**Quality Management System**

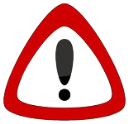
**Level-II -QUALITY MANAGEMENT SYSTEM PROCEDURE**

**Document Title**

**PROCEDURE FOR CONTROL OF OUTSOURCED ACTIVITIES**

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 and  Updated as per ISO 13485 & IMDR 2017 requirements | --------- |

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# **PURPOSE**

This procedure describes the method followed to identify and control of outsourced activities which affect product conformity, at Serwell Medi - Equip (P) Ltd.

# **SCOPE**

This procedure applies to all such processes that are outsourced and that have a bearing on the product conformity with requirements, directly or indirectly such as Design, Manufacturing, Maintenance, Calibration services, Third party testing services, Validation services, Pest control services etc..

# **RESPONSIBILITY**

* 1. **All Dept. HOD’s :** Identifying processes that would be outsourced.
  2. **Purchase Head :** Selection and evaluation of such outsourced process providers rests with the team comprising the Department Head, Production Head, Purchase Executive and Site QARA.
  3. **Maintenance Head :** Coordination with the service provider to ensure the process completion along with document evidence.

# **DEFINITION & ABBREVIATIONS**

**QA :** Quality Assurance

**QMS :** Quality management System

**HOD :** Head of the Department

# **REFERENCE**

5.1 ISO 13485:2016 Standard

5.2 IMDR 2017

5.3 SME-QMS-M01 – QMS Manual

# **PROCEDURE**

* 1. Respective Department Head shall identify the processes & services to be outsourced and discuss with the Purchase Head for further processing.
  2. Analyze the advantages and disadvantages of outsourcing the process.
  3. Purchase personnel shall identify the outsourcing supplier.
  4. Prepare the outsourcing project initiation document setting out business case and financial impact analysis, objectives, scope, acceptance criteria, assumptions, constraints, risks, controls, timescale, service levels etc. required.
  5. Submit project initiation document to the respective department personnel for approval. Based on approval Purchase Head precedes with the outsourcing supplier.
  6. The controls that are to be followed by the Outsourcing supplier are determined and established with the appropriate personnel along with the Production Head and Site QARA / MR.
  7. The outsourced supplier is finalized as per the procedure Purchase process and Supplier Selection SME-QMS-P12.
  8. Following this activity, the Purchase Head shall evaluate potential Outsourced suppliers by researching their capability, visiting their premises, evaluating their QMS, etc.
  9. Any special processes that are to be used at the outsourced suppliers end, the output of which cannot be verified and hence requires validation, shall be identified by the respective personnel during the initial evaluation process. The same will be communicated to the supplier.

* 1. The Purchase Head shall request a map of the process flow; documentation related to the outsourced processes & services from the supplier, etc. during final negotiations, at the time of signing an agreement with the supplier, this shall be mutually agreed upon by the supplier andSerwell Medi - Equip (P) Ltd.
  2. Upon the successful agreement, the outsourced supplier and their services details are updated in the SME-QMS-P12-F03A – Approved Supplier List – Service Providers (Including Outsource process)
  3. The outsourced services performances are periodically monitored and reviewed during the Management Review Meeting.
  4. The outsourced supplier should be verified as per the mutual agreement for the Quality Management system effectiveness. They shall be informed to communicate the changes in the system or any deviation of the service or the product supplied.
  5. Any deviation observed from the outsourced services or processes, the respective department personnel should issue a corrective & preventive action to the supplier and the immediate action for the deviation.
  6. The Outsourced Process evaluation is carried out as per the procedure, Purchase Process and Supplier Selection SME-QMS-P12.

# **ASSOCIATED PROCEDURE, FORMS / TEMPLATES**

1. Purchase process and supplier selection SME-QMS-P12
2. Supplier Audit Schedule SME-QMS-P12-F01
3. Supplier Rating SME-QMS-P12-F02
4. Approved Supplier List (Critical / Non-critical) SME-QMS-P12-F03
5. Approved Supplier List - Service Provider / Outsource activity SME-QMS-P12-F03A
6. Supplier Registration Form SME-QMS-P12-F04
7. Supplier Assessment Form SME-QMS-P12-F05
8. Purchase Order SME-QMS-P12-F06
9. Supplier Agreement SME-QMS-P1-F10