BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

SOP Title:	**Materials Management and Inventory Control (MMIC) Program**
SOP Number:	**20003**
Revision:	**05**

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1. PURPOSE

This procedure defines the Materials Management and Inventory Control (MMIC) Program for the Biopharmaceutical Development Program (BDP).

2. SCOPE

This procedure is applicable to all materials within the BDP that will be classified, received, processed, and dispositioned through the (MMIC) program and the Process Analytics/Quality Control (PA/QA) and Biopharmaceutical Quality Assurance (BQA) departments.

3. RESPONSIBILITIES

3.1 Biopharmaceutical Development Program (BDP) employees

- Request's part numbers
- Assists in the development of material specifications.
- Orders Inventoried Materials Using pc/MRP Inventory System.
- Distributes Products and Materials to Requestors and Subcontractors.
- Accounts for CGMP products.
- Stores and controls CGMP Buffers.

3.2 Materials Management and Inventory Control (MMIC)

- Processes all controlled materials at BDP.
- Assigning Part Numbers to CGMP Manufacturing Associated Materials
- Orders, receives, and quarantines of materials.
- Assigns BDP Lot Numbers to materials.
- Notifies the BDP Purchasing Agent of any problems with an order.
- Handles Rejected and Expired Materials.

- Receipts of Materials Using the pc/MRP Inventory System.
- Establishes Raw Material Part Numbers and master Specifications Using the Part Number/Master Specification Program.
- Orders Inventoried Materials Using pc/MRP Inventory System.
- Fills Inventory Orders Using pc/MRP Inventory System.
- Creates and Updates Purchase Orders Using pc/MRP System.
- Creates Receipt of Products from Outside Contractors.
- Distributes of Products and Materials to Requestors and Subcontractors.

3.3 Process Analytics/ Quality Control (PA/QA)

- Establishes Part Numbers and Specifications for BDP Components and Materials.
- Samples, Tests, and Reviews CGMP Materials by BQC.
- Assists in the determination of expiration dating and sampling plans.
- Sampling and tests materials per specification(s).
- Dispositions B inspection level raw materials and recommends the disposition for C and D level raw material.

3.4 Biopharmaceutical Quality Assurance (BQA).

- Assists in the Development of Material Specifications
- Assists in the determination of expiration dating and sampling plans
- Performs the final dispositioning of C, D and E inspection level raw materials.
- Provides quality oversight.

4. DEFINITIONS

- **Controlled Material:** Items classified and assigned a Part Number per SOP 21902 - Requirements for Establishing Part Numbers and Specifications for BDP Components and Materials.
- **GMP Product:** BDP manufactured materials made by the Biopharmaceutical Development Program must follow SOP 20303 - CGMP Product Accountability, SOP 20004 - Use of Freezer Works Database, SOP 20101 - Receipt of Products from Outside Contractors and SOP 20201 - Distribution of Products and Materials to Requestors and Subcontractors and SOP 21106 - Certificate of Origin Policy for Raw Materials/Components Used at the BDP.
- **Inventoried Items:** Any items or materials classified and assigned a Part Number per SOP 21902 - Requirements for Establishing Part Numbers and Specifications for BDP Components and Materials.
- **Staging:** Any project specific inventoried item that will be held in a specified location (under MMIC control) for a given length of time.

5. PROCEDURE OR USE

5.1 Guidelines for Issuance of Materials.

5.1.1 Only materials that have been either labeled as “Approved” or “Released” are to be issued to any area that will be using the material for CGMP production.

5.1.2 Items that are received as CGMP may be labeled with Blue and White Development stickers. However, once labeled as Development, they cannot be relabeled as Released without approval of BQA.

5.1.3 Quarantined materials must not be issued under any circumstances. If materials are needed on an emergency basis, prior to release, the requestor must complete a deviation requesting “Conditional Release” of the material and have it approved by BQA. A copy of the deviation must accompany the order for materials.

NOTE: Materials are withdrawn from inventory on a “first-in,” “first-out” basis. In the event that a requested material is not available, and a back order occurs, MMIC will order the material. When the material is available, MMIC will fill the back-order quantity and deliver the material.

NOTE: See Attachment 1 (Flow Chart).

5.2 Classification and Ordering.

5.2.1 Employees wishing to place an order for controlled materials must first determine if a part number has been assigned to the material (SOP 21902 - Requirements for Establishing Part Numbers and Specifications for BDP Components and Materials.

5.2.2 If a part number exists for the item(s), the employee can requisition the material from inventory using the pc/MRP Inventory System per **SOP 20309 - Ordering Inventoried Materials Using pc/MRP Inventory System**. (Skip to step 5.2.4).

5.2.3 If a part number does not exist, one must be requested (SOP 21903 - Using the Part Number/Master Specification Program to Establish Raw Material Part Numbers and master Specifications).

NOTE: Items requiring release by either PA/QC and/or BQA will also need specifications per SOP 21902 and as required Certificate of Origin, per **SOP 21106 - Certificate of Origin Policy for Raw Materials/Components Used at the BDP.**

5.2.4 Employees must order materials using the pc/MRP Inventory System per **SOP 20309**. If the material is available, it is delivered to the requester. If not available, MMIC fills the order per **SOP 20310 - Filling Inventory Orders Using pc/MRP Inventory System** or creates a purchase order using the pc/MRP Inventory System per **SOP 20311 - Creating and Updating Purchase Orders Using pc/MRP System.**

5.2.5 Upon receipt of purchase order, MMIC will receive materials using the pc/MRP Inventory System per **SOP 20312 - Receiving of Materials Using the pc/MRP Inventory System** and will fill the original request according to SOP 20310.

