

Protein Therapeutics Process Development

**Proven expertise and capabilities to support
your product development efforts**

*ILLUSTRATION:
Microscopic view of CHO cells*





Process Development Capabilities



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.

Upstream (Mammalian Cell Culture) Process Development

WuXi AppTec's cell culture process technology platform provides for optimization of media, seeding densities, feeding and bioreactor process control strategies to maximize expression, enhance process reproducibility and facilitate scale-up.

- Adaption of cell line to suspension culture process
- Adaption of cell line to serum-free/animal protein-free media
- Media optimization and evaluation
- Development of Fed-batch bioreactor process
- Cell culture characterization and optimization
- Scale-up
- Analysis of risk and cost benefits for various types of cell culture processes



Downstream (Recovery & Purification) Process Development

WuXi AppTec's downstream process development program will optimize yields, improve product purity and provide a robust, reproducible purification process using technologies and raw materials suitable for cost-effective large-scale manufacturing.

- Clarification development (depth filtration, dead-end filtration, TFF)
- Chromatography purification optimization (IEX, Affinity, HIC)
- Chromatography resin screening
- Chromatography resin dynamic binding capacity studies
- Chromatography resin lifetime, aging and cleaning studies
- Viral inactivation and viral filtration development (nanofiltration, low pH)
- Scale-down process characterization for viral clearance studies
- Scale-Up
- Analysis of risk & cost benefits for various purification process unit operations



Technology Transfer



Photo Courtesy of Sartorius Stedim

Our scientific expertise and multi-functional project teams allow for efficient transfer of methods, assays and processes from clients. This transfer of information (and its initial verification) provides both WuXi AppTec and Sponsor with a defined baseline by which to measure the effects of operating procedures, raw materials, manufacturing scale-up, process optimization, protein characterization, and product release criteria.

Analytical Development & Support

Ongoing analytical support is offered to process development and manufacturing operations. Assays are developed and validated for in-process analysis, bulk and final product stability studies, and final product quality control (sterility, purity, potency, identity and concentration).

Project Management

A dedicated WuXi AppTec project manager oversees all aspects of a sponsor's project, serves as a single point of contact to stream-line 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.

Technologies

Mammalian Cell Culture Systems

- Flasks (all types)
- Spinner / Shake Flasks
- Wave- and Stir-Form Bioreactors
 - 24 x 1-liter bioreactors (DASGIP)
 - 16 x 1-liter bioreactors (Applikon)
 - Ambr micro-bioreactor system (TAP)
 - 12 x 2.5-liter (Sartorius B. Braun)
 - 10 x 10-liter (Sartorius B. Braun)
 - 5 x Wave-form Bioreactors: 2L – 50L capacity (GE & Sartorius Stedim)
 - 3 x 50-liter & 3x200L Single-Use Bioreactor (Hyclone & Sartorius Stedim)
 - ATF system (Refine Technologies)
- Cell Culture Analyzers
 - 2 x Bioprofile Flex (Nova Biomedical)
 - 3 x Bioprofile 400 (Nova Biomedical)
 - 1 x Cedex (Innovatis/Roche)
 - 4 x Vi-Cell (Beckman Coulter)

Cell Culture Clarification

- Depth Filtration
- Tangential Flow Filtration
- Centrifugation

Ultrafiltration & Diafiltration

Custom Process Steps

Chromatography

- Ion Exchange
- Affinity
- Hydrophobic Interaction (HIC)
- Mixed Mode Chromatography

