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| **Department** |  Packaging |
| **Job Title** |  Inspection & Packaging Supervisor | **FLSA Status** |  Exempt |
| **Role** |  N/A |
| **Sub Role (If any)** | N/A |
| **Reports To** |  Head of Production |

**1. Role Purpose:**

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

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| * Lead and manage visual inspection and packaging operations in compliance with cGMP and regulatory standards.
* Ensure inspection qualification programs (defect kits, inspector performance) are effectively maintained and documented.
* Oversee daily packaging activities including serialization, aggregation, labeling, and shipping preparation.
* Develop staffing plans, schedules, and workload distribution to support uninterrupted operations.
* Drive achievement of departmental metrics such as changeover times, output per shift, and defect detection rates.
* Provide coaching, training, and development opportunities to inspection and packaging staff.
* Implement continuous improvement initiatives to increase efficiency, reduce documentation errors, and strengthen compliance.
* Collaborate with cross-functional partners (Quality, Engineering, Validation, Supply Chain) to resolve issues and support audits.
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**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)*

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| * Develop and maintain staffing plans (weekly/monthly) by assessing workload, shift demands, line throughput, and scheduled changeovers, to ensure adequate departmental coverage.
* Conduct workload analysis and forecast resource needs, flagging staffing gaps and proposing mitigation strategies (e.g. overtime, cross-training).
* Lead, coach, and develop staff through regular 1:1s, performance reviews, goal setting, and career development planning.
* Oversee cross-training programs so that operators and inspectors can perform in multiple roles (inspection, packaging, line support).
* Define key performance metrics for inspection and packaging (e.g. changeover times, output per shift, rejection / defect rates, line speed attainment, yield, downtime) and monitor performance against targets.
* Conduct morning / shift startup meetings to establish goals, review yesterday’s metrics, identify risk areas, and communicate expectations for the shift.
* Drive changeover efficiency by analyzing past changeover data, implementing best practices, and benchmarking to reduce times.
* Monitor output requirements and dynamically communicate to staff their progress versus daily targets, triggering interventions when targets lag.
* Manage inspection qualification programs, including creating, staging, and overseeding defect kits, periodically testing inspectors’ detection performance (e.g. 80 % detection threshold), maintaining records of qualification and retraining.
* Design or improve defect kits (if applicable) by producing representative rejects and items to seed into kits to challenge inspectors.
* Supervise packaging / serialization process: ensure carton, insert, shipper, and pallet serialization is performed correctly, with proper aggregation (e.g. unit → carton → shipper → pallet).
* Manage the AQL / AOQL sampling program: coordinate with QA to sample, inspect, accept/reject lots, follow retest / reinspection logic, and ensure compliance with sampling plans.
* Lead investigations of defects, deviations, or nonconformities in inspection / packaging; initiate corrective and preventive actions (CAPA) and root cause analyses.
* Maintain documentation accuracy by auditing forms, logs, and batch record entries; propose and implement improvements (SOP updates, checklist redesigns, electronic controls) to reduce errors.
* Interface cross-functionally with Quality, Filling / Sterile Operations, Materials, Validation, Engineering, and Supply Chain to ensure alignment and resolve issues.
* Lead continuous improvement initiatives (lean, process optimization, waste reduction) in inspection and packaging operations.
* Ensure compliance with cGMP, site safety, environmental, and quality systems within the department.
* Support audits / inspections (internal, external, regulatory) by preparing records, training staff, and guiding process compliance in the inspection/packaging area.
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**3.Typical Supervisory Responsibility:**

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

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| * Directly supervise a team of inspectors, packaging operators, and support personnel.
* Accountable for hiring, performance reviews, coaching, disciplinary actions, training, and overall team development.
* Approve work schedules, vacation / shift assignments, overtime requests within budget constraints.
* Foster a culture of safety, quality, accountability, and continuous improvement within direct reports.
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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 considered.)*

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| **Education Requirement** | **Specialization (If any)** |
| * Bachelor’s degree in life sciences, pharmaceutical sciences, chemistry, engineering, or related field preferred; a combination of education and significant industry experience may substitute.
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| **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 experience*.)