5.3 Receipt of Materials

5.3.1 Materials are received from ATRF Receiving by MMIC and are inspected upon arrival (SOP 20302 - Receipt and Inspection of Materials) for any obvious damage. If the packaging/materials are damaged, MMIC will refuse the shipment. The shipment is returned to ATRF Receiving for resolution.

5.3.2 Acceptable packages are evaluated to determine if received materials require a temperature-controlled environment.

5.3.3 If yes, these materials(s) are processed first or are staged for later processing in a temperature-controlled area.

5.3.4 The Packing Slip is removed from the shipment and reconciled to the Purchase Order. If incorrect materials or quantities are delivered, MMIC will notify the BDP Purchasing Agent.

5.4 Processing of Materials (Purchase Order and Packing Slip agree)

5.4.1 MMIC processes all received materials, entering the receipt into the receiving log and compares quantity ordered to that received. An Inspection and Receiving Report is completed for each different item per **SOP 20302 - Receipt and Inspection of Materials.**

5.4.2 If the material does not have a BDP part number (direct purchase order), the MMIC Staff Member will notify the requester via E-mail that the material has arrived. The Requester or Requester's designee can retrieve the material during normal business hours.

5.4.3 Research and Development material received will be processed by SOP 20302.

5.4.4 If the material has an Inspection Code of A, B, C, D, E or F, MMIC will assign a BDP Lot Number as per SOP 20302.

5.4.5 Inspection level A and F materials will be processed according to SOP 20302

5.4.6 MMIC will quarantine materials with Inspection Codes of B, C, D or F as per SOP 20302. In addition, complete a master component inventory card (if applicable) along with applicable documents.

NOTE: The quarantine label, should be close to the vendor's label, but not cover vendor label.

5.4.7 Inspection Code B.

5.4.7.1 MMIC will forward a copy of the Inspection and Receiving Report to PA/QC along with any other paperwork (COA, Certificate of Compliance (COC), etc.).

5.4.7.2 PA/QC will compare the vender certification document to the specification. If acceptable, PA/QC will release the material. MMIC applies release labels over the quarantine label and moves the material to the appropriate area.

5.4.7.3 If not acceptable, either PA/QC or MMIC will contact the manufacturer regarding the contents of certificate and or obtain corrected document. If the material is still not acceptable per documentation, the material is rejected and is placed in the rejected area per **SOP 20401 - Handling Rejected and Expired Materials.**

NOTE: It is preferred that PA/QC contact the manufacturer directly so that the request for information is direct and specific.

5.4.8 If Inspection Code C or D, MMIC completes a Component Inventory Card along with a PA/QC Requisition for Testing. These are forwarded to PA/QC and logged in the appropriate logbook(s).

5.4.8.1 PA/QC samples the material according to the Master Specification.

5.4.8.2 PA/QC either tests the material or ships sample(s) to an external lab for testing per **SOP 22002 - Request for Quality Control Testing.**

5.4.8.3 PA/QC evaluates test results per **SOP 22714 - Sampling, Testing, and Review of CGMP Materials by BQC.**

5.4.8.4 PA/QC recommends disposition and forwards all documentation to BQA for review and approval.

5.4.9 If Inspection Level F, forward the original Inspection and Receipt of Materials Form along with any other documentation accompanying the shipment to QA. MMIC may maintain a copy until final disposition is assigned.

5.4.10 BQA Disposition.

5.4.10.1 If materials are acceptable, they are given the status of released by BQA.

5.4.10.2 If material(s) are not acceptable, they are given the status of Rejected per (SOP 20401 - Handling Rejected and Expired Materials) or other appropriate non-GMP use status (R&D use only).

5.4.10.3 The raw material documentation package (Inventory Control Card and Form 21903-01) containing the material disposition is forwarded to MMIC for Processing.

5.5 Labeling and Storage of Materials

5.5.1 MMIC applies label(s) to the smallest deliverable container within the unit per **SOP 20302 - Receipt and Inspection of Materials.**

5.5.2 Material is moved to either the Release or Reject Secured Area per SOP 20401 or SOP 20302.

5.5.3 An end user may void the release status of any item by drawing one diagonal line or two lines (in the form of an 'X') through the green release label. If desired, an end user may obtain blue and white "Research and Development" labels from MMIC to apply over the green release label to reassign the material from GMP use to research and development use. However, once green label is crossed-out or labeled with blue and white R&D label as research and development it may no longer be used for GMP activities.

5.6 Storage of Material in the Warehouse Areas

Materials are stored on metal shelving units in the warehouse. The lowest shelf is maintained at a minimum height of 6 inches to facilitate cleaning under the shelving units.

6. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
20004	Use of FreezerWorks Database
20101	Receipt of Products from Outside Contractors
20201	Distribution of Products and Materials to Requestors and Subcontractors
20302	Receipt and Inspection of Materials
20303	CGMP Product Accountability
20309	Ordering Inventoried Materials Using pc/MRP Inventory System
20310	Filling Inventory Orders Using pc/MRP Inventory System
20311	Creating and Updating Purchase Orders Using the pc/MRP Inventory System
20312	Receipt of Materials Using the pc/MRP Inventory System
20315	Storage and Control of CGMP Buffers
20316	Security Requirements and Password Options for pc/MRP Inventory System

Document Number	Title
20401	Handling Rejected and Expired Materials
21106	Certificate of Origin Policy for Raw Materials/Components Used at the BDP
21902	Requirements for Establishing Part Numbers and Specifications for BDP Components and Materials
21903	Using the Part Number/Master Specification Program to Establish Raw Material Part Numbers and Master Specifications
22002	Request for Quality Control Testing
22714	Sampling, Testing, and Review of cGMP Materials by BQC

7. ATTACHMENTS

Attachment 1 MMIC Flow Diagram

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