1. PURPOSE

1.1 This document defines the process for ordering, receiving, and handling GMP consumables, raw materials and container components at LiquiGlide in Billerica, MA.

2. SCOPE

2.1 The procedure defines the Materials Management controls for all consumables, container components, raw materials and finished products used in cGMP manufacturing processes at LiquiGlide's manufacturing facility in Billerica, MA.

2.2 This procedure does not apply to any manufacturing processes established in the Cambridge, MA facility.

3. RESPONSIBILITIES

Role	Responsibility
All Associates	- Sign for any incoming materials - Keep all materials in original containers upon receipt - Notify Head of Manufacturing or Manufacturing Associate upon arrival of Consumable, Container Components & Raw Materials to Billerica, MA manufacturing site
Manufacturing Associate or designee	- Ordering Consumables, Raw Materials & Container Components for cGMP production - Initiating the Material Receiving & Release Form and Finished Product Materials Management & Release Form for cGMP materials - Inspecting incoming shipments for damage or missing documentation - Initiating the Raw Material Tracking Form - Sampling and submitting raw material samples for shipment to 3rd party labs for testing - Shipping raw material and finished products samples to 3rd party labs for testing & coordinating test methods for each raw material - Properly labeling materials during each step in the material workflow
Head of Manufacturing or designee	- Approving orders for Consumable, Raw Materials & Container Components for cGMP production - Review sample submission forms prior to shipping samples to 3rd party testing - Sign Approval for Release on Material Receiving & Release Form.

Quality Assurance:	- Verifying that purchased cGMP materials have the proper documentation and the documentation is attached to the Material Receiving & Release Form. - Verifying that the proper analytical test methods were performed for raw material and finished product testing - Verifying that all raw material and finished product test results are within specification - Approving and archiving Material Receiving & Release Forms, Raw Material Tracking Forms, Material Disposal Forms, and Finished Product Material Management & Release Forms - Maintaining an archive of all completed forms

4. DEFINITIONS

4.1. **Consumable:** Any material considered as single use and does not have direct contact with cGMP products. Examples are Personal Protective Equipment (PPE), sample jars and cleaning solutions.

4.2. **Container Components:** Any container and associate components used for direct storage of cGMP manufactured coating suspensions at LiquiGlide. This can include 5-gallon pails with or without a lid, bins for incorporating raw materials or any other container with direct product contact with cGMP product.

4.3. **LG Code:** Specific LiquiGlide Raw Materials identifier where materials are assigned a “S” or “L” along with an appropriate number according to the “LiquiGlide Materials Database”.

4.4. **Received Materials:** Secure Warehouse area where received materials are held prior to sampling.

4.5. **Quarantined Materials – Awaiting Release:** Secure Warehouse area for received materials that are awaiting 3rd party test results and have not yet been released for manufacturing.

4.6. **Quarantined Materials – Investigation:** Secure Warehouse area for materials that are pending investigation and have not yet been released for manufacturing.

4.7. **Manufacturing Released Materials:** Secure area designated for Raw Materials or Finished Product that have been released by Quality Assurance for manufacturing or shipment. Designated areas are specified in attachment 6.1 Materials Workflow – Billerica.

4.8. **Rejected Materials:** Secure Warehouse area designated for Raw Materials or Container Components that do not meet specifications.

4.9. **Finished Product:** Manufactured coating product produced during a manufacturing run using a Master Batch Record.

4.10. **Product Quarantine – Awaiting Release:** Secure Manufacturing area designated for Finished Product materials that are awaiting in-house analytical results and 3rd party testing results to release for shipment.

4.11. **FTIR:** Fourier Transform Infrared Spectroscopy used for identification testing of raw materials.

4.12. **Master Batch Record:** Document that captures all manufacturing activities for a specific coating manufacturing lot.

5. PROCEDURE

5.1. General Guidance

5.1.1. No consumable, container components, raw material, or finished product to be used in any cGMP processes may be used without being properly released for use in cGMP manufacturing.

