BioReliance

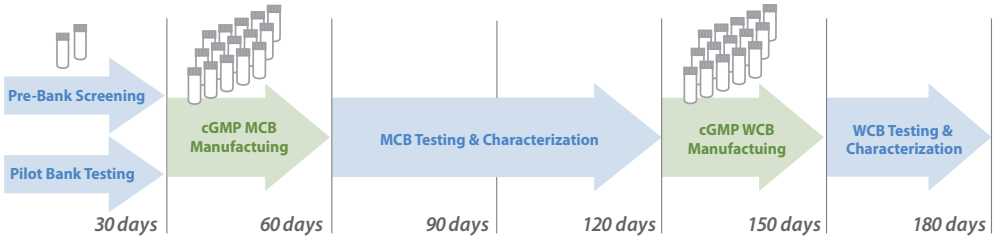
Biomanufacturing and Biologics Safety Testing

cGMP manufacturing and testing for CHOZN® cell lines

The CHOZN® Platform, developed by SAFC, is a CHO (Chinese Hamster Ovary) based cell expression system designed for accelerated selection and scale up of clones producing high levels of recombinant protein. Key to the CHOZN® Platform is the development of the CHOZN® ZFN (Zinc Finger Nuclease) modified cell lines (GS -/- and DHFR -/-) that allow for more rapid clone construction and selection.

In order to develop and manufacture clinical-grade and commercial product using the CHOZN® Platform, a cGMP compliant Master Cell Bank (MCB) and Working Cell Bank (WCB) (derived from a CHOZN® clone) must be manufactured and tested according to exacting regulatory standards. BioReliance, now part of SAFC, offers manufacturing and testing services tailored to the development of CHOZN® cell lines for use in bioprocessing. These services are backed by more than 20 years of experience and regulatory knowledge.

A typical CHOZN® cGMP MCB and WCB manufacturing timeline:



Comprehensive service, confident results

BioReliance's scientists are experts in cGMP cell bank manufacturing and cell line characterization. Biosafety testing and characterization methods utilized include sterility and mycoplasma testing, isoenzyme analysis, in vitro and in vivo assays for adventitious viral contaminants, reverse transcription assays, antibody production assays, transmission electron microscopy, PCR and Q-PCR assays, bovine and porcine virus assays, and retroviral infectivity assays. A CHOZN® cGMP Master and Working Cell Bank can be produced in the time frames outlined above. Please contact your BioReliance Account Manager to discuss the specifics of your CHOZN® cGMP Cell Bank project.

- Combining the power of SAFC's CHOZN® cell lines with the regulatory expertise of BioReliance's manufacturing and testing services ensures your success from clone to bioreactor
- All cell bank manufacturing and testing is performed to cGMP standards to enable easy regulatory submission
- Product development timelines can be accelerated by accessing CHOZN® platform cell lines, media, manufacturing and testing services

BioReliance® by SAFC

cGMP manufacturing and testing for CHOZN® cell lines, continued

Here is the recommended CHOZN® cell line manufacturing and testing program. All tests are performed (except where noted) to a GMP standard.

Pre-bank Screening
Sterility Testing Using a Direct Inoculation Method
Sterility Method Suitability Testing Using a Direct Inoculation Method
Test for Presence of Agar-Cultivable and Non-agar Cultivable Mycoplasma without Avian Controls (USP, EP, 1993 PTC)
cGMP Master Cell Bank (MCB) Manufacturing
Small-scale Pilot Bank Manufacturing Study (Non-GMP Cell Bank)
cGMP MCB Manufacturing
Master Cell Bank Testing & Characterization
Sterility Testing Using a Direct Inoculation Method
Sterility Method Suitability Testing Using a Direct Inoculation Method
Test for Presence of Agar-Cultivable and Non-agar Cultivable Mycoplasma without Avian Controls (USP, EP, 1993 PTC)
Qualification of the Test Article for the Detection of Agar-Cultivable Mycoplasma in accordance with USP/EP/PTC Requirements (Without Avian Controls)
28-day In Vitro Assay for Adventitious Virus Detection, 3 Cell Lines
In Vivo Adventitious Virus Detection using Suckling and Adult Mice, Guinea Pigs, Embryonic Hen Eggs
Bovine 9CFR In Vitro Assay for 7 Viruses
Porcine Modified 9CFR In Vitro Viruses Assay, PT-1 Cells
MAP: Mouse Antibody Production Test (GLP in US, GMP in UK)
HAP: Hamster Antibody Production Test (GLP in US, GMP in UK)
Mus Dunni Cells / RT and Feline S+L- Assays for Retrovirus Detection
Evaluation for Retroviral Reverse Transcriptase Activity
Quantitative TEM Detection of Viruses, Fungi, Yeasts, Bacteria and Mycoplasmas
Isoenzyme Analysis
cGMP Working Cell Bank (WCB) Manufacturing
cGMP WCB Manufacturing
Working Cell Bank Testing & Characterization
Isolator Sterility Testing Using a Direct Inoculation Method
Test for Presence of Agar-Cultivable and Non-agar Cultivable Mycoplasma without Avian Controls (USP, EP, 1993 PTC)
Isoenzyme Analysis

References

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Center for Biologics Evaluation and Research, Food and Drug Administration. Points to Consider in the Manufacturing and Testing of Monoclonal Antibody Products for Human Use, 1997.

The Rules Governing Medicinal Products in the EU. Production and Quality Control of Human Monoclonal Antibodies. Vol 3A Quality and Biotechnology Guidelines 1994: 3AB4

International Conference for Harmonisation. Quality of Biotechnological Products: Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin. 1997; Step 4 Consensus Guideline, Topic Q5A.

International Conference for Harmonisation. Quality of Biotechnological Products: Derivation and Characterization of Cell Substrates used for Production of Biotechnological/Biological Products. 1997; Step 4 Consensus Guideline, Topic Q5D.

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Center for Biologics Evaluation and Research Food and Drug Administration. Guidance for industry: Characterization and Qualification of Cell Substrates and Other Biologic Materials Used in the Production of Viral Vaccines for Infectious Disease Indications, Feb. 2010.

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