

Vaccine Testing Services

**Expertise, experience and regulatory knowledge –
regardless the type of vaccine**

*ILLUSTRATION:
Influenza virus*

 **WuXi AppTec**

**THE
VIROLOGY
EXPERTS**

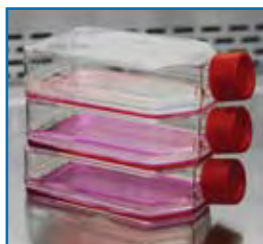


Vaccine Testing Services

A full spectrum of services to speed vaccines from discovery to commercialization

WuXi AppTec offers GLP/GMP testing programs for viral, VLP, whole cell, rprotein, peptide and DNA-based vaccines. With many years of experience in providing fully integrated biosafety testing programs, we have supported a number of successful BLA and IND applications for vaccines.

GMP CELL BANKING AND CRYOPRESERVATION



Seven GMP cell banking suites are available to manufacture mammalian cell banks. Manufacturing is conducted to client specifications, under exacting standards and QA oversight, in closely monitored, secure and controlled environments. GMP cell banks (mammalian and microbial) can be stored long-term at WuXi AppTec sites in highly controlled and regulated GMP facilities. Various levels of segregation can be reserved for cell banks within the vapor phase of liquid nitrogen.

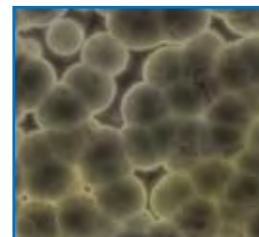


VIRAL BANK SAFETY TESTING & CHARACTERIZATION

WuXi AppTec offers all of the assays mandated by regulatory authorities worldwide for the biosafety analysis of viral banks (stocks) used in gene therapy programs. In addition, custom identity, purity and potency testing is available for viral vector stocks using molecular biology or virology methodologies.

CELL LINE CHARACTERIZATION

Whether mammalian cells or microbial cells, WuXi AppTec offers complete biosafety, identification and characterization assessment of cell banks and cells at the limit of in-vitro cell age. All testing is conducted under FDA and ICH guidelines. The comprehensive battery of test methodologies – including genetic stability analysis required for most species – is conducted by our in-house laboratories.



TOXICOLOGY

Capabilities include a wide variety of animal models including non-human primates. Study support includes tissue cross-reactivity, ADME/DMPK, safety pharmacology, and in-house clinical pathology and histopathology services. Our quality systems have been audited and accepted by regulatory authorities worldwide.



DETECTION OF PROCESS-RELATED IMPURITIES

Includes:

- Host cell protein • Antibiotics • Detergents
- Media components • Residual host cell DNA / DNA Sizing

Technical & Regulatory Guidance

From a foundation of over 20 years of industry experience and in-depth knowledge of global regulatory guidances, WuXi AppTec's technical experts will provide you with the necessary information to assure that your product meets the highest expectations of regulatory authorities worldwide.



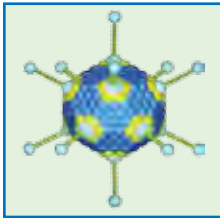
LOT RELEASE

*For Unprocessed Bulk/Viral Harvest,
Bulk Drug Substance and Final Drug Product*

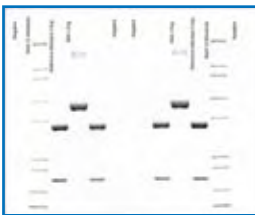
WuXi AppTec can develop or perform technology transfer from the Sponsor for the various biosafety and analytical methods required for these lot release program criteria:

- Purity • Concentration • Potency • Identity • Consistency
- Host Cell and Process Residuals • Adventitious Virus Detection
- Mycoplasma • Sterility/Microbial Enumeration

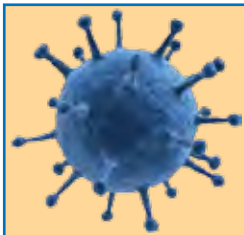
PRODUCT STABILITY



A wide variety of analytical or biosafety methodologies are available for use in product stability studies. We maintain ICH validated chambers at a variety of temperature and humidity settings. Stability programs are conducted under GMP guidelines.

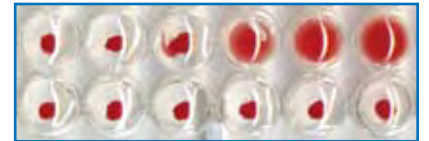


VIRAL CLEARANCE / INACTIVATION STUDIES



Ten viral clearance suites, molecular biology labs, highly experienced staff and extensive process equipment are available to help you meet your critical timelines and drug-filing needs. WuXi AppTec is an industry leader in viral stock manufacture and purification, which ensures the integrity of your data. An extensive database utilizing over 20 years of viral clearance data can be mined to assist your process development efforts.

RAW MATERIALS TESTING AND SUPPLY CHAIN ASSESSMENT



Animal-derived raw material lot testing to detect adventitious agents is available using microbiology, molecular biology and 9 CFR approaches including PCR and infectivity assays for porcine circovirus detection. WuXi AppTec can provide raw material or supply chain assessments, which include written risk evaluations in support of regulatory filings or for review by your product development partners.

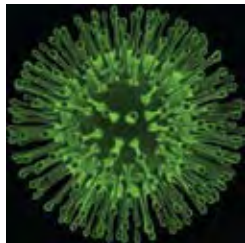
Additional Services

• PRODUCT OR REFERENCE STANDARD CHARACTERIZATION

A battery of regulatory-compliant tests for product characterization and comparability of reference standards are available, including methods for molecular weight and extinction coefficient determinations.

• ASSAY DEVELOPMENT AND VALIDATION

We can develop or perform technology transfer of assays, working with you to establish the appropriate assay acceptance criteria for its intended use. Phase-appropriate assay validation and product specific qualifications can be conducted to perform assays under GMP conditions.



Vaccine Testing Services

No matter the type of vaccine – virus (live, attenuated, and inactivated), whole cell, peptide or recombinant protein – or how it is produced – in eggs, microbial or mammalian cell culture, or derived from plants – WuXi AppTec will develop a comprehensive biosafety testing plan that will meet regulatory scrutiny.

EXPERIENCE

- Multiple cell-based potency and identity assays developed and validated for specific virus vaccines.
- Hundreds of cell banks and viral banks characterized.
- Thousands of clinical lots tested under GLP & GMP.
- Over 50 cell lines and 60 viruses available as indicator cell lines or positive controls for potency, identity or biosafety assays.
- Over 80 PCR assays developed for the detection of specific adventitious or contaminating viruses.
- Thousands of clinical samples assessed to detect viruses.

PROGRAM FEATURES

- Custom assay development for vector potency and identity for use in lot release or clinical trials.
- Both in-house animal facilities and analytical laboratories available for toxicology studies.
- Established protocols for GMP suite cleaning validations and environmental monitoring.
- Testing plans and assays available to screen for adventitious agents from animal-derived raw materials or other raw material sources.
- Development of tumorigenicity & oncogenicity assays to assess producer cell lines.
- Multiple, Ph.D.-level virologists with expertise to develop custom assays from novel vectors.
- Access to industry leading regulatory, quality or CMC vaccine consultants.



Contact WuXi AppTec for your gene therapy testing:

(1) 651-675-2000 / 888-794-0077 • www.wuxiapptec.com • www.virologyexperts.com