Standard Operating Procedure

Title: Vendor Certification Procedure

Department	**Quality Management**		**Document no**	**QMS-050**	
Prepared by:		Date:		Supersedes:	
Checked by:		Date:		Date Issued:	
Approved by:		Date:		Review Date:	

Document Owner

Procurement / Quality Assurance Manager

Affected Parties

All colleagues working in a team for vendor selection, evaluation and certification process from the Procurement, QA, Technical Services, Manufacturing and Laboratory Departments.

Purpose

This procedure aims to describe the process by which a vendor may be certified to supply materials or services.

Scope

This procedure applies to vendors that supply a material or service to be used at any stage of manufacture by operations.

Definition

Certification	"Is the act of approving quality control results provided by the supplier in relation to a specific material, thus eliminating the need to undertake some or all laboratory tests on receipt of that material unless specifically required to meet regional/local GMP and/or regulations".
De-certification	"Is the act of reverting back to full or partially increased testing of a specific material on receipt from the supplier".
Certified Material	A certified material is evaluated based on agreed testing by the Vendor and may also undergo additional laboratory testing by the buyer, if the supplier does not perform all tests required to release the material.
Supplier	An umbrella term that covers both Vendors / Contractors.
Vendor	A supplier of commercially available materials and/or services.
Certification Team	The team is to comprise of the following representatives; QA Manager and Procurement Manager.
C of A	Certificate of Analysis
DR	Deviation Report

Related Documents

TEM-005	Raw Material Specification and Test Report Template
TEM-100	Quality Assurance Agreement Template
TEM-150	Packaging Material Specification and Test Report
QMS-015	Quality Documentation Management and Change Control
QMS-030	Preparation, Maintenance and Change Control of Master Documents
QMS-035	Deviation Report System

2.5. Initiate a Quality audit of the supplier. (See SOP **QMS-080**)

2.6. Liaise with supplier to enhance their understanding of company requirements.

2.7. Create or review and update the relevant Raw Material Control Test Methods to reflect required testing terminology, requirements and methods.

2.8. Together with Procurement, present a report to the Management Certification Committee requesting certification of the supplier. The report is composed of typically the following; quality supply history, delivery performance, Project plan, Change Control request, audit information, Supply agreement, a Certificate of Analysis from the vendor, supplier inspection planning requirements, matrix.

2.9. Produce a Certificate to be presented to the successful vendor

3. Technical Service Department

The Technical Department is to:

3.1. Determine any Regulatory impact of changes to testing procedure and provide support for obtaining Regulatory approvals as required.

3.2. For relevant suppliers, review current Raw Material testing carried out on site and provide a summary of proposed testing to be performed by the Vendor. Liaise with the vendor and buyer's Laboratory to obtain agreement on testing accountabilities and format of Certificate of Analysis provided by the vendor.

3.3. For Printed Materials,

3.3.1. Produce and distribute Packaging Specification Templates signed off by the supplier.

3.3.2. Produce and distribute Packaging Specifications created from the Packaging Specification Templates for each supplied material. A controlled copy of each template is provided to the supplier.

3.4. Produce Raw Material/Packaging Material Specification and Test Report on approved Raw Material/packaging material specifications respectively. A controlled copy of the Test Report is provided to the supplier.

4. Laboratory

The Laboratory is to:

4.1. Review all components delivered.

4.2. Raise a **DR** (See SOP **QMS-035**) for both rejection and quality issues, where required.

4.3. Liaise with the supplier and Technical Service Department regarding testing to be performed and presentation of results on a Certificate of Analysis.

5. Production

Production area is to:

5.1. Advise Quality Assurance Department of any quality issues using a Deviation Report supported by an example of the issue.

