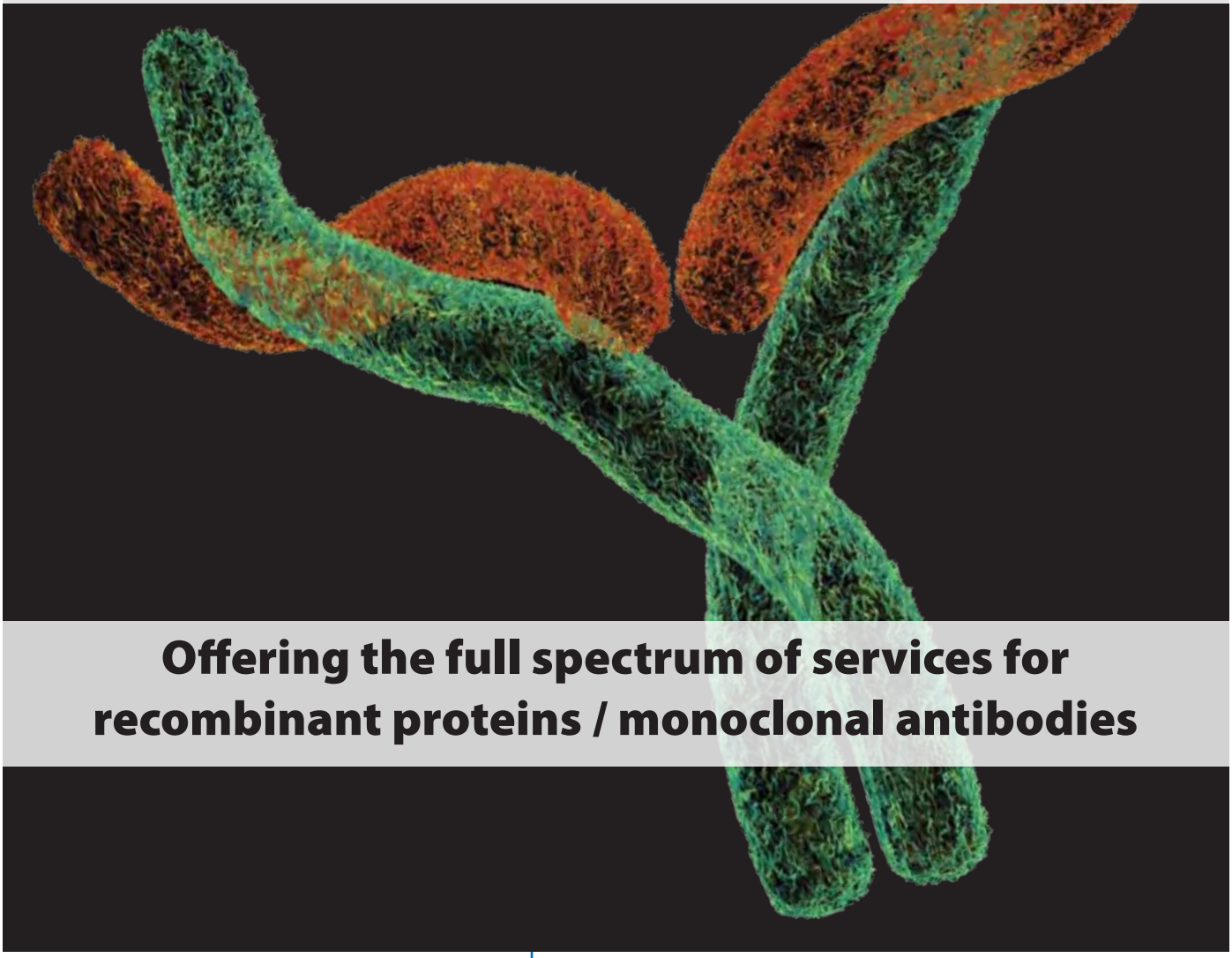
SERVICES FOR

Mammalian-Derived Protein Therapeutics



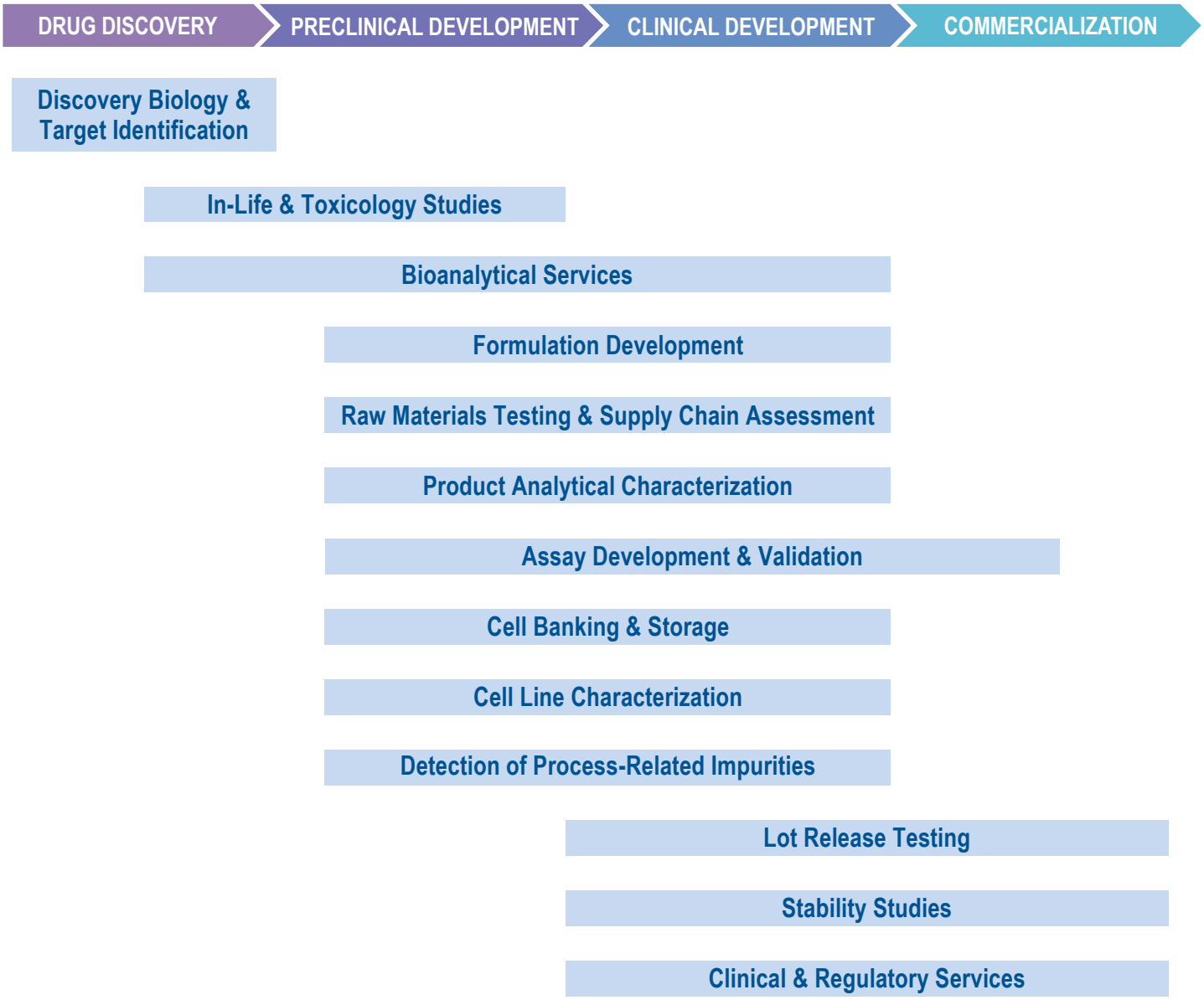
Offering the full spectrum of services for recombinant proteins / monoclonal antibodies

ILLUSTRATION:
Monoclonal Antibody

药明康德
WuXi AppTec

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

WuXi AppTec, an R&D & GMP/GLP contract manufacturing and testing company, offers a unique, single-source, fully integrated approach for development of biotherapeutic protein products produced from mammalian cell culture.



Novel MAb Discovery
High-throughput MAb discovery includes antibody generation using human phage library, advanced hybridoma methodologies and fully-human transgenic animals.

Discovery Biology & Drug Screening
Antibody screening services include assessment of functionality, affinity, reactivity, pharmacokinetic, pharmacodynamic, and safety pharmacology properties using a wide variety of in-vitro and in-vivo models.

Cell Line Engineering & Construction
Cell line development capabilities start at DNA sequences provided by clients and finish with the delivery of high yielding stable single clones.

In-Life & Toxicology Studies
A wide variety of skill sets are available to assist in all facets of your program, leveraging a wide range of animal models and expertise in preclinical toxicology and biodistribution.

