

Recombinant Protein / Monoclonal Antibody Biosafety Testing



AppTec is a unique single source for comprehensive GLP/GMP-compliant testing, contract research and development, and specialized cGMP manufacturing services for biopharmaceuticals, medical devices, cellular therapeutics, and tissue-based products. We provide our clients the highest level of state-of-the-art science, regulatory expertise and individualized customer service.

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 a number of successful BLA and IND applications.

Cell Line Characterization

Species identification by isoenzyme electrophoresis and IFA, genetic stability by DNA profiling, 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 1997, European Pharmacopoeia and research tests designed to culture and detect the presence of mycoplasma using direct and indirect methods. 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" and 9 CFR 1997 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.



For more information about our wide range of services,
contact an AppTec Account Manager at 888.794.0077.

www.apptec-usa.com