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1.0 Purpose

This SOP defines the procedure for the accountability of Current Good Manufacturing Practices (CGMP) Materials made by the Biopharmaceutical Development Program (BDP).

2.0 Scope

This procedure applies to products (in-process, bulk and final vialed product) manufactured by the BDP under CGMP conditions. It also applies to those Research and Development, and Good Laboratory Practices (GLP) materials, as well as any externally-manufactured materials, that need to be tracked through the Materials Management and Inventory Control (MMIC) system.

3.0 Authority and Responsibility

3.1 The Program and Technical Director, Biopharmaceutical Development Program (BDP) has the authority to define this procedure.

3.2 Personnel submitting materials to MMIC are responsible for ensuring that those materials are properly packaged and labeled and that appropriate documentation as defined in this procedure has been completed.

3.3 MMIC personnel are responsible for recording the receipt and distribution of CGMP manufactured products and GLP/Research and Development materials.

3.4 Biopharmaceutical Quality Assurance (BQA) is responsible for quality oversight of this procedure.

4.0 Definitions

4.1 **Leidos Biomedical Research, Inc., (LBR) Retains**: Containers of final product which are stored for future analysis as directed by Leidos corporate management.

4.2 **QC Samples**: Number of samples defined by Process Analytics/Quality Control (PA/QC) for final product release testing as well as stability testing.

4.3 **Product**: Remainder of acceptable final product after the removal of LBR Retains and QC samples.

5.0 Procedure

5.1 BDP personnel must contact MMIC at least twenty-four (24) hours in advance to schedule the exact time of the transfer of the material to or from Manufacturing laboratories and operations to MMIC. This includes notification of materials being received from an outside contractor.

NOTE: Leaving a voice mail or sending an email without receiving confirmation from MMIC does not constitute suitable contact.

5.2 Product will be submitted (as applicable) per the project's Batch Production Record.

5.3 BDP personnel must submit in-process sample retains for storage in MMIC at one time at the end of a production. Samples to be submitted must be in boxes; ziploc bags are not acceptable. (Appropriate boxes are available through MMIC Inventory). See 5.6 for additional information on submitting in-process retains.

5.4 BDP manufacturing personnel shall fill in the following on **Form 20303-01 (Attachment 1).**

NOTE: If more than one page of **Form 20303-01** is needed, multiple copies are to be printed and filled out completely to ensure traceability**.**

5.4.1 Part Number: Enter the part number if one has been assigned.

5.4.2 BDP Project No: Enter the complete 4-digit project number associated with the sample.

5.4.3 Material Description: Enter the complete description of the material exactly as it is typed on the label. The form description field must match exactly what is on the label of the material or it will be returned for correction.

5.4.4 Process Stage: Choose one of the options available to describe the process stage of the material. Options are as follows:

- Accession Bank
- Master Cell Bank
- Working Cell Bank
- End of Production Cell Bank
- Master Virus Bank
- Bulk Harvest

- In-Process Sample
- Bulk Intermediate
- Bulk Product
- Final Vialed Product
- Validation Sample
- Reference Standard

5.4.5 Lot Number: Enter the product's BDP lot number.

5.4.6 Sample Type: Choose one of the options available that best describes the type of sample. Options are as follows:

- Mammalian
- Bacterial
- Viral
- Peptide
- Oligonucleotide
- Buffer
- Plasmid
- DNA
- Protein

5.4.7 Hazard: Choose one of the options available to describe the type of samples. Options are as follows:

- Virus
- Select Agent
- Cell
- Chemical
- Other
- None

5.4.8 Infectious: Choose one of the available options to describe the materials infectious level. (Options are as follows: Yes or No).

5.4.9 Controlled Substance: Choose one of the available options to describe the materials DEA control level. Options are as follows:

- Schedule 1
- Schedule 2
- Schedule 3
- Schedule 4
- Not a controlled substance

5.4.10 Grade: Choose one of the options available to describe the grade level of the material. (Options are as follows; R&D, GLP/Tox, GMP)

5.4.11 Production Date: Enter the date of production.

5.4.12 Container Size: Enter the container size.

5.4.13 Fill Volume: Enter the volume of material per container.

5.4.14 Concentration: Enter the concentration of the material.

5.4.15 Responsible Manager: Enter the name of the manager supervising the BDP person submitting the material

5.4.16 Storage Conditions: Chose the appropriate option available for the storage condition of the material. (Options are as follows: 20-25°C, 2-8°C, -10 to -30°C, ≤-70°C, Liquid Nitrogen-Vapor Phase, Other)

5.4.17 Project Scientist name: Enter the name of the project scientist, as applicable. .

5.4.18 Complete the initial inventory line for quantity entered. If from an outside contractor, obtain a copy of their documentation stating the quantity received.

