

Cellular Therapeutics

Contract GMP/GTP Manufacturing and Testing Services



WuXi AppTec, a GMP/GTP/GLP contract manufacturing and testing company, offers a unique single-source, fully integrated approach for cellular therapeutics – from procurement to cell expansion to testing and release. Our expertise in the area of cell-based products – combined with our advanced facility – ensures that we can provide the cutting-edge capabilities required by today's cell therapy companies.

WuXi AppTec is a global leader in providing discovery, testing and manufacturing services for the pharmaceutical, biotechnology 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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Manufacturing / Processing Capabilities

- Stem cell processing
- Autologous processing
- Cell expansion for allogeneic cell therapies and vaccines
- Cryogenic storage
- Commercial-scale production
- GMP monoclonal antibodies for cell selection
- GMP cell bank production
- Media optimization
- Packaging & shipping validation (stability)

Cell Culture Production Options

- Flasks (all types)
- Roller Bottles
- Spinner / Shake Flasks
- Wave
- Cell Factories
- Bioreactors

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:

- cell line characterization
- mycoplasma, sterility & endotoxin assays
(including rapid mycoplasma testing by PCR according to EP Section 2.6.7)
- flow cytometry
- microbiological and adventitious viral agent testing
- molecular biology assays
- biodistribution and expression analysis
- potency / purity / identity testing
- raw material testing
- stability testing

The WuXi AppTec Facility

Manufacturing is conducted in facilities operating under strict GMP and GTP compliance, and comprising individually equipped, positive-pressure suites with ISO Class 5 (Class 100) laminar flow hoods. The suites, which meet ISO Class 7 (Class 10,000) standards, are HEPA filtered and the rooms and equipment are continuously monitored and alarmed. Validated systems and procedures ensure the highest quality in aseptic processing.

Customized Programs

WuXi AppTec's scientists are experts in developing customized manufacturing and regulatory-accepted testing programs to meet a client's particular needs.



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

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