SOP Title: **Inspection of Labeled Vials of Finished Product**
SOP Number: **15125**
Revision: **06**

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1. PURPOSE

This SOP describes the procedure for inspection of labeled vials containing cGMP-finished product.

2. SCOPE

This SOP specifies BDP requirements for the visual inspection of labeled vials of cGMP finished product. Prior to labeled vial inspections, all unlabeled vials are inspected as per **SOP 15113** - **Inspection of Unlabeled Vials of Finished Product**. The inspection process is a joint effort by Manufacturing and Process Analytics\Quality Control (PA\QC) personnel with assistance by Biopharmaceutical Quality Assurance (BQA) personnel as indicated in the SOP.

3. RESPONSIBILITIES

3.1 Director / Technical Operations

- Define procedure

3.2 Manufacturing Personnel / Manufacturing

- 100% screening and documentation of labeled vials of finished product
- Document total lot defects
- Investigate for lots exceeding quality limits

3.3 PA / QC

- Sampling and inspecting samples according to the specified sampling plan and defect categories.
- Documentation of lot defects from PA\QC inspection.
- Evaluating the disposition of the lot (or the need for QA screening)

3.4 Biopharmaceutical Quality Assurance (BQA)

- Review and oversight
- Final decision for acceptable labels
- Assist investigation for lots exceeding quality limits

4. PROCEDURE OR USE

Overview:

The Manufacturing department performs a 100% inspection of labeled vials of finished product. Vials with label irregularities that are categorized as “minor,” “major,” and “critical” are culled from the batch (and may be relabeled and returned to the batch). A subsequent sampling of vials is screened by PA\QC to monitor the quality of the inspection performed by Manufacturing. This sampling is conducted according to ANSI/ASQC Z1.4, General Inspection Level II. Acceptable Quality Levels have been established for minor (AQL = 6.5), major (AQL = 1.5) and critical (AQL = 0.1) defects. After screening by PA\QC, BQA will review the results of the PA\QC screening, inspect the PA\QC culled vials, and make a determination about the need for additional screening or relabeling of the lot. BQA will also make a determination about the need for any investigation required. A decision to re-label the lot requires the authorization of a rework plan.

4.1 Manufacturing Screening (Manufacturing personnel are to perform a 100% inspection of the vials.)

4.1.1 Inspect each vial to detect defects in the following: (see the table on **Form 15125-01** for a listing of specific defects in each category)

- Label Content
- Label Appearance
- Label Application
- Label Stability

4.1.2 If label defects are detected, cull the vial from the lot.

4.1.3 Categorize and note the type of defect as requested on **Form 15125-01**.

4.1.4 Culled vial may be relabeled.

4.1.4.1 Completely remove rejected labels from the vial and attach them to a blank sheet of paper for accountability.

4.1.4.2 Apply a new label to the vial and re-inspect as per Section 4.1

4.1.5 A total of minor, major, and critical defects detected by the Manufacturing screening for the lot is performed and recorded on **Form 15125-01**.

4.2 PA/QC Screening

4.2.1 PA\QC will then perform a visual inspection on randomly chosen vials found to be acceptable by manufacturing personnel according to ANSI/ASQC Z 1.4, General Inspection Level II. The sampling plan is presented in the Acceptance/Relabeling Criteria Table on **Form 15125-01**. The inspection will be performed as per guidelines specified in Section 4.1.

4.2.2 PA\QC will cull unacceptable vials from the lot and will note the type and number of defects found on **Form 15125-01**. These vials are returned to manufacturing personnel for relabeling and inspection. The rejected labels are placed on a sheet of paper and destroyed.

4.2.3 PA\QC will evaluate and document the results of their inspection on **Form 15125-01** as :

- Inspection results acceptable, (any vials culled by Process Analytics during their screening may be relabeled and returned to the lot)

OR

- AQL exceeded for major/minor/critical defects (circle applicable). BQA review required.

4.3 BQA Review

4.3.1 Additional steps BQA will inspect the vials culled by PA\QC and make a determination about the need for additional screening/relabeling of the lot. Decision will be documented on **Form 15125-01**.

4.3.1.1 If BQA determines that the entire lot requires rescreening, a new **Form 15125-01** will be initiated and titled "RESCREENING." The process for rescreening will start at Section 4.1.

4.3.1.2 If BQA determines that the entire lot requires relabeling, and there are not enough correct labels to perform the relabeling immediately, then the lot will be appropriately stored until the relabeling can be authorized.

4.3.2 BQA may also make a decision on the relabeling of culled vials. (For example, of vials that were culled by PA\QC, BQA may determine if any of the vials should be relabeled and reinspected).

4.3.2.1 For relabeling, Manufacturing will completely remove rejected labels from the vial and attach them to a blank sheet of paper for accountability. Label the sheet "PA\QC Screening."

4.3.2.2 Manufacturing will apply a new label to the vial.

4.3.2.3 BQA will inspect the relabeled vial.

4.4 Storage

All vials, once acceptably labeled, will be transferred to Material Management and Inventory Control (MMIC) for proper storage to await final product release by BQA. Labeled vials may also be placed into an interim storage location until transferred to MMIC.

5. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
15113	Inspection of Unlabeled Vials of Finished Product
15125-01	Inspection of Labeled Vials Containing Finished Product