5.5 At the time of transfer, MMIC and a second person will verify the information entered on the form. Forms with incomplete or inaccurate information will be rejected and returned for correction.

5.5.1 MMIC, with a second independent verifier, inspects and verifies the container count to be transferred.

5.5.2 Both signatures of the personnel executing Step 5.5.1 are required for each custody seal; custody seals are not used for in-process materials, only for final product (BDP PN 70018 or an approved alternate).

5.6 Separate forms 20303-01 shall be completed for each item submitted for storage/inventory management. An item, for this purpose is defined by the description, container size, fill volume and lot number. This is necessary so that items can be easily and clearly cataloged and retrieved. In-process retains are to be treated as a single item, with a list of all samples comprising the set attacted to the form and the total number of samples recorded as the initial quantity. The samples should be contained within a box that is labeled with the description on the form.

5.7 All inappropriately packaged materials are returned to the submitter for correction.

5.8 At the time of the transfer, BDP personnel must also have the manufacturing batch record available to record MMIC signatures in the space available to document the transfer of the material (as appropriate).

5.9 MMIC transfers the material to the designated storage location in the Advanced Technology Research Facility (ATRF) Repository, Room B1402 or alternate designated area.

5.9.1 MMIC assures material is located together and is at the appropriate storage location.

5.9.2 MMIC will record the location of the material on **Form 20303-01**. (Freezer ID and location within freezer) in the comments field. MMIC also enters the information from **Form 20303-01** into Freezerworks as per ***SOP 20004 - Use of the Freezerworks Database***. (See **Attachment 1**).

5.10 Requests for withdrawal of materials must be made in writing to MMIC, using **Form 20303-02**, at least 24 hours in advance. Requests for shipments must be made at least 48 hours for domestic and 5 Days for International shipments in advance per ***SOP 20201 - Distribution of Products and Materials to External Recipients.***

5.11 MMIC retains records of CGMP product accountability. Copies may be provided to BDP personnel, as requested. All copies are annotated as such.

5.12 MMIC reviews each form as soon as it is completed and/or the product is distributed, to verify that all blanks have been completed and that the counts are correct (calculation verification), the withdrawal is also recorded in Freezerworks per ***SOP 20004 - Use of the Freezerworks Database.***

5.13 Return completed forms to BQA for filing in the product file.

6.0 Cycle Counts

6.1 Cycle counts will be performed on a regular basis, at least once every three years.

6.1.1 Each freezer inventory notebook will contain a section for cycle count information.

6.1.2 A listing of the freezer contents, per the Freezerworks database, will be generated from the database.

6.1.3 For on-site units, the list will be compared to a physical inspection of the contents.

6.1.4 For off-site units, the list will be reconciled with a report from the storage site.

6.1.5 Any discrepancies found will be noted, justified and a corrective action specified.

6.1.6 All non-discrepancies will also be noted by placing a check mark or “OK” next to that list item.

6.1.7 Completed counts will be signed and dated, and filed in the freezer inventory notebook.

7.0 Relocation of Materials

7.1 If material(s) is /are being relocated to another freezer or location, the new location will be noted on Form 20303-01 in the comments field, and the location will be updated in Freezerworks per ***SOP 20004 - Use of the Freezerworks Database.***

7.2 If a freezer is being taken out of service and the entire contents are relocated to another freezer in the same internal locations, the existing notebook may be relabeled with the ID of the new freezer and a signed, dated note placed in the front of the notebook documenting the global change and each individual form within the notebook does not need to be updated. The location change will also be updated in Freezerworks per ***SOP 20004 - Use of the Freezerworks Database*.**

7.3 When a freezer's contents are completely relocated, a cycle count should be documented per section 6.0, whether relocation to the same positions in a replacement freezer or not.

8.0 References and Related Documents

8.1 **SOP 20004** *Use of the Freezerworks Database*

8.2 **SOP 20201** *Distribution of Products and Materials to External Recipients*

8.3 **Form 20303-01** MMIC CGMP Manufacturing Product Inventory

8.4 **Form 20303-02** Inventory Withdrawal Request