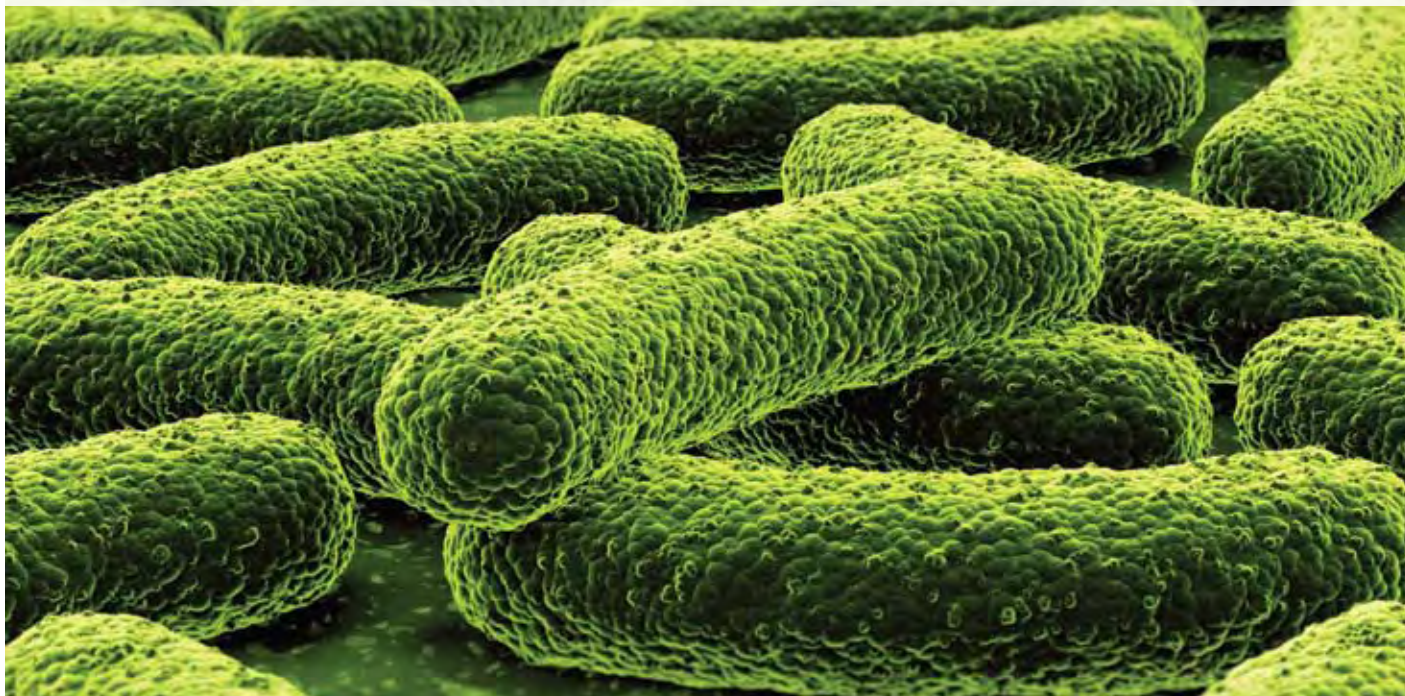


**TESTING PROGRAMS FOR**

# **Microbial-Derived Protein Therapeutics**



**Comprehensive biosafety and analytical services –  
from development to commercialization**

*ILLUSTRATION:  
Rod-shaped bacteria (e.g., E. coli)*

 **WuXi AppTec**

# Comprehensive Testing Programs for Microbial-Derived Protein Therapeutics – from Discovery to Commercialization

WuXi AppTec offers GLP- and GMP-compliant testing programs for recombinant proteins derived from prokaryotic (microbial) 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 Biology & Target Identification

Cell Line Engineering & Construction

In Life & Toxicology Studies



### TOXICOLOGY

WuXi AppTec offers a full-range of in vivo and in vitro methodologies in both the U.S. and China to support preclinical safety evaluation programs. Testing services are based on current national and international guidelines and recommendations. Our quality systems have been audited and accepted by regulatory authorities worldwide, and our scientists have decades of experience designing these programs.

### 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. Custom assays are available for other raw materials. 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.

Raw Materials Testing & Supply Chain Assessment

Product Analytical Characterization

Assay Development & Validation

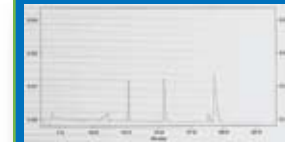
Fermentation & Purification Process Development

Cell Line Characterization & Cell Bank Storage

Detection of Process-Related Impurities

Lot Release Testing

Stability Studies



### PRODUCT OR REFERENCE STANDARD CHARACTERIZATION

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

### ASSAY DEVELOPMENT AND VALIDATION

WuXi AppTec can develop or perform technology transfer of assays from the Sponsor. Our scientists work with the sponsor to establish the appropriate acceptance criteria and to verify that the assay works for its intended use. Phase-appropriate assay validation and product-specific qualifications can be conducted at WuXi AppTec so that assays can be run under GMP conditions.



### CELL LINE CHARACTERIZATION

Cell line testing programs include assays for cell line viability, purity, identity and antibiotic resistance, and tests for plasmid identity, retention and copy number. Characterization includes assessment of the cell line for the presence of contaminating bacteriophage. Protocol templates for custom genetic characterization assays available for unique cell lines.

### CYROPRESERVATION, STORAGE AND SHIPMENT



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. Vials from cell banks can be shipped as needed for manufacturing.



### DETECTION OF PROCESS-RELATED IMPURITIES

Includes:

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



### 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, and in addition, stability-indicating assays can be developed or verified via forced degradation studies. A dedicated stability program coordinator monitors and initiates testing with the laboratories for the various time points required in each program.

### LOT RELEASE

(For Bulk Drug Substance & Final Drug Product)

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

- Purity
- Concentration
- Potency
- Consistency
- Identity
- Biosafety



# Testing Programs for Microbial-Derived Protein Therapeutics

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

## 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.
- ▶ Expert advice/consulting on U.S. and inter-national regulatory requirements.
- ▶ Custom assay program available for unique microbial cell lines and products.
- ▶ Dedicated project management team and on-line sample tracking and ordering.
- ▶ Comprehensive quality systems that meet global regulatory acceptance.
- ▶ Commitment to Continuous Improvement and LEAN initiatives to ensure consistency in meeting meeting Sponsor's service expectations.

## ADDITIONAL SERVICES

The highest level of critical regulatory and technical expertise is offered for the testing of mammalian cell-culture-derived monoclonal antibodies, recombinant proteins, cell/tissue-based therapeutics, vaccines and gene therapy products, as well as the testing of biologic-sourced raw materials.

Services include:

- ▶ GMP Cell Banking (eukaryotic/mammalian) and Cell Line Characterization
- ▶ Master Viral Bank Characterization
- ▶ 9 CFR Raw Materials Testing and Supply Chain Assessments
- ▶ Viral Clearance and Inactivation Studies
- ▶ Viral and Microbial Cleaning Validation Studies
- ▶ GMP Lot Release and Stability Programs
- ▶ In-Life, Toxicology and Biodistribution Studies
- ▶ GMP Manufacturing of Cellular Therapeutics



Contact WuXi AppTec regarding your microbial-derived therapeutic:

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