Title: Requirements for Establishing Part Numbers and Specifications for BDP Components and Materials

SOP Number: 21902 Revision Number: 06

Supersedes: Revision 05 Effective Date: JAN 24 2019

Originator/Date: [redacted]

Approval/Date: [redacted]

Approval/Date: [redacted]

Table of Contents

1.0 Purpose

This SOP defines the standards for assigning part numbers and specifications to Biopharmaceutical Development Program (BOP) materials and components.

2.0 Scope

This SOP is applicable to BOP personnel who will request part numbers and establish specifications for raw materials/components.

3.0 Authority and Responsibility

3.1 The Program and Technical Director, BOP has the authority to define this procedure.

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [redacted]

3.2 BDP personnel are responsible for:

3.2.1 Initiating Part Number (PN) Requests and determining the Master Specifications (MS).

3.2.2 Completing the Part Number and Master Specification Request Forms, in their entirety, and obtaining approvals.

3.2.3 Working with Process Analytics/Quality Control (PA/QC) and Biopharmaceutical Quality Assurance (BQA) to set acceptable quality standards and tests for each component/material used.

3.2.4 Supplying the information necessary to properly determine the classification of the item. Accurate classification determines the part number assigned by the PN/MS program.

3.2.5 Specifying materials from non-animal sources when available. If the component or material is of animal origin, refer to ***SOP 21106 - Certificate of Origin Policy for Raw Materials/Components Used at the BDP*****,** for guidance on obtaining a Certificate of Origin (COO) for the material.

3.3 Process Analytics/Quality Control (PA/QC) is responsible for review and approval of the Master Specifications.

3.4 BQA is responsible for:

3.4.1 Review and approval of the part number requests and Master Specifications.

3.4.2 Recording receipt of the approved PN/MS form to permit entry into the pcMRP database, scanning the approved form onto BDP Public.

3.4.3 Maintaining the Part Number/Master Specification master files.

3.4.4 Quality oversight of this procedure.

4.0 Definitions

4.1 **Certificate of Analysis (COA**): A document relating specifically to results of testing of a representative sample drawn from the lot or batch of material to be delivered or purchased.

4.2 **Certificate of Conformance (COC)**: A document that specifies the quality parameters that the material was manufactured against**.**

4.3 **Certificate of Origin (COO**): A document provided by the material/component manufacturer for all constituents used in the manufacture of the material/component, identifying whether the constituents are of animal origin. If the constituents are of animal origin, the manufacturer must provide the country of origin and the source of the constituents. Materials/components requiring a COO are identified in ***SOP 21106 - Certificate of Origin Policy for Raw Materials/Components Used at the BDP***.

4.4 **Certificate of Sterilization/Certificate of Irradiation (COS/COI**): A document from a sterilization/irradiation facility that attests that a specific lot of product received a listed type and dose of sterilization/irradiation.

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [redacted].

4.5 **Master Specification (MS**): The document that defines the quality parameters to which the materials or components must conform and which serves as a basis for quality evaluation.

4.6 **Part Number (PN**): A unique five-digit number that is assigned by the PN/MS program outlined in ***SOP 21903 - Using the Part Number/Master Specification Program to Establish Raw Material Part Numbers and Master Specifications***.

4.7 **Component**: An item with independent functionality that is a constituent part of a piece of equipment (i.e., a pressure gauge, pH probe).

4.8 **Material**: Any unprocessed product used in manufacture (raw material); final product resulting from manufacture.

4.9 **Inspection Levels**

4.9.1 **Inspection Level A**: Requires receipt inspection (per ***SOP 20302 - Receipt and Inspection of Materials***) only.

4.9.2 **Inspection Level B**: Requires receipt inspection and a lot-specific certification such as a COA/COC stating that the material meets the criteria in the specification.

4.9.3 **Inspection Level C**: Requires receipt inspection; lot-specific certification such as a COA/COC stating that the material meets the criteria in the specification; visual inspection (unless material is hazardous or not able to be inspected without compromising quality); and requires an identification test on each shipment received, if appropriate.

