

Protein Therapeutics Manufacturing

**Fully integrated, cost-effective
global manufacturing solutions**

*ILLUSTRATION:
Monoclonal antibodies*

 药明康德
WuXi AppTec

cGMP Manufacture and Fill

WuXi AppTec, a global R&D and GMP/GLP contract manufacturing and testing company, offers a unique single-source, fully integrated approach for biotherapeutic protein products produced from mammalian cell culture. Our proven competencies cover the full spectrum of therapeutic recombinant protein and monoclonal antibody development — from product discovery, to preparation and testing of cell banks, through cGMP clinical manufacture and lot release testing of bulk drug substance and final drug product.



Technology Transfer

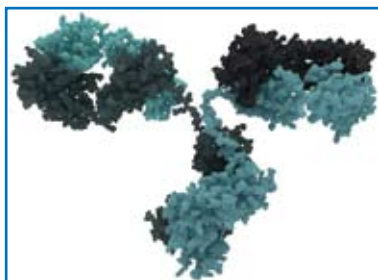
Our scientific expertise and multifunctional project teams allow for efficient transfer of Sponsor methods, assays and processes. The transfer of information and initial methods verification provides both WuXi AppTec and the Sponsor with a defined baseline to measure effects of operating procedures, raw materials, manufacturing scale-up, process optimization, protein characterization and product release criteria.

GMP Cell Banking and Storage

Cell banks are manufactured to client specifications, under exacting standards and QA oversight, in the closely monitored, secure and controlled environments of seven GMP cell banking suites. 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.

Bulk Drug Substance (BDS) Production

Designed for flexibility, the BDS product suites are available for client projects on a campaign basis. Each suite comprises separate cell expansion, cell culture and purification areas (including separate post-viral downstream processing) using disposable bioreactor and purification unit operations. *[Photos courtesy of Sartorius Stedim]*



Mammalian Cell Culture Capacity

Non-GMP

1 L – 50 L, 200 L, & 500 L

GMP

50 L, 100 L, 200 L, 500 L,
1000 L & 2000 L

Downstream Technologies

Cell Culture Clarification

Depth Filtration
Tangential Flow Filtration

Chromatography

Ion Exchange
Affinity
Size Exclusion
Reverse Phase
Hydrophobic Interaction (HIC)

Viral Clearance / Inactivation

Nanofiltration
Solvent Detergent
Low pH

Ultrafiltration & Diafiltration

Custom Process Steps



Final Product Formulation & Fill



WuXi AppTec offers final drug product formulation and filling 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 fill capabilities (2 ml, 20 ml, 50 ml)

Automated vial wash, sterilization, filling and capping line

Class 100 environment

Standard glass vial, rubber stopper, metal seal (1-50 ml)
container configurations available

Project Management

A dedicated WuXi AppTec project manager oversees all aspects of a sponsor's project, serves as a single point of contact to streamline communication, and interfaces with project team members to ensure timelines and cost objectives are met. To facilitate sponsor interaction throughout the project, WuXi AppTec developed dedicated space for sponsors to work on-site during technical transfer, while assisting in critical project phases or as a "person-in-plant."

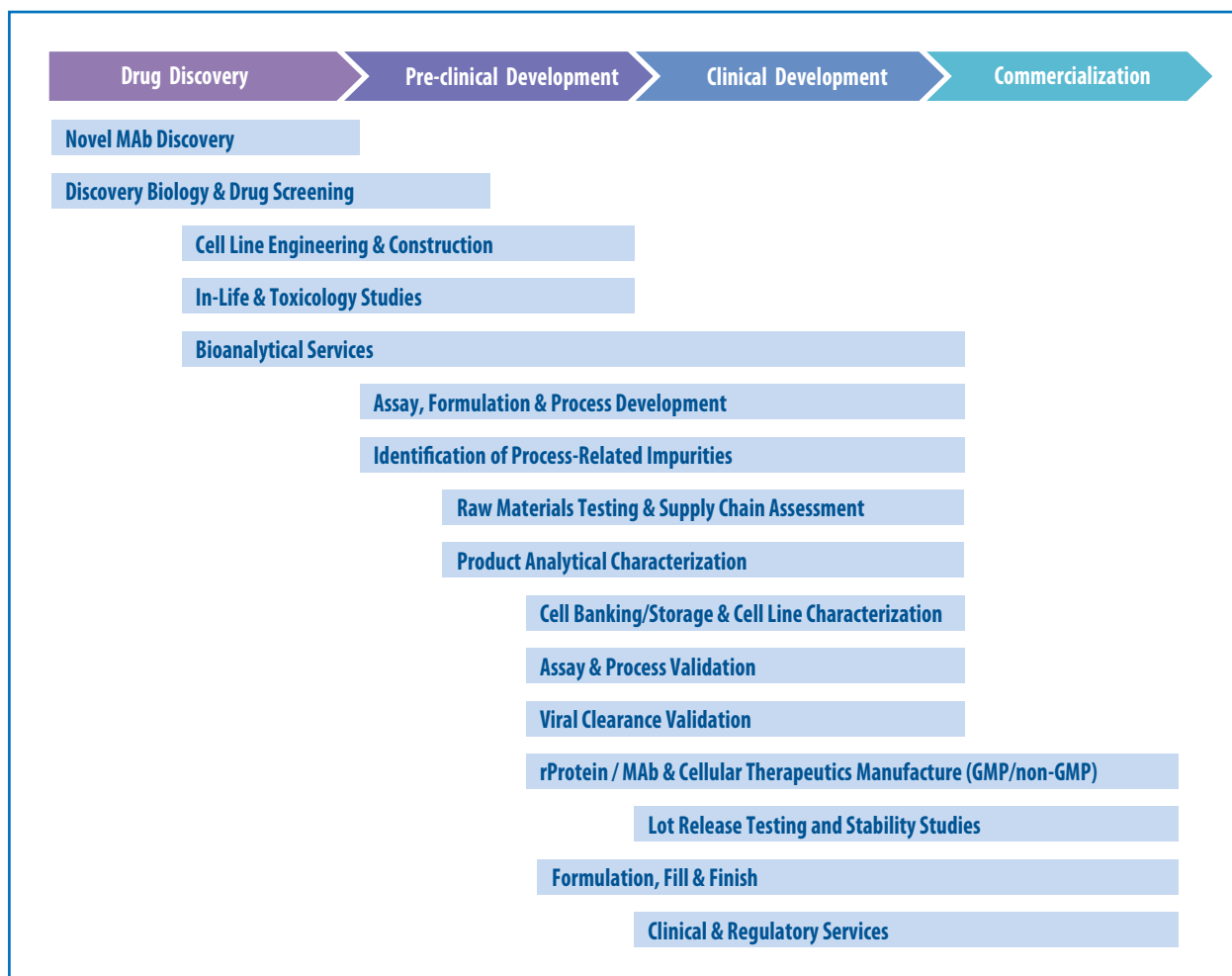
Facilities and Staff



All China- and U.S.-based WuXi AppTec facilities are state-of-the-art and designed to meet worldwide quality standards. Senior-level operational and quality staff offer extensive, wide-ranging industry experience from the U.S., Europe and China to ensure the highest level of technical and regulatory support.

Comprehensive Integrated Services from WuXi AppTec

WuXi AppTec provides a seamless, high-quality, single-source approach for the development, manufacture and testing of biotherapeutics. This single-source strategy can reduce the time-to-clinic and decrease significantly the cost of our customers' drug development efforts.



Contact us to learn more about our cGMP manufacturing and other services:
(1) 651-675-2000 / 888-794-0077 • info@wuxiapptec.com • www.wuxiapptec.com