Supplier Control

1. PURPOSE

- Assure that all items and services purchased for use in or with company products comply with applicable quality requirements.
- Provide guideline for purchasing non-controlled items.

2. SCOPE

This procedure applies to all materials, components, parts, services or products ("materials") obtained from outside vendors that may, in whole or part, be commercially distributed by UOC. The procedure also applies to the purchase of non-controlled items.

3. REFERENCES

3.1 QM-01-00001Quality Manual
3.2 SOP-01-00021: Inventory receiving/inspection procedure
3.3 SOP-03-00005: Nonconforming Product Process
3.4 FR-01-00004: Supplier Quality Agreement Template
3.5 FR01-00010: Supplier Audit Form
3.6 FR-01-00013: Approved Supplier List
3.7 US FDA 21 CFR PART 820 Quality System Regulation

4. DEFINITIONS AND ACRONYMS

4.1 Approved Supplier: A supplier who has been certified, through a written survey form. It has, or will establish, a record of supplying materials and/or services of satisfactory quality on a continuing basis.

4.2 Key Supplier: A supplier of a material or materials and/or services that has been determined to be critical in producing a medical product that is safe and effective, or the failure of such materials and/or services which will render the finished product inoperative or ineffective. UOC USA does not have any suppliers designated as Key Suppliers.

4.3 Supplier Site Audit: A review of the facilities and process control exercised at a supplier site.

5. RESPONSIBILITIES

5.1 Quality
- Responsible for oversight and control of this procedure.
- Responsible for reviewing, approving and following this procedure.

5.2 All Personnel performing tasks controlled by this procedure
Responsible for understanding and following current version of this procedure.

PROCEDURE

6.1 Purchase of Controlled Materials

6.1.1 All materials with drawings/specifications/work instructions at alphabetical revision levels (released to production) must be purchased from an approved supplier as listed on the "Approved Supplier List".

6.1.2 The purchaser can cancel or change the order as needed. Any such changes must be noted. Any such changes must be communicated to all personnel who provided an approval signature.

6.1.3 The purchaser is responsible for all communications with the supplier, including order status, changes to the order, delivery changes, etc.

6.1.4 If the order was complete

6.1.4.1 Update the System or alternative purchasing documentation. Note the number of items received.

6.1.4.2 Follow Inventory receiving/inspection Procedure for the receipt and disposition of the items.

6.1.5 If the order was incomplete

6.1.5.1 Upon receipt of the remaining items of an incomplete order, receive the remainder of the shipment and then proceed as described in 6.1.11.

6.2 Supplier Certification

6.2.1 All materials / components covered under the Device Master Record System must have an approved Supplier Site Audit Record in place before materials and/or services can be ordered from the supplier. At the discretion of UOC USA, the audit may be on site or a paper based audit conducted internally at UOC USA. Where products are off-the-shelf or where UOC otherwise does not contribute to development of the specification, the supplier may be qualified without a signature from the supplier.

6.2.2 Vendors supplying consulting services on an on-going basis will also be qualified. Consultants will be selected based upon their expertise in the area in which consulting services are to be contracted. No audit is required, however the qualifications of the vendor will be verified.

6.2.3 Approved suppliers will be included on the Approved Supplier List

6.2.4 Approved suppliers are not required to be re-audited. They remain on the list unless unsatisfactory performance results in the vendor being disqualified as a vendor.

6.2.5 Suppliers failing to meet quality standards after due notice will be decertified and cannot continue to supply materials and/or services. The company may decide to work with or advise the supplier in its efforts to become recertified or the company may elect to find an alternate source.

6.2.6 When an approved vendor is decertified, they will be notified and be removed from the approved supplier list and purchasers will be notified that the vendor is no longer approved for production supplies

6.2.7 All records pertaining to certification and ongoing performance will be maintained in the Supplier's file.

6.3 Supplier Audit

6.3.1 Supplier audits will be conducted for all suppliers.

6.3.2 Supplier audits may be done in person, via email, over the phone, or through publicly available information.

6.3.3 Not all sections of the supplier audit form will apply to all suppliers.

6.3.4 The audits will be conducted by qualified representatives of UOC.

6.3.5 The Supplier Site Audit will minimally include the following information:

- The name, complete address and telephone number of the supplier.
- The name and contact information for the Supplier's Quality Representative.
- The name and contact information for the Supplier's Management Representative (this may be the same as the Quality Representative). In the case of off-the shelf purchases, the contact may be the sales representative.
- Supplier background information.
- The materials and/or services, including part numbers, considered for purchase.
- Audit questions applicable to the general quality operations if applicable.
- A request for a statement from the supplier regarding its ability to comply with applicable regulatory requirements (not applicable for off-the shelf items or where UOC USA does not contribute to the specification)
- A Manufacturing Control Statement (if applicable)
- Endorsement of supplier company representative certifying that the Supplier Compliance Statements and the Manufacturing Control Statements are complete and accurate. (if applicable)

    - Manufacturing Control Statement*: UOC will be notified of any changes to Supplier's process and/or material, as it relates to the product or service provided to UOC. This will allow us to determine the effects it may have to our finished devices. This is a requirement of our Quality System and 21CFR 820.60 (b)*

- Suppliers who make product may also be asked to enter into a separate Supplier Quality Agreement. If a supplier makes modifications where UOC is solely in control of the quality, no separate agreement is required. Approval of the Supplier as an Acceptable source for the materials and/or services specified.
- Additional checklists as described in section 6.3.7.

6.3.6 All documentation in addition to the Supplier Audit Record will be referenced in the General Comments section of the Supplier Audit Record.

6.3.7 The auditor(s) will prepare an appropriate checklist prior to undertaking the audit, and it must include: (if applicable)

- Questions specific to the proper manufacture and control of the materials and/or services considered for purchase.
- Questions specific to applicable regulatory standards, or parts thereof, that are pertinent to the materials and/or services considered for purchase.
- Questions regarding any special cautions or considerations relevant to the manufacture and control of the materials and/or services considered for purchase.

- If a previously certified supplier has provided substandard materials and/or services at any time, questions designed to determine if appropriate corrective action has been undertaken and satisfactorily completed.

6.3.8 A proposed supplier that is judged unsatisfactory in the audit report will be evaluated by management, which may decide whether to assist the particular supplier in upgrading its operations to achieve certification or chose an alternate source for the materials and/or services.

6.3.9 A previously certified supplier that is judged unsatisfactory may be decertified; management may then decide on a course of action.

6.4 Records

6.6.1 All records pertaining to supplier control must be carefully and accurately maintained.

6.6.2 Records pertaining to product traceability will be maintained either by UOC or by qualified vendors.

6.7 Purchase of non-controlled Items

6.7.1 Items such as office supplies and materials without part numbers do not require supplier control.

6.7.2 This section of the procedure is to be used as a guideline to provide some consistency in purchasing practices.

END OF PROCEDURE.