compliance with regulatory requirements.
- Provide scientific rationale/strategy for studies of new or modified GMP equipment and processes.
- Ensure all aspects of validation and qualification adhere to site and corporate policies and procedures, including safety and training.
- Review all errors, protocol deviations, and comments with the respective user department Management and QA and resolve discrepancies.
- Manage responsibilities and workload to assure accurate and timely data and reports.
- Perform scheduled preventive maintenance, and instrument calibrations.
- Document all instrument calibrations and equipment preventive maintenance.
- Complete any associated work order documentation.
- Review completed validation, PM, and calibration documentation for accuracy and GMP compliance.
- Comply with FDA guidelines, Site and Corporate Policies for Data Integrity.
- Other duties as assigned.

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**3. Typical Supervisory Responsibility:**

*(Identify any responsibilities the role has for supervising others)*

N/A
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**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)
A college degree (B.S.) is preferred	Technical discipline (sciences, engineering) or related field
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

**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.)*

<b>Technical competencies</b>	<ul style="list-style-type: none"> <li>• Preferred to have 6-8 years of technical experience in validation in a GMP environment, including pharmaceutical manufacturing and project management.</li> <li>• Ability to manage and plan multiple projects.</li> <li>• Knowledge of cGMP's, GDP's and regulatory requirements as they related to qualification and validation activities (IQ/OQ/PQ).</li> <li>• Possess a working knowledge of Microsoft Word, Windows, Excel, Power Point, and Statistical tools such as Minitab/Jmp.</li> <li>• Must possess excellent analytical skills, good problem-solving technique and data analysis skills using Excel.</li> <li>• Employee must have excellent communication skills, both written and verbal</li> <li>• Employee must be collaborative when working with groups.</li> <li>• Attention to detail is required.</li> </ul>
<b>Certifications</b>	N/A
<b>Licenses</b>	N/A

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<b>Other</b>	<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*