4.9.4 **Inspection Level D**: Requires receipt inspection, lot-specific certification such as a COA/COC stating that the material meets the criteria in the specification; visual inspection (unless material is hazardous or not able to be inspected without compromising quality); requires an identification test (if appropriate) and/or additional analytical tests on each shipment received as listed on the approved specification.

4.9.5 **Inspection Level E**: Reserved only for items that have been assigned a National Drug Code (NDC) number. Requires receipt inspection (per ***SOP 20302 - Receipt and Inspection of Materials***), and the container must be labelled with a NDC number, which is also verified and recorded at the time of inspection.

4.9.6 **Inspection Level F**: Reserved for unique raw materials that are not easily classified into Inspection Levels A – E. Level F items may include product-specific cell banks, viral banks, plasmids, etc., obtained from an external source. A COA may or may not be available. Level F items require submission of the COA and/or other supporting documentation to QA and PA/QC for inspection and evaluation as to whether any additional testing is required or if the existing COA/documentation is sufficient to release the material for use.

NOTE: Part Numbers that are requested for materials produced internally by the BDP are not assigned an Inspection Level, as indicated in the table in Section 5.1.

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [redacted].

4.10 **Manufacturer**: A person or business engaged in manufacturing, preparing, propagating, compounding, processing, packaging, or labeling of a desired commodity.

4.10.1 **Primary Manufacturer**: The preferred manufacturer listed on the PN/MS.

4.10.2 Secondary Manufacturer**: An approved alternate manufacturer. The distinction between the Primary and Secondary Manufacturer may be based on manufacturer history, product support, quality of product, and supporting documentation, etc. See *SOP 21109 - Supplier Qualification Program***.

4.11 **Supplier/Distributor**: A person or business engaged in the distribution of products from a manufacturer.

NOTE: Suppliers will not routinely be listed on the PN/MS. They will be listed if the manufacturer is not known. Listing the manufacturer rather than the supplier will allow material from either of the specified manufacturers to be ordered from any supplier.

4.12 **Part Classifications:**

4.12.1 10,000: Raw materials such as chemicals, resins, cell culture media and cell/virus banks used for GMP manufacturing. All raw materials that fall into this category are used for GMP.

4.12.2 20,000: Equipment parts, components, product contact disposables such as pipettes, tubing, vials, plastic ware, labels and filters.

4.12.3 30,000: PA/QC raw materials, raw materials used for R+D, reference standards, or Toxicology products. **Materials within this classification may not be used in GMP manufacturing**.

4.12.4 40,000: In-house buffers and solutions only.

4.12.5 50,000: Products (in-process bulk or final) only. In process cell banks such as End of Production banks. Virus and cell banks used as a final product fall under this classification.

4.12.6 70,000: Miscellaneous items such as charts, batteries, freezer boxes and biohazard bags.

NOTE: In some cases, an item may be assigned two different classification part numbers such as 10,000 and 30,000. There are different release criteria for each classification. If the material is intended for GMP, the 10,000 number must be used. If the item is used strictly for PA/QC the 30,000 number must be used.

5.0 Part Numbers

5.1 Determining Classifications

5.1.1 Materials are classified based on their description and intended use. A part number must be assigned to any raw material used by Process Analytics and GMP manufacturing.

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [redacted].

5.1.2 The minimum inspection level represents the minimum requirements for each classification. BQA may, at its discretion, apply higher levels or additional requirements to particular items on an as-required basis.

Description	Minimum Inspection Level	PN Classification
Eauioment oarts/comoonents	A	20000
Non-oroduct contact disoosables	A	20000
Product contact disoosables		
Pipettes	A	20000
Tubing	B	20000
Containers, sterile (bottles)	A	20000
Media bags	B	20000
Growth vessels	A	20000
Filters	B	20000
Manufacturina materials		
Growth media	0	10000
Chemicals	C	10000
Resins	B	10000
Final product vials	0	20000
Labelina	0	20000
Items assianed a NOC number	E	10000
Externally obtained, project-specific plasmids, peptides, etc.	F	10000
In-house solutions and buffers	N/A	40000
Cell/virus banks		
BOP manufactu red/subcontracted cell/virus banks	N/A	10000
Externally-obtained cells/viruses (non-product-specific)	B	10000
Externally-obtained cells/viruses (product-specific)	F	10000
PA materials		
PA reaaents/media/enzvmes/supplies	A	30000
PA standards/controls	B	30000
Media plates	0	30000
Resins	B	30000
Products (process banks, in-process bulk or final)	N/A	50000
Miscellaneous	Item-specific	70000

