

Cell Banking Under GMP Guidelines



Many biopharmaceuticals are composed of mammalian cells or mammalian cell-based products. The worldwide regulatory agencies require a continuing supply of the specific cell lineage that is integral to the manufacturing process. Thus, cell banks are created to supply a stock of cells that have a comprehensive history, which includes a documentation trail and safety and characterization data as part of the overall product and process validation program.

WuXi AppTec is a global leader in providing discovery, testing and manufacturing services for the pharmaceutical, biologics and medical device industries. Research-driven and customer-focused, with operations in China and the U.S., WuXi AppTec offers a broad and integrated portfolio of services designed to assist our customers with cost-effective and efficient outsourcing solutions.

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Batch Record Development

With each cell bank, WuXi AppTec partners with the client to develop a client-specific batch record. This is accomplished with direct, open communications between WuXi AppTec's scientific staff and the client's tissue culture specialist. Likewise, all raw material requirements will be discussed and agreed upon prior to finalizing the batch record.

Cell Expansion and Harvest

Many different species of mammalian or insect cell banks – ranging in size from 10 to 800 vials – can be manufactured using a variety of media types. Both adherent and suspension cells can be grown using cell culture methods that include T-flasks, cell factories, roller bottles, shakers and spinner flasks. Upon approval of a price agreement, the client submits the necessary seed stock material to WuXi AppTec. Prior to entering the GMP space, these cells are first tested with USP Sterility and Points to Consider mycoplasma assays. Concurrent with this testing, the raw materials for the GMP bank will be ordered, received and tested (if required). Once released for GMP manufacturing, cells are expanded to the requisite density (typically 5×10^6 – 1×10^7 cells/ml) to fill the agreed-upon number of cryovials for the cell bank.

All cell banks are strictly segregated and produced on a campaign basis (i.e., one cell bank is produced within each suite at a time). Validated changeover and cleaning procedures, requiring Quality Assurance release of each suite prior to use, ensures cell line integrity and minimizes adverse events and contamination. Raw materials used for the production of the cell banks are obtained from QA-approved vendors or the client may provide these materials to WuXi AppTec to be released under WuXi AppTec's 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 / Characterization

Cell banks created at WuXi AppTec are tested for recovery viability after cryopreservation. Testing services are also available for complete biosafety and characterization of the cell banks under FDA and ICH guidelines.

Reports

A QA-approved Certificate of Analysis will be issued, including a copy of all cell bank manufacturing, harvest and freezing documentation and viability data. 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 to support regulatory filings.

Cryopreservation, Storage and Shipment

Cells are frozen at a controlled rate to minimize freeze-related trauma and can be stored long term at one or two of the WuXi AppTec sites in highly controlled and regulated GMP storage facilities. Various levels of segregation (including client-dedicated freezers) can be reserved for your cell bank within the vapor phase of liquid nitrogen. Vials from the cell bank can be shipped as needed for manufacturing. Shipment of the entire bank should be in multiple individual transports.

Facilities

The GMP cell bank facility at WuXi AppTec offers clients an opportunity to manufacture cell banks grown to client specifications, under exacting standards and QA oversight, in a highly monitored, secure and controlled environment. All work is Batch Record- and SOP-driven and documented, and performed in ultra-clean tissue culture suites by gowned, highly skilled personnel.

WuXi AppTec maintains five individually monitored GMP cell banking suites, with rooms that are classified as ISO 7, Class 10,000. Each suite is supported by 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. Cells are expanded within temperature mapped and validated incubators.

The suite complex operates under a stringent security program, which 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.

For more information on WuXi AppTec's services please contact:

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