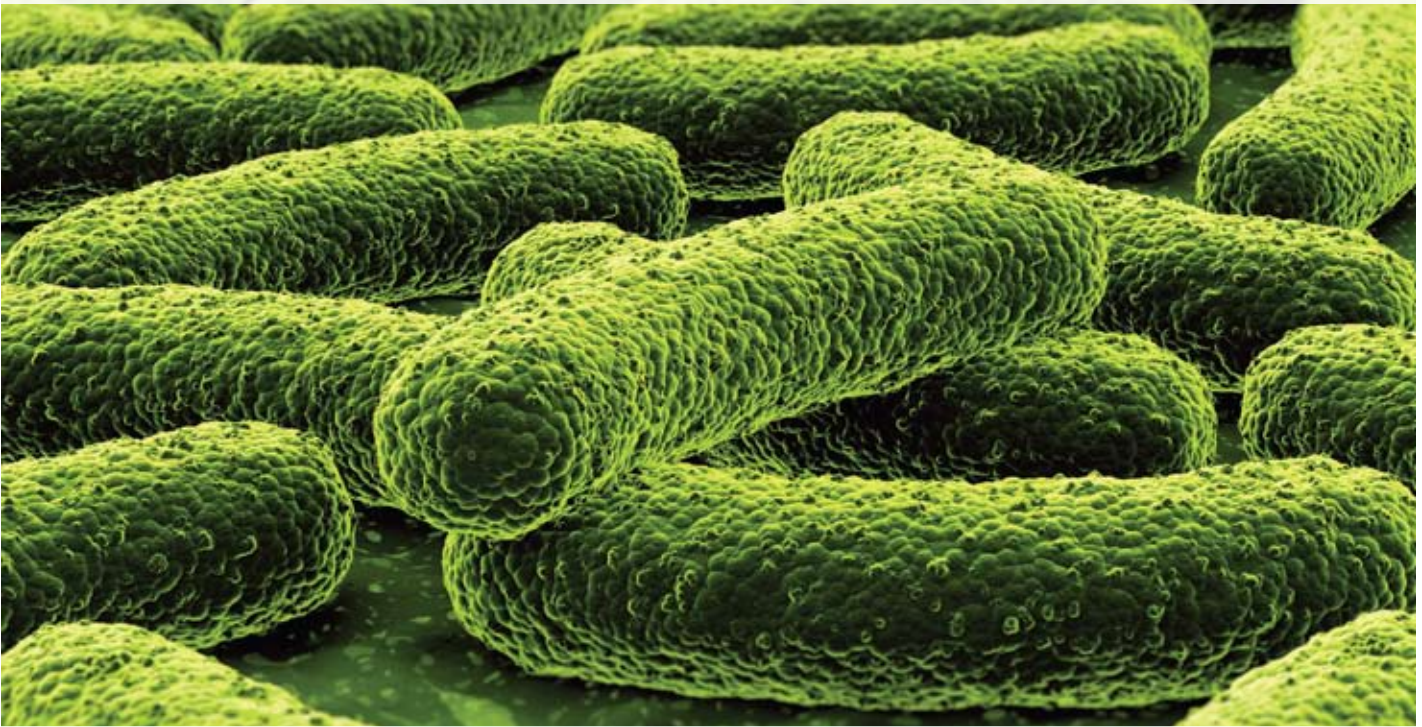


SERVICES FOR

Microbial-Derived Protein Therapeutics



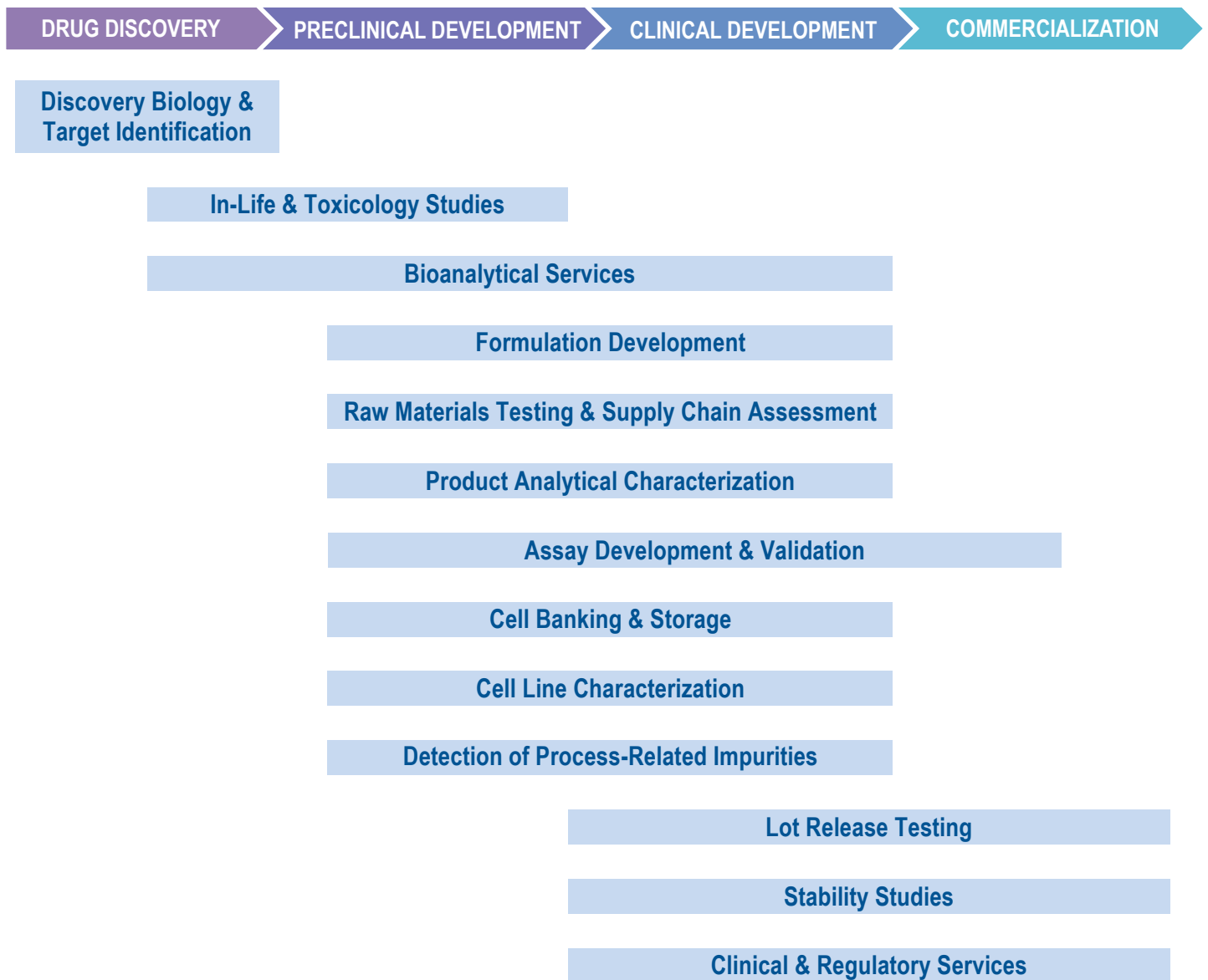
**Comprehensive product development, biosafety
and analytical services you can trust**

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



Comprehensive, Integrated Services for Microbial-Derived Protein Therapeutics – from Discovery to Commercialization

WuXi AppTec offers GMP- and GLP-compliant programs for recombinant proteins derived from prokaryotic (microbial) production systems. Services include IND-enabling GMP cell banking, 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.



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.



BIOANALYTICAL SERVICES

Full-service bioanalytical services include: PK/PD/TK, immunogenicity, BE and BA sample analysis using state-of-the-art high throughput technology. All facilities are US FDA registered and our GLP regulatory-compliant laboratories deliver high quality and accurate data under a strict quality control program.

FORMULATION DEVELOPMENT

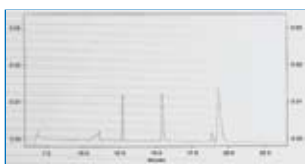
In-house expertise is available for developing rprotein drug product liquid and lyophilization formulations, including high-concentration protein formulation development.

RAW MATERIALS & SUPPLY CHAIN ASSESSMENT



Animal-derived raw material lot testing to detect adventitious agents is offered 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.

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 & 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.

GMP CELL BANKING & STORAGE AND CELL LINE CHARACTERIZATION

Cell banks are manufactured to client specifications, under exacting standards and QA oversight, in secure, monitored cell banking suites. Long-term storage is available at WuXi AppTec sites in highly controlled and regulated GMP facilities.

