SOP Title: QA Disposition of CGMP Raw Materials
SOP Number: 21708
Revision: 05

TABLE OF CONTENTS

1. PURPOSE

This SOP defines Biopharmaceutical Quality Assurance (BQA) dispositioning of Current Good Manufacturing Practice (CGMP) raw materials.

2. SCOPE

This procedure applies to BQA personnel responsible for the review and release of raw materials in the inspection level categories of “C,” “D,” and “F.” This procedure also applies to BQA personnel who are responsible for updating previously “approved” or “released” raw material to “quarantined” or “rejected” status due to additional information that indicates the raw material’s status should be changed.

3. BACKGROUND

GMP raw materials are purchased and received according to **SOP 20302 - Receipt and Inspection of Materials.** According to these policies, raw materials are categorized into inspection levels A, B, C, D, E, and F depending on the criticality of the raw material to the safety of the product. The degree of inspection or evaluation of the material is defined by this inspection level. “C,” “D,” and “F” items require BQA review and approval before they are available for GMP activities. This SOP describes the process of BQA review and disposition. This SOP also describes how BQA personnel update the status of released or approved items when they become aware of information that indicates a previously cleared raw material status needs to be re-evaluated.

4. RESPONSIBILITIES

4.1 Biopharmaceutical Quality Assurance (BQA)

- Reviews documentation received from Process Analytics\Quality Control (PA\QC) for items with Inspection Level of "C," "D," and "F" for completeness and accuracy.
- Reviews\Approves raw material status labels (Released, Conditional Release, Reject, or Quarantine).
- Issues a Material Status Change Notification Form, as needed, for Conditional Release, Quarantining, or Rejecting Materials and for material shelf-life extension requests.

4.2 Process Analytics\Qualify Control (PA\QC)

- Submits documentation to BQA upon completion of testing, including any deviations or investigations per **SOP 22714 - Sampling, Testing, and Review of CGMP Materials by BQC**, as they relate to material testing.

4.3 Materials Management and Inventory Control (MMIC)

- Prepares\Prints and applies status labels (Released, Conditional Release, Reject, or Quarantine).
- Labels materials with status labels reviewed\approved from PA\QC or BQA.
- Stores material in appropriate storage temperature.
- Transfers of materials to appropriate storage locations after labeling.

5. PROCEDURE

5.1 Materials can be dispositioned in the following ways by BQA.

5.1.1 From initial status of Quarantine for incoming raw material to either Release, Conditional Release, or to Reject. (Reference Section 5.2 for additional details).

5.1.2 From a previous Release status to either a Quarantine or to a reject status. (Reference Section 5.5 for additional details).

5.2 For incoming "C", "D" and "F" inspection level raw materials held in Quarantine by MMIC pending testing and release, BQA reviews the documentation submitted by PA\QC and confirms the following are present\complete.

5.2.1 Inspection and Receipt of Materials, **Form 20302-01 (SOP 20302 - Receipt and Inspection of Materials).**

5.2.1.1 All blanks are complete, and any errors have been corrected as per **SOP 21409 - Good Documentation Practices.**

5.2.1.2 The Vendors Lot Number on the attached Quarantine label matches. The BDP Receipt Number assigned by MMIC matches Inspection and Receipt of Materials, **Form 20302-01**.

5.2.1.3 The Expiration date assigned is in accordance with SOP **21902 - Requirements for Establishing Part Numbers and Specifications for BDP Components and Materials.**

5.2.1.4 The quantity sampled, and number of containers sampled is in accordance with **SOP 22714 - Sampling, Testing, and Review of CGMP Materials** by Process Analytics\Quality Control.

5.2.2 Testing Records for "C," "D," and "F" Inspection Level Items and Status Label

5.2.2.1 The manufacturer's COA has been reviewed and accepted by PA\QC (PA\QC staff have signed and dated the COA).

5.2.2.2 All blanks are complete, and any errors have been corrected per **SOP 21409 - Good Documentation Practices.**

5.2.2.3 The Materials and Equipment listed in the submitted analytical test records show that:

- The lot numbers for materials\reagents used are within their expiration dates.
- The instrumentation listed is within the calibration due date.

5.2.2.4 Required analytical tests are performed per the approved material specification.

5.2.2.5 Calculations are checked for accuracy.

5.2.2.6 Numbers transcribed from equipment\data printouts to the Test Record are correct.

5.2.2.7 Attached data printouts are labeled to provide traceability.

5.2.2.8 Test records indicate PA\QC review and recommendation for reject or release per **SOP 22714 - Sampling, Testing, and Review of CGMP Materials** by PA\QC.

