



BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

SOP Title: Assigning and Requesting Lot Numbers for Product
SOP Number: 21405
Revision: 06

TABLE OF CONTENTS

1. PURPOSE	1
2. SCOPE	1
3. BACKGROUND	1
4. RESPONSIBILITIES	2
5. DEFINITIONS	2
6. PROCEDURE.....	3
7. DOCUMENTATION AND RECORDS.....	6
8. REFERENCES AND RELATED DOCUMENTS.....	7

1. PURPOSE

This document describes the numbering system used to assign lot numbers. Lot numbers identify specific batches of product.

2. SCOPE

This procedure applies to Biopharmaceutical Development Program (BDP) staff who request lot numbers for products manufactured in the BDP for either Current Good Manufacturing Practices (CGMP) or non-GMP processes. This procedure may also apply to products manufactured by an outside vendor for the BDP.

This SOP does not apply to raw materials received from outside sources. Refer to **SOP 20302 - Receipt and Inspection of Materials**.

This SOP does not apply to assignment of lot numbers for solutions, buffers, and reagents produced by BDP Manufacturing for internal use, see **SOP 15106 - Assignment of Part Numbers and Lot Numbers for Solutions, Buffers, and Reagents**

3. BACKGROUND

Lot numbers are unique codes assigned to differentiate specific batches of material. Lot numbers provide the mechanism for identification, control, and traceability of products. Use of a unique identifier for lot identification is required by GMP (21 CFR 211). Lot numbers are requested by Manufacturing (or designee) by sending an email to the QA Compliance Outlook in-box. Assignment of lot numbers is made by QA according to a specific algorithm that provides a unique code for every lot. The lot number for a product becomes the identifier for a specific batch and the specific documentation that is associated with this unique lot number.

SOP Title: Assigning and Requesting Lot Numbers for Product
SOP Number: 21405
Revision: 06

4. RESPONSIBILITIES

- 4.1 Director of Regulatory Compliance
 - Defines this procedure.
- 4.2 Quality Assurance (QA)
 - Implements this procedure.
 - Assigns lot numbers that are unique and maintains the database (found on BDP Public drive under BDP Database folder) of assigned lot numbers.
 - Provides quality oversight to this procedure.
 - Notifies requesting BDP personnel of completed lot number request.
- 4.3 BDP Managers/Supervisors
 - Trains staff in this procedure.
 - Determines the type of lot number to be requested (i.e., GMP, Tox lot, split lots, etc.)
- 4.4 BDP Personnel
 - Requests lot numbers prior to initiating production operations.
- 4.5 Biopharmaceutical Quality Assurance Documentation (BQAD)
 - Issues batch production records with the assigned lot number
 - Notifies requesting BDP personnel of completed Lot Number/BPR request

5. DEFINITIONS

- **Lot Number** – A unique number that identifies each specific batch of product or material used in or produced from a cGMP or Good Laboratory Practices (GLP) process or production.
- **Split Lot** – A lot which is divided into two or more portions which are treated differently, either in purification, filling, labeling, etc. Any portion of a lot that is treated differently is considered a split lot and must receive its own unique lot number or lot number suffix.

SOP Title: Assigning and Requesting Lot Numbers for Product
SOP Number: 21405
Revision: 06

6. PROCEDURE

6.1 Requesting Product Lot numbers.

6.1.1 Before a lot number can be assigned, a part number must be issued for GLP and GMP items. See **SOP 21902 - Requirements for Establishing Part Numbers and Specifications for BDP Components and Materials**.

6.1.2 Send requests for assignment of lot numbers via email to the QA Compliance Outlook email inbox (NCIFBQACompliance@mail.nih.gov) using **Form 21405-01, Request for Lot Number**. This form can also be used to request a batch production record (BPR) at the same time as requesting a lot number. Refer to **SOP 21923 – Control and Issuance of Batch Production Records for Use in Manufacturing** for BPR requests. Send information at least two working days in advance of needing the lot number.

6.1.3 Form 21405-01, **Request for Lot Number/Batch Production Record**, captures the following information:

- Name of Requestor
- Date of request
- Batch Production Required (BPR) selection
- Lot number needed by date
- BPR needed by date (if applicable)
- Part number (if applicable)
- Product Name
- Project number
- BPR request Table that includes: (if applicable)
 - Lot# order
 - MPR Number
 - Title of MPR
 - Paper Type (Refer to **SOP 21923**)
- Lot number assigned previously to starting material (if applicable)
- Type of product/process (R&D, GLP, GMP, other)
- Note box (if applicable)
- The QA and BQAD lot number/BPR request fulfillment box.

6.1.4 Lot numbers must be issued prior to the manufacture of the material receiving the lot number.

BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

SOP Title: Assigning and Requesting Lot Numbers for Product
SOP Number: 21405
Revision: 06

6.2 Lot Numbers

Lot numbers are not duplicated. Lot numbers are assigned as follows:

The lot number is an 8-character code composed of the letter “L”, the last two digits of the calendar year the number was assigned, the month (2 digits), and a three-digit sequential number. For example: L2304001.

