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1.0 Purpose

This Standard Operating Procedures (SOP) describes the use, labeling and storage of raw materials, supplies, samples and equipment in Biopharmaceutical Development Program (BDP) Manufacturing.

2.0 Scope

This SOP applies to the BDP, most critically to personnel working in BDP Manufacturing.

3.0 Authority and Responsibility

3.1 The Director, Technical Operations, BDP has the authority to define this procedure.

3.2 The Director, Technical Operations, BDP is responsible for training personnel in the procedure and for documenting this training to Biopharmaceutical Quality Assurance (BQA).

3.3 The Director, Technical Operations, BDP is responsible for the implementation of this procedure.

3.4 BDP personnel are responsible for performing operations in compliance with this SOP.

3.5 BQA is responsible for quality oversight of this procedure.

4.0 Raw Materials and Supplies

4.1 Raw materials and supplies in use during GMP manufacturing operations are to be released for GMP use and be within their expiry, as applicable. Raw materials and supplies that can be re-used across multiple batches of the same product (e.g., packed purification columns, column resins, filters, etc.) will be stored between product batches in a GMP production area, and in a sealed and/or sequestered state.

4.2 Raw materials and supplies used in GMP manufacturing operations may be interchangeably used for both GMP and "non-GMP" productions (Technical runs, Engineering productions etc.) as long as the materials/supplies are maintained in accordance with GMP controls. For example, a raw material or supply must have appropriate documentation (batch record, lab notebook, etc.) that establishes traceability, be used and stored in GMP compliant areas, and only be exposed to GMP grades of buffers and solutions in order to be considered suitable for GMP production.

4.3 Weigh raw materials per **SOP 21500 - *General Policies and Procedures for Balances***. Raw materials may be batched immediately or labeled for later use.

4.4 Label each raw material with:

- Formulation name (if applicable) (i.e., Seed Media)
- Component name
- Component part number
- Release number/Expiration date
- Process lot number
- Storage temperature (ºC): (i.e., ≤-70 -10 to -30 2-8 (Ambient) RT)
- Component weight/volume
- Date and Initial

4.5 The information may be handwritten, or adhesive backed labels may be used. The labels may be made using a label template such as Avery 5164 with **Bolded** fields preprinted for the specific process.

4.6 Labeling information must be present on the primary storage container and placed on any secondary dispensing containers. Follow the MPR whenever specific labeling information is provided.

5.0 Samples

5.1 Collect samples per Master Production Record (MPR) and/or SOP.

5.2 Each sample label should include at a minimum:

- Sample name.
- Production Lot Number.
- Sample volume/mass with units.
- Initials.
- Date.

5.3 Follow the MPR whenever specific labeling information is provided. Some samples may require additional information such as:

- Storage Condition (i.e., 2-8ºC).
- Precautions (i.e., Biohazard).
- Process step.
- QC request number.

6.0 Equipment

6.1 Within BDP Manufacturing Operations, the same equipment is commonly used for both GMP and non-GMP (toxicology, engineering) productions and processes. This is an acceptable practice as long as the equipment is maintained in accordance with GMP procedures for use, maintenance and cleaning during the non-GMP production efforts. This includes but is not limited to: use of released, unexpired raw materials and buffers; area and utility controls as applicable; sufficient process and raw material documentation; verifiable cleaning and inter-product cleaning documentation, etc. If equipment is to be used for any purpose that might compromise its GMP-readiness, a documented plan for returning it to a GMP state needs to be worked out in conjunction with BQA.

6.2 The status of product contact equipment during the production campaign must be displayed using EQUIPMENT STATUS labels so that status can be assessed at a glance. Also refer to **SOP 14150 - *Labeling of cGMP Purification Equipment for Cleaning Status***, for additional guidance if appropriate.

6.2.1 The label must include:

- Equipment ID.
- Indicate if the equipment is clean:
  - Equipment is clean and ready to be used
  - Equipment is in use (production label may apply)
  - Equipment needs to be cleaned
- Date of last cleaning (if applicable).
- Project Name or #:
- Last lot number
- Operator initials and date.

6.2.2 Special notes or comments may also be included such as: EQUIPMENT NOT IN SERVICE, EQUIPMENT NOT FOR CGMP USE, etc.

6.3 Non-product contact-controlled temperature storage equipment located in rooms where both R&D and GMP storage units reside should be clearly labeled to indicate the status of the contents (i.e., – R&D material storage or GMP material storage).

7.0 Storage Guidelines

7.1 Raw Materials and Samples

7.1.1 The use of secondary containers for storage and transport is recommended.

7.1.2 Follow storage guidelines for temperature and verify containers and closures are compatible.

7.1.3 Always leave room within the container for expansion when freezing samples.

7.2 Equipment

7.2.1 Store per equipment cleaning SOP if storage is specified.

7.2.2 Equipment should be empty, dry and sealed, or openings covered using sterilization wrap or appropriate fittings, and remain in that status until next use.

8.0 Documentation

8.1 Record/Affix all label information directly onto the primary container or equipment.

8.2 Performance of this procedure may be documented within the MPR or other appropriate form.

8.3 Record equipment operations according to **SOP 21531 - *Equipment Logs***.

9.0 References and Related Documents

SOP 14150 *Labeling of cGMP Purification Equipment for Cleaning Status*

SOP 21500 *General Policies and Procedures for Balances*

SOP 21531 *Equipment Logs*

21CFR211.101(b) Charge-in of Components

…If a component is removed from the original container to another, the new container shall be identified with the following information:

(1) Component name or item code;

(2) Receiving or control number;

(3) Weight or measure in new container;

(4) Batch for which component was dispensed, including its product name, strength, and lot number.

21CFR211.105(a) Equipment identification.

All compounding and storage containers, processing lines, and major equipment used during the production of a batch of a drug product shall be properly identified at all times to indicate their contents and, when necessary, the phase of processing of the batch.

Attachment 1 Raw Material Label Template

Attachment 1

Raw Material Label Template

RAW MATERIAL

Formulation (_____)

Component Name:_____

BDP PN:_____

Release No/Expiration Date:_____

Process Lot No.:_____

Component Wt/Vol.:_____

Storage Temp (ºC): ≤-70 -10 to -30 2-8 Ambient
(Circle one)

Initials/Date:_____

Equipment Status Label