Procedure: Storage and Distribution

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| Author signs to confirm technical content | | | |
| Prepared by: | Job title: | Signature: | Date: |
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Modify this procedure to reflect the practices of the company. For larger companies, it may be appropriate to consider splitting this procedure into two. Give special consideration to devices with short shelf lives or where sterilisation of the device is out-sourced.

# Purpose

This procedure describes a system, provides instructions and to assign responsibilities for:

* use and maintenance of the warehouse/storage areas
* the inventory management system
* control of product distribution

# Scope

The scope of this procedure includes storage and holding areas for materials, components, subassemblies and finished products and to distribution of finished products at [Company].

# Responsibilities

|  |  |
| --- | --- |
| Role | Responsibility |
| Storeman | Operates the warehouse and its related storage and holding areas. |
| Production Manager | Maintains any storage areas in production. |
| Quality Manager | Responsible for non-conforming product holding and the quarantine areas. |

Identify who is responsible for maintaining each storage, holding and quarantine area in [Company].

Amend roles and responsibilities according to your company processes and structure.

# Procedure

## Storage areas

ISO 13485 does not have specific requirements regarding storage areas. This procedure should describe the practices used by [Company].

The warehouse has several areas:

* incoming materials (raw materials and components)
* quarantined materials (awaiting inspection and testing)
* raw materials and components approved for use
* rejected materials
* finished product

Use the terminology in use at the company. Modify the above list to reflect the actual practices and to provide more detail.

The warehouse is maintained in good condition to prevent damage or deterioration of stored products and is kept free of dust, insects, rodents and other pests.

Storage areas are identified and grouped according to the type or status or the product held. A "first-in-first-out" (FIFO) system is maintained for all goods.

## Inventory management system

An inventory management system is not explicitly required by ISO 13485, however, it is important for sales and production scheduling.

The warehouse is controlled using an inventory management system. This controls movement and status of stock used in production and distribution of finished product.

Incoming raw materials and parts are entered into the inventory system with their part number, description, quantity, warehouse location, purchase order or job number and expiry date, as applicable.

Modify the above clause to reflect the company’s requirements.

The inventory management system reports on stock availability, quantities and turn-over and is used to minimise inventory levels, optimise turn-over and ensure stock rotation.

Every twelve months a full stock-take is carried out and the count reconciled with the inventory management system (refer to Section 4.3).

## Assessment of stock

Periodic assessment of stock was a requirement from ISO 13485:1996 but is not explicitly required by ISO 13485:2003. CFR 820.150 states "...condition (of stock) shall be assessed as appropriate,". It is appropriate that some type of stock assessment is performed.

Warehouses are inspected and cleaned annually and stock is assessed for damaged or deterioration. Product identification is checked and inappropriate materials removed.

An NCR (Form *FM805-1: Product Non-Conformity Report*) is completed as per Procedure *QP805: Control of Non-Conforming Product* when damaged or deteriorated product is identified. Inventory levels are also checked (refer to the reference to the twelve month stock take in Section 4.2).

## Receipt and dispatch authorisation

This section complies with CFR 820.150(b) which requires that there be procedures defining methods for authorising receipt and dispatch.

Products are only authorised for dispatch or transfer between different sections of the warehouse after appropriate approval. Approval to transfer is given automatically as intermediate or product status is approved:

* products that pass incoming inspection are authorised to be placed in the warehouse or production storage areas
* products passing in-process inspections are authorised for release to the next processing stage
* final products that pass final acceptance inspection are authorised for transfer to the finished product warehouse or for dispatch

Non-conforming products, unidentified products and products with unknown status must not be released to the warehouse or to production nor dispatched to subcontractors or customers.

Products of unknown status must be placed in appropriate quarantine or holding areas.

## Special storage conditions

Edit to reflect the products, equipment and records appropriate to [Company]. Consider additional work instructions for complex operations.

When materials, components or finished products require special storage conditions (e.g. specific temperature or humidity), environmental requirements must be documented in appropriate specifications and communicated to relevant managers.

Special storage conditions must be monitored and recorded to ensure they are maintained without interruption and that product is not compromised.

ISO 13485 clause 7.5.5 specifically requires the monitoring of storage areas.

Methods of monitoring and recording environmental conditions should be developed in consultation with QA. They may include (automatic) data recorders or manual, periodic recording of the monitored parameter.

## Other supplies

Warehouses typically are used for storage of a wide range of materials and supplies. It is important that different areas are clearly identified to avoid mix-up of raw materials, intermediates, final product and other non-product-related materials.

Warehouses may contain supplies not intended for incorporation into finished product (refer Section 2, Application). These supplies typically are not status labelled and their movement in and out of the storage areas is not controlled.

Care must be taken to prevent mix-up with production materials.

## Shipping and distribution

CFR 820.160 requires distribution records for all devices while ISO 13485 clause 7.5.3.2.2 requires it only for active implantable and implantable devices. This procedure follows the more stringent requirements of CFR 820.

Modify this procedure to describe the systems of [Company]. If more detailed shipping and distribution information is required, consider splitting creating this section as a separate procedure.

Customer orders are received and processed in accordance with Procedure *QP702: Order Processing and Review*. This includes an order review to ensure that ambiguities and errors are resolved before being accepted.

Distribution is initiated by a shipping order issued by Sales. The order identifies:

* shipping consignee and address
* due date
* type and number of products required
* packing requirements (if non-standard)
* labelling requirements
* transport mode

Edit to describe the company’s shipping system.

Only products that have passed final acceptance and are on the inventory system are available for shipping to customers.

Product acceptance status is verified by checking for a green ACCEPTED label.

The expiry date of product with a designated shelf life must be checked and marked on the packages and/or cartons.

Edit to describe how the company ensures only products approved for release are shipped. Serial or batch numbers assist in identifying acceptance status.

Before packaged products are dispatched, the shipping supervisor verifies the shipment meets the order and the shipping requirements. Following satisfactory verification, the supervisor authorises the order for release.

## Distribution records

After the shipment is dispatched, the shipping order is retained as a distribution record. It includes the following information:

* name and address of the consignee
* identification of the product and quantity shipped
* date shipped
* any serial or batch numbers used

If serial or batch numbers are not used, delete the last item.

Agents and distributors must maintain their own distribution records.

Appendices

Amend as required or delete.

Definitions

Amend as required or delete.

| Term | Definition |
| --- | --- |
|  | Insert terms/abbreviations and definitions for those used within the procedure. Do not include any terms or abbreviations not used within the procedure. |
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Document Information

| Revision History | | | |
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| Revision | Modified by | Change Control No. | Description of Change |
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Complete the above fields for each revision of this document. Ensure that there is sufficient description of changes so that the change history of this document can be followed. Additional columns can be added to include document/change tracking numbers generated by your company’s systems if required (eg. change control).

| Associated forms and procedures | |
| --- | --- |
| Doc. No. | Document Title |
| QP702 | Order Processing and Review |
| QP805 | Control of Non-Conforming Product |
| FM805-1 | Product Non-Conformity Report |

List all controlled procedural documents referenced in this document (for example, policies, procedures, forms, lists, work/operator instructions

| Associated records | |
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| Doc. No. | Document Title |
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List all other referenced records in this document. For example, regulatory documents, in-house controlled documents (such as batch record forms, reports, methods, protocols), compliance standards etc.

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