SOP: Environmental Monitoring and Swab Testing Routine

This SOP details the **environmental monitoring and swab testing routine**, including procedures for sampling, testing, and analyzing environmental surfaces to detect microbial contamination. It emphasizes consistent monitoring schedules, proper sample collection techniques, documentation, data review, and corrective actions. The goal is to maintain hygiene standards, ensure product safety, and comply with regulatory requirements by identifying and controlling contamination risks in production and processing environments.

1. Purpose

To establish a standard routine for environmental monitoring and swab testing in order to detect and control microbial contamination within production and processing environments.

2. Scope

This SOP applies to all production, processing, and packaging areas where hygiene and product safety must be controlled through regular environmental monitoring.

3. Responsibilities

- **Quality Assurance (QA):** Oversight of program, sample scheduling, data review and reporting.
- **Designated Personnel:** Sample collection and documentation.
- **Laboratory Staff:** Testing, result interpretation, and reporting.
- **Production/Facilities Management:** Implementation of corrective actions.

4. Procedure

4.1 Monitoring Schedule

- Establish routine (e.g., daily, weekly, monthly) sampling schedules for each area.
- Define sampling frequency based on risk assessment and regulatory requirements.
- Document schedule on the Environmental Monitoring Calendar.

4.2 Sampling Procedure

1. Wear appropriate PPE.
2. Select sampling sites as per the pre-defined site map (e.g., food-contact, non-food-contact surfaces, air).
3. Label swabs/sample bags with location, date, and sampler initials.
4. Follow aseptic techniques to collect swab samples over a defined area (typically 10x10 cm).
5. Store and transport samples to the laboratory under specified conditions (e.g., within 2 hours at 2-8Â°C).

4.3 Testing and Analysis

- Process samples following validated laboratory methods (e.g., plate count, pathogen detection).
- Record and review results against established limits.
- Flag and investigate any out-of-specification (OOS) or positive results.

4.4 Documentation

- Complete Environmental Monitoring Log for each sampling event.
- Document all results, deviations, and actions taken.

4.5 Review and Corrective Action

1. QA to review all data and trends regularly.
2. If contamination is detected, initiate root cause analysis, increase sampling frequency, and perform corrective measures (e.g., cleaning, sanitization, retraining).
3. Document all investigations and corrective actions in the Deviation Record.
4. Follow up to verify effectiveness before routine schedule resumes.

5. Records

- Environmental Monitoring Calendar
- Sampling Site Map
- Environmental Monitoring Log
- Laboratory Test Results
- Deviation/Corrective Action Records

6. References

- GMP Guidelines
- ISO 14698 / ISO 18593
- Internal Quality Procedures
- Local Regulatory Requirements

7. Revision History

Version	Date	Description	Approved By
1.0	2024-06-xx	Initial SOP release	QA Manager