



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

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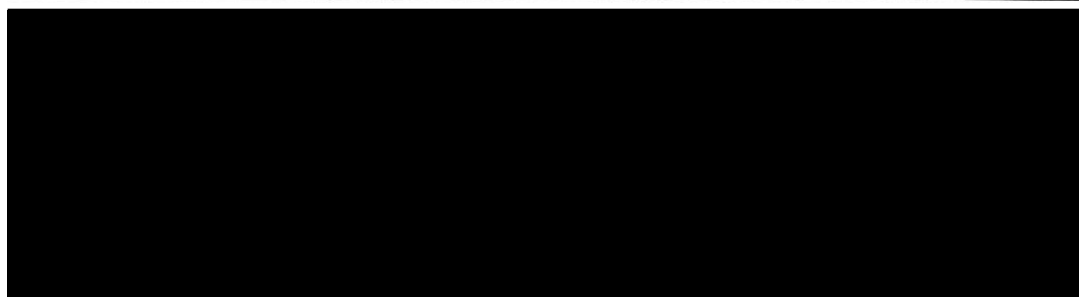


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1.0 Purpose

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 Authority 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

- 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

- 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.