charles river

Cell Banking and Storage

Regulatory-compliant cell bank production provides assurance that a uniform population of cells is preserved 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 and monitored storage environment. The Biologics Testing Solutions group at Charles River has more than 20 years of experience in manufacturing cell banks and our processes have been developed from this large base of experience to ensure a successful outcome for your manufacturing campaign.

Cell Banking

Mammalian, Insect, Avian and Stem Cells

Our cell banking team is capable of producing up to a 1,000 vial cell bank in cGMP-compliant suites. To provide the best timelines for you, we have multiple cell banking suites available for manufacture. Standard release criteria of viability and sterility are provided, and full characterization and biosafety capabilities are also available for further regulatory-based testing of your cell bank.

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 conducted under appropriate controlled conditions. We have dedicated, fully equipped cGMP-compliant suites with the capability to produce up to an 800 vial cell bank.

Cell Bank Experience

- All major mammalian cell lines
- Insect cell lines
- Avian cell lines
- Stem cells
- Aerobic and anaerobic microorganisms

Cell Banking Facilities

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

Customer Service

- Reliable communication from our project management team
- Assistance with shipping and permits

Related Services

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

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Cell Banking Support

Charles River offers many support services in order to expedite the receipt of your cell seed stocks and production of your cell bank. If necessary, our team of experts is able to offer assistance with import permits and provide appropriate shipping vessels. After the seed stock arrives, our project management team will guide you through the manufacturing process from pre-seed testing and generation of the manufacturing batch record through to the manufacture, release and characterization testing of the cell bank. It is our top priority to make sure you are kept informed throughout the manufacturing process.

Storage, Retrieval and Shipment of Cell Banks

Storage of Cell Banks

At Charles River, maintaining the security and integrity of client cell banks is a priority. Cell banks are stored at -70°C or in vapor-phase liquid nitrogen 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 materials. 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 an appropriate shipping container with a recording device that documents the temperature for the duration of the shipment. All vapor phase liquid nitrogen shipments are shipped in a qualified dewar. These practices, coupled with appropriate custody documentation, ensure that your cell bank vials are maintained under controlled conditions.