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

|                   |                         |                |                          |              |        |
|-------------------|-------------------------|----------------|--------------------------|--------------|--------|
| First Name        |                         | Middle Initial |                          | Last Name    |        |
| Hire Date         |                         | Department     | Manufacturing            |              |        |
| Location          | 110 Terry<br>100 Campus | Job Title      | Manufacturing Supervisor | FLSA Status: | Exempt |
| Role              | Production Supervisor   |                |                          |              |        |
| Sub role (If any) | N/A                     |                |                          |              |        |

**2. Role Purpose:**

Responsible for supervising the manufacturing of Oral solid dosage (OSD) and liquid products manufacturing. Production Supervisor to ensure to maintain area and equipment's to deliver a quality product, upkeep the documents as per CGMP standard and strictly implemented the policies and procedure to main clean room and quality system.

**3. Key Duties & Responsibilities:**

- Oversees monitors and coordinates Manufacturing activities, giving importance to individual members and overall team achievement for policy deployment objectives.
- Involved in the employees' training including execution of Batch Records, SOP's and validation protocols.
- Plan, coordinate, troubleshoot and procure all the tools necessary and support the production operators in achieving the productivity targets.
- Develops and oversees, scheduled, manufacturing requirements and headcount to determine the most cost effective and efficient methods of obtaining necessary resources while ensuring improved performance in quality, cost, delivery, safety and morale.
- Supports and develops a comprehensive continuous and structured training program for the department
- Directs the placement of all manufacturing personnel to weighing, compression, encapsulation and coating areas.
- Ensures that operators are adhering to all safety procedures and identifying/communicating the necessary adjustments to address potential safety concerns.
- Ensures that operators are wearing the proper PPE (personal protective equipment).
- Manage and coordinate with Quality Assurance and Quality Control on all Production activities.
- Ensure the production operators are in compliance with the cGMP requirements.
- Identifies employee development needs based upon personal assessment and feedback from team leaders.
- Works with production teams to ensure that goals are being met.

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- Maintains primary communication of goals and requirements as identified by production management.
- Focuses on driving productivity improvements while maintaining high quality standards.
- Supports review and approval of Batch Manufacturing Records and SOP's.
- Establishes creative manufacturing solutions. Establishes/monitor standard operating procedures with in manufacturing.
- Supports attainment of department and operator goals.
- Assists in investigation writing and root cause analysis, Corrective Action and Preventive Actions execution (CAPA).
- Comply with FDA guidelines/Company Policies of Data Integrity
- Other duties as assigned.

**4. Typical Supervisory Responsibility:**

- Prepares Production schedule and ensure the execution
- Collects data compiles production reports
- Troubleshoots issues with process or equipment's where required
- Ensure that the team has access to all relevant resources and equipment ensure smooth running of production
- Ensuring production downtime is kept to a minimum
- Work with cross functional teams to ensure that the production team, equipment's are fully compliant and up-to-date with training
- Perform reviews of the production processes to try to identify areas for improvements
- Ensure that all documentation necessary for regulatory compliance areas for improvements
- Technical sound in at least one unit operation compression or encapsulation process.

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

|                        |   |
|------------------------|---|
| Technical competencies | <ul style="list-style-type: none"> <li>• 5 + years of experience in Pharmaceutical industry</li> <li>• Understanding of IQ, OQ, and PQ</li> <li>• Handle and complete special projects as required</li> <li>• Other duties as required or delegated</li> <li>• Document all performed analysis as per cGMP, USFDA and 21CFR211.194 guidelines.</li> <li>• Follow cGMP (current Good Manufacturing Practices), GLP (Good Laboratory Practices), 21CFR211.22, 21CFR211.28 and 21CFR211.170.</li> <li>• Follow the OSHA (Occupational Safety and Health Administration) and EPA (Environmental Protection Agency) safety regulations.</li> </ul> |
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|   | <ul style="list-style-type: none"> <li>• Follow all DEA (Drug Enforcement Agency) guidelines</li> <li>• Computer literate with basic knowledge of Microsoft Office</li> <li>• Basic knowledge of an Inventory reporting system, e.g., SYSPRO, JDE, SAP, Vantage</li> <li>• Must be flexible, responsive, respectful and have good communication skills</li> <li>• Must be able to read, write, and communicate in English.</li> <li>• Must have leadership skills with the ability to work in a fast-paced environment.</li> <li>• Detail-oriented self- starter with strong organizational skills.</li> <li>• Understanding the accuracy needs in reporting to batch records</li> <li>• Entering information accuracy in log books for DEA, and FDA purposes</li> <li>• Must be a critical thinker with a “can do” attitude, and be able to think “outside the box”.</li> <li>• Process troubleshooting</li> </ul> |
| Education/Certifications/Licenses/Other | <ul style="list-style-type: none"> <li>• Bachelor Degree required</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