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**Quality Management System**

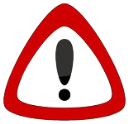
**Level-II -QUALITY MANAGEMENT SYSTEM PROCEDURE**

**Document Title**

**PURCHASING PROCESS AND SUPPLIER SELECTION**

1. **APPROVAL**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name** | | **Designation** | **Signature** | **Date** |
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**B. REVISION HISTORY**

|  |  |  |  |
| --- | --- | --- | --- |
| Rev. No. | Revision Date | Description of change | Reason for Revision |
| 00 | New Procedure | New Level-II procedure is defined as per clause 7.4.  Updated as per ISO 13485 & IMDR 2017 requirements | ----------- |

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1. **PURPOSE:**

This procedure is to establish and maintain a procedure for the process of purchasing. It also describes methods which at Serwell Medi - Equip (P) Ltd adopt to evaluate and select suppliers, to review and authorize Purchasing information and methods adopted to verify purchased products.

1. **SCOPE:**

This procedure is applicable to the suppliers to be approved, and to include in the approved supplier list at Serwell Medi - Equip (P) Ltd

1. **RESPONSIBILITY:**
   1. Selection and evaluation of suppliers and outsourced processes are done by the team, consisting members from D&D, Production, Quality, Maintenance or associated user and Purchase department.
   2. The approval of such suppliers after necessary qualification is by the authorized purchase person.
   3. Purchase personnel are responsible for generating the purchase order which is approved by the authorized Purchase Head.
   4. Quality department is responsible to test and approve / reject the purchased material confirming to approved standard specification.
2. **DEFINITION & ABBREVIATIONS:**

**QMS –** Quality Management System

**PR –** Purchase Requisition

**PO / WO –** Purchase Order / Work Order

**ASL –** Approved Supplier List

**BOM –** Bill of Material

**Critical Materials –** Materials are identified by the QA Team as critical to the functioning of Serwell Medi - Equip (P) Ltd finished products and meet the intended use requirements

**Noncritical Materials –** All other materials that are part of BOM used to build Serwell Medi - Equip (P) Ltd product that are deemed non critical by the QA team

**MR –** Management Representative

**RM –** Raw Material

**PM –** Packing Material

**QA –** Quality Assurance

**SCAR –** Supplier Corrective Action Request

**COA–** Certificate of Analysis.

**5.0 REFERENCE:**

5.1 ISO 13485:2016 Standard

5.2 IMDR 2017

5.3 SME-QMS-M01 – QMS Manual

# **PROCEDURE**

* 1. **Supplier selection:**

The Organization identifies the suppliers and outsourced process suppliers based on the reference, Historical data from the literature & will be selected based on the capability / feasibility to supply material to meet Serwell Medi - Equip (P) Ltd requirements. The form SME-QMSP12-F05 (Supplier Assessment Form) is used to acquire all information about the supplier and outsourced processes and Supplier Registration Form SME-QMSP12-F04.

Further a visit may be arranged to verify the supplier’s facilities and resources.

Selection of the supplier and outsourced processes is based on any one or several of the following Criteria:

1. Approval of samples / trial lots / processing test report
2. Possessing a recognized system and / or product certification.
3. Being authorized representatives / agents of the recommended manufacturers.
4. Supplier visit and assessment by team.
5. Recommendation or approval from customer.
6. Being already an existing supplier and supplying materials per requirements.
7. Third party test lab assessment of material quality.
   1. **Supplier Assessment :**
8. Supplier Assessment will be done for all the suppliers before approval. Once a supplier is identified, a trail sample is received from the supplier and it will be analyzed by the concerned designee.
9. If the results are within the specification, one sample batch can be ordered and tested.
10. If the batch results are within the specification, it can be used in the process and monitored continuously with the validation process.
    1. **Approval of Supplier :**
11. Approved suppliers are included in the SME-QMSP12-F03-Approved Supplier List (Critical / Non Critical Material) and SME-QMSP12-F03A Approved Supplier List – Service provider and outsourced process based on the sample batch results and verification/validation results.
12. This list is maintained by QA and updated regularly by QA and shared with purchase to facilitate procurement.

An agreement should be made between Serwell Medi - Equip (P) Ltd & approved Suppliers explaining the elements including Time lines & frequency for the product / material / service delivery without any non-conformance & deviations. The Product / service delivery must be provided with the certificate of analysis or certificate of compliance. All the requests & proposals should be discussed in the disclosure agreement. And the agreement can be renewed as per the mutual understandings (SME-QMSP12-F10, Supplier Agreement).

