

General Eukaryotic Cell Bank Screening

BioOutsource offers extensive capabilities in the characterization and safety testing of Master, Working and End-of-Production cell banks used in the manufacture of Biologics and Vaccines. Our team combines extensive scientific experience with current regulatory knowledge and provides our clients with a first class service.

GMP

BioOutsource is a GMP-compliant facility with all testing performed to GMP quality standards. The quality systems department takes a proactive approach throughout the life cycle of your project in order to provide you with complete compliance with all applicable EU and US GMP regulations.

BioWeb

BioOutsource is committed to forming open and transparent partnerships with our clients, and, with this end in mind, BioOutsource has developed a proprietary, web-based system which allows our clients transparent access to our laboratory operations.

Through the BioWeb, clients can access

- Relevant SOPs
- Study protocols
- Study reports, Certificates of Analysis via a secure, encrypted web portal.

The BioWeb technology has been developed to facilitate interactions between BioOutsource and our clients to ensure that as far as possible, clients can access the data and information that they want, when they want it.

Services Offered By BioOutsource

In some respects no two cell banks are alike and therefore the testing and characterisation requirements should be specific to the purpose of the bank. Testing cell banks requires a number of very different assays to be performed which when considered in total provide the requirements for the safety assessments required of the regulations. At BioOutsource we encourage sponsors to discuss their requirements with our scientists to reach an agreed package of tests.

Identity Testing and Characterisation

- DNA Fingerprinting – Human, Simian, Hamster, Mouse and Insect Cell Lines
- Isoenzyme analysis
- Direct Nucleic Acid Sequencing – mRNA and genomic DNA
- Insert Copy Number Determination
- Southern Blotting



Sterility

- Performed to US Code of Federal Regulations
- Performed to European Pharmacopeia Guidelines

Mycoplasma

- Performed to European Pharmacopeia Guidelines
- Performed to FDA "Points to Consider"
- PCR Detection of Mycoplasma to European Pharmacopeia Guidelines

Adventitious Agents

- *In vivo* adventitious agent testing
- *In vitro* 14 and 28 Day adventitious agent testing using Human, Simian (numerous species), Rodent, Avian, Bovine, Porcine, Feline, Rabbit and Horse cell lines.

Retrovirus testing

- *In vitro* mink and feline S+L- Assay for the detection of Xenotropic retrovirus
- *In vitro* XC assay for the detection of Ecotropic murine retrovirus
- Co-cultivation assay with *Mus dunni* cells for the detection of murine retrovirus
- Co-cultivation with Human 293 cells for the detection of "humantropic" retrovirus
- PCR- Based detection of Reverse Transcriptase Enzyme (PERT)
- Transmission Electron Microscopy

Species-Specific Testing

Bovine and Porcine

- Detection of Bovine viruses as presented in 9CFR and EMEA Guidelines
- Detection of *Bovine Polyoma* virus using quantitative PCR
- Detection of Porcine viruses as presented in 9CFR and EMEA Guidelines

Murine

- Detection of Murine viruses using Mouse Antibody Production Assay

- Detection of *Minute Mouse* virus using quantitative PCR

Hamster

- Detection of Hamster viruses using Hamster Antibody Production Assay

Simian

- *In vitro* techniques using RK-13 cells to detect Herpes B virus
- Detection of *Simian Immunodeficiency virus*, *Simian T-Lymphotropic virus*; *Simian Cytomegalovirus* and *SV-40 virus* using quantitative PCR

Human

- Detection of Human viruses using quantitative PCR: *Human Immunodeficiency virus*, *Human T-Lymphotropic virus*; *Hepatitis's A, B, C and E virus*; *Human Herpes virus type 6, 7 and 8*; *Cytomegalovirus*, *Epstein Barr virus*, *Human Polyomaviruses JC and BK*.

Sample Requirements

BioOutsource will work closely with sponsors to minimise the numbers of vials from a cell bank which are sacrificed to provide sufficient samples for the characterisation and safety testing.

Reporting of Results

The purpose of the testing of cell banks as described above is to provide sufficient data to demonstrate that the cells can be safely used to produce a product which can be used in human clinical trials. Each test carried out by BioOutsource will be individually reported in a Quality reviewed report. However the testing should be described in total in a summary report which will bring together all of the data and provide a scientifically justified conclusion. BioOutsource scientists can prepare or assist in the preparation of such summary reports. All reports and study documentation are available through the secure BioWeb application.