

SOP Template: Room and Equipment Cleaning, Line Clearance, and Changeover Procedures

This SOP details **room and equipment cleaning, line clearance, and changeover procedures** to ensure hygiene, prevent cross-contamination, and maintain production efficiency. It covers step-by-step cleaning protocols, verification of line clearance, proper equipment sanitation, and systematic changeover steps to comply with safety and quality standards in manufacturing environments.

1. Purpose

To describe standardized procedures for cleaning rooms and equipment, ensuring line clearance, and conducting changeovers in manufacturing areas.

2. Scope

This SOP applies to all personnel responsible for cleaning, maintenance, and production in manufacturing environments requiring strict hygiene and contamination control.

3. Responsibilities

- **Production Staff:** Execute cleaning and changeover procedures.
- **Supervisors:** Verify completion and adequacy of cleaning and line clearance.
- **Quality Assurance:** Audit, document, and approve the processes.

4. Definitions

| Term | Definition |
|----------------|--|
| Line Clearance | Process of ensuring no materials or documents from a previous batch remain in the area before starting new activities. |
| Changeover | Transitioning from one product/lot to another, requiring cleaning and line clearance. |
| Sanitization | Reduction of microbial contamination to safe levels as per regulations. |

5. Procedure

5.1 Room and Equipment Cleaning

1. Review cleaning instructions specific to the area/equipment in the cleaning log or SOP annexes.
2. Remove all products, waste, and unrelated materials from the area.
3. Use approved cleaning agents and materials (e.g., detergents, sanitizers, wipes).
4. Clean from least to most contaminated areas (e.g., ceilings, walls, equipment, floors).
5. Disassemble equipment as specified, clean all parts thoroughly, and reassemble when dry.
6. Inspect surfaces for residues or visible dirt.
7. Document cleaning activities in the cleaning log, including date, time, and personnel initials.

5.2 Line Clearance

1. Verify removal of all previous batch materials, products, labels, and documents from the area/equipment.
2. Check all waste containers are emptied and replaced.
3. Confirm area status with line clearance checklist.
4. Supervisor or QA must inspect and sign off in the line clearance record.

5.3 Changeover Procedure

1. Complete required batch documentation for previous production run.
2. Follow room and equipment cleaning procedures as above.

- 3. Conduct line clearance process and obtain required approvals before starting new operations.
- 4. Update area and equipment status boards/signages to reflect readiness for new activity.
- 5. Ensure all SOP deviations, issues, or unusual findings are documented and reported.

6. Documentation

- Cleaning Logs
- Line Clearance Checklist/Records
- Changeover Logs
- Deviation Reports (if any)

7. References

- GMP Guidelines
- Company-specific SOPs and Work Instructions
- Cleaning Agent MSDS

8. Revision History

| Version | Date | Description | Approved By |
|---------|------------|-----------------|--------------|
| 1.0 | 2024-06-17 | Initial release | [Name/Title] |