Standard Operating Procedure (SOP)

Product Packaging Process Steps and Line Clearance

This SOP details the **product packaging process steps and line clearance**, encompassing the preparation and setup of packaging materials, step-by-step guidelines for efficient and accurate packaging operations, inspection and verification of product quality before packaging, proper labeling and coding procedures, and thorough line clearance protocols to prevent contamination or product mix-ups. The aim is to ensure consistency, safety, and compliance throughout the packaging process, enhancing product integrity and traceability.

1. Purpose

To outline the standardized method for product packaging and ensure thorough line clearance, maintaining product quality, regulatory compliance, and preventing cross-contamination or mix-ups.

2. Scope

Applicable to all personnel involved in the packaging of finished products at [Facility/Department Name].

3. Responsibilities

- **Packaging Personnel:** Follow SOP steps, report non-conformities, and participate in line clearance activities.
- **Supervisors/QA:** Oversee process adherence, conduct inspections, verify clearances, and maintain documentation.

4. Definitions

- **Line Clearance:** The systematic removal of all previous product, components, documents, and waste from the packaging line before starting a new batch or product.
- **WIP:** Work-in-Progress.

5. Materials and Equipment

- Approved packaging materials (cartons, labels, inserts, wrappers, etc.)
- Packaging equipment (conveyor, labeler, coder, sealing machine, etc.)
- Quality check tools (scales, vernier calipers, etc.)
- Line clearance checklist and batch documentation forms
- Personal protective equipment (PPE)

6. Procedure

1. **Preparation and Setup**
   a. Verify availability and approval status of packaging materials.
   b. Clean and, if necessary, sanitize the packaging area and equipment.
   c. Set up equipment and calibrate as per manufacturer recommendations.
   d. Display correct batch records and product information at the workstation.
2. **Product Quality Inspection Before Packaging**
   a. Inspect WIP products for quality parameters in line with specifications.
   b. Segregate and document any non-conforming products/materials for disposal.
   c. Record inspection status in batch log sheet.
3. **Packaging Operations**
   a. Feed verified products and packaging materials into the respective equipment.
   b. Monitor the packaging process for accuracy and efficiency.
   c. Perform in-process checks on weight, appearance, seal integrity, and count at defined intervals.
   d. Correct any discrepancies immediately and record actions taken.
4. **Labeling and Coding**
   a. Ensure labels and codes match product and batch information.
   b. Perform sample checks for legibility, adhesion, and accuracy.
   c. Document label and code verification in the batch record.
5. **In-process Quality Control**
   a. Conduct quality checks as per QA sampling plan.
   b. Record results and report any out-of-specification findings.
   c. Adjust process parameters as recommended by QA/Supervisor, if needed.
6. **Line Clearance Procedure**
   a. Upon completion or changeover, stop the packaging line and remove all products, materials, and

waste related to the previous batch.
  b. Check equipment, surfaces, floors, and surrounding areas for remnants.
  c. Remove and discard old batch records, labels, and documents.
  d. Inspect line using the standardized line clearance checklist.
  e. Supervisor/QA verifies completeness of clearance and documents authorization to proceed.

7. Documentation and Records

- Batch Packaging Records
- Line Clearance Checklist
- Label and Coding Verification Sheets
- In-process Quality Control Logs

8. References

- Current Good Manufacturing Practices (cGMPs)
- [Company/Facility Quality Manual]

9. Revision History

Version	Date	Description of Change	Approval
1.0	[Date]	Initial SOP creation	[Approver Name/Title]