

Cell Stock Manufacture

**Creation of Cell Stocks for Use in
Drug Screening or Quality Control Assays**

*ILLUSTRATION:
Microscopic View of CHO Cells*

 **WuXi AppTec**

**THE
VIROLOGY
EXPERTS**



Outsourcing Your Cell Stock Manufacture to WuXi AppTec Can Save Time and Money

When well-characterized cell stocks are needed for assay development and/or conducting screening or lot release tests, generating the cell stocks in-house can be time-consuming and a drain on critical resources such as facilities, equipment and personnel. Outsourcing your cell stock manufacturing – either GMP or non-GMP – to WuXi AppTec is an economical and time-saving alternative.

With our comprehensive expertise, state-of-the-art facilities and robust quality systems, WuXi AppTec can provide assurance that your cell stocks will be manufactured to the highest standards of quality. And we utilize over 25 years of biosafety and characterization experience in performing screens of your cell line for adventitious agents.

CAPABILITIES

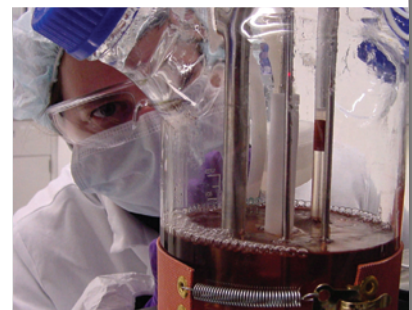
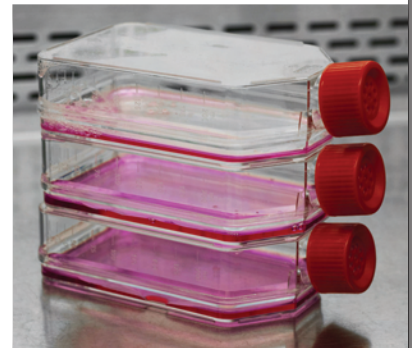
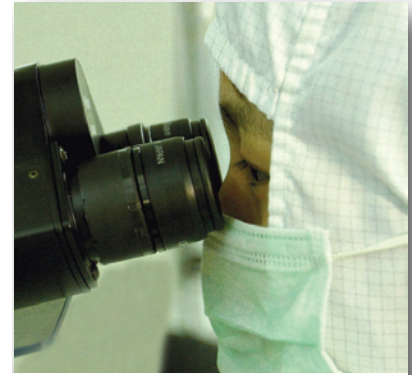
- ▶ Familiarity with a wide variety of different tissue types from the following species:
 - Hamster
 - Murine
 - Human
 - Simian
 - Insect
 - Canine
 - Bovine
 - Porcine
 - Feline
 - Avian
 - Equine
- ▶ Cell banks/stocks quantity from 10 to 1200 vials
- ▶ Expertise with both adherent and suspension cells
- ▶ In-depth knowledge of various media types used in multiple cell culture methods including:
 - T-flasks
 - Cell Factories
 - Roller Bottles
 - Shaker Flasks
 - Spinner Flasks
 - Bioreactors (small scale)

FACILITIES

The cell stock manufacture facility at WuXi AppTec offers clients an opportunity to manufacture cell stocks grown to their specifications, under exacting standards and (if applicable) QA oversight, and within a secure, controlled and monitored environment. All work is batch record- and/or SOP-driven and documented, and performed in ultra-clean tissue culture suites by gowned, highly skilled personnel.

Each GMP suite features single-pass, positive-pressure, HEPA-filtered air. Flow within each suite is unidirectional, with entry and exit air locks. All cell culture work is conducted within certified ISO Class 5 (Class 100) laminar flow biosafety cabinets, and cells are expanded within temperature mapped and validated incubators.

The GMP suite complex operates under a stringent security program that includes redundant temperature monitoring; 21 CFR, Part 11-compliant computer systems; fire protection; and an auxiliary back-up power generator. In addition, the entire facility is monitored by a security system tied into a central station where a 24-hour watch is maintained on system signals.





