

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

<b>Department</b>	Manufacturing		
<b>Job Title</b>	Encapsulation Operator	<b>FLSA Status</b>	Non-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)*

Responsible for performing tasks to specifications related to oral solid dose pharmaceutical manufacturing. Process includes Encapsulation manufacturing.

**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)*

- Ensure the proper set-up and operation of standard pharmaceutical process equipment such as Encapsulation machine and ancillary equipment (Ex. metal detector, empty capsule shell sorter, capsule check weigher, capsule deduster, scales).
- Perform all in-process testing, sampling and inspections as required by the Master Batch Record (i.e. capsule weight, capsule closure, visual inspection etc.).
- Clean and sanitize equipment and manufacturing rooms including walls, floors, and ceilings per current SOPs.
- Perform machine cleaning, changeovers and set up as required while maintaining a clean working environment
- Perform start-ups and reconciliation as per the batch record instructions
- Ensure proper execution of Master Batch Records, standard operating procedures and validation protocols.
- Ensure accurate completion of equipment logs.
- Ensure cleanliness and proper assembly of manufacturing equipment per approved procedures (SOP's).
- Interface and consult with Quality Assurance personnel.
- Identify and report quality issues
- Total compliance at all times by following batch records instructions, SOPs and all company policies
- Report accidents, unsafe conditions or unusual circumstances to supervisor.
- Adhere to all relevant cGMP and FDA regulations.
- Maintain a neat and orderly work area at all times

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- Comply with FDA guidelines/Company Policies of Data Integrity
- Other duties as assigned or delegated.

**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)
High School Diploma or equivalent or technical school certificate 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.)*

<b>Technical competencies</b>	<ul style="list-style-type: none"> <li>• Excellent written and verbal communication skills</li> <li>• Excellent math skills</li> <li>• Ability to read and comprehend SOP's, Batch Records and training documents.</li> <li>• Ability to multi-task effectively</li> <li>• Excellent interpersonal skills and ability to effectively interact with different functional groups</li> <li>• Must be able to stand for at least an 8-hour shift and lift, push or pull up to 50 pounds.</li> <li>• Capable of wearing any type of personal protective equipment</li> </ul>
<b>Certifications</b>	N/A

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<b>Licenses</b>	N/A
<b>Other</b>	N/A

**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 50 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