Standard Operating Procedure

Title: Distribution of Cell Lines Maintained in Bioanalytical Development and Process Analytics Laboratories to Other Laboratories

SOP Number: 16129 **Revision Number: 02**

Supersedes: Revision 01 **Effective Date: FEB 14 2011**

Originator/Date: [redacted]

Approval/Date:

Approval/Date:

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1.0 Purpose

This procedure outlines the distribution of cell lines maintained in Process Analytics (PA) and Bioanalytical Development (BD) to non-PA/BD Laboratories within the BDP.

2.0 Scope

This procedure applies to the distribution of cell lines (from R &D and GMP assay cell banks) in use, and maintained under the control, of BD and PA testing laboratories. This SOP does not apply to cell lines that are maintained under control of BDP cGMP Cell Culture Laboratories.

Note: This SOP does not pertain to the distribution of cells which are submitted to PA for the growth and production of accession banks or the growth of cells to produce samples for testing in-house or by outside contractors.

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract HHSN261200800001E.

3.0 Authority and Responsibility

3.1 The Director, Process Analytics (PA), has the authority to define this procedure.

3.2 BD/PA are responsible for training laboratory personnel and documenting this training to Biopharmaceutical Quality Assurance (BQA).

3.3 PA/BD personnel are responsible for the performance of this procedure.

3.4 PA/BD personnel are responsible for reviewing the data and documentation of the results of this procedure.

3.5 The Head of the requesting laboratory is responsible for the control of cell lines provided to the R&D laboratory. Cells obtained from BD/PA cell lines are not intended for use in work leading to, or related to cGMP manufacturing (e.g., derivation of seed stocks, production of toxicology materials, etc).

3.6 BQA is responsible for quality oversight of this procedure.

4.0 Rationale and Segregation of BD/PA Testing Cell Lines

The cells in use and controlled by the BD/PA Testing Laboratories are not intended for use in cGMP production of products. The following procedure will be used to control the distribution cells from BD/PA Laboratories when requested.

5.0 Procedure

5.1 Distribution of cells among BD/PA testing laboratories will be properly documented on cell culture log sheets according to **SOP 22140**, ***Mammalian Cell Culture - Initiation and Maintenance of Cell Cultures in BQC***.

5.2 Distribution of cells to Non-BD/PA laboratories

Cell cultures within the BD/PA laboratories which are being maintained for use in assays are usually not shared with R&D laboratories for projects linked to a cGMP manufacturing process. However, should a request be made for the use of a BD/PA cell line, the following procedure will be followed.

5.2.1 The head of the R&D laboratory (Project Scientist) makes a written request using Form 16129-01 for distribution of cells from BD/PA. The PA Director authorizes the distribution of cells to the requesting laboratory.

5.2.2 The BD/PA Laboratory providing the cells clearly narrates the source of the cells on the distribution form (origin/passage history). Documentation of the transfer of cells will be made on the cell culture form (22140-01). A copy of the requesting document will be kept in the cell line passage book. If requested, a copy of the passage history of the cell may be made for the requesting laboratory (Form 22140-01).

6.0 Documentation

6.1 Maintain records in laboratory notebooks or SOP record forms. Each page is numbered, dated and initialed as per **SOP 21409*, Good Documentation Practices*** and **SOP 21408*, Laboratory Notebooks – Control and Use*.**

6.2 Record data for cell subcultures on Form 22140-01, and medium formulation on Form 22140-02, as per **SOP 22140*, Mammalian Cell Culture - Initiation and Maintenance of Cell Cultures in BQC*.** The complete Form 16129-01 will be submitted to BQAD for filing. Copies of the form may be made by BD/PA or requesting laboratory as needed.

7.0 References and Related Documents

7.1 **SOP 21408** *Laboratory Notebooks – Control and Use*

7.2 **SOP 21409** *Good Documentation Practices*

7.3 **SOP 22140** *Mammalian Cell Culture - Initiation and Maintenance of Cell Cultures in BQC*

8.0 Attachments

8.1 **Attachment 1** Form 16129-01, Request for Cells from BD/PA Laboratory

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract HHSN261200800001E.

Attachment 1

NCI-Frederick
SOP No.: 16129
Form No.: 16129-01
Revision 02:

Request for Cells from BD/PA Laboratories

Requesting Laboratory: _____

Cell Line required: _____

Intended Use: _____

_____

NOTE: Cells obtained from BD/PA are not intended for use in work leading to, or related to, cGMP manufacture (e.g., derivation of seed stocks, production of toxicology material, etc.).

Approvals:

Title	Printed Name	Signature	Date
Head of Requesting Laboratory			
BD/PA Laboratory Director			

Cell line: _____

BDP PN (if assigned): _____

Lot Number: _____

Project Number (if assigned): _____

Date of thaw: _____ Passage # at thaw: _____

Source (Bldg #, Room #): _____

Passage #: _____

Obtained from (personnel): _____ Date: _____

Received By: _____ Date: _____

NOTE: Submit completed form to BQAD.

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