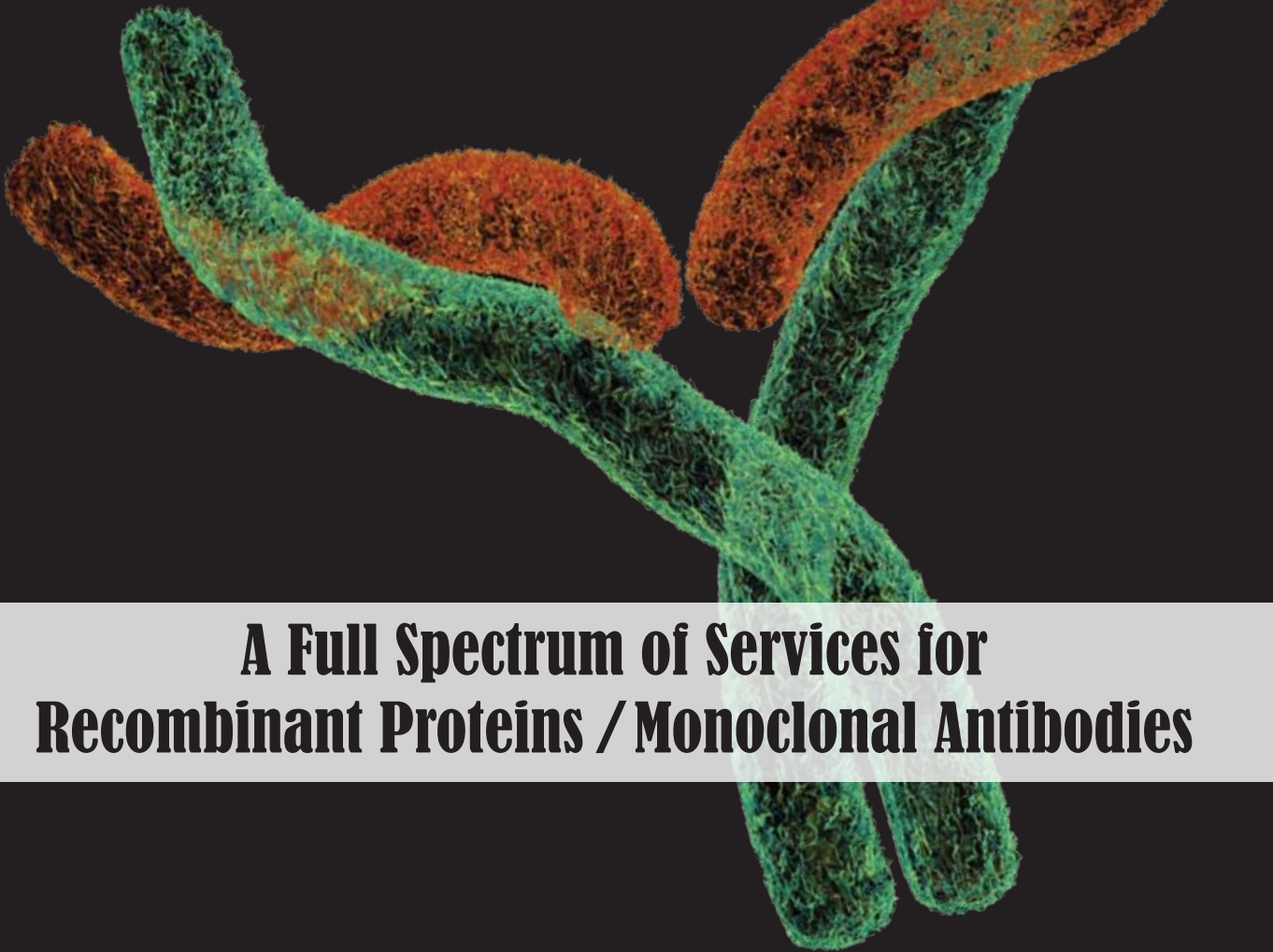


SERVICES FOR

Mammalian-Derived Protein Therapeutics



**A Full Spectrum of Services for
Recombinant Proteins / Monoclonal Antibodies**

*ILLUSTRATION:
Monoclonal Antibody*

 WuXi AppTec

**THE
VIROLOGY
EXPERTS**



Comprehensive Development and Testing Programs for Mammalian-Derived Protein Therapeutics – from Discovery to Commercialization

WuXi AppTec offers GLP- and GMP-compliant testing programs for recombinant proteins and monoclonal antibodies derived from mammalian cell culture production systems. Services include IND-enabling cell line and product/reference standard characterization and toxicology programs through to the development, validation and execution of GMP lot release and stability assays for clinical and commercial production lots.