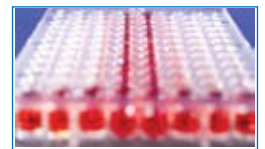


Cell line testing programs include assays for cell line viability, purity, identity and antibiotic resistance, and tests for plasmid identity, retention and copy number. Characterization includes assessment of the cell line for the presence of contaminating bacteriophage. Protocol templates for custom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

DETECTION OF PROCESS-RELATED IMPURITIES

Includes:

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



LOT RELEASE TESTING

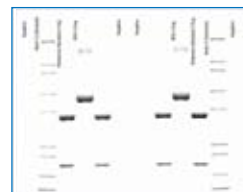
(For Bulk Drug Substance & Final Drug Product)

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

PRODUCT STABILITY

A wide variety of analytical or biosafety methodologies are offered 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.



Services for Microbial-Derived Protein Therapeutics

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

PROGRAM FEATURES

- Strong track record of supporting IND, BLA and market approvals by regulatory agencies worldwide.
- Dedicated cell banking suites and testing laboratories for microbial cell lines.
- 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 international 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 Sponsor's service expectations.

ADDITIONAL SERVICES

The highest level of critical regulatory and technical expertise is offered for 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
- GMP Manufacturing of Protein Therapeutics from Mammalian Production Systems

Contact WuXi AppTec regarding your microbial-derived therapeutic:

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