This procedure is made avaliablethrough federal funds from the National Cancer Institute, NIH, under contract [redacted]

5.2 Issuance and Control of Part Numbers

5.2.1 Part Numbers are assigned automatically by the PN/MS Program.

5.2.2 Part Numbers are not reassigned.

5.2.3 A Part Number may be obsoleted, by submitting Form 21419-01, Document Control Record. BQA will document the deletion of the PN and its associated specification, if one exists for that item, per ***SOP 21419 - Origination, Modification, and Approval of Documents***. The part number will then be deleted from the PN/MS program by BQA.

5.2.4 Storage Requirements:

5.2.4.1 Controlled Room Temperature (15 to 30°C).

5.2.4.2 2 to 8°C.

5.2.4.3 -10 to -30°C

5.2.4.4 ≤-70°C

5.2.4.5 Liquid Nitrogen Vapor Phase (LN2)

5.2.4.6 Storage under non-specific conditions (Ambient) – For components/ materials with no specific vendor storage directions or limitations, it is understood that conditions of storage and distribution include protection from moisture, freezing, and excessive heat.

5.2.5 Shelf Life: Each component/material lot shall receive an assigned shelf life as follows.

5.2.5.1 If the manufacturer has assigned a shelf life, components and materials will be assigned the same shelf life. Inspection level E items have a vendor-assigned shelf life. Inspection level F items are assigned a shelf life, if appropriate, by QA after review of the documentation accompanying the item.

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [redacted].

5.2.5.2 If the manufacturer does not assign a shelf life, follow the guidelines in the table below to determine the shelf life.

Material	Shelf Life
Chemicals	
Non-hygroscopic salts	4 years
Other	3 years
Plasticware/Paperware	
Sterile	3 years
Other	6 years
Growth Media and Media Components	
Liquid: 2-8°C storage	1 year
Liquid: Frozen	4 years
Dry	2 years
Glassware	
Sterile	3 years
Other	N/A
Resins	
Affinity	2 years
Other	4 years
Buffers/Solutions	1 year

6.0 Master Specification

6.1 Issuance and Control of Component/Material Master Specifications

6.1.1 A specification form must be filled out for components and materials designated with inspection levels B, C, or D.

6.1.2 A Master Specification is initiated through the PN/MS program found on BDP Public at H:\BDP_database\partspecs\prg

6.1.3 The requestor, in consultation with PA, completes the MS form.

6.1.4 Provide a copy of the vendor specifications, COA or COC, or COS/COI as appropriate.

6.1.5 When a MS is signed off, a copy will be scanned to a BQA only accessible folder on BDP Public and the original will be kept with BQA.

NOTE: An approved MS is required before orders can be placed for the material.

6.2 Master Specification Form, Part A: Part Number Information

6.2.1 Release Requirements: Release requirements shall be the following, unless otherwise modified in ***SOP 21109 - Supplier Qualification Program.***

6.2.1.1 Inspection Level B items: certificate inspection, no testing required.

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [redacted].

6.2.1.2 Inspection Level C and D items: certificate inspection plus additional testing as specified.

6.2.2 For chemicals, provide the Grade, Chemical Abstracts Service (CAS) Number, Chemical Formula and Formula Weight.

6.2.3 For other components/materials, provide Composition and Size. In this case, size refers to **dimensional specifications of the component/ material**.

6.2.3.1 Material will be assigned a BDP expiration/retest date as part of the release/approval process in ***SOP 20302 – Receipt and Inspection of Materials*** using the guidance in ***SOP 22714 - Sampling, Testing, and Review of CGMP Materials by Process Analytics/Quality Control***.

