SOP: Temperature Control and Monitoring Protocols

This SOP details the **temperature control and monitoring protocols** vital for maintaining optimal environmental conditions. It covers procedures for accurate temperature measurement, equipment calibration, monitoring schedules, setting temperature thresholds, and responding to deviations. The objective is to ensure product quality, safety, and compliance with regulatory standards by implementing consistent and effective temperature management practices.

1. Purpose

To outline standardized procedures for controlling, monitoring, and documenting temperature in relevant environments, ensuring product quality, safety, and regulatory compliance.

2. Scope

This SOP applies to all personnel responsible for temperature-sensitive processes, including storage, manufacturing, testing, and transportation areas.

3. Responsibilities

- **Supervisors:** Ensure staff are trained and protocols are followed.
- **Staff:** Perform temperature checks, documentation, and report deviations.
- **Quality Assurance (QA):** Review records and investigate deviations.

4. Procedure

4.1 Temperature Measurement

1. Use calibrated digital temperature sensors or thermometers appropriate for each environment.
2. Place sensors in representative locations, avoiding proximity to fans, doors, or direct sunlight.
3. Record temperature readings as per the monitoring schedule below.

4.2 Equipment Calibration

1. Calibrate all temperature monitoring equipment at intervals recommended by the manufacturer or regulatory authority.
2. Document each calibration, including date, responsible personnel, and calibration results.
3. Immediately remove and label any device found out of calibration; do not use until recalibrated.

4.3 Monitoring Schedule

Area/Equipment	Frequency	Responsible Person
Refrigerators/Freezers	Daily (Minimum Twice)	Assigned Technician
Storage Rooms	Daily	Warehouse Staff
Transport Vehicles	Every Shipment	Logistics Staff

4.4 Temperature Thresholds

- Set acceptable temperature ranges for each environment (e.g., 2-8Â°C for refrigerators, 15-25Â°C for storage rooms).
- Display thresholds on equipment and monitoring logs for easy reference.

4.5 Response to Deviations

1. Immediately inform supervisor and QA if temperatures fall outside set thresholds.
2. Document the deviation, including date, time, duration, and suspected cause.
3. Take remedial action as specified in the deviation protocol (e.g., move products, adjust equipment).
4. QA to review, investigate root cause, and determine need for product evaluation or additional action.

5. Documentation

- Record all temperature data in logbooks or electronic systems.
- Maintain calibration certificates and deviation reports for audits.

6. Training

- Provide initial and refresher training on temperature control protocols and equipment use.
- Document all training sessions and participant attendance.

7. References

- Manufacturer guidelines for monitoring equipment
- Applicable regulatory standards (e.g., GMP, GDP, ISO)
- Internal quality management policies

8. Revision History

Date	Version	Description	Approved By
2024-06-21	1.0	Initial version	QA Manager