Viral Clearance / Inactivation

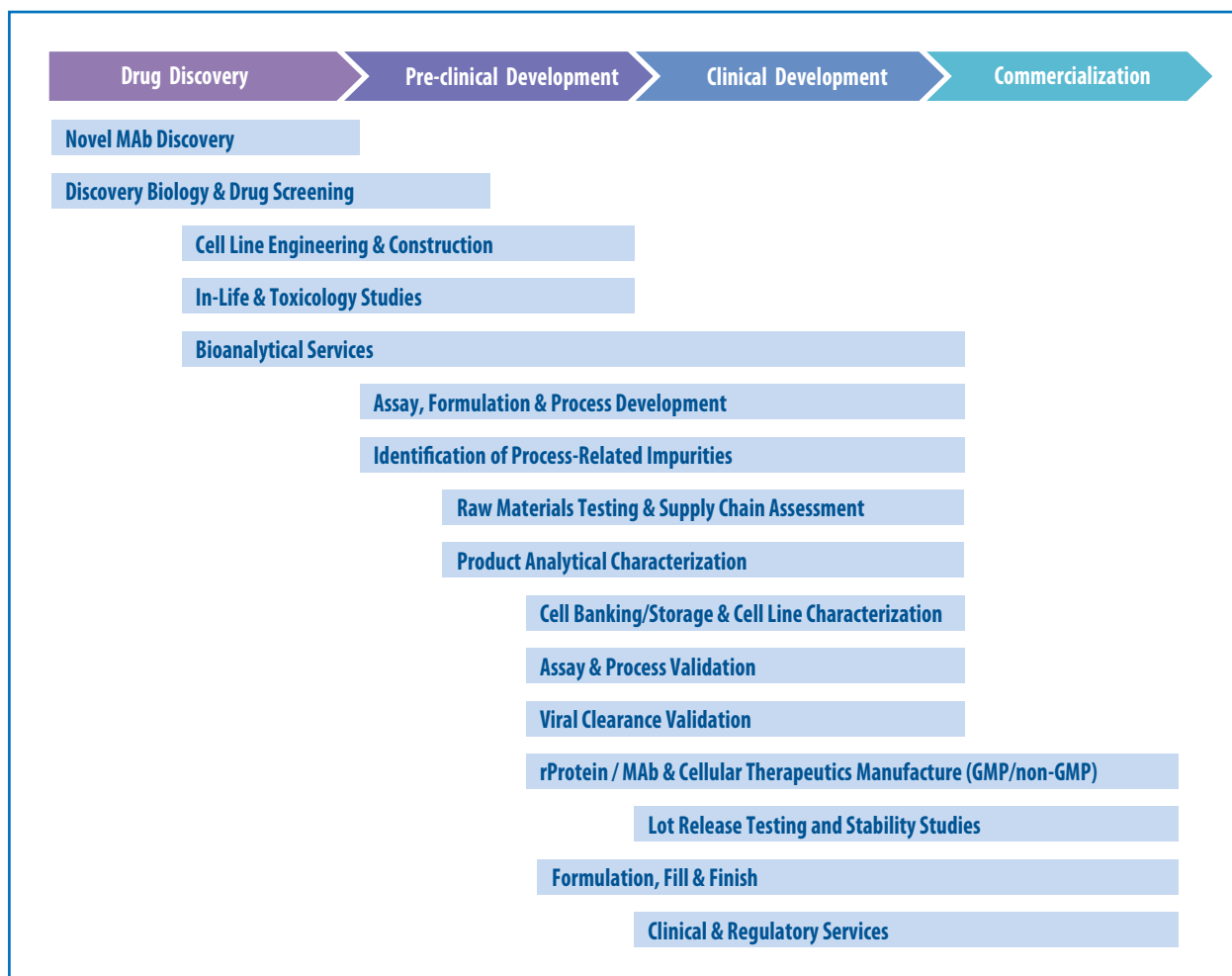
- Nanofiltration
- Low pH
- Chromatography

Downstream Purification Platforms

- 2 AKTA Avant
- 5 AKTA Explorer
- 2 AKTA Purifier
- 1 AKTA Xpress
- 1 AKTA Prime
- 2 AKTA Pilot
- 1 AKTA Ready
- 1 AKTA Bioprocess skid

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 process development and other services:
(1) 651-675-2000 / 888-794-0077 • info@wuxiapptec.com • www.wuxiapptec.com