Product Storage and Environmental Controls

1. PURPOSE

This SOP provides instructions for the proper control of storage areas to prevent product mix-ups, damage, deterioration, or contamination. This procedure also provides general guidance regarding the environment in which product is stored.

2. SCOPE

This procedure covers product warehoused at the Company.

3. REFERENCES

3.1. QM-01-00001: Quality Manual
3.2. 21 CFR Part 820

4. DEFINITIONS AND ACRONYMS

4.1. Finished Goods: Top level part numbers, as described on device master records that are available for sale or distribution.
4.2. 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.
4.3. Raw Materials: Parts and materials that are used to create component level parts. UOC USA is not currently responsible for any raw materials.

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 producing or inspecting this product are responsible for understanding and complying with this procedure.

6. PROCEDURE

6.1. Storage environment

6.1.1. General Conditions
- The product storage areas are heated and air-conditioned.
- Temperatures and humidity are maintained within the labeled range for sterile products.
- Exterminator contracts are maintained to ensure a pest-free environment.
- Floors and surfaces are periodically cleaned.
- Products may be provided sterile or non-sterile.
- Sterile product are labeled with their validated required storage conditions (temperature and humidity range).
- No special storage conditions (temperature/humidity) are required for non-sterile product.

6.2. Storage locations

6.2.1. Products are segregated in the product storage area by both product type and status. All areas described in this section are segregated from one another.

6.2.2. Storage Areas

6.2.2.1. Released Product Storage Areas

- Sterile and non-sterile finished goods are stored in the finished goods section of the product storage area.

6.2.2.2. Incoming Inspection storage areas

When items are received from an external vendor or from manufacturing, they are to be received into the inspection quarantine location of the warehouse.

6.2.2.3. MRB/Hold storage area.

Items not passing inspection are transferred into the MRB Hold area.

6.2.3 Signage for Storage Locations.

The signs used to label storage locations and to assist in the segregation of product by both type and status will clearly indicate the nature of each location.

6.3. Prevention of use of non-conforming, un-inspected, or non-released product.

6.3.1. Items received, but not yet inspected.

Products that have not been inspected are placed in the designated inbound receiving area until they can be processed.

6.3.2. Items not passing inspection

Any product that does not pass inspection is placed in the quarantine area and labeled as non-conforming..

6.4. First-in, First out Policy

6.4.1. Finished goods that are distributed as sterile products have a finite shelf life as described in their respective product specification and as appears on the package labeling.

- Within the finished goods storage location items should bestored in order of age. Frequent checks of finished goods will be made to ensure they are stored in order of their age.
- Any expiring stock will be transferred to the MRB Quarantine Hold location, and labeled as non-conforming.

6.4.2. Non-sterile finished goods, components, and raw materials do not have a finite shelf life. These items should be issued on a first-in, first-out policy.

7. END OF PROCEDURE