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## Title: Assigning and Requesting Lot Numbers for Product

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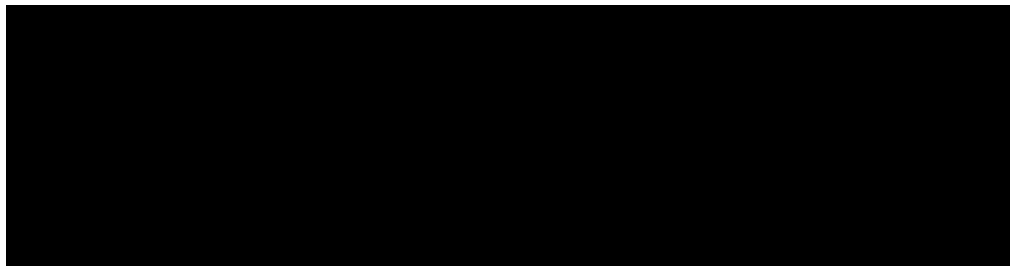
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#### 1.0 Purpose

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

#### 2.0 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**.

Part numbers, rather than lot numbers, are used to identify the type of product being produced, see **SOP 21902 - Requirements for Establishing Part Numbers and Specifications for BDP Components and Materials**.

**Overview:** 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 from Biopharmaceutical Quality Assurance/Regulatory Affairs (BQA/RA) (or designee) by sending an email to the BQAD Outlook in-box. Assignment of lot numbers is made by BQA/RA (or designee) 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.

### 3.0 Authority and Responsibility

- 3.1 The Director of Biopharmaceutical Quality Assurance (BQA) has the authority to define this procedure.
- 3.2 Biopharmaceutical Quality Assurance is responsible for the implementation of this procedure.
- 3.3 BDP Managers/Supervisors are responsible for ensuring that their staff is trained in this procedure and for reporting this training to BQA.
- 3.4 BDP personnel are responsible for requesting lot numbers prior to initiating production operations.
- 3.5 BQA/RA, or designee, is responsible for assigning lot numbers that are unique and maintaining the lot number database ( [REDACTED] ) of assigned lot numbers and the QA lot number binder.
- 3.6 BQA is responsible for quality oversight of this procedure.

### 4.0 Definitions

- 4.1 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.
- 4.2 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.

### 5.0 Procedure

- 5.1 Requesting Product Lot numbers.

- 5.1.1 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**.
- 5.1.2 Send requests for assignment of lot numbers to the BQAD Outlook email inbox using **Form 21405-01, Request for Lot Number (Attachment 1)**. The current form can be found at [REDACTED]. Send information at least two working days in advance of needing the lot number.
- 5.1.2.1 This **Form 21405-01** can also be used to request a batch production record (BPR) at the same time as requesting a lot number (refer to **SOP 21418 - Control and Request of Documents/Records** for BPR requests.)
- 5.1.3 Emergency requests for lot numbers may initially be sent via e-mail to the BQAD Outlook In-box.
- 5.1.4 Telephone requests for lot numbers will not be honored. Submit **Form 21405-01, Request for Lot Number**, via e-mail (see section 5.1.2 above) or paper copy as soon as possible prior to the manufacture of the material receiving the lot number.
- 5.1.5 BQA/RA (or designee) notifies the requester by email of the lot number to be assigned.
- 5.2 Assignment of Lot Numbers
- 5.2.1 Lot numbers may not be duplicated.
- 5.2.2 Lot numbers are assigned as follows:
- The lot number is an 8-digit 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: L1504001.
  - L for lot number; 15 is the year 2015, 04 is the month of April, and 001 is the number sequence. (First lot number assigned in April of 2015.)
- 5.3 A new lot number or lot number suffix must be assigned to split lots within a given production batch and for reworked lots.
- 5.4 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.

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

T	Portion of lot to be used for Toxicological studies prior to official release of the lot for clinical use
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
‘(prime)	Second labeling of a remaining portion of the same lot of product
“(double prime)	Third labeling of a remaining portion of the same lot of product
RD	Research and Development lot

For example: L1504001T

- 5.5 The lot number requester will be informed of the lot number assigned via e-mail.

5.6 Unused Lot Numbers

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

## 5.7 Aborted Runs

- 5.7.1 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 BQA as soon as possible. Lot numbers may not be reassigned.

