

SERVICES FOR
Cellular Therapeutics & Vaccines

**Integrated, single-source services for
clinical to commercial-scale manufacturing**

ILLUSTRATION:
Stem cell



Flexible and adaptable manufacturing solutions utilizing our integrated, single-source services



As a GMP/GTP/GLP contract development, testing, and manufacturing 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 flexible service options, capabilities, expertise and facilities provides cell therapy clients a distinct advantage – a unique single-source, fully integrated service company for cellular therapeutics, from procurement, process development, cell expansion, and fill/finish to comprehensive product testing and release.

Clinical and Commercial-Scale Manufacturing / Processing Capabilities

- ▶ Autologous cell therapies and vaccines
- ▶ Allogeneic cell therapies and vaccines
- ▶ GMP cell bank production
- ▶ Cryogenic storage

Cell Culture Production Options

- ▶ Nunc Cell Factories / Corning Cell Stacks
- ▶ Corning HyperFlasks™ and HyperStacks™
- ▶ Custom tube sets
- ▶ Bag manifold systems
- ▶ Single-use tangential flow filtration
- ▶ Single-use bioreactor systems
- ▶ T-flasks and roller bottles

Process Development and Supporting Services

- ▶ Media optimization
- ▶ Scale-up
- ▶ Process optimization
- ▶ Packaging and shipping validation (stability)



Twenty-one (21) active cell culture suites are available for GMP or non-GMP projects.

Media optimization, scale-up and development of "closed" systems are key components of our process development services.



Capabilities include large-scale cell expansion with state-of-the-art production methods.



Controlled-rate freezing and cryogenic storage services are provided on site.



Comprehensive Biologics Testing Services

With over 20 years' experience in the testing of biotherapeutics, WuXi AppTec is able to offer unparalleled capacity and guidance to reduce time to clinic and significantly decrease the cost of our customers' drug development efforts. We provide the full spectrum of testing services, including rapid methods for critical situations where products have limited stability.

Biologics testing services include:

- ▶ Cell line characterization
- ▶ Mycoplasma, sterility & endotoxin assays (including rapid mycoplasma testing by PCR according to EP Section 2.6.7)
- ▶ Flow cytometry
- ▶ Adventitious viral agent testing
- ▶ Biodistribution and expression analysis
- ▶ Toxicology
- ▶ Potency / purity / identity testing
- ▶ Raw material testing
- ▶ Stability testing
- ▶ Extractables/Leachables testing
- ▶ Product package testing

Validated Shipping Process

Each cell therapy program has unique packaging and shelf-life constraints that will warrant validation of the shipping procedures. WuXi AppTec has experience with designing and implementing these critical validation programs by utilizing our worldwide facilities and existing distribution channels and shipping procedures.

Features include: Procedures already validated for most standard shipping temperatures • Import licenses for a wide array of cell types for entry into the U.S. from foreign countries • Proper containers to ensure materials are not compromised during shipping • Validated temperature control and tracking systems.

Project Management

Our project management teams are composed of executive management-level directors, a dedicated project manager, and manufacturing, QA and testing/QC core team members. We utilize an integrated project management process to facilitate timely decisions and foster communication between project teams. WuXi AppTec encourages customer involvement and has a long-established "person-in-plant" program.

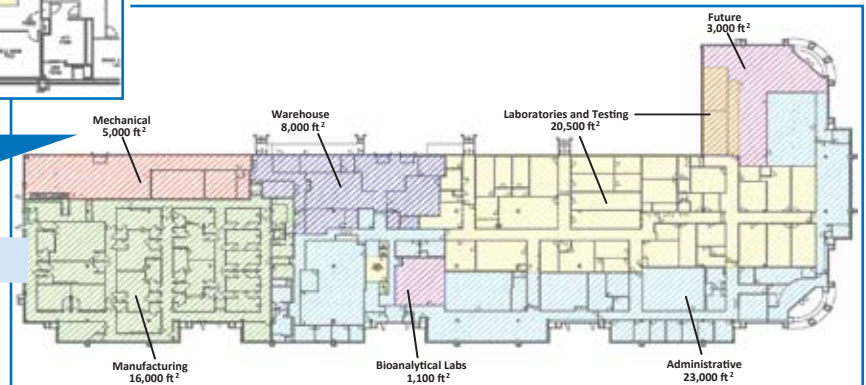


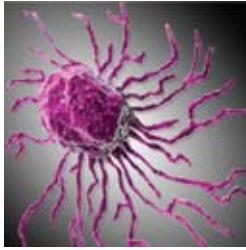
The WuXi AppTec Facility Philadelphia, Pennsylvania

WuXi AppTec's 75,000-square-foot site in Philadelphia consists of GMP cell banking and GMP/GTP cellular therapeutics manufacturing facilities along with testing laboratories. Our GMP and GTP manufacturing is conducted in individually equipped, positive-pressure suites with Class 5 laminar flow hoods. All suites are HEPA filtered and the rooms and equipment are continuously monitored and alarmed. Validated systems and procedures, as well as routine environmental monitoring, ensure the highest quality in aseptic processing.



GMP MANUFACTURING SPACE





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ACCREDITATIONS & REGISTRATIONS

Among WuXi AppTec's accreditations/registrations are the following relevant to services for cellular therapeutics and vaccines.

- American Association for Laboratory Accreditation: Certificate of Accreditation – ISO/IEC 17025:2005
- U.S. Food and Drug Administration (FDA) Registration of Drug Establishment
- U.S. Food and Drug Administration (FDA) Establishment Registration and Listing for Human Cells, Tissues and Cellular- and Tissue-based Products (HCT/Ps)
- MHRA Certificate of GMP Compliance (EMA)

PROGRAM FEATURES

- Twenty-one (21) active cell culture suites for GMP or non-GMP projects.
- Flexible and adaptable capacity to perform large-scale projects with customized production methods.
- Experience with: mesenchymal stem cells, chondrocytes, dendritic cells, amniotic stem cells, retinal pigmented epithelial cells.
- Expertise in shipping validations and cold-chain management for short-shelf-life or temperature-sensitive therapeutics.
- Full in-house testing capabilities for biosafety and product release.
- Various container and closure systems (e.g., cryovials, cryobags).
- Aseptic process validation / fill qualifications.
- Project management to oversee every step of your project – from initiation to final report delivery.
- Comprehensive quality systems that meet global regulatory acceptance.
- Commitment to Continuous Improvement and LEAN initiatives to ensure consistency in meeting Sponsor's service expectations.

**Contact WuXi AppTec regarding your cellular therapeutic or vaccine:
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