Procedure: Purchasing

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| Reviewed by: | Job title: | Signature: | Date: |
| Quality representative signs to confirm document complies with quality management system | | | |
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This procedure only addresses purchasing activities specifically required by the standard. It does not attempt to cover non-compliance/non-regulatory issues.

# Purpose

This procedure describes the system, provides instructions and identifies responsibilities for preparation of quality related purchasing documents and activities at [Company].

# Scope

This scope is the same as procedure QP705.

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

Components and services include:

|  |  |
| --- | --- |
| Components | Services |
| 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 |
| Purchasing Manager |  |
| Quality Manager |  |

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

# Procedure

## 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.

Ensure this matches section 4.4 of QP705 Supplier Evaluation and Monitoring.

An approved supplier list is maintained and is available to personnel involved in preparing and authorising the company's purchasing documents (refer to Procedure QP705: Supplier Evaluation and Monitoring).

Purchase of materials and services must only be from companies who are listed as either APPROVED or PROVISIONAL on the approved suppliers list.

## Purchasing information

The lists in the 2nd, 3rd and 4th clauses below are derived from the standard but the terminology may be altered to suit the company’s practices. Items which are obviously not relevant may be deleted.

Purchasing documents are prepared by the purchasing department.

Purchasing documents must clearly and completely identify the ordered products and should include, as applicable:

* a product identification (name, part number, type, grade, etc.)
* the title and revision level of specifications, drawings or other such technical documents defining the product
* delivery requirements, including the required delivery date

The level of detail required in a purchase order should be relevant to the importance of the material or service to the quality of the product that the company is going to manufacture.

Where appropriate, purchase orders should include the requirement for the following evidence of product quality:

* manufacturing quality records -
* conformance to manufacturing specifications
* inspection and test records
* control charts or other Statistical Process Control (SPC) evidence
* conformity of materials
* certificates of analysis
* evidence of an effective quality management system
* QMS compliance certificate from a recognised certifying body
* second or third part audit records

Quality records supplied with the purchased products are important for determining the amount of receiving inspection.

If complex components or equipment are not purchased, the above clause should be deleted.

In critical instances or for complex equipment, purchasing documents may also specify requirements for qualification of the products, procedures, processes, equipment and personnel used in the realisation of products or services being purchased.

This typically includes requirements for submission of product samples, manuals, procedures, equipment specifications, process performance and capability studies and personnel qualification and training.

## Product change notification

Change notification is a requirement of CFR 820.50(b) only. It is not specified in ISO 13485, however, there is value in applying the ECR (Engineering Change Request) system to purchased products.

Where appropriate, purchase orders should include a requirement that suppliers, contractors and consultants notify [Company] of any changes to the product or service. This is to enable the company to determine whether changes affect the quality of its finished device.

If the product or service change results a design change (i.e. a revision of a Device Master Record (DMR) document is required), the change notification is processed as an Engineering Change Request (ECR) in accordance with Procedure *QP704: Control of Design and Process Changes*.

## Review of specified requirements

CFR 820 specifies the review, approval and signoff of purchasing documents before release whereas ISO 13485 only requires the company to "... ensure the adequacy of specified purchase requirements ..." This procedure follows the more stringent requirements of CFR 820 and may be relaxed to comply with ISO 13485 only.

Purchase orders for critical or complex items or services must be reviewed and approved by the QA, Engineering Design and Purchasing Managers.

Purchase orders for less complex items may be reviewed and approved by the Purchasing Manager only, as appropriate.

The purpose of the reviews is to verify:

* the supplier status is either APPROVED or PROVISIONAL
* products are clearly identified
* technical documents defining products, such as standards, specifications, drawings, etc, are clearly identified, are current and are enclosed with the order
* quality records such as inspection and test records, SPC charts, quality system certificate, etc, are explicitly requested in the purchase order
* purchasing documents include requirements for qualification of products, procedures, processes, equipment and personnel involved in realisation of the products or services being purchased

The Purchasing Manager verifies that the cost, credit, financial and payment conditions are the best obtainable and are in accordance with the company’s agreements and purchasing policies.

This type of verification in the clause above is not a requirement of the quality standard.

When the purchase order and supporting documents have been reviewed and are satisfactory, they are approved by the Purchasing Manager and, where appropriate, the Design Engineer and/or QA Manager.

Where appropriate, be more specific in describing this review and approval process.

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 | | | |
| --- | --- | --- | --- |
| Revision | Modified by | Change Control No. | Description of Change |
| 01 |  |  |  |
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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 |
| QP704 | Control of Design and Process Changes. |
| QP705 | Supplier Evaluation and Monitoring |

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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