5.1.2. Release of materials for cGMP manufacturing will be tracked by [QA-009-FRM-01] Material Receiving & Release Form.

5.1.3. The following associated documents will be attached to the Material Receiving & Release Form:

5.1.3.1. Packing slip

5.1.3.2. Safety Data Sheet (for raw materials or relevant consumables)

5.1.3.3. Certificate of Analysis (for raw materials)

5.1.3.4. Test results from 3rd party labs

5.1.3.5. Certificate of Conformance (when available)

5.1.3.6. Any additional shipping forms (when available)

5.1.4. Release of finished product will be tracked by [QA-009-FRM-04] Finished Product Material Management & Release Form.

5.2. Purchasing cGMP Materials

5.2.1. All consumables, container components and raw materials used in cGMP manufacturing must be purchased from an Approved Supplier as outlined in [QA-011] Supplier Management.

5.2.2. A Manufacturing Associate or designee trained on this procedure and [QA-011] Supplier Management may purchase approved cGMP Consumables, Container Components and/or Raw Materials.

5.2.3. A Manufacturing Associate or designee will specify that any purchased materials will require the following information upon arrival to the LiquiGlide manufacturing site:

5.2.3.1. All Materials require a packaging slip.

5.2.3.2. Consumables require a Safety Data Sheet when applicable (e.g. cleaning solutions).

5.2.3.3. Raw Materials require a Safety Data Sheet and a valid Certificate of Analysis.

5.2.4. A Manufacturing Associate or designee will track the arrival of purchased cGMP materials by logging the arrival date into [QA-009-FRM-02] Raw Material Tracking Form.

5.3. Receiving & Quality Inspection

5.3.1. cGMP Consumables, Container Components and Raw Materials will be received at the LiquiGlide manufacturing site in Billerica, MA.

5.3.2. Any Associate is authorized to sign for incoming material at LiquiGlide. The Head of Manufacturing or Manufacturing designee shall be notified as soon as possible after new shipments arrive.

5.3.3. Any materials for use in cGMP manufacturing must be kept in their original container for receiving by the Head of Manufacturing or Manufacturing designee.

5.3.4. In order to receive any Consumable, Container Components or Raw Materials to be used in cGMP manufacturing, a [QA-009-FRM-01] Material Receiving & Release form must be initiated by the Head of Manufacturing or Manufacturing designee. This form shall be initiated within 1 business days of the consumable, container components or raw material arriving at the LiquiGlide manufacturing site.

5.3.5. Upon initiation of the [QA-009-FRM-01] Material Receiving & Release form, the shipping container shall be inspected for damage or leaks.

5.3.6. In order to be received, all cGMP materials must have the following documentation:

5.3.6.1. A valid packing slip or shipping documentation with a date and quantity of materials shipped.

5.3.6.2. A valid Safety Data Sheet for any Raw Materials or applicable consumable.

5.3.6.3. A valid Certificate of Analysis, which must contain a manufacturer's lot number and expiration date (or retest date), in order to accept any Raw Material.

5.3.7. If any documentation is missing, the supplier shall be contacted to request the required documentation. Material may not be officially received until all required documentation is received.

5.3.8. All shipments shall be confirmed against the packing slip to ensure that the correct material and quantities were received.

5.3.9. All shipments shall be inspected to ensure they are free from any debris or nonrelated materials.

5.3.9.1. Open 1 shipment container per lot to visually inspect shipment.

5.3.9.2. If foreign debris or nonrelated materials are detected, then open and inspect all shipment containers per lot.

5.3.10. Raw Materials shall additionally be checked for the material matching specifications.

5.3.10.1. Identify the correct Raw Material Specification Number assigned to the specific raw material as outlined within the [QA-033-FRM-01] Specification Log.

5.3.10.2. Use the Raw Material Specification Number to access the distinct Raw Material Specification form within ZenQMS.

5.3.10.3. Review the specific Raw Material Specification form to ensure the material description and analytical results match specifications.