* 1. **Supplier Rating (Supplier Annual Evaluations)** 
     1. To improve the effectiveness and efficiency of the organization’s purchasing provisions and for continual improvement, the suppliers are monitored **once in a year** and the evaluation is recorded in SME-QMSP13-F02 Supplier Rating. This is responsible for outsourced processes and service providers like calibration etc. as well.
     2. Quality, quantity, delivery schedule, price, response to queries are the factors considered for supplier Rating.
     3. The performance of the Suppliers is evaluated into weighted by percentages **annually**. Suppliers are evaluated annually and rated as per the following weightage criteria

**40% weightage for Quality,**

**35% for quantity,**

**15% for delivery and**

**10% for service**.

Suppliers who are rated below **80% are delisted from the** SME-QMSP12-F03 Approved Supplier List (Critical / Non Critical Material) and SME-QMSP12-F03A Approved Supplier List-Service Provider and Outsourced process.

Serwell Medi - Equip (P) Ltd 10 days tolerance for import suppliers and 2 days for local suppliers if they are unable to deliver on the scheduled date. In the same way we are giving a quantity tolerance **of 5% for Raw Materials and 10% for packing materials**.

* + 1. In case of non-conformity, the same is communicated to the supplier and take necessary action for supplier through SCAR Form SME-QMSP12-F09 (Supplier corrective action request).
    2. However Site QARA / MR is empowered to avoid their preclusion from the List of approved suppliers based on their past performance, reputation in industry and other market conditions like availability of competitors etc. But Site QARA / MR is not permitted to avail such waiver not more than three times for a supplier. In such situations only MRM could take further decisions.
    3. List of approved suppliers and service providers is maintained in SME-QMSP12-F03-Approved Supplier List (Critical / Non Critical Material) and SME-QMSP12-F03A-Approved Supplier List-Service Provider and outsources process.
  1. **Controls on the supplier and the purchased products :**

The controls on the supplier and outsourced suppliers and the purchase products are based on any one or several of the following.

* + 1. **Supplier controls**

1. Supplier agreements.
2. Supplier Assessment Form specific to category of supplier
3. Suppliers process audits or visits.
4. ISO certification of suppliers
5. Annual verification of Supplier through rating & Questionnaire to check capability, change of location, change in personnel, contacts etc.
6. Sales authorization letters from manufacturers for resellers and distributors.
   * 1. **Purchased products controls**
7. Sampling plan switching rules
8. Specific outsourced input and outputs through control forms.
9. Input Goods inspection checklist
10. Grid sampling
11. Periodic third party lab checks.
    1. **Purchasing Information**

Serwell Medi - Equip (P) Ltd purchasing information shall include requirements that are appropriate to the part that is to be purchased. The Purchase Head shall communicate these requirements to the supplier, in order to ensure quality of the purchased product.

* + 1. Receive production plan for a period from Head Marketing / Production Planning Control Manager / Production Head.
    2. Purchase and Production refer to the Bill of Materials and purchase refers to stores stock to generate a requirement list for the materials to meet the plan Pending orders on suppliers are also considered for the plan.
    3. Stock of Raw material and chemicals & Packing material are updated and maintained in Commercial who is responsible for the purchase will be placing the Purchase requisitions based on the stock levels and the packaging material requirement based on the confirmed customer orders.
    4. In the case of major raw/ packing materials, steps for purchase are initiated whenever stock drops to Minimum Stock Requirements (MRS) for 2 months production in case of imported materials, 1 month production for locally sourced materials, by Stores Incharge in the form of Material requisitions.
    5. Also purchases based on unexpected market demand and pending orders are also anticipated in certain occasions even though MRS is fulfilled.
    6. Generate the Purchase Order as per format SME-QMSP12-F06 on the approved suppliers.
    7. Purchase requisitions contain details such as order quantity in units, approximate unit price, quantity required, specifications, make, delivery time etc.
    8. Purchase Executive will review and give approval to Head Marketing to approve the requisition as deemed fit by him. On this occasion he is guided by available market trends, pending orders etc.
    9. Quotations will be collected before issuing the Purchase Order, even telephonically, if it is not a regular item and cost is more than Rs. 5,000/-. Priority is done among competitors based on make, specification, quality, rate, dispatch details etc. Purchase is done from the party which is rated first.
    10. Purchase order is issued by Purchase Head with a copy to Head Finance. This shall enable the store in-charges to cross check the purchase order against their requirement and to make follow up. Party name with address, item name, specification, unit, quantity, rate, value, delivery terms, payment terms and statutory details are mentioned in the Purchase order. The specification is attached to the PO for every purchase, or whenever there is a change in specification. The reference of specification shall be made available in the PO.
    11. All purchasing documents related to product traceability are retained for a period not less **than 10 years, as the shelf life of the medical device is 5 years**.
    12. For material inward and payment, Procedure for storage, issue & dispatch is established and maintained.
    13. All quality checking of the items purchased are governed by Procedure for Quality Assurance.
    14. MSDS is collected from the supplier for bulk items that have major bearing on quality of the product and is forwarded to Site QARA for necessary action.
  1. **Engineering Items, Lab items, Stationary, Miscellaneous items etc.**

