SOP Template: Sampling Plan and Frequency for In-Process Checks

This SOP details the **sampling plan and frequency for in-process checks**, outlining the systematic approach to selecting sample units during manufacturing or production processes. It specifies the types of samples, sampling methods, sample size, and the frequency of sampling to ensure consistent product quality and compliance with regulatory standards. The procedure aims to detect and prevent defects early, minimize variation, and provide data for process control and continuous improvement.

1. Purpose

To establish a standard methodology for sampling and conducting in-process quality checks during manufacturing, ensuring compliance with product specifications and regulatory requirements.

2. Scope

This SOP applies to all production lines and personnel involved in sampling and in-process quality checks.

3. Responsibilities

- **Quality Assurance (QA):** Define sampling plans, review results, and approve corrective actions.
- **Production:** Collect samples as per plan, perform checks, and document results.
- **Supervisors:** Ensure procedure compliance and provide training.

4. Definitions

- **Sample Unit:** An individual item or set of items selected for inspection or testing.
- **In-Process Check:** Quality assessment performed during manufacturing at specified stages.

5. Procedure

1. **Sampling Plan Design:**
    - Identify critical process steps requiring in-process checks.
    - Determine sample type (e.g., units, batches, lots) and characteristics to be assessed.
    - Establish sampling method (random, stratified, systematic).
    - Calculate minimum sample size based on risk, process variability, and regulatory guidelines.
2. **Sampling Frequency:**
    - Define how often samples are to be collected (e.g., hourly, per batch, shift-wise).
    - Consider product complexity, process stability, and historical data in setting frequency.
3. **Conducting In-Process Checks:**
    - Collect and label samples as per schedule.
    - Perform specified tests or inspections.
    - Document results in the in-process check log.
4. **Response to Out-of-Specification Results:**
    - Immediately report findings to QA and Production Supervisor.
    - Isolate affected batches and perform root cause analysis.
    - Implement corrective and preventive actions as required.

6. Sampling Plan Table (Example)

Process Step	Sample Type	Sampling Method	Sample Size	Frequency	Check Parameter(s)
Mixing	Bulk Material	Random	3 samples	Per batch	Homogeneity, pH, Viscosity
Filling	Filled Units	Systematic	5 units	Every 30 min	Weight, Volume

Packing	Finished Packs	Stratified	5 packs	Per shift	Labeling, Seal Integrity

7. Documentation

- Record all sampling and in-process check results in designated logbooks or electronic systems.
- Maintain records as per company data retention policies.

8. References

- Applicable regulatory guidelines (e.g., GMP, ISO standards)
- Company Quality Manual

9. Revision History

Revision	Date	Description	Approved By
00	2024-06-15	Initial Release	QA Manager