

# Gene Therapy Testing Services

**W**uXi AppTec offers GLP/cGMP testing programs for somatic cell, viral, and plasmid DNA-based gene therapies. With many years of experience in providing fully integrated biosafety testing programs for the cell and gene therapy fields, we have supported a number of successful BLA and IND applications.

## Replication-Competent Viral Vector Testing

Sensitive in vitro cell culture assays are used to detect replication-competent viral vectors. WuXi AppTec can work with clients to provide custom replication-competent virus detection assays for a particular vector construct.

## Cell Bank and Viral Bank Safety Testing and Characterization

WuXi AppTec offers all of the assays mandated by regulatory authorities worldwide for the biosafety analysis and characterization of cells, cell lines and viral banks (stocks) used in gene therapy programs.

In addition, custom purity and potency testing is available for viral vector stocks.

## Vector Purification Process Validation for Viral Clearance

Most biopharmaceuticals require viral clearance studies to validate the removal of potential contaminants, such as those from bovine components or from helper viruses (adenovirus in AAV production). WuXi AppTec can provide custom design and performance of viral clearance studies for various vector purification processes.

## Custom Testing Programs for Somatic Cell, Ex Vivo Cell, and Tissue Therapies

WuXi AppTec can guide you through the process of designing and implementing a unique biosafety testing program that meets the needs of your specific project.

## Sterility and Mycoplasma Testing

Complete sterility and mycoplasma testing services (including mycoplasma PCR) are provided in accordance with USP, EP, CFR and Points to Consider guidelines.

## Biodistribution

WuXi AppTec offers comprehensive in life capabilities to support biodistribution programs. In addition, using real-time PCR technology, our program provides a powerful tool for evaluating the efficacy and safety of nucleic acid protocols by quantifying the copy number of a DNA or RNA target in a defined set of organs and tissues.

## Raw Material Testing

The introduction of viruses into cultures via animal-derived medium supplements is a concern to the regulatory authorities. WuXi AppTec has developed protocols for testing media supplements and cells/harvest fluids for the presence of animal viruses. If you are using animal-derived supplements in any part of your process (i.e., from MCB through Final Product), you may wish to consider testing these supplements and your cell banks for adventitious viruses of animal origin.

## Molecular Biology

WuXi AppTec's extensive molecular biology capabilities include custom replication-competent and adventitious virus detection PCR assays, genetic stability analysis, RNA/DNA isolation and quantification, DNA sequencing, residual DNA, reverse transcriptase assays and copy number determination.

## Technical and Regulatory Guidance on Gene Therapy Product Testing

WuXi AppTec's Technical Services will provide you with the technical and regulatory expertise to assure that your product meets the highest expectations of regulatory authorities worldwide.

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

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