SOP: Quality Assurance Checks and Parameter Validation

This SOP details the procedures for **quality assurance checks and parameter validation**, including systematic inspection protocols, adherence to specified quality standards, validation of critical process parameters, documentation requirements, corrective action implementation, and continuous improvement practices. The objective is to ensure product consistency, compliance with regulatory standards, and the maintenance of high-quality outputs through rigorous monitoring and validation processes.

1. Purpose

To define the standard procedures for performing quality assurance checks and validating critical process parameters to maintain product quality and regulatory compliance.

2. Scope

This SOP applies to all production and quality assurance personnel involved in monitoring, verifying, and validating process parameters and product quality across all departments.

3. Responsibilities

Role	Responsibilities
Quality Assurance (QA)	Conducts checks, maintains records, initiates corrective actions, and reviews compliance with standards.
Production Supervisor	Ensures process control parameters are set, maintained, and documented; reports deviations to QA.
Operators	Monitor parameters in real time and alert supervisors/QAs to deviations.
QA Manager	Approves documentation and oversees continuous improvement initiatives.

4. Procedure

4.1 Systematic Inspection Protocol

- Inspect products/processes at defined intervals using approved checklists.
- Verify all critical control points (CCPs) and key process parameters.
- Record findings in the Quality Assurance Log.

4.2 Adherence to Quality Standards

- Ensure procedures comply with regulatory and internal standards.
- Use calibrated instruments for measurements.

4.3 Parameter Validation

- Identify and document critical process parameters for each product/process.
- Validate parameters at the start of production and when there is a process change.
- Document any deviations and report immediately.

4.4 Documentation Requirements

- Complete the Quality Assurance Log and Validation Forms promptly.
- Document corrective and preventative actions in CAPA log.
- Maintain records for audits and reviews.

4.5 Corrective Action Implementation

- Initiate corrective actions upon identification of deviations or non-conformities.

- Document root cause analysis and actions taken.
- Follow up to ensure effectiveness of correction.

4.6 Continuous Improvement

- Review quality records periodically to identify trends and areas for improvement.
- Update SOPs and training based on improvement findings.
- Encourage staff involvement in quality improvement initiatives.

5. Documentation & Records

Document	Description	Retention Period
Quality Assurance Log	Daily record of product/process checks	3 years
Validation Forms	Parameter validation at batch/process start and change	3 years
CAPA Log	Corrective and Preventive Actions	5 years

6. References

- Company Quality Policy
- Applicable Regulatory Standards (e.g., ISO 9001, GMP)
- Equipment Calibration Records
- Change Control Procedures

7. Revision History

Version	Date	Description of Change	Author
1.0	2024-06-27	Initial release	QA Department