6.3 Shelf-life Extension Requests

6.3.1 Materials not assigned an expiry date by the vendor or with a BDP expiration shorter than the manufacturer may have their shelf life extended by submitting **Form 21902-01, Request for Extension of Material Shelf Life**, to BQA. If material in unopened containers remains after the original assigned shelf life, the material may be retested based on its specifications or the modified testing listed **on Form 21902-01**. Containers that have been opened for just PA sampling are also included as unopened containers. If the material conforms to these specifications, then a new (extended) shelf life may be assigned that is no more than half of the original assigned shelf life. This process may be performed once. If the material does not meet specifications, it is rejected.

6.4 Master Specification Form, Part B: Manufacturer's Test Verification

6.4.1 Provide a list of the manufacturer's tests and specifications to be verified for release of each shipment of the component/material. These tests are found on the documentation that accompanies each shipment of material, such as the COA, COC, or COI or other vendor supplied documentation as appropriate. The tests and their specifications listed in Part B will be compared to the data obtained from the appropriate documentation (COA, COC, etc.).

NOTE: Indicate if the Vendor's certificate has a signature.

6.4.2 If the grade of the material is United States Pharmacopeia (USP), take the tests and specifications from the current USP. If the grade of the material is American Chemical Society (ACS), take the tests and specifications from the current ACS Reagent Chemicals book. Both books are available in BQA.

6.5 Master Specification Form, Part C: In-House Sampling and Testing Instructions

6.5.1 Provide sampling instructions (sample and retention sample holding period) based on requirements outlined **in *SOP 22714 - Sampling, Testing, and Review of CGMP Materials by Process Analytics/Quality Control***.

6.5.2 Safety instructions: If included on the MS, safety equipment other than a BSC and Personal Protective Equipment (PPE) is mandatory during sampling.

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [redacted].

6.5.3 Additional required testing (for C and D items): List the required test, procedure to be followed (i.e., SOP number) and specifications in the table in Part C of the MS.

7.0 References and Related Documents

7.1 **SOP 21106** *Certificate of Origin Policy for Raw Materials/Components Used at the BDP*

7.2 **SOP 21903** *Using the Part Number/Master Specification Program to Establish Raw Material Part Numbers and Master Specifications*

7.3 **SOP 20302** *Receipt and Inspection of Materials*

7.4 **SOP 21109** *Supplier Qualification Program*

7.5 **SOP 21419** *Origination, Modification, and Approval of Documents*

7.6 **SOP 22714** *Sampling, Testing, and Review of CGMP Materials by Process Analytics/Quality Control*

8.0 Attachments

8.1 **Form 21902-01** Request for Extension of Raw Material Shelf Life

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [redacted].

Attachment 1

Form 21902-01, Request for Extension of Raw Material Shelf Life

FNLCR, BDP
Form No.: 21902-01
SOP No.: 21902
Revision 06: JAN 24 2019

Request for Extension of Raw Material Shelf Life

Raw Material Information:

Raw Material Description: _____ BDP PN: _____

BDP Lot Number (R#):_____ Manufacturer's Lot Number: _____

Current Expiration Date: _____ Material Shelf Life: _____

Package Size: _____ Number of Units to be extended: _____ (un-opened containers)

Extension Request:

Requested Extended Expiration Date: _____ (max of half original assigned expiry date)

Requester (Print or Type name): _____ Date of Request: _____

BDP Department: _____

Project Number (if applicable): _____ MPR Number (if applicable): _____

SOP Number (if applicable): _____

Assays to be conducted to support extension:

A current copy of the Specification Sheet and MMIC Release Documents for the lot affected must accompany this request form.

Select Option:

☐ Repeat Process Analytics/Quality Control assays per Master Specification Sheet

☐ Conduct Modified PA/QC assays as described below (include justification for modified testing):

_____

_____

_____

Requester/Date: _____

Approvals

Supervisor or Project Scientist/Date: _____

Process Analytics Management/Date: _____

Quality Assurance Management/Date: _____

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [redacted].