

1.0 Purpose

1.1 This document explains [Company's] policies for label control.

2.0 Scope

2.1 This procedure applies to controlled labels printed at [Company's] [City], [State] (0X) and [City], [State] (4X) facilities.

2.2 This procedure also applies to externally sourced labels.

3.0 Responsibility

3.1 Document control

3.1.1 Maintains label specifications and label artwork in the electronic document management system.

3.2 Quality Assurance (QA)

3.2.1 Ensures that label specifications and label artwork are created. QA also revises them, as needed, for the chain of identity (COI) labels.

4.0 Reference documents

4.1 SOP-100XX, Preparation of part number specifications

4.2 SOP-103XX, Externally sourced labeling control procedure

4.3 SOP-108XX, eDoc document change control

4.4 SOP-110XX, Label specifications, label artwork, and electronic label templates

4.5 SOP-109XX

4.6 FRM-XXX, Label issuance and reconciliation form

5.0 Definitions

5.1 Chain of identity (COI) labels: This is any label used to maintain the identity of a product. It remains with the product from collection through final product shipment and use.

5.2 Externally sourced labeling: This is preprinted material that the company bought from an external vendor. This type of labeling does not include lot-specific information. These include:

5.2.1 Labels

5.2.2 Packaging inserts (PI)

5.2.3 Instructions for use

5.2.4 Shipping or packaging materials

- 5.3 Label artwork: This is a version-controlled document that contains the label layout. It includes mandatory text elements and font properties for a specific label.
- 5.4 Label specification: This is a revision-controlled document that contains the [Company] requirements for creating a specific label.

6.0 Equipment and materials

- 6.1 NA

7.0 Safety

- 7.1 NA

8.0 Procedure

8.1 Control of blank label stock

- 8.1.1 Create part number specifications for all blank label stock used to create [Company] COI labels.

- 8.1.2 Create and revise specifications for label stock per SOP-100XX.

8.2 Control of labels created by [Company]

8.2.1 Label artwork and label specifications

- 8.2.1.1 The Quality Assurance department will create and revise label artwork and label specifications per SOP-110XX.

- 8.2.1.2 Review and approve label artwork and label specifications per the signature matrix in SOP-108XX.

- 8.2.1.3 Maintain the most recent versions of label artwork and label specifications in the electronic document management system. The document types are ART and LBS, respectively.

8.2.2 Label generation, verification, and reconciliation

- 8.2.2.1 Write procedures that document the generation, verification, and reconciliation of COI labels created by [Company].

- 8.2.2.2 Inspect labeling areas immediately before use. Ensure that you have removed all labeling materials from the previous operation.

- 8.2.2.3 Trained individuals will create COI labels. Additional trained individuals will verify that the content is correct.

- 8.2.2.4 Document and reconcile the quantity of COI labels created, issued, rejected, and used.

- 8.2.2.5 Destroy all excess controlled labels that have lot numbers and document their destruction.

- 8.2.2.6 If the variation in the labeling material balance is greater than zero percent, you must investigate and document the cause.

8.2.3 Label qualification

- 8.2.3.1 Before using the COI labels in GMP manufacturing, qualify the labels. Ensure they remain in place and are legible during the customary conditions of their use.
- 8.2.3.2 As required, qualify COI labels to ensure they have no impact on the product's integrity.

8.3 Control of externally sourced labeling

8.3.1 Label artwork and label specifications

- 8.3.1.1 Create label artwork and label specifications for all externally sourced labels.
- 8.3.1.2 The Quality Assurance department will create and revise label artwork and label specifications for externally sourced labels per SOP-110XX.
- 8.3.1.3 Review and approve label artwork and label specifications for externally sourced labels per the signature matrix in SOP-108XX.
- 8.3.1.4 Maintain the most recent versions of label artwork and label specifications for externally sourced labels in the electronic document management system. The document types are ART and LBS, respectively.
- 8.3.1.5 [Company's] Quality Assurance will approve and maintain the original artwork or artwork revisions from a label vendor or design firm per SOP-103XX.

8.3.2 Label receipt, inspection, disposal, and retention

- 8.3.2.1 Write procedures that document the receipt, inspection, disposal, and retention of externally sourced labels.
- 8.3.2.2 Quality Assurance will sample and inspect the preprinted labels we receive per the applicable label specification. QA will do this before they are used in labeling operations.
- 8.3.2.3 Maintain records for each shipment that we received of the different labeling materials. Indicate the receipt, inspection, and final disposal.

8.3.3 Issuance and reconciliation

- 8.3.3.1 Maintain controlled labels in an isolated location in the controlled access warehouse space.
 - 8.3.3.1.1 Only Quality Assurance and Materials Management personnel will have access to controlled label locations.
- 8.3.3.2 Quality Assurance personnel must record on FRM-XXX when they issue controlled labels to batches at the time the label is used.
- 8.3.3.3 Materials Management personnel will use the approved software to issue materials logged on FRM-XXX daily, as required.

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8.3.3.4 Reconciliation of labels

8.3.3.4.1. This occurs when a label is used on the batch record (BR).

8.3.3.4.2. This occurs on a periodic basis per the cycle counting procedures described in SOP-109XX.

9.0 Attachments

9.1 NA