Title: Qualification of Mammalian Cells and Cell Banks for PA/QC Use

SOP Number: 22703 **Revision Number: 01**

Supersedes: Revision 00 **Effective Date:** JAN 2 6 2016

Originator/Date: [redacted]

Approval/Date:

Approval/Date:

Table of Contents

1.0 Purpose

This procedure lists the test requirements for Mammalian Cell Banks utilized in Process Analytics/Quality Control (PA/QC) for specified testing of cells.

2.0 Scope

This procedure applies to Biopharmaceutical Development Program (BOP) PA\QC personnel responsible for preparation of mammalian cell banks for testing.

3.0 Autho rity and Responsibility

3.1 The Director, Director, Technical Operations, Process Analytics \Quality Control (PA/QC) has the authority to defines this procedure.

3.2 PA/QC personnel are responsible for the accurate performance of this procedure.

3.3 BOA is responsible for quality oversight of this procedure

4.0 Testing and Acceptance Criteria for Incoming Mammalian Cells for PA/QC Use

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

4.1 The required PA/QC tests for incoming mammalian cells prior to cell culture work are mycoplasma (Points to Consider and/or PCR-based methods) and microbial sterility. These two tests are the minimum requirements before the cells can be cultured by PA/QC staff in the PA/QC labs. Both tests are typically outsourced, although initial mycoplasma screening by PCR may be conducted in-house. After these tests are completed by BQA approved vendors, the formal QC test report will be reviewed by QC and approved by BQA.

4.2 Outsourced tests shall be performed by BQA approved qualified vendors whenever possible.

4.3 Incoming cell lines from other BDP groups (i.e. Manufacturing and Development) can be cultured, provided they have previously been documented to be sterile and mycoplasma free.

4.4 Cell lines obtained from audited CGMP or GLP-compliant facilities which have either a Certificate of Analysis or traceable, audited CGMP or GLP-compliant test results are treated differently. These cell lines do not need to be retested, provided these tests were performed in a qualified CGMP/GLP laboratory according to current technical "state-of-the-art" standards.

5.0 Testing and Acceptance Criteria of Mammalian Master and Working Cell Banks for PA/QC Use

5.1 Testing of Master Cell Banks for PA/QC Use.

5.1.1 The required and recommended QC tests for Master Cell Banks are mycoplasma (required), sterility (required), in vitro adventitious virus/agents assay, and genetic speciation/identity testing (e.g. Karyotyping, STR/CODIS, Isoenzyme, etc.). Other tests may be conducted following the requirements for mammalian cells for CGMP Manufacturing use (Refer to SOP 13200). These tests are performed in-house or may be outsourced.

5.2 Recommended Testing of Mammalian Working Cell Banks for PA/QC Use.

5.2.1 It is recommended that Working Cell Banks be qualified by testing for mycoplasma and sterility. A WCB may be created before testing on the MCB is complete but it cannot be used until the MCB testing has been completed and the MCB CoA is approved.

5.3 Outsourced tests shall be performed by BQA qualified vendors whenever possible.

5.4 Acceptance Criteria for Mammalian Master and Working Cell Banks

5.4.1 QC Master cell banks must be sterile, free of mycoplasma contamination. When adventitious virus assays tested, QC MCB lots must also be free of adventitious viral agents.

5.4.2 Working QC cell banks, when tested, must be shown to be sterile, free of mycoplasma contamination and, when adventitious virus assays tested, free of adventitious viral agents.

5.4.3 Identity testing must conform to the expected species specific identification.

6.0 Documentation

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

6.1 At the completion of testing and following review and acceptance by PA/QC and BQA, a Certificate of Analysis (CoA) will be issued for the cell bank, signed by PA/QC and BQA reviewers.

6.2 The CoA will specify that the bank is for “PA/QC use.”

6.3 Cell line CoAs will be retained in the BDP Public/APs-MSs-COAs sub-folder titled “QC Cell Lines.”

6.4 Cells are acceptable for PA/QC use upon approval of the CoA.

7.0 Definitions

7.1 **Master Cell Bank (MCB) –** An aliquot of a single pool, dispensed into multiple containers and stored under defined conditions. The MCB is used to derive working cell banks, or may be used directly in bioanalytical test methods.

7.2 **Working Cell Bank (WCB) –** The WCB is prepared from aliquots of a homogeneous suspension of cells obtained from culturing one or more vials of the MCB.

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