# Bill of Materials Process

## 1. PURPOSE

This SOP provides instructions to establish a bill of materials process and procedure which can be used to establish bill of material generation as well as manage updates or revisions to existing and/or obsolete bills of materials and their contents.

## 2. SCOPE

This procedure covers bill of materials for released reusable trays which have been cleared for distribution in the United States.

## 3. REFERENCES

3.1 QM-01-00001: Quality Manual
3.2 SOP-01-0027: DCO
3.3 SOP-01-0028: Identification and numbering
3.4 21 CFR Part 820.60 Identification
3.5 21 CFR Part 820.80 Receiving, in-process, and finished device acceptance
3.6 21 CFR Part 820.140 Handling
3.7 21 CFR820.150 Storage
3.8 21 CFR 820.160 Distribution

## 4. DEFINITIONS AND ACRONYMS

4.1 Components: Parts that will be issued in their current state to create top level part numbers of sterile or non-sterile finished goods. UOC USA is not currently responsible for any components.

## 5. RESPONSIBILITIES

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

5.2. All Personnel who work with product inventory are responsible for understanding and complying with this procedure.

## 6. PROCEDURE FOR NEW BILL OF MATERIALS

6.1. Establish what the bill of materials should be. Requests shall be routed to Quality detailing the bill of material requirements.

6.2. Quality will turn it into a controlled document, assign internal document number and rev according to controlled documents procedure.

6.3. Quality will release it as a controlled document into the bill of materials folder.

6.4. Management approval is required for the release of new bill of materials (minimally this will include President and senior management quality as well as marketing)

6.5. Bill of materials should be established per tray and may include optional instrumentation or different versions of instrumentation which should be clearly indicated on the bill of materials with an asterisk mark.

6.6. When new products are released, quality shall inspect tray contents against the established bill of materials.

## 7. 7.0 PROCEDURE FOR UPDATING EXISTING BILL OF MATERIALS

7.1. Periodically, existing bill of materials may require updates or modifications to existing bill of materials that have been released as controlled documents.

7.2. Requests shall be routed to Quality detailing the changes to be made. Updates will be made according to the document control process. Revisions will be tracked in redline and will require management approval to authorize changes.

7.3. Quality will obtain management signature and make updates to the controlled document.

7.4. Bill of materials should be established per tray and may include optional instrumentation or different versions of instrumentation which should be clearly indicated on the bill of materials with an asterisk mark.

7.5. When bill of materials need to be modified, quality shall inspect tray contents against the proposed bill of materials changes. Any concerns or questions shall be routed accordingly.

## 8. TRAINING

8.1. All employees who process reusable trays shall be trained and notified when new bill of materials or modifications to existing bill of materials are released.

## 9. END OF PROCEDURE