

# Standard Operating Procedure

## Title: Vendor Certification

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- 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.