

SOP Template: Documentation of Changeover Activities and Production Start-up

This SOP details the **documentation of changeover activities and production start-up**, encompassing the systematic recording of all procedures during equipment transition, verification of setup parameters, quality checks, and initial production runs. It ensures accurate tracking, minimizes downtime, maintains product quality, and facilitates smooth production flow by providing clear guidelines for logging activities from changeover initiation to full operational status.

1. Purpose

To standardize the documentation of changeover activities and production start-up, ensuring traceability, quality assurance, and compliance with operational procedures.

2. Scope

This SOP applies to all production lines/equipment undergoing product or batch changeover and start-up operations.

3. Responsibilities

- **Production Operators & Technicians:** Carry out and record changeover and start-up tasks as per procedure.
- **Supervisors:** Verify records, confirm completion of critical steps, and authorize production start-up.
- **Quality Assurance:** Review documentation for compliance and completeness.

4. Definitions

- **Changeover:** Transition of equipment from one product/batch to another.
- **Start-up:** Activities conducted to initiate production following a changeover.

5. Procedure

1. **Initiate Changeover**
 - Stop production and document last product/batch details.
 - Record date, time, and name of responsible personnel.
2. **Perform Equipment Cleaning & Preparation**
 - Document cleaning activities, including cleaning agents used, method, lot numbers, and inspections performed.
 - Record verification of equipment cleanliness before setup.
3. **Set Up Equipment**
 - Record all changed parts, equipment settings, and setup parameters (temperatures, speeds, etc.).
 - Attach checklists and calibration records as required.
4. **Conduct Pre-Production Checks**
 - Document quality checks (visual inspections, measurements, etc.).
 - Record test run results and adjustments made.
5. **Authorize Start-up**
 - Ensure supervisor reviews all documentation and signs off authorization for full production start.
6. **Production Start-up**
 - Record start time, batch number, and operator initials.
 - Log any deviation or issue encountered during initial production.

6. Documentation Requirements

- Changeover Log Sheet
- Equipment Cleaning Checklist
- Setup Parameter Sheet
- Pre-production Quality Check Record
- Production Start-up Authorization Form

7. Reference Documents

- Related SOPs for equipment operation and cleaning
- Batch production records
- Quality assurance guidelines

8. Changeover & Start-up Documentation Log (Sample Table)

Date/Time	Activity	Details	Responsible Person	Verification/Comments
YYYY-MM-DD HH:MM	Changeover Initiation	Stopped batch X, cleaned lines	Operator Name	Supervisor initials
YYYY-MM-DD HH:MM	Equipment Setup	Adjusted filler settings, replaced parts	Technician Name	QA remarks
YYYY-MM-DD HH:MM	Pre-production Check	Test run samples within specs	Operator Name	Supervised and approved
YYYY-MM-DD HH:MM	Production Start-up	Started batch Y, all systems OK	Operator Name	--

9. Attachments/Forms

- Attachment 1: Changeover Log Sheet “ Template
- Attachment 2: Equipment Cleaning Record
- Attachment 3: Production Start-up Checklist

10. Revision History

Revision	Date	Description	Prepared by	Approved by
00	YYYY-MM-DD	Initial issue	Name	Name