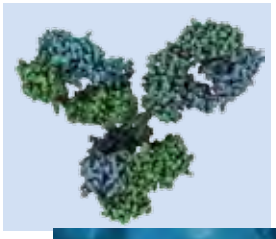
Bioanalytical Services
Our bioanalytical services team utilizes a diverse set of techniques and equipment to analyze for both large and small molecules including PK/TK/PD analysis, immunogenicity, high-throughput analysis and more.

Assay, Formulation & Process Development
Working with the Sponsor, WuXi AppTec can develop or perform technology transfer of assays and establish the appropriate acceptance criteria for their intended use. In-house expertise in developing MAb and rprotein drug product liquid and lyophilization formulations, including high-concentration Mab formulation development.

Identification of Process-Related Impurities
WuXi AppTec supports assays for detection and identification of a variety of process-related impurities including host cell protein, antibiotics, detergents, media components, and residual host cell DNA / DNA Sizing.

Raw Materials & Supply Chain Assessment
WuXi AppTec's experts can assist with assessing your supply chain and developing testing programs not only to detect potential viral and microbial adventitious agents, but also help prevent contamination from a wide variety of manufacturing components and reagents.

Product Analytical 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.



Cell Banking/Storage & 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. 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 in our in-house laboratories.

Assay & Process Validation
WuXi AppTec has developed over 3,000 assays for various analytical or biosafety purposes. Custom assays can be transferred from clients and optimized and validated or we can work with clients to develop new assays by utilizing the technical expertise of our laboratory staff.

Viral Clearance Validation
Industry-leading capacity with 12 viral clearance suites, ultra-pure high titer viral stocks, molecular biology labs, highly experienced staff and wide range of process equipment help ensure critical timelines and drug-filing needs are met. A database with over 20 years of viral clearance data can be mined to assist in process development efforts.

rProtein / MAb & Cellular Therapeutics Manufacture (GMP/non-GMP)
Offering the utmost in flexibility, 50 L, 100 L, 200 L, 500 L, 1000 L and 2000 L bioreactor options are available for client projects on a campaign basis. Each BDS suite comprises separate cell expansion, cell culture and purification areas.

Lot Release Testing & Stability Studies
For unprocessed bulk, bulk drug substance and final drug product, WuXi AppTec can develop or perform technology transfer from Sponsor for the various biosafety and analytical methods required for lot release. Additionally, a wide range of analytical or biosafety methodologies can be conducted under GMP guidelines for use in product stability studies.

Formulation, Fill & Finish
Final drug product formulation and filling is offered under cGMP conditions as defined by the various regulatory agencies and the Code of Federal Regulations (CFR). • Up to ~80,000 Vial Lot Size
• Liquid or Lyophilization Fills

Clinical & Regulatory Services
WuXi AppTec's dedicated and professional C&R teams have rich experiences in both clinical trial management and regulatory affairs consultation services, encompassing all phases of clinical trials. Working closely with clients to understand their objectives, the C&R teams generate solutions tailored to address specific issues and goals.

Services for
Mammalian-Derived Protein Therapeutics

WuXi AppTec, a leading global contract services organization, provides services of exceptional quality, leveraging more than 20 years of experience in the discovery, development, manufacturing and testing of mammalian-derived protein therapeutics.

PROGRAM FEATURES

- Strong track record of supporting IND, BLA and market approvals by regulatory agencies worldwide.
- Experienced and highly trained operational and quality staff with extensive experience in the U.S., EU and China.
- Dedicated project management.
- Comprehensive quality systems to conduct GLP and GMP programs that meet global regulatory acceptance.
- Specific expertise in a wide variety of product development areas including MAb discovery and screening, formulation and assay development and GMP manufacture and fill.
- Thousands of raw material and commercial product lots released under GMP guidelines or undergoing stability assessment.
- Over 2200 custom viral clearance studies performed for IND, BLA, and market approvals.
- 70-80 GMP cell banks manufactured or characterized each year.

BENEFITS

- Established, open-access technology platforms to expedite global protein therapeutics development.
- Economical development and production options.
- Comprehensive, integrated, single-source provider allows for all product development activities, performed with one organization utilizing one project management system.
- All major upstream and downstream processes utilize single-use manufacturing unit operations thus reducing expensive and time consuming process and facility changeover and validation programs.
- Intimate knowledge of China and other worldwide regulatory environments, including product development and approval pathways.
- Global access to the world's largest and growing healthcare markets.

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Contact WuXi AppTec regarding your mammalian-derived therapeutic:

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