**Engineering Items**

* + 1. **In the case of engineering items**, requests for materials are initiated by Maintenance Head or any other functions to Production Head in Purchase indent. The requisition contains data clearly describing the name of the material, make, specification if any, quantity required, expected date of delivery at factory and current stock etc.
    2. Purchase Head will review and approve the indent as deemed fit by him. On this occasion he is guided by the Maintenance Head based on Machine specific items, age and life condition of machinery, production schedule etc. Once it is approved it is sent back to the Commercial department for execution.
    3. Quotation is collected from suppliers, even telephonically, and if the item is not a regular item and the amount is more than Rs.5000/-. a quotation comparison chart is done among competitors based on make, specification, quality, rate, dispatch details, credit terms, market credibility etc. Purchase is done from the party which is rated first in the quotation.
    4. Based on the Quotation Comparison Chart, Commercial shall arrange the procurement and delivery. Party name with address, item name, specification, unit, quantity, rate, value, delivery terms, payment terms and statutory details are mentioned in the Purchase order. If the specification is not fully mentioned in the PO, the same shall be communicated prior to the supplier.
    5. Once the materials are received in the factory, the concerned person who initiated the Purchase request shall verify the item against the specification mentioned in PO and then Production Head shall accept or reject as deemed fit.

**Lab Items**

* + 1. **In the case of lab items** the same procedure is adopted. In such cases the purchase order is initiated by QC Manager and forwarded to Head Operations through Site QARA. The activity is executed through Purchase Executive only. Once the materials are received in the factory, the concerned person who initiated the Purchase request shall verify the item against the specification mentioned in PO and then Site QARA shall accept or reject as deemed fit.

**Miscellaneous Items**

* + 1. **In the case of miscellaneous items** and stationery the purchase indent is initiated by Executive Purchase assistant or any other interested person and forwarded through HOD and activity is executed through Commercial only. Once the materials are received in the factory, the concerned person who initiated PO and then HOD shall verify the item against the specification mentioned in PO and accept or reject as deemed fit.
  1. **Verification of Purchased product**
     1. The purchased product shall be verified before use in production. The Stores Personnel shall check the goods against the PO to verify quality, identification, quantity, condition of received items, etc.
     2. If verification is to be performed at the suppliers’ premises, the verification arrangements and method of product release shall be documented on the PO.
     3. Verification of the Purchased products/ outsourced process is done Receiving inspection and testing of the QA department. For other materials purchased which are not directly a Bill of material item, the indenter is responsible for verification and approval.
     4. Verification of the purchase product is based on the supplier evaluation results and proportionate to the risk associated with the product, A Risk based approach report is maintained.
     5. Verification ensures any changes to the purchased product affect the manufacturing process and in such cases a material is moved for sample production and release/accepted based on the sample results.
     6. Serwell Medi - Equip (P) Ltd, aware of any changes to the purchased product, determined these changes affect the product manufacturing process through Procedure for Change Control SME-QMS-P03 by Site QARA and the same has been communicated to relevant departments through email.
  2. **Outsourcing**

For detailed explanation of Procedure for control of outsourced activities, refer SME-QMS-P14

1. **ASSOCIATED PROCEDURE, FORMS / TEMPLATES**
2. Change Control process SME-QMS-P03
3. Procedure for Control of Outsourced activities SME-QMS-P14
4. Supplier Audit Schedule SME-QMS-P12-F01
5. Supplier Rating SME-QMS-P12-F02
6. Approved Supplier List (Critical / Non-critical) SME-QMS-P12-F03
7. Approved Supplier List - Service Provider / Outsource activity SME-QMS-P12-F03A
8. Supplier Registration Form SME-QMS-P12-F04
9. Supplier Assessment Form SME-QMS-P12-F05
10. Purchase Order SME-QMS-P12-F06
11. Quality & Delivery Summary SME-QMS-P12-F07
12. Material Indent SME-QMS-P12-F08
13. Supplier Corrective action Request SME-QMS-P12-F09
14. Supplier Agreement SME-QMS-P12-F10