5.3.10.4. Record Specification Number/Revision and Expiration Date on [QA-009-FRM-01] Material Receiving & Release Form.

5.3.11. Once Received, each material shall be labeled as "Received" with LG Code and Manufacturer's Lot number prominently displayed on the label. Refer to [QA-028] Label Handling & Management.

5.4. Material Segregation & Labeling

5.4.1. Once Received, materials shall be segregated and labeled in the following way:

5.4.1.1. For Raw Materials, the material must be added to [QA-009-FRM-02] Raw Material Tracking Form by the Head of Manufacturing or Manufacturing designee.

5.4.1.2. List the LG Code and Manufacturing Lot Number on the [QA-009-FRM-01] Material Receiving & Release form.

5.4.1.3. Each Raw Material shall have a label with the LG Code and Manufacturer's Lot number.

5.4.1.4. Each Raw Material shall have its expiration date visibly displayed on the label that is applied to the outside packaging of the material for easy reference.

5.4.1.5. Each Raw Material shall be labeled as "Received." Refer to [QA-028] Label Handling & Management.

5.4.1.6. Move the material into the designated "Received Materials" area within the Warehouse of the LiquiGlide manufacturing space, see section 6.1 Materials Workflow - Billerica. Designated areas for received, quarantined and rejected materials are clearly identified in the warehouse and manufacturing areas. The Raw Materials must remain quarantined in the "Received Materials" area until they are ready to be sampled.

5.4.2. For Consumables or Container Components, ensure the shipping container is placed in the "Received Materials" area. Each container component shall be labeled as "Received".

5.4.3. For all GMP materials, ensure that the labels listed in this section are clearly visible on the outer packaging of the GMP material. Refer to [QA-028] Label Handling & Management.

5.5. Raw Materials Sampling Plan and Tracking

5.5.1. Once a Raw Material has been moved to the "Received Materials" area of the LiquiGlide manufacturing space, the Raw Material will need to be sampled and submitted to a 3rd party testing facility prior to release for manufacturing. Each Raw Material and subsequent sample will be tracked during this process.

5.5.2. **Sampling Plan:** Raw material containers must be sampled for testing prior to use in cGMP Manufacturing per [QA-018] Sample Handling & Submission. At a minimum, Identification (FTIR) & Microbial Bioburden (USP <61> and USP <62>) testing are required to release raw materials per lot for use in cGMP manufacturing.

5.5.3. Any Manufacturing associate or designee trained on the [QA-018] Sample Handling & Submission can take samples from the "Received Materials" area, sample the raw materials, and submit them for shipment to the 3rd party analytical testing labs. The sample size of each sample must be sufficient for testing, as specified within the [QA-018] Sample Handling & Submission.

5.5.4. If multiple containers are received from the same lot of a raw material, then sampling depends upon the desired test being performed:

5.5.4.1. For Identification (FTIR) and Absence of Specified Pathogens (USP <62>), then 1 sample per lot is submitted for 3rd party analytical testing.

5.5.4.2. For Microbial Enumeration Test (USP <61>), then each of the $\sqrt{N}+1$ containers (rounded) must be opened and sampled. For example, if 10 containers are received of the same lot, then 4 must be sampled (3.16 + 1 ≈ 4).

5.5.5. Each sample must be labeled “Sampled” with appropriate Sample ID and label prior to shipment. Refer to [QA-018] Sample Handling & Submission.

5.5.6. Each Raw Material container that was sampled must be labeled as “Sampled” with corresponding Sample ID, sample number, and “Box X of Y” per lot shipment.

5.6. **Sample Tracking:** [QA-009-FRM-02] Raw Material Tracking Form shall be initiated to track use of the material.

5.6.1. When the form is first initiated, the Material Information section shall be filled out by the Head of Manufacturing or Manufacturing designee.

