SOP Template: Trial Run and Quality Checks with First-Off Samples

This SOP details the **trial run and quality checks with first-off samples** process, including preparation for the trial run, methods for collecting and inspecting first-off samples, criteria for quality assessment, documentation of findings, corrective action procedures, and approval protocols before full-scale production. The aim is to ensure that products meet specified quality standards and to identify and resolve any issues early in the manufacturing process.

1. Purpose

To ensure that all products meet defined standards by performing trial runs and conducting quality checks using first-off samples prior to commencing full-scale production.

2. Scope

This procedure applies to all manufacturing lines and processes where first-off samples are required before mass production.

3. Responsibilities

- **Production Supervisor:** Oversees trial run and sample collection.
- **Quality Inspector:** Conducts sample inspection and documents results.
- **Production Operator:** Produces first-off samples and assists with set-up and corrective action.
- **Quality Manager:** Reviews inspection findings and approves production.

4. Procedure

1. **Preparation for Trial Run**
    - Verify production setup according to approved specifications and work instructions.
    - Ensure measuring instruments and inspection tools are calibrated and available.
    - Inform Quality Inspector of the scheduled trial run.
2. **Conducting the Trial Run**
    - Start the production line and produce the required number of first-off samples (as per control plan).
3. **Sample Collection and Identification**
    - Label the first-off samples clearly with date, time, batch/lot number, and operator ID.
    - Deliver samples to Quality Inspection.
4. **Quality Inspection**
    - Inspect samples against defined criteria, drawings, and quality standards.
    - Record all findings on the First-Off Sample Inspection Report (see template below).
5. **Assessment and Documentation**
    - Determine pass/fail status based on inspection results.
    - Document any non-conformities and notify the Production Supervisor immediately.
6. **Corrective Actions**
    - If samples fail, investigate root cause and implement corrective actions.
    - Repeat the trial run and inspection as necessary until samples pass all criteria.
7. **Approval Protocol**
    - Submit completed inspection reports to the Quality Manager for review.
    - Obtain signed approval before commencing full-scale production.

5. Documentation

All trial run results, sample inspection reports, and corrective actions must be recorded and filed for traceability and future audits.

6. First-Off Sample Inspection Report Template

Report No.		Date	
Product Name/Code		Batch/Lot No.	
Operator		Inspector	
Inspection Criteria & Results			
Characteristic	Specification	Result	Pass/Fail
Non-Conformities Observed			
Corrective Actions Taken			
Approved By		Date	

7. References

- Work Instructions for Production Equipment Setup
- Quality Manual and Control Plan
- Calibration Records

8. Revision History

Rev.	Date	Description	By
01		Initial Release	