SOP Template: Raw Material Storage and Temperature Monitoring

This SOP details the procedures for **raw material storage and temperature monitoring**, ensuring optimal conditions to maintain material quality and safety. It includes guidelines for proper storage environments, temperature control requirements, routine monitoring, documentation, and corrective actions to prevent contamination or spoilage. The aim is to uphold product integrity and compliance with regulatory standards throughout the storage phase.

1. Purpose

To define the procedures for storing raw materials and monitoring their storage temperatures to ensure safety, quality, and compliance with regulatory requirements.

2. Scope

This SOP applies to all personnel involved in the storage and handling of raw materials at [Facility Name].

3. Responsibilities

- **Warehouse Staff:** Store materials as per guidelines, conduct daily temperature checks, maintain records, and report deviations.
- **Quality Assurance (QA):** Verify compliance, review records, and oversee corrective actions.
- **Maintenance Team:** Ensure temperature monitoring devices are calibrated and functioning.
- **Warehouse Supervisor:** Oversee the implementation of this SOP.

4. Procedure

4.1 Storage Requirements

- Store raw materials in designated, clean, and organized areas to prevent contamination.
- Segregate materials based on type, status (e.g., quarantined, approved), and storage condition requirements.
- Store away from direct sunlight, pests, chemicals, and incompatible materials.
- Materials requiring controlled temperatures (e.g., refrigerated, frozen) must be stored in equipment meeting specified ranges.

4.2 Temperature Control

- Maintain storage areas at temperatures specified for each raw material (*see material specifications*).
- Place calibrated temperature monitoring devices (e.g., digital thermometers, data loggers) at appropriate locations within each storage area.
- Ensure alarms are set for critical temperature thresholds (where applicable).

4.3 Temperature Monitoring and Documentation

- Record storage area temperatures at least twice daily (start and end of shift) or as specified.
- Document readings in the **Temperature Monitoring Log** (see Appendix 1).
- Review records daily; file completed logs for traceability and audits.

4.4 Corrective Action

- If temperatures fall outside specified limits, immediately inform QA/warehouse supervisor.
- Quarantine affected materials until quality status is determined.
- Investigate root cause and implement corrective actions, including equipment repair and retraining if necessary.
- Document findings and actions taken.

5. Records

- Temperature Monitoring Log (retain for at least [X] years)
- Corrective Action Reports
- Calibration Certificates for monitoring devices

6. References

- Material specifications and SDS (Safety Data Sheets)
- Regulatory guidelines ([e.g., FDA, GMP, ISO])
- Equipment manuals

7. Appendix 1: Temperature Monitoring Log (Sample)

Date	Time	Storage Area	Temperature (°C)	Recorder Initials	Remarks/Deviation
YYYY-MM-DD	08:00	Refrigerator 1	4.2	ABC	Within range
YYYY-MM-DD	16:00	Refrigerator 1	7.5	DEF	Out of range â€“ Informed QA