5.6.2. The Raw Material Tracking form shall stay with the raw material container during use. Whenever the container is opened for sampling or manufacturing use after release, an entry shall be filled out in the [QA-009-FRM-02] Raw Material Tracking Form. Any GMP or manufacturing associate can make entries in the [QA-009-FRM-02] Raw Material Tracking Form

5.6.3. The log is considered complete when:

5.6.3.1. The Raw Material has been rejected and cannot be released to manufacturing.

5.6.3.2. The Raw Material has expired and no longer can be used for manufacturing.

5.6.3.3. The Raw Material has been fully exhausted during manufacturing.

5.6.4. Once the log is complete, it shall be submitted to QA for review and archiving.

5.6.5. Once a Raw Material has been sampled and tracking started, the Raw Material must be move to the “Quarantine Materials – Awaiting Release” area.

5.7. **Quarantined Materials Awaiting Investigation**

5.7.1. Raw Materials that require further investigation prior to manufacturing release shall be labeled “Pending Investigation” and moved to the “Quarantine Materials – Investigation” area.

5.7.2. Investigations can occur when:

5.7.2.1. Raw Materials results (from 3rd party testing or otherwise) do not pass specifications.

5.7.2.2. A deviation occurred during sampling, handling or material movement.

5.7.2.3. There is a change in the Raw Material Specification. Changes to Raw Material Specifications will be managed through [QA-005] Change Control.

5.7.3. Quality Assurance will review all proper documentation and make the determination whether the Raw Material can be released for manufacturing or rejected. Quality Assurance will append appropriate labels to the containers and move the Raw Materials to the proper designations.

5.8. Material Release for cGMP Use

5.8.1. **For Consumables and Container Components**: Once all required documentation has been received and all sections of the [QA-009-FRM-01] Material Receiving and Release Form have been filled out, the Head of Manufacturing or Manufacturing designee can sign the Approval for Release section of the form.

5.8.2. **For Raw Materials**: Once all required documentation and 3rd party testing results have been received, and all sections of the [QA-009-FRM-01] Material Receiving and Release Form have been filled out, the Head of Manufacturing or Manufacturing designee can sign the Approval for Release section of the form.

5.8.3. Quality Assurance will verify that the Material Receiving & Release Form has been filled out correctly, all required documentation is attached to the form, and all raw material test results are within specification. Once all information has been verified, if all raw material test results are within specification Quality Assurance can sign the Approval for Release Section of the Form and archive the form.

5.8.3.1. If the required documentation has not been received, or the raw material test results are not within specification, Quality Assurance must indicate that the material is not approved for cGMP use.

5.8.3.1.1. Material that is not approved for cGMP use shall be labeled as “Rejected” and immediately removed from any cGMP area. The material shall not be used for any further manufacturing activities.

5.8.3.1.2. Rejected materials will be immediately moved to the “Rejected Materials” area and await proper disposal by the Head of Manufacturing or manufacturing designee, or transfer for use in R&D/Innovation work at LiquiGlide.

5.8.4. Quality Assurance will verify that the materials have been labeled and disposed or transferred out of the GMP material area.

5.8.5. Material that has been approved by the Head of Manufacturing and Quality Assurance can be labeled as “Released” and shall be moved to the “Manufacturing Released Materials” area.

5.9. Finished Product Sampling Plan and Tracking

5.9.1. **Sampling Plan:** Samples and retains are taken during the coating manufacturing at intervals specified in the Master Batch Record. Any Manufacturing Associate or designee trained on the [QA-018] Sample Handling & Submission can take samples during coating manufacturing.

5.9.1.1. Retains shall be stored on premises under designated storage conditions for greater than 1 year pass product shelf life or 3 years from last date of distribution of product.

5.9.1.2. During coating manufacturing, a Manufacturing Associate or designee shall initiate [QA-009-FRM-04] Finished Product Materials Management & Release Form to record number of samples taken during the manufacturing process.

5.9.1.3. Samples must be tested prior to release for shipment as per [QA-018] Sample Handling & Submission. At a minimum, 1 sample shall be submitted for in-house analytical testing and 1 sample shall be submitted for Identification and Microbial Bioburden testing to release the Finished Product for shipment.