L for lot number; 23 is the year 2023, 04 is the month of April, and 001 is the number sequence. (First lot number assigned in April of 2015.)

Additional suffixes can be added, refer to the table of suffixes in step 6.4.

6.3 A new lot number or lot number suffix must be assigned to split lots within a given production batch and for reworked lots.

6.4 Lot numbers are assigned to identify the following (the list below is not inclusive).

- Accession Banks (ACB)
- Master Cell Banks (MCB)
- Working Cell Banks (WCB)
- End of Production (EOP) Cell Banks
- Intermediate Bulk
- Purified Bulk
- Final Vialled Products
- Toxicological Lots
- Research and Development (For external distribution or at the discretion of the Project Scientist)
- Pilot Production Runs
- Practice Runs
- Validation Runs
- Bioreactor Harvests
- Fermentation or Cell Culture Harvest
- Reference lots
- Conditioned medium to be stored for later use

NOTE: Intermediate product and other biological material that are the subject of a request for external distribution of product must be assigned a lot number. This does not include analytical samples or R&D materials.

Lot number suffixes are comprised of an alpha character or symbol to differentiate sublots or restricted use of a portion of a lot of product. A new lot number may be issued to sublots if it is more appropriate to do so for a particular situation. Suffixes are usually assigned as follows (other

BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

SOP Title: Assigning and Requesting Lot Numbers for Product
SOP Number: 21405
Revision: 06

characters than those listed may also be used if adequately defined in the batch record).

Suffix	Description
T	Either an entire lot or portion of a clinical lot to be used for specifically for Toxicological studies only
R	Designation for a Reworked lot or for a portion of a lot that is reworked
A	First subplot
B	Second subplot
X (etc.)	Additional sublots (excluding R and T)
RD	Research and Development lot

For example: L2304001T

- L for lot number; 23 is the year 2023, 04 is the month of April, and 001 is the number sequence. (First lot number assigned in April of 2015.)
- T is for toxicological studies

6.5 The lot number requester will be informed of the lot number assigned via e-mail by QA. (Refer to Section 7 for assigning a lot number)

6.6 Unused Lot Numbers

When a lot number is assigned to a production run and then that run is not performed using that lot number, the blank or partially completed production record must be returned to BQAD as soon as possible. That lot number may not be reissued.

6.7 Aborted Runs

If a lot number is assigned to a run and the run is aborted, the blank or partially completed production record with the lot number must be returned to QA as soon as possible. Lot numbers may not be reassigned.

BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

SOP Title: Assigning and Requesting Lot Numbers for Product
SOP Number: 21405
Revision: 06

7. DOCUMENTATION AND RECORDS

- 7.1 After receipt of Form 21405-01 Request for Lot Number/Batch Production Record, QA will review the form to ensure all required information is present.
- 7.2 QA maintains a master list of all lot numbers assigned. The master list is located on BDP Public under the BDP database folder. It is accessible to BDP staff as “read-only”. The information in the master list includes:
- Lot Number
 - Description of the product
 - Project Number
 - MPR numbers (if applicable)
 - Part Number (if applicable)
- 7.3 **Form 21405-02, Biopharmaceutical Development Program SEQUENTIAL Assignment of Lot Number**, captures the following information:
- Date of request
 - Name of person requesting lot number
 - Part number (if applicable)
 - Lot number assigned.
 - Master Production Record Number (if applicable)
 - Title of Master Production Record (if applicable)
 - Name of Person Issuing the lot number
 - Date lot number issued.
 - Database Entry by/Date
 - Type of batch record: R&D, GLP, GMP, or validation
 - Comments (usually includes BDP project number and product name)
- 7.4 Lot numbers are not provided until the information identifying the product or material has been entered into **Form 21405-02**.
Form 21405-02 is electronically saved to 6QA/QAOnly/BQAD/Lot Number Issuance folder.
- 7.5 After the completion of **Form 21405-02**, QA will complete the “For BQA Use Only” table on **Form 21405-01**.
- Part Number
 - Lot Number
 - BPR Number
 - Lot Number Assigned by/Date:



BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

SOP Title: Assigning and Requesting Lot Numbers for Product
SOP Number: 21405
Revision: 06

- 7.6 QA sends the link for **Form 21405-01** to BQAD (NCIBDPQAD@mail.nih.gov) for BPR issuance and completion of the “For BQAD Use Only” Table.
- Revision issued.
 - Tracking number
 - BPR issued by/Date.
 - Final BPR Issuance By/Date
- 7.7 **Form 21405-01** is electronically saved to 6QA/QAOnly/BQAD/Lot Number Issuance folder.

8. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
15106	Assignment of Part Numbers and Lot Numbers for Solutions, Buffers, and Reagents
20302	Receipt and Inspection of Materials
21405-01	Request for Lot Number
21405-02	Biopharmaceutical Development Program SEQUENTIAL Assignment of Lot Number
21418	Control and Request of Documents/Records
21923	Requirements for Establishing Part Numbers and Specifications for BDP Components and Materials
21923	Control and Issuance of Batch Production Records for Use in Manufacturing