Procedure: Supplier Evaluation and Monitoring

|  |  |  |  |
| --- | --- | --- | --- |
| Document information, authorship and approvals | | | |
| Author signs to confirm technical content | | | |
| Prepared by: | Job title: | Signature: | Date: |
| Subject matter expert reviewer signs to confirm technical content | | | |
| Reviewed by: | Job title: | Signature: | Date: |
| Quality representative signs to confirm document complies with quality management system | | | |
| Authorised by: | Job title: | Signature: | Date: |

Table of Contents

[1. Purpose 3](#_Toc407093847)

[2. Scope 3](#_Toc407093848)

[3. Responsibilities 3](#_Toc407093849)

[4. Procedure 3](#_Toc407093850)

[4.1. General 3](#_Toc407093851)

[4.2. Supplier evaluation 3](#_Toc407093852)

[4.3. Quality performance monitoring 4](#_Toc407093853)

[4.4. Approved supplier list 5](#_Toc407093854)

[4.5. Supplier quality management system development 5](#_Toc407093855)

[4.6. Records 5](#_Toc407093856)

# Purpose

This procedure describes the system, provides instructions and identifies responsibilities for evaluating and monitoring of suppliers, subcontractors and consultants supplying goods and services within the Quality Management System (QMS) at [Company].

# Scope

The scope of this procedure includes contractors, subcontractors and consultants that supply the following components or services that may affect product quality.

| Components | Services |
| --- | --- |
| raw materials  primary packaging components  substances  laboratory equipment  manufacturing equipment  finished goods labelling | design  laboratory testing  contract cleaning  calibration  maintenance  software  delivery  expertise |

# Responsibilities

Amend to reflect company structure.

|  |  |
| --- | --- |
| Role | Responsibility |
| Production Manager | Evaluate and approve suppliers. |
| Quality Manager | * Evaluate and approve suppliers. * Manage the system of evaluating and training staff in its implementation. |
| Purchasing Officer | Ensures purchase orders are only placed with approved suppliers, sub-contractors and consultants. |

# Procedure

## General

All suppliers, sub-contractors and consultants must be evaluated and selected based on their ability to supply product in accordance with [Company] requirements. Criteria for selection and periodic evaluation are described here.

## Supplier evaluation

### New suppliers

New suppliers are evaluated as to their ability to supply product that conforms to the standards required by the company.

They must provide the following documents and information to support their quality system.

|  |  |
| --- | --- |
| Type of Supplier | Documents and Information |
| Product | * If quality certified, then obtain a certificate of quality system registration or other evidence of a QMS. * If not quality certified, obtain a copy of their quality assurance manual. * Obtain samples of similar products or workmanship. |
| Services | Obtain professional resumes or references (quality-related and financial). |

Once the information is obtained, where appropriate request a follow-up audit to complete the evaluation.

The Quality Assurance (QA) department then documents the results and classifies each supplier using a Supplier Quality File (SQF). All documents supporting the initial evaluation and qualification of the supplier are placed in the file. The file is also used for keeping records of the supplier's ongoing quality performance.

|  |  |
| --- | --- |
| Supplier Classification | Description |
| Approved | A satisfactory supplier with a proven history or good quality system. Products or services may be ordered from this company. |
| Provisional | A new supplier, a supplier with little or no quality history or with a doubtful quality history or with recent, unresolved issues. Components or services may be ordered from this company however, it may have been presented with a corrective action which must be implemented within the specified period.  If outstanding issues are not resolved satisfactorily, the supplier is either reclassified as not approved or incoming inspection criteria are increased to compensate for the lack of confidence.  Supplies should not remain on the Provisional list indefinitely. |
| Not approved | A supplier who is not qualified due to major non-conformities or other issues. Components or services may not be purchased from this supplier. |

### Existing suppliers

Suppliers may be exempt from the initial evaluation if there is a history of satisfactory supply for at least six months prior to implementation of this procedure. They may be classified as approved.

Existing suppliers whose performance is not entirely satisfactory should be classified as provisional. If there are known outstanding issues, it may be necessary to issue a *Form FP704-1: Corrective Action Request* (CAR).

Existing unsatisfactory suppliers must be either removed from the supplier list or given a not approved status.

Regardless of their past record, all suppliers are subject to ongoing monitoring of their quality performance.

## Quality performance monitoring

Supplier quality performance is continually monitored by assessing:

* Delivered product quality - all incoming product is sampled by a Quality Control (QC) inspector and then checked for conformity with specifications.

If a non-conformity is identified, the QC inspector initiates a Deviation Report according to Procedure QP805: Managing Deviations. The supplier is contacted and informed. When it is sufficiently serious or recurring, the supplier is requested to propose and implement corrective actions and report back on their progress (refer to Procedure QP809: Corrective and Preventative Action). Deviation reports, CARs and associated communication are kept in the SQF.

* Delivery schedule performance - deliveries are tracked with respect to on-time performance and records are maintained in the SQF. Suppliers with unsatisfactory delivery performance are asked to investigate the causes and are required to implement appropriate corrective actions.

Suppliers are encouraged to focus their corrective actions on improving the capabilities of their manufacturing processes.

Suppliers who regularly fail to deliver satisfactory products or do not deliver on time, despite repeated requests, are downgraded to either provisional or not approved status.

## Approved supplier list

Purchasing and Quality Assurance are responsible for maintaining an Approved Supplier List which records all acceptable suppliers (approved and provisional). The list is regularly maintained and any changes authorised by the QA and Purchasing Managers. The list is released and distributed in accordance with Procedure QP401: Document Control.

## Supplier quality management system development

Suppliers of components and services are required to implement an appropriate quality management system. Certification of the QMS by a recognised body such as ISO is highly regarded.

Where applicable, suppliers are encouraged to implement a QMS and may be given assistance in achieving this.

## Records

An SQF for each supplier on the approved supplier list is kept by Purchasing and is maintained jointly by QA and Purchasing.

Depending on the nature and performance history of the supplier, the SQF typically includes records and documents related to the initial supplier evaluation (refer Section 4.2) and pertaining to ongoing monitoring of the supplier’s performance (e.g. delivery records, non-conformances, CARs, etc).

Appendices

Amend as required or delete.

Definitions

Amend as required or delete.

| Term | Definition |
| --- | --- |
|  | Insert terms/abbreviations and definitions for those used within the procedure. Do not include any terms or abbreviations not used within the procedure. |
| CAR | Corrective Action Request |
| QA | Quality Assurance |
| QC | Quality Control |
| QMS | Quality Management System |
| SQF | Supplier Quality File |

Document Information

| Revision History | | | |
| --- | --- | --- | --- |
| Revision | Modified by | Change Control No. | Description of Change |
| 01 |  |  |  |
|  |  |  |  |
|  |  |  |  |

Complete the above fields for each revision of this document. Ensure that there is sufficient description of changes so that the change history of this document can be followed. Additional columns can be added to include document/change tracking numbers generated by your company’s systems if required (eg. change control).

| Associated forms and procedures | |
| --- | --- |
| Doc. No. | Document Title |
| QP401 | Document Control |
| QP805 | Managing Deviations |
| QP809 | Corrective and Preventative Action |
| FP704-1 | Corrective Action Request |

List all controlled procedural documents referenced in this document (for example, policies, procedures, forms, lists, work/operator instructions

| Associated records | |
| --- | --- |
| Doc. No. | Document Title |
|  |  |

List all other referenced records in this document. For example, regulatory documents, in-house controlled documents (such as batch record forms, reports, methods, protocols), compliance standards etc.

DOCUMENT END