5.2.2.9 Confirm that all required test results are within specification.

5.2.2.10 Confirm that the sample raw material quarantine label has the correct information printed on the label.

5.2.2.11 Confirm that the expiry date has been assigned and is correct.

5.2.3 Deviation(s)\Investigations (if applicable)

5.2.3.1 Verify that the documentation has been reviewed and approved by BQA.

5.2.3.2 Check that the information contained in the documentation, as it relates to the raw material release procedure, has been completed.

5.2.4 Should errors be encountered, or should clarification be needed during this review process, return the documentation to either MMIC or PA\QC for correction\resolution as appropriate.

5.2.5 Once the documentation has been reviewed and found acceptable, PA\QC recommends Released, Rejected, or Quarantine status for the material.

5.2.6 BQA approves the raw material release label information by initialing and dating on the label information line on **Form 20302-01**. Should corrections be required to the label, BQA will reject the packet and the label information is corrected. Corrections are handwritten and initial\date the changes next to the label. BQA will verify the corrections.

5.2.7 BQA approves the release of the raw material by signing\dating the release line on **Form 20302-01**.

5.2.8 Submit the original Form **20302-01** to MMIC for raw material status labeling and completion of the remaining lines by MMIC on **Form 20302-01**. A copy is included in the QCTR packet.

5.2.9 The packet is returned to PA\QC for processing.

5.3 Released Materials that are Nearing\Exceeding Expiration Dating

5.3.1 Materials not assigned an expiry date by the vendor may have their shelf-life extended by following **SOP 21902 - Requirements for Establishing Part Numbers and Specifications for BDP Components and Materials and submitting Form 21902-01.**

5.3.2 Materials that have been assigned an expiry date by the vendor may only have their shelf-life extended if:

5.3.2.1 Documentation can be obtained from the vendor that supports an extended shelf-life.

5.3.2.2 Ample extended shelf-life data is available and documented for multiple lots that justifies extending the shelf-life.

5.3.2.3 Upon completion of acceptable PA\QC testing (as required per **Form 21902-01**, Request for Extension of Raw Materials Shelf Life), BQA reviews the data and dispositions the raw material using **Form 21708-01**. The new expiry date to be applied is obtained from **Form 21902-01**.

5.3.3 BQA completes Sections A and B of Form **21708-01.**

5.3.4 **Form 21708-01** is forwarded to MMIC for labeling of the material. Alternatively, if there are only a few items to be labeled, the items label may be hand corrected by BQA to reflect the new expiration date.

5.4 Conditional Release of Raw Materials

5.4.1 Upon request and with an approved deviation signed by BQA, raw materials may be conditionally released prior to the completion of the PA\QC testing specified on the Master Specification.

5.4.2 Follow the steps in Section 5.2.1 for review of MMIC records. BQA will also review the vendor's COA and other supplied documentation (if applicable).

5.4.3 BQA completes Sections A and B of **Form 21708-01.**

5.4.4 **Form 21708-01** is forwarded to MMIC for labeling of the material.

5.5 Raw Materials Status Change to Quarantine or Rejected

5.5.1 Released materials that need to have their status changed to "Quarantined" or "Rejected" will be processed using **Form 21708-01**.

5.5.2 BQA completes Section A and B of Form **21708-01**.

5.5.3 **Form 21708-01** is forwarded to MMIC for labeling of the material.

6. DOCUMENTATION AND RECORDS

6.1 **Form 20302-01** and the component inventory card are maintained on file in MMIC. Upon completion, these documents are returned to BQA for archiving.

6.2 The PA \QC Test Request, Master Specification, Vendor's COA, and supporting records are returned to PA \QC to allow closure of record in accessioning. The original documentation will be returned to BQA for archiving.

6.3 The completed **Form 21708-01** is filed in MMIC along with the original inspection and receipt documentation for the raw material. A copy of the completed form is returned to BQA for filing with BQA Management.

7. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
20302	Receipt and Inspection of Materials.
22714	Sampling, Testing, and Review of CGMP Materials by Process Analytics\Quality Control.
21409	Good Documentation practices
21902	Requirements for Establishing Part Numbers and Specifications for BDP Components and Materials.
21708-01	Raw Material Status Change Notification
20302-01	Inspection and Receipt of Materials - Inventoried Materials
21902-01	Request for Extension of Raw Material Shelf Life