

## Recombinant Protein/Monoclonal Antibody Biosafety Testing



**W**uXi AppTec offers GLP- and GMP-compliant testing programs for proteins derived from eukaryotic, prokaryotic, or transgenic sources. Experienced in testing a variety of monoclonal antibodies, recombinant proteins, human blood products, enzymes, and hormones, we have provided complete testing support for many successful BLA and IND applications.

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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### Cell Line Characterization

Species identification by isoenzyme electrophoresis and IFA, genetic stability by gene copy number determination, Southern and Northern Blot analyses, adventitious agent testing, cell growth and morphology characterization.

### Product-Specific Viral Clearance / Inactivation Validation

Custom scale-down and verification of manufacturer's process, introduction of high-titer, well-characterized virus stock, and quantitation of virus removal or inactivation.

### Lot Release Testing

GLP and GMP testing on unprocessed bulk (cell harvest / end of production cells), bulk drug substance (BDS) and final drug product (DP) for determination of product safety (detection of adventitious agents), purity, potency, identity, consistency and concentration using a wide-variety of analytical, molecular biology and in vitro or cell-based methods. Technology transfer of previously designed sponsor assays or custom assay development capabilities in addition to assay verification, qualification and validation services are available.

### Product Stability & Shelf-Life Studies

Temperature and humidity controlled ICH validated chambers and an array of analytical and safety tests to assess product stability. Determination of stability indicating methods utilizing forced degradation methodologies also available.

### Mycoplasma Testing

"Points to Consider," 9 CFR, 21 CFR, European Pharmacopoeia and research tests designed to culture and detect the presence of mycoplasma using direct and indirect methods. Rapid PCR methods also available.

### Sterility Testing

Tryptic Soy Broth (TSB) and Fluid Thioglycollate Medium (FTM) cultures to detect bacterial and fungal contamination.

### GLP / cGMP Residual DNA Testing

Validated, precise and sensitive assays capable of detecting less than 1 pg of contaminating DNA from multiple species by qPCR or slot blot.

### Adventitious Viral Agent Testing

In vitro and in vivo assays to detect human, murine, bovine, porcine, and other mammalian or avian viruses in accordance with "Points to Consider," 9 CFR, and European guidelines.

### Raw Materials Testing

Serum and trypsin lot testing to detect adventitious agents, including non-cytopathic viruses is available using molecular biology and 9 CFR approaches. Custom assays available for other raw materials.

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

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