Procedure: Labelling and Packaging

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ISO 13485 does not contain specific requirements for controlling packing and labelling operations. However, section 7.5.5 outlines some general requirements for control of product identification.

Packing and labelling operations vary significantly from company to company. This procedure therefore provides only a very general structure and must be adapted to the company’s specific practices.

The methods used to control these operations depend on:

a) the type of packaging

b) the information printed on the package

c) the type of labels

d) how they are applied (to the packaging or to the product itself)

e) whether labels include expiration dates and batch or lot numbers

f) packaging performance requirements (especially for sterile product)

g) the degree of automation in packing and labelling.

When editing this procedure, ensure it describes the company’s operations and that it complies with CFR 820.120 (if required) and ISO 13485.

# Purpose

This procedure describes a system, provides instructions and identifies responsibilities for controlling the packing and labelling processes.

# Scope

The scope of this procedure includes finished product packing and labelling and related processes at [Company].

# Responsibilities

|  |  |
| --- | --- |
| Role | Responsibility |
| Packing Manager |  |
| Production Manager |  |
| Quality Manager |  |

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

# Procedure

## General

Packing and labelling are an integral part of the product and production. Product is not completed and cannot be released until it is packed and labelled.

Requirements of the Quality Management System (QMS) that apply to the product and manufacturing also apply to packing and labelling. In particular the procedures and documents related to:

* design control, including design validation and control of design output
* control of the packing and labelling process
* related procedures and work instructions
* personnel training
* process validation
* process monitoring and records
* inspection and final acceptance of packing and labelling
* establishment and maintenance of the required records

## Packing and labelling design and validation

Labelling, packaging and the associated artwork are developed during product design (refer to Procedure *QP703: Design Control*).

If product design is not relevant and ISO 13485 section 7.3 and CFR 820.30 do not apply, delete QP703 Design Control and expand this section to explain how the development of packing and labelling is controlled. It should at least include document control, change control and verification/validation.

Packaging may be designed to meet performance requirements such as protection from physical damage, heat, light or contaminants. Such packaging must be validated by testing under actual or simulated conditions of distribution, storage and use.

Packaging for sterile products must be similarly validated to test packaging materials and the integrity of seals. Where applicable, validation studies should involve statistical techniques and/or risk analysis.

Identify only those characteristics relevant to the packing and labelling used at the company

Label integrity is validated to ensure that labels remain in place and legible under normal storage and use conditions.

The suitability of packaging and labelling artwork should be validated by a person who is not familiar with the product, operating the device according to the label instructions.

## Receiving inspection and storage

Packing and labelling practices vary significantly from company to company and therefore control methods will vary accordingly.

ISO 13485 is non-specific with regards to labelling but CFR 820.120(b), Labelling Inspection states:

”Labelling shall not be released for storage or use until a designated individual(s) has examined the labelling for accuracy including, where applicable, the correct expiration date, control number, storage instructions, handling instructions, and any additional processing instructions. The release, including the date and signature of the individual(s) performing the examination, shall be documented in the DHR.

This procedure assumes inspection is carried out for each batch of labels with unique expiration date and/or control number. If expiry dates and control numbers are not used, perform this inspection as a receiving inspection, e.g. when packaging/labelling is received into the company store.

Packaging and labels are inspected and approved before they are released for use in the packing and labelling area. The inspection is performed by a designated QC inspector.

In this procedure packaging artwork is assumed to include product information and instructions. It is controlled together with and in the same way as labelling.

Packaging and labelling inspection includes verification that:

* packaging and labels are printed using approved artwork
* materials and printing comply with specifications
* expiration dates and control numbers are printed correctly

The results, the name of the person performing the inspection and the date carried out are recorded in the work order in the packing and labelling block.

If work orders (QP708) are not used, describe how the inspection record is established and maintained.

Approved packaging and labels are stored in designated containers or cabinets in the packing area. Where labels are similar, and in order to minimise the possibility of a mix-up, similar labels are stored in separate containers or cabinets.

## Packing and labelling operations

This procedure should be expanded for sterile medical devices. Clearly define the controls applied to the packing processes and to verification (e.g. some manufacturers test (blow up) samples from before and after sterilisation.

Packing and labelling operations are considered production processes. All process control requirements and procedures that apply to manufacturing also apply to packing and labelling, in particular, the operational procedures and other quality system documentation related to:

* design transfer, e.g. development of packing and labelling processes
* validation of special processes (e.g. for sterile products)
* process operator training and work instructions
* process control and monitoring activities
* inspecting and testing the packaging and applied labels

A complete line clearance must be performed before commencing packing or labelling a new product or batch. The area must be completely clear of packaging and labels from previous operations.

Expand this section to reflect the company’s practices and procedures. Packing and labelling of sterile products will require careful detailing to ensure that the package integrity is maintained.

Procedures may include things like package and label reconciliation to ensure that all issued materials are accounted for and to minimise the risk of incorrect packages or labels being used inadvertently.

The packing and labelling operations and the associated inspections and verifications are specified in the work order (refer to Procedure *QP708: Production Work Order and History Record*). Inspections are part of the finished product acceptance, as described in Procedure *QP804: Final Acceptance Inspection*.

Where applicable, expiration dates and any control numbers are recorded in the work order, exactly as they should appear on the applied labelling.

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 |
| QP703 | Design Control |
| QP708 | Production Work Order and History Record |
| QP804 | Final Acceptance Inspection |

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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