DISCOVERY

PRECLINICAL DEVELOPMENT

CLINICAL DEVELOPMENT

COMMERCIALIZATION

Discovery Biology & Target Identification

Cell Line Engineering & Construction

In Life & Toxicology Studies

Raw Materials Testing & Supply Chain Assessment

Product Analytical Characterization

Assay Development & Validation

Fermentation & Purification Process Development

Cell Line Characterization & Cell Bank Storage

Detection of Process-Related Impurities

Viral Clearance/Inactivation Validation

Lot Release Testing

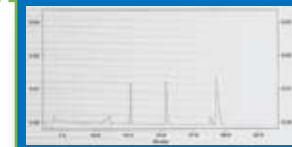
Stability Studies

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. WuXi AppTec can provide raw material or supply chain assessments, which include written risk evaluations in support of regulatory filings or for review by Sponsor product development partners.

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.

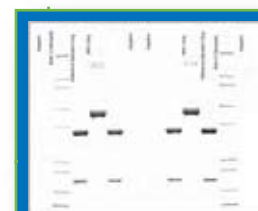
LOT RELEASE

For Unprocessed Bulk, 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 the following lot release program criteria:

- Purity • Concentration • Potency • Identity
- Consistency • Sterility/Microbial Enumeration
- Adventitious Virus Detection • Mycoplasma

PRODUCT STABILITY



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

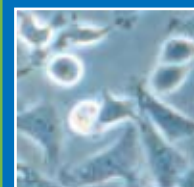


TOXICOLOGY

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.

ASSAY DEVELOPMENT AND VALIDATION

WuXi AppTec can develop or perform technology transfer of assays from the Sponsor. We work with the sponsor 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.



CELL LINE CHARACTERIZATION

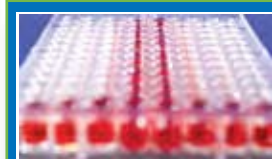
Complete biosafety, identification and characterization assessment of cell banks and cells at the limit of *in-vitro* cell age is conducted under FDA and ICH guidelines. The comprehensive battery of test methodologies – including genetic stability analysis required for most species – is conducted in our in-house laboratories.

GMP CELL BANKING AND CYROPRESERVATION



Cell banks are manufactured to client specifications, under exacting standards and QA oversight, in the closely monitored, secure and controlled environments of seven GMP cell banking suites. GMP cell banks 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.

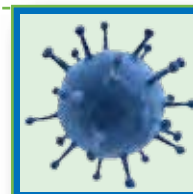
DETECTION OF PROCESS-RELATED IMPURITIES



Includes:

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

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.



Services for Mammalian-Derived Protein Therapeutics

WuXi AppTec provides services of exceptional quality, utilizing more than 20 years of experience in the analysis and testing of mammalian-derived protein therapeutics.

EXPERIENCE

- Thousands of commercial product lots or raw material lots released under GMP guidelines.
- Over 2000 custom viral clearance studies performed for IND, BLA, and market approvals.
- 70-80 cell banks manufactured or characterized each year.
- Over 40 viral PCR probes and over 100 PCR assays developed and implemented to assess potential virus contamination.
- Over 40 product stability programs conducted annually.
- Rapid response to and custom assays developed for new threats or specific environmental isolates of concern.
- Performance and writing of risk assessments for raw materials and process step control programs.

PROGRAM FEATURES

- Strong track record of supporting IND, BLA and market approvals by regulatory agencies worldwide.
- Senior staff members serve on industry task forces to be involved with and remain current on regulatory policies.
- Access to industry-leading regulatory, quality and CMC consultants.
- Custom assay program available for unique products.
- Dedicated project management team and on-line sample tracking and ordering.
- Comprehensive quality systems that meet global regulatory acceptance.
- Dedicated microbiology, virology, molecular biology, cell biology, and analytical labs.
- Extensive in-life facilities in both the U.S. and China.
- Commitment to Continuous Improvement and LEAN initiatives to ensure consistency in meeting Sponsor's service expectations.



Contact WuXi AppTec regarding your mammalian-derived therapeutic:

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