Cell Line Cloning & Development

WuXi AppTec can perform cell line development or engineering and can conduct clonality studies. Expertise is available for molecular cloning if required (e.g., to insert genes to express specific antigens or biomarkers).

Documentation / Batch Records

Whether you are partnering with us to develop a client-specific batch record, or using our standard documentation panels, WuXi AppTec provides flexible documentation alternatives to match your needs, quality oversight, preferences and intended cell stock use. In each case, a proven technology transfer and communication process exists between WuXi AppTec's experienced staff and the client's tissue culture specialist.

Cell Expansion & Harvest

Expansion of the cells can be performed in any of seven GMP suites, the cell biology laboratory (for non-GMP work), or in one of several suites available for large-scale expansion projects. Cells can be expanded to the requisite client-defined density to fill the agreed-upon number of cryovials. If required (such as for GMP cell banks), cell banks can be strictly segregated and produced on a campaign basis.

Raw materials used for the production of the cell banks are obtained from QA-approved vendors or you may provide these materials to WuXi AppTec for release under our QA raw material release program. If required, WuXi AppTec can perform serum-free, animal protein-free or suspension adaptations of the cell lines prior to banking.

Testing

Cell banks created at WuXi AppTec are tested for recovery viability after cryopreservation. In addition, testing services are also available for complete biosafety and characterization of the cell banks and include:

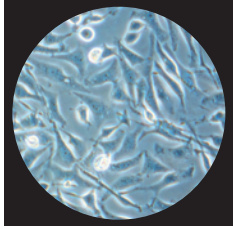
- Sterility and Bacteriostasis / Fungistasis (Harmonized USP/EP/JP method)
- Mycoplasma (USP/EP, PTC or TD-PCR)
- Adventitious Virus (qPCR or general *in vitro* viral screens)
- Identity (isoenzyme or client-supplied methodology)
- Biomarker Identification (Flow Cytometry or ELISA)

Reports

If banks are manufactured under GMP, a QA-approved Certificate of Analysis will be issued, including a copy of all cell bank manufacturing, harvest and freezing documentation and viability data. For non-GMP banks, an R&D report or a customized report is available depending on the level of documentation and quality oversight requested by the client. If biosafety and characterization testing is conducted by WuXi AppTec on the cell bank, individual assay reports supported by 100% QA review of raw data will also be provided.

Cryopreservation, Storage & Shipment

Cells are frozen at a controlled rate to minimize freeze-related trauma and can be stored long term at a WuXi AppTec site in highly controlled and regulated GMP storage facility. Various levels of segregation can be reserved for your cell bank within the vapor phase of liquid nitrogen.



Cell Stock Manufacture

Outsource your cell line manufacturing to WuXi AppTec whenever you need well-characterized cell stocks for assay development and/or conducting screening or lot release tests.

EXPERIENCE

- ▶ 25-year history in the manufacture of cell stocks.
- ▶ 40-45 GMP cell banks manufactured each year.
- ▶ Cell stocks created/maintained for over 50 cell lines used in WuXi AppTec assays.
- ▶ Thorough understanding of testing to address worker safety and cell stock performance for cell lines used in drug screening or quality control assays.
- ▶ Over 60 viruses available as positive controls, and over 100 PCR and infectivity assays developed and implemented to assess potential virus contamination of cell stocks.

PROGRAM FEATURES

- ▶ Seven dedicated GMP cell banking suites and seven additional cell culture rooms for GMP or non-GMP projects.
- ▶ Capacity to perform large-scale cell expansion projects including experience in producing 50 billion (5.0×10^{10}) cells/lot using 40 stack cell factories.
- ▶ Full in-house testing capabilities for biosafety and cell line characterization testing.
- ▶ Adaptable documentation systems (for either GMP or non-GMP cell stock creation).
- ▶ Experienced, highly trained staff.
- ▶ Cell line development capabilities.
- ▶ GMP cryostorage.
- ▶ Custom assay development.



Contact WuXi AppTec for cell stock manufacturing services:

(1) 651-675-2000 / 888-794-0077 • www.wuxiapptec.com • www.virologyexperts.com