5.9.1.4. Each sample must be labeled “Sampled” with appropriate Sample ID and label prior to shipment. Refer to [QA-018] Sample Handling & Submission.

5.9.2. Sample Tracking. All samples submitted for 3rd party testing or in-house analytical testing will be tracked via their respective sample submission forms. Refer to [QA-018] Sample Handling & Submission.

5.9.3. Once the coating manufacturing process is complete for a given lot, the Finished Product must be moved to the “Product Quarantine – Awaiting Results” area of the LiquiGlide manufacturing space await results prior to release for shipment.

5.9.4. Finished Product can only be released for shipment upon receipt of analytical results and approval from Quality Assurance that all analytical results pass specifications.

5.9.4.1. In addition to analytical results, the Finished Product must have the following valid documentation prior to shipment:

5.9.4.1.1. Packing slip

5.9.4.1.2. Safety Data Sheet

5.9.4.1.3. Certificate of Analysis

5.9.4.1.4. Certificate of Conformance

5.9.4.1.5. Commercial product label

5.9.4.1.6. Expiry date

5.9.4.2. The Finished Product must be moved to the “Manufacturing Released Materials” area within the manufacturing space if the Finished Product is not immediately ready for shipment.

5.10. Material Expiration Dates and Disposal

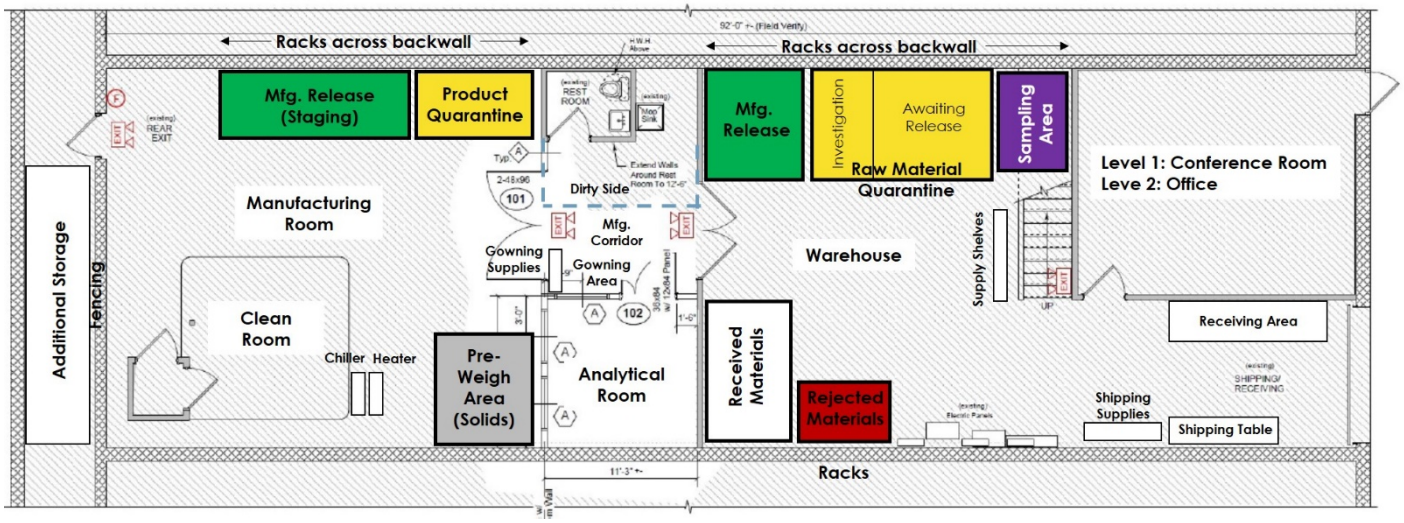
5.10.1. Any materials stored within the “Manufacturing Released Materials” and labeled “Released” will be periodically checked against their supplier expiration date.

5.10.2. If any material is determined to be past the supplier expiration date, it shall be labeled as “Rejected” and “Expired - not for GMP use”. The material is promptly removed from the “Manufacturing Released Materials” area and no longer available for cGMP use.

