



# Cell Banking and Storage

The creation of a regulatory-compliant cell bank is an essential element in the production of uniform biological products. Cell banking systems provide assurance that a uniform population of cells is preserved, that their integrity is maintained, and that a sufficient supply of material is readily available for the life of the product. Of equal importance is the maintenance of these banks in a secure, controlled, and monitored storage environment. The implementation of an appropriate tiered cell banking system and storage program will assist in a compliant, reliable, and expeditious path to market.

The Biopharmaceutical Services (BPS) group at Charles River has more than 20 years of experience in manufacturing cell banks in compliance with current Good Manufacturing Practice (cGMP). We typically manufacture more than 100 research and cGMP cell banks annually, and our processes for controlling manufacture have been developed from this large base of experience to ensure a smooth and successful outcome for your manufacturing campaign.

## Cell Banking

### Mammalian and Other Eukaryotic Cell Banking

Our mammalian cell banking team is capable of producing up to 1,000 vials of a master cell bank (MCB) or working cell bank (WCB) under appropriate controlled conditions. The cell banks are prepared in cGMP-compliant suites. To ensure freedom from cross-contamination, campaign banking strategies are used for all cGMP-manufactured cell banks. In addition, to provide the best available timelines for you, we have multiple cell banking suites available for cGMP manufacture. Standard release criteria of identity and sterility are provided, and full characterization and biosafety capabilities are also available for further regulatory-based testing of your cell bank.

Charles River also has the ability to manufacture cGMP cell banks for other Eukaryotic host systems and cell lines, including avian, insect and stem cells. All cell banking services are conducted in cGMP-compliant suites.

### Microbial Cell Banking

Our microbial cell banking team has a wealth of experience in manufacturing *E. coli*, yeast, and other aerobic and anaerobic microbial cell banks to the highest standards. As with our mammalian cell banks, microbial cell banking services are also conducted under appropriate controlled conditions. We have dedicated, fully equipped cGMP-compliant suites, with the capability to produce up to 800 vials of a MCB or WCB.

## Cell Bank Experience

- All major mammalian cell lines
- Aerobic and anaerobic microorganisms  
*E. coli*, *S. cerevisiae* and *P. pastoris*
- Insect cell lines
- Avian cell lines
- Stem cells

## Cell Banking Facilities

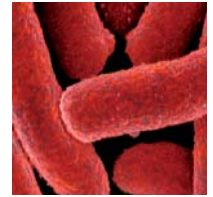
- Separate, dedicated mammalian and microbial facilities
- cGMP-compliant environments
- Seamless flooring

## Customer Service

- Reliable communication
- Shipping vessels provided
- Client-specific batch records
- Project management

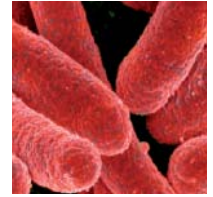
## Additional Services

- Cell line characterization
- Lot release/drug product release testing
- Viral clearance studies
- Protein characterization
- Product stability testing
- In-process/drug substance testing



## Initiating Studies

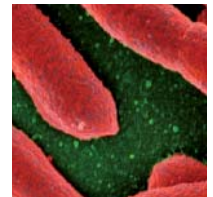
To ensure material reaches Charles River in a condition suitable for initiating cell growth, we provide our clients with support in a number of relevant areas, including initial generation of the manufacturing batch record, support in applying for importation licenses, and, if required, supply of appropriate shipping vessels.



## Storage

### Cell Bank Storage

At Charles River, maintaining the security and integrity of client cell banks is a priority. Cell banks are stored at  $-70^{\circ}\text{C}$  or in vapor-phase liquid nitrogen, as appropriate, in dewars located in a controlled-access area. A multi-layered approach is taken to ensure the security and performance of the cell storage facility. In addition to technical security aspects, our clients' cell banks are divided and stored in multiple, validated, liquid nitrogen dewars. Separate dewars are maintained for quarantined (untested) and released (characterized) materials. Cell banks are also segregated by cell type. Once in storage, vial locations are identified and entered into our inventory control system, and unique identification numbers for each bank are provided to you to enable complete confidentiality and expeditious vial retrieval.



### Cell Bank Retrieval and Shipment

To maintain the integrity of our secure storage processes, cell bank retrieval and shipment from Charles River occurs only at the request of an authorized client representative. Vials of a cell bank are removed from storage and transferred to a qualified, dry nitrogen shipping dewar. Each dewar contains a recording device that documents the temperature for the duration of the shipment. These practices, coupled with appropriate custody documentation, ensure that the materials are maintained under controlled conditions.

Cell banking and storage are part of the comprehensive services provided by the BPS group at Charles River to support the manufacture of biologics. Complementary services include cell characterization, lot release, viral clearance studies, protein characterization, stability testing, and drug product release. Please contact us for further information.