

1. Employee details:

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|-------------------|-------------------------------------|----------------|------------------------|--------------|------------|
| First Name | | Middle Initial | | Last Name | |
| Hire Date | | Department | Manufacturing | | |
| Location | 110 Terry Drive 100 Campus Drive | Job Title | Encapsulation Operator | FLSA Status: | Non-Exempt |
| Role | N/A | | | | |
| Sub role (If any) | N/A | | | | |

2. Role Purpose:

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

3. Key Duties & Responsibilities:

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

4. Typical Supervisory Responsibility:

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|----------|---------------------------------|
| KVK Tech | Employee Job Description |
|----------|---------------------------------|

N/A

5. Education/Technical Competencies/ Certifications/ Licenses:

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

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 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