5.10.3. The expired material will be appropriately disposed by the Head of Manufacturing or Manufacturing designee and recorded via [QA-009-FRM-03] Material Disposal Form.

6. ATTACHMENTS

6.1. Materials Workflow - Billerica



7. REFERENCE DOCUMENTS

7.1. [QA-009-FRM-01] Billerica Material Receiving & Release Form

7.2. [QA-009-FRM-02] Billerica Raw Material Tracking Form

7.3. [QA-009-FRM-03] Billerica Material Disposal Form

7.4. [QA-009-FRM-04] Billerica Finished Product Materials Management & Release Form

7.5. [QA-005] Change Control

7.6. [QA-011] Supplier Management

7.7. [QA-018] Billerica Sampling Handling & Submission

7.8. [QA-028] Label Handling & Management

7.9. [QA-033] Specifications

7.10. [QA-033-FRM-01] Specifications Log

7.11. LiquiGlide Materials Database

REVISION HISTORY

Version 01 Effective on 24-Jun-2019
New Document

Version 02 Effective on 12-May-2020
Updated ordering, receiving, sampling, handling raw materials and finished products within Billerica manufacturing space.

Version 03 Effective on 13-May-2020
Minor edits: 1) Added "check shipment against packing slip to ensure correct material and quantities have been received." 2) Updated reference section to include "Billerica" in the title forms/documents

Version 04 Effective on 13-May-2020
Changed from "all Raw Materials" to just "Raw Materials" for sampling plan. Also, added recommended storage conditions and time to keep retain samples.

Version 05 Effective on 01-Jun-2020
Updated due to "sample tracking" references in QA-018 Sample Handling & Submission. Using sample submission forms as tracking forms as well.

DOCUMENT ELECTRONIC SIGNATURES

DOCUMENT APPROVAL WORKFLOW

Author Approval

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I am the author of this document.
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Required Workflow Steps for this Category

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LiquiGlide Inc / Quality Assurance Approval
I have reviewed and approve this document.
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1. PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the process for the request, creation, issuance and use of status labels and tags used by for the release, quarantine, and rejection of materials and product.

2. SCOPE

This procedure applies to the handling of GMP materials and their labels at LiquiGlide.

3. RESPONSIBILITIES

Role	Responsibility
GMP Associates	Understand the different labels and their meaning
Head of Quality Assurance or designee	Maintains label templates and approves templates as required Creates, issues, purchases, stores, and disposes of labels for GMP materials Reconciles the number of labels issued, used, and returned
Head of Manufacturing, or designee	Issues requests for labels and returns any and all that are unused or damaged

4. DEFINITIONS

4.1. **Status Label**: Labels issued and approved by Quality Assurance to indicate the disposition status of GMP materials

5. PROCEDURE

5.1. All GMP materials will be handled and labeled in accordance with **[QA-009] Materials Management**.

5.2. Quality Assurance (QA) or direct designee shall be responsible for the creation, purchase, storage, use, issuance, and disposal of all labels for GMP materials.

5.3. Other Associates shall not create, affix, remove, or otherwise alter labels for GMP materials, except as specified in written procedures, or otherwise authorized by Quality Assurance.

5.4. GMP production areas shall not contain the equipment or facilities to produce or generate labels.

5.5. Label templates may be generic for use with multiple materials or may be specific to a product or material.

5.5.1. Labels may be purchased as a pre-printed template, if so; they must meet the requirements of this procedure. When ordered and received by QA, they must be reviewed to assure compliance.

5.5.2. The minimum dimensions shall be 2 inches by 1 inch.

5.6. Information on labels may be pre-printed or written on labels using blue or black indelible ink.

5.7. Labels must be defaced by drawing an X through the label using a black sharpie marker prior to a subsequent status label being applied. The information on the label should not be obscured by the X.

5.8. Each status label must include a line or area to initial and date when the label has been applied, and by whom

5.9. Labels for raw materials will be printed with specific colors and headers, which indicate the status to be assigned to the material. The following labels with header and dimension are available for QA use.