## 6.0 Documentation

- 6.1 BQA/RA (or designee) maintains a master list of all lot numbers assigned and records lot numbers and information describing the product to which the lot number pertains on **Form 21405-02, Biopharmaceutical Development Program SEQUENTIAL Assignment of Lot Number (Attachment 2)**, and then into the lot number database which is on found on BDP Public under the BDP\_database folder. It is accessible to BDP staff as “read-only.”

- 6.1.1 Form 21405-02, Biopharmaceutical Development Program SEQUENTIAL Assignment of Lot Number, (Attachment 2) captures the following information:

- Date of request
- Name of person requesting lot number
- Part number (if applicable)
- Lot number assigned
- Production Record Number (if applicable)
- Title of Production Record (if applicable)
- Name of Person Issuing the lot number
- Date lot number issued
- Database Entry by/Date
- Whether the process is R&D, GLP, GMP, or for validation work
- Any Comments

- 6.1.2 Lot numbers will not be provided until the information identifying the product or material has been entered into Form 21405-02 (see the example on **Attachment 2**).

- 6.1.2.1 The electronic version of Form 21405-02 will be obtained from the OnLine forms folder on the BDP Public drive under the 6QA folder each time a new form is required. It will be placed in a [REDACTED] [REDACTED] for limited access for QA personnel only.

- 6.1.2.2 QA personnel will assign lot numbers by filling out Form 21405-02 electronically and saving the form to [REDACTED].

- 6.1.2.3 Once all rows of Form 21405-02 are completed, the QA/RA person completing the form will print a hard copy and place the completed form in the QA lot number binder. Completed electronic forms will be kept in the BQAD folder.

## 7.0 References and Related Documents

- 7.1 **SOP 15106** *Assignment of Part Numbers and Lot Numbers for Solutions, Buffers, and Reagents*
- 7.2 **SOP 20302** *Receipt and Inspection of Materials*
- 7.3 **SOP 21902** *Requirements for Establishing Part Numbers and Specifications for BDP Components and Materials*
- 7.4 **SOP 21418** *Control and Request of Documents/Records*

## 8.0 Attachments

- 8.1 **Attachment 1** *Request for Lot Number Form 21405-01*
- 8.2 **Attachment 2** *Sequential Assignment of Lot Number Form 21405-02*

**Attachment 1****Form 21405-01, Request for Lot Number/Batch Production Record**

FNLCR, BDP  
Form No.: 21405-01  
SOP No.: 21405  
Revision 05: FEB 11 2020

**Request for Lot Number/Batch Production Record**

Requestor: \_\_\_\_\_ Date: \_\_\_\_\_ Batch Production Record Required: ☐ Yes ☐ No  
Date Lot Number Needed \_\_\_\_\_ Date BPR Needed \_\_\_\_\_ Part Number Assigned: \_\_\_\_\_  
(Use Notebook Number and Page Number for R&D Projects)  
Product Name: \_\_\_\_\_ Project Number: \_\_\_\_\_

Number and Title of Production Record: (Must have Number, Title and order of lot number)

Lot # Order	MPR Number	Title of MPR	Paper Type
			Clean Room
			Clean Room
			Clean Room
			Clean Room
			Clean Room
			Clean Room

Lot Number Assigned Previously to Starting Material:

This material was received from: (Example – Material received from Recovery, Outside Organization, etc. Lot Number of Vendor)

Please complete the following.

This Product/Process is: ☐ R&D ☐ GLP (ie. Tox Lot) ☐ GMP ☐ Other

NOTE: Please provide more detail/comments if necessary. (Explain if several BPR's need same lot number)

**For BQA Use Only**

Part Number	Lot Number	BPR Number

Lot Number Entered Database by/Date

Lot Number Assigned By/Date

## Attachment 2

### Form 21405-02, SEQUENTIAL Assignment of Lot Number

FNLCR, BDP  
Form No.: 21405-02  
SOP No.: 21405  
Revision 05: FEB 11 2020

#### Biopharmaceutical Development Program SEQUENTIAL Assignment of Lot Number

Product Name	Lot Number	Batch Number	Manufacture Date	Expiry Date	Product Description	Lot Number	Batch Number	Manufacture Date	Expiry Date	Product Description
112A>112020	12:WS	RD	Steil@F1tra1ion Pmlocol	D2101121120	02/01/2020	R&D				
112m'211211	56789	MPft-sc-l)S9	Va l Ulbefing Protoa,j	D2102121120	02/02/2020	Gt.IP				
						R&D				
						R&D				
						R&D				
						R&D				
						R&D				