Procedure: Supplier Evaluation and Monitoring

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This procedure allocates responsibility for evaluating and monitoring suppliers to both Quality Assurance and Purchasing. The level of responsibility each takes depends on the nature of the company’s suppliers and the criticality of the materials.

# Purpose

This procedure describes the system, provides instructions and identifies responsibilities for evaluating and monitoring of suppliers, subcontractors and consultants at [Company].

# Scope

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

|  |  |
| --- | --- |
| Components | Services |
| raw materials  substances  pieces  parts software  firmware  labelling  assemblies to be included as  part of the finished product | design  (laboratory) testing  contract cleaning  calibration  maintenance  software  sterilisation  delivery |

Modify the above lists to reflect those components and services applicable to the company.

# Responsibilities

|  |  |
| --- | --- |
| Role | Responsibility |
| Production Manager | Evaluate and approve suppliers. |
| Quality Manager | * Evaluate and approve suppliers. * Managing 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. |

Amend roles and responsibilities according to your company processes and structure.

# Procedure

## Supplier evaluation

This procedure adopts two status levels for suppliers but some companies have a more detailed grading system with several classifications (the standard only requires “approved” or “not approved”).

The quality capability of suppliers is evaluated jointly by Quality Assurance and Purchasing. New suppliers are requested to provide the following documents and information to support their quality system:

This list is an example and may be modified as appropriate.

* a certificate of quality system registration or other evidence of a QMS (Quality Management System)
* copy of quality assurance manual (if not quality certified)
* description of critical process equipment and machines
* professional resumes (if engineering or consulting is involved)
* samples of similar products or workmanship
* references (quality related and financial)

The Quality Assurance (QA) department evaluate the information provided and classifies each the suppliers using a Supplier Quality File (SQF). Where appropriate, a follow-up audit may be requested. All documents supporting the initial evaluation and qualification of the supplier are placed in the file; establish an SQF for each supplier. 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. |

## Quality performance monitoring

Supplier quality performance is continually monitored in the following aspects:

Monitoring of delivered product quality is explicitly required in the standards. Monitoring of on-time performance is optional but may contribute to satisfying the requirements of ISO 13485 clause 8.5.

* Delivered product quality - all incoming product is sampled by stores staff or a QC inspector and then checked for conformity with specifications.
* If a non-conformity is identified, the QC inspector or stores staff initiates a Non-Conformance Report as per Procedure QP805: Control of Non-conforming Product. The supplier is contacted and informed. If it is sufficiently serious or recurring, the supplier is requested to propose and implement corrective actions and report back on their effectiveness (refer to Procedure QP810: Corrective and Preventive Action).
* Non-conformity 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.

## Existing suppliers

This section allows for “grandfathering” existing suppliers at the time of implementation of the QMS. This must be on a supplier-by-supplier and not a blanket approval of all existing suppliers.

Suppliers may be exempt from the initial evaluation (refer to Section 4.1) if there is a history of satisfactorily 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 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.

## Approved supplier list

There is an implied requirement in the standard for an approved supplier list as supplier status must be communicated to all personnel involved in purchasing. This procedure uses a list for this purpose.

Purchasing and Quality Assurance are responsible for maintaining an Approved Supplier List which records all acceptable suppliers (APPROVED and PROVISIONAL). The list is reviewed monthly and any changes are authorised by the QA and Purchasing managers. The list is released and distributed in accordance with Procedure QP401: Control of Documents.

## Supplier quality management system development

Neither ISO 9001 nor ISO 13485 specifically require that key suppliers be certified to a QMS. However there is an expectation that suppliers have some sort of quality system and that it be evaluated. If key suppliers are not ISO certified, they must be audited regularly.

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

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

## Records

An SQF will be set up for each supplier on the approved supplier list. The file 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 to Section 4.1) 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. |
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Document Information

| Revision History | | | |
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| Revision | Modified by | Change Control No. | Description of Change |
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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 | Control of Documents |
| QP805 | Control of Non-conforming Product |
| QP810 | Corrective and Preventive Action |

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.

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