5.9.1. **Received:** used for materials that have been received but have not yet been sampled/released.

5.9.1.1. The label shall have a white background and include black text **at top of the label** reading “Received”.

5.9.1.2. The label shall include the following information:

5.9.1.2.1. Material

5.9.1.2.2. Lot

5.9.1.2.3. Part Number

5.9.1.2.4. Amount

5.9.1.2.5. Pending

5.9.1.2.6. Date and Initials

5.9.2. **Sampled:** used for materials that have been sampled but are awaiting test results or final release. The label shall have a yellow background and include black text reading “Sampled.”

5.9.2.1. The label shall include the following information:

5.9.2.1.1. Sample ID

5.9.2.1.2. Sample Number

5.9.2.1.3. Container X of Y

5.9.2.1.4. Date and Initials

5.9.3. **Quarantine:** used for materials that have been sampled but are awaiting test results or final release. The label shall have a yellow background and include black text reading “Quarantine.”

5.9.3.1. The label shall include the following information:

5.9.3.1.1. Material

5.9.3.1.2. Lot

5.9.3.1.3. Part Number

5.9.3.1.4. Amount

5.9.3.1.5. Pending

5.9.3.1.6. Date and Initials

5.9.4. **Released**: strictly used for materials that have been released for GMP use. The label shall have a green background and include black or white text reading “Released”

5.9.4.1. The label shall include the following information:

5.9.4.1.1. Material

5.9.4.1.2. Lot

5.9.4.1.3. Part Number

5.9.4.1.4. Amount

5.9.4.1.5. Date and Initials

5.9.5. **Rejected:** strictly used for materials that have not been released for GMP use and must be destroyed and/or transferred to R&D/innovation work. The label shall have a red background and include black or white text reading “Rejected”

5.9.5.1. The label shall include the following information:

5.9.5.1.1. Material

5.9.5.1.2. Lot

5.9.5.1.3. Part Number

5.9.5.1.4. Amount

5.9.5.1.5. Reason for Rejection

5.9.5.1.6. Date and Initials

5.9.6. **Final Product Labels:** strictly used for Final Product that has been dispositioned and released by Quality Assurance for distribution. The label shall have a white background and include black or white text reading “Released”.

5.9.6.1. A sample of the Final Product Release label shall be attached to the applicable executed batch record

5.9.6.2. The label shall include the following information:

5.9.6.2.1. Manufacturer

5.9.6.2.2. Product Description

5.9.6.2.3. Lot #

5.9.6.2.4. Quantity

5.9.6.2.5. Date of Manufacture

5.9.6.2.6. Expiration Date

5.9.6.2.7. Storage Condition

5.9.6.2.8. Date and Initials

5.10. Quality Assurance will ensure that all containers and materials (raw and in process) are properly labeled and will store and control the supply of labels.

5.11. Quality Assurance will ensure that the number of labels issued and the total number of labels applied are recorded on **[QA-028-FRM-01] Label Issuance and Reconciliation Log**.

5.12. For additional labels, or final product labels:

5.12.1. The Head of Manufacturing, or their designee, will initiate a request for labels to and deliver it to Quality Assurance.

5.12.2. Quality Assurance will generate and issue the labels to Manufacturing and then record the number issued on **[QA-028-FRM-01] Label Issuance and Reconciliation Log**.

5.12.3. The Head of Manufacturing will return any and all unused or damaged labels, and Quality Assurance will reconcile using **[QA-028-FRM-01] Label Issuance and Reconciliation Log** to ensure all labels are accounted for.

6. ATTACHMENTS

6.1. N/A

7. REFERENCES

7.1. [QA-028-FRM-01] Label Issuance and Reconciliation Log
7.2. [QA-009] Materials Management

REVISION HISTORY

Version 01 Effective on 29-Jun-2020
New Document

DOCUMENT ELECTRONIC SIGNATURES

DOCUMENT APPROVAL WORKFLOW

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Required Workflow Steps for this Category

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