**GMP Manufacturing of Cellular Therapeutics**

As a GMP/GTP/GLP contract manufacturing and testing company, WuXi AppTec offers a range of solutions and GMP manufacturing suite capacities for the expansion or processing of cells for therapeutic or vaccine applications. Our combination of service options, capabilities, expertise, and facilities provides cell therapy clients a distinct advantage – a unique single-source, fully integrated service to translate cellular therapeutics from research to clinical reality.

Additionally, with extensive technical and regulatory expertise within the biologics and medical device industries, WuXi AppTec is uniquely qualified to address the challenges of manufacturing and testing whole cell vaccines and allogeneic or autologous cellular therapeutics.

## cGMP Facilities

Manufacturing is conducted in ISO-accredited facilities operating under strict GMP and GTP compliance, and comprising individually equipped, various size suites with ISO Class 5 (Class 100) biosafety cabinets. In addition, campaign-driven, dedicated GMP cell banking suites can be used for production of mammalian cell banks or select cell therapy programs. The suites – which meet ISO Class 7 (Class 10,000) standards – feature HEPA-filtered air supply, continuous monitoring of environment and equipment, and back-up system redundancy. Validated systems and procedures ensure the highest quality in aseptic processing. Comprehensive environmental monitoring programs have been established for both open and closed manufacturing operations, along with validation of aseptic manufacturing processes.

## Process Development/Pre-GMP Activities

WuXi AppTec has expanded capabilities to support process development services for cell therapies with additional personnel who bring years of experience and specific expertise in the technology platforms and strategies required to maximize cell expansion, enhance process reproducibility, and facilitate scale-up. Our ability to support process development and the challenges of scale-up early on allows for more efficient forward integration and can provide enhanced process performance, product quality, and time savings as you advance your program. Capabilities include:

* Technology transfer
* Process development and optimization
  + Development of closed-processing systems
  + Media selection and optimization
  + Scale-up/out
* Verification runs
* Raw materials sourcing and screening
* Matrix compatibility testing
* Packaging & shipping validation (stability)

## Manufacturing / Processing Capabilities

* cGMP clinical- and commercial-scale manufacturing
* Large-scale expansion (up to 72 x 10 layer cell factory/lot experience)
* Autologous cell selection, expansion and processing
* Cell expansion for allogeneic cell therapies and vaccines
* Cell selection with GMP monoclonal antibodies
* GMP cell bank production
* Broad range of container/closure systems for final product
* Controlled rate freezing
* Short and long term Cryogenic storage

## Cell Culture Production Options

* Flasks (all types)
* Roller Bottles
* Cell Factories/Cell Stacks
* Automated Cell Processing Systems
* Tangential Flow Filtration
* Single-use Bioreactors
* Wave / Bag Manifold Systems
* Spinner / Shake Flasks

## Cell/Tissue Type Experience

* Mesenchymal Stem Cells (hBM ,hUCB)
* Chondrocytes
* Dendritic Cells
* Amniotic Stem Cells
* Amnion Membrane
* Transduced and other cell populations

## Customized Programs

WuXi AppTec's scientists are experts in developing customized manufacturing and regulatory-accepted testing programs to meet a client's particular needs. Bar code sample tracking is available for large-scale programs.

## Testing Services

With over 20 years of experience in testing biotherapeutics, WuXi AppTec is able to offer clients a comprehensive testing program for their projects.

## Available testing services include:

* Rapid mycoplasma & sterility assays (including rapid mycoplasma testing by PCR according to EP Section 2.6.7 and BacT/Alert® rapid sterility testing options)
* Cell line characterization
* Flow cytometry
* Microbiological Testing (USP/EP sterility, bioburden& endotoxin assays)
* Adventitious viral agent testing
* Molecular biology assays (qPCR, DNA sequencing)
* Biodistribution and expression analysis
* Potency / purity / identity testing
* Raw material testing
* Stability testing
* Extractables & Leachnables Testing
* Foreign Particle Identification