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| * Demonstrated leadership or supervisory experience overseeing inspection and/or packaging operations.
* Strong background in visual inspection of sterile injectable products (e.g., vials, syringes), including inspector qualification processes and defect kit management.
* Hands-on experience with packaging operations, including serialization, aggregation, labeling, and line clearance.
* Proven ability to manage departmental metrics such as line speed attainment, output per shift, and changeover times.
* Direct involvement in AQL/AOQL sampling processes and collaboration with Quality Assurance in lot disposition.
* Experience leading or supporting regulatory inspections and audits (FDA, EMA, or equivalent).
* Demonstrated success in implementing continuous improvement initiatives to reduce errors, improve efficiency, and enhance compliance.
* Familiarity with documentation practices, deviation management, CAPA, and change control systems in a regulated environment.
* Proficiency in using manufacturing systems (MES/ERP) and Microsoft Office tools for reporting and analysis.
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| Number of Years (Minimum to Maximum) | 5+ years in a cGMP pharmaceutical or biopharmaceutical manufacturing environment.  |

**Technical competencies/ Certifications/ Licenses**:

*(Briefly describe the required competencies such as skill, ability, and knowledge an individual must possess to perform the role. Also, identify any certification or licenses required to perform the role.)*

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| Technical competencies | * In-depth knowledge of cGMP regulations, FDA/EMA guidance, and aseptic processing requirements.
* Expertise in visual inspection practices, including defect recognition, inspector qualification, and defect kit management.
* Strong understanding of packaging operations such as serialization, aggregation, labeling, and shipper/pallet processes.
* Ability to analyze and manage departmental performance metrics (e.g., changeover times, output rates, defect trends).
* Proficiency in AQL/AOQL sampling methodologies and statistical quality control principles.
* Skilled in documentation accuracy, including batch records, SOPs, and deviation reporting.
* Experience with continuous improvement tools (Lean, Six Sigma, root cause analysis, CAPA).
* Strong leadership and team development capabilities, including training, coaching, and cross-training strategies.
* Effective problem-solving and decision-making skills to address production challenges in real time.
* Proficiency in manufacturing execution systems (MES/ERP) and common business software (e.g., Microsoft Excel, Word, PowerPoint).
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| Certifications | * Six Sigma Green Belt or Lean certification preferred.
* GMP / Quality training certification preferred.
* Quality or process certifications relevant to pharmaceutical manufacturing optional.
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| Licenses | N/A |
| Other | * Must successfully complete internal training and qualification for gowning and aseptic operations.
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**5.Physical demand and Work environment:**

*(Provide details regarding the physical demands and work environment that are essential to the role)*

* 1. Physical demands:

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| * Ability to stand and walk for extended periods during inspection and packaging activities.
* Capability to perform fine visual and manual tasks, including handling small components such as vials and packaging materials.
* Frequent reaching, bending, and lifting of materials up to approximately 40 pounds in accordance with safe handling practices.
* Sustained visual acuity and color discrimination required for accurate defect detection.
* Regular use of personal protective equipment (PPE), including sterile gowning, gloves, masks, and eyewear in controlled environments.
* Occasional climbing of stairs or access to elevated work platforms as needed.
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* 1. Work environment:

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| The role is performed primarily within a cleanroom and controlled production environment that adheres to cGMP standards. The position requires strict compliance with sterile gowning procedures and environmental monitoring requirements. Employees will work in temperature-controlled areas, with exposure to controlled humidity and lighting conditions necessary for inspection activities. The role involves interaction with cross-functional teams and may require flexibility in scheduling, including evenings, weekends, or overtime, to support production demands. Noise levels are typical of a pharmaceutical manufacturing facility and all safety, environmental, and quality protocols must be consistently observed. |

**6.Compliance:**

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| * Comply with all Company codes, policies, and procedures concerning ethics, quality, and compliance, including compliance with applicable laws, rules and regulations, including the Food, Drug and Cosmetic Act and all associated regulations.
* Timely and satisfactory completion of all required training, including training related to ethics, compliance, quality, and position-specific requirements.
* Understand the compliance responsibilities of your role.
* Commit to the Company’s culture of ethics and compliance.
* Report all known or potential violations of Company codes, policies, and procedures, or of applicable laws, rules and regulations, to the Company as contemplated by the Company’s policies and procedures, including SOP-0015 (Escalation to Management on Critical Matters Pertaining to Quality and Regulatory Compliance), or through the Company’s FaceUp portal, available by telephone or online (details below).

**Compliance Hotline # (205) 354-2405**[**www.faceup.com**](http://www.faceup.com)**Download Faceup App using the****Passcode # PLSxxxx1842****Or scan QR Code below** |