SOP: Verification of Supplier Documentation and Certificates

This SOP details the process for **verification of supplier documentation and certificates**, including the review of compliance certificates, authenticity checks, validation of quality standards, and record keeping. It aims to ensure that all supplier documents meet regulatory requirements and company standards to maintain product quality and supplier reliability.

1. Purpose

To outline procedures for verifying supplier documentation and certificates to ensure compliance with legal, regulatory, and internal requirements.

2. Scope

This SOP applies to all personnel involved in the procurement, quality assurance, and regulatory functions relating to supplier selection and ongoing supplier qualification.

3. Responsibilities

- **Procurement Team**: Initial collection and review of supplier documents.
- **Quality Assurance (QA)**: In-depth verification and archival of documentation.
- **Regulatory Affairs**: Assessment of regulatory compliance of documentation and certificates.

4. Definitions

- **Supplier Documentation**: Certificates, statements, and reports provided by a supplier as proof of compliance, authenticity, or quality.
- **Certificates**: Includes ISO certificates, compliance declarations, test reports, and other regulatory documents.

5. Procedure

1. **Document Receipt**
    - Procurement team obtains necessary documents and certificates from suppliers during vendor approval or re-evaluation processes.
2. **Initial Review**
    - Check documents for completeness, legibility, and correlation with the supplied materials/services.
3. **Authenticity Check**
    - Validate certificate authenticity through:
        - Direct confirmation from issuing authority if needed
        - Cross-verification with online databases of certifying bodies
        - Review of official seals, signatures, and validity dates
4. **Quality and Compliance Verification**
    - Check compliance with applicable regulatory standards (e.g., ISO, GMP, local requirements).
    - Verify certificate coverage matches the supplied product/service.
5. **Document Validation**
    - If required, escalate suspect documents to QA/Regulatory Affairs for further investigation.
6. **Approval or Rejection**
    - Approve supplier only upon successful verification; rejected suppliers are informed and corrective actions requested.
7. **Record Keeping**
    - Archive verified documents electronically or physically as per company policy.
    - Log actions in supplier qualification/monitoring system.
    - Maintain a list of approved suppliers and document expiry dates for renewal reminders.

6. Documentation and Forms

- Supplier Documentation Checklist
- Supplier Approval Form
- Exception/Non-conformance Report (if required)

7. References

- Applicable regulatory standards (e.g., ISO 9001, ISO 13485, GMP regulations)
- Company's Supplier Qualification Procedure
- Quality Management System Documentation

8. Revision History

Version	Date	Description	Approved By
1.0	2024-06-14	Initial release	Quality Manager