

WuXia™ CHO-K1 Platform, the Ideal
Solution from cDNA to GMP Production



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WuXia™ = Ideal

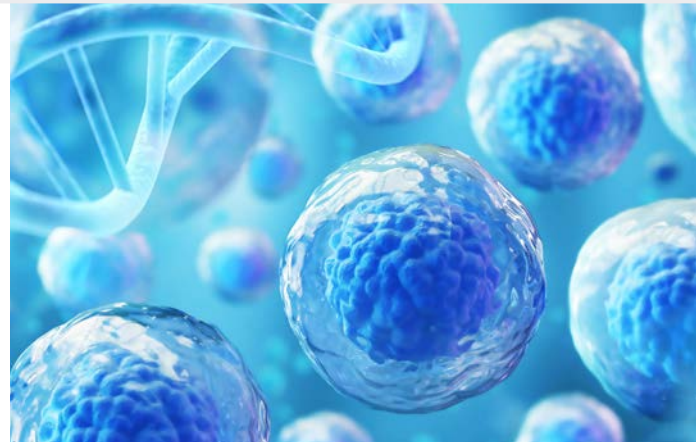
The Chinese word “WuXia” translates to “ideal” in English. Which is why we chose that word to describe our cell line development (CLD) platform. The WuXia™ CHO-K1 platform is a proven, high yielding technology accepted by regulatory agencies worldwide.

The WuXia CHO-K1 system has already been used for the production of > 900 antibodies and proteins now in clinical trials and five in commercial production, including one in the U.S. and Europe.

Technology Platform



Our program typically starts with client-provided DNA or amino acid sequences and extends to the delivery of high-yielding, well-characterized, stable single clones. The same cell line and vector system is used for candidate screening, rapid bulk pool material generation, developability studies, and CLD through GMP production.



WuXia CLD System Is Ideal for a Wide Variety of Biologics



Monoclonal Antibodies



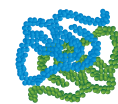
ADC Therapeutics



Bispecific Antibodies



Fc-fusion Proteins







Recombinant Proteins



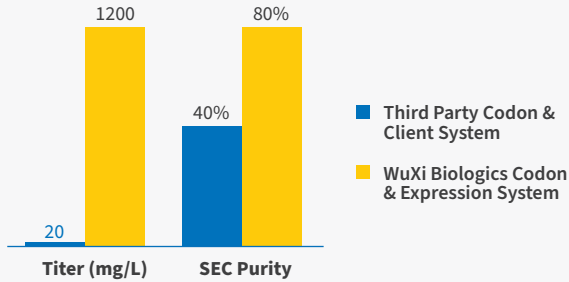
Antibody Fragments

Features and Advantages of WuXia CLD Platform:

 Productivity	 Speed	 Quality	 Expertise
Robust host CHO-K1 cell line	Rapid bulk pool material generation	Host cell toolbox designed to meet global regulatory requirements	>900 cell lines developed
Proprietary codon optimization algorithm	Automated high throughput systems for clone screening	NGS-guided clone selection resulting in no mutations at the genetic level	>220 cell lines developed for bispecific antibodies
Average clone titer 6.0 g/L	DNA to PCB/MCB in 9-10 weeks	Excellent clone stability	>220 cell lines in clinical trials
Typical productivity >5 g/L for over 80% of clones	Timelines of 2.5 to 12-month to IND (accelerated vs platform)	Comprehensive analytical testing and cell line characterization	1 commercial product in U.S. and Europe, 4 commercial products in China

These three cases highlight how the WuXia CLD platform overcomes the challenges to provide clones with high titer and good product qualities in CMC development.

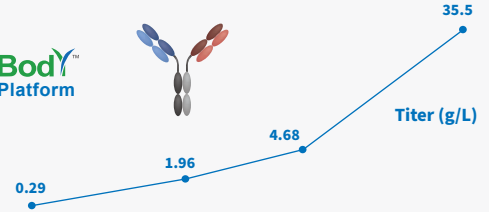
Case Study: WuXian™ Transient Expression



Proprietary codon optimization can increase the expression level as well as the product quality for a bispecific antibody molecule.

Case Study: Bispecific Antibody Achieving >35 g/L Titer*

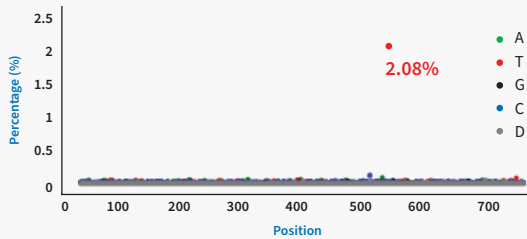
*IND Approved in 2020



Stage	Feasibility Study	Developability	Top 1 Clone	Process Development
Platform	WuXian Transient	WuXian Express	WuXia CLD	WuXiUP™

Integrated CMC services provide significant titer boost by using our WuXiUP cell culture development technology, making this an ideal solution for situations where target molecules have low titer.

Case Study: NGS Provides Higher Resolution Than Traditional Sanger Sequencing



Using NGS in clone screening, the WuXi Biologics cell line development platform guarantees no mutations at the genetic level.

A comprehensive toolbox for overcoming challenges in bispecific antibody development.

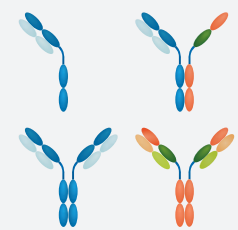
Balanced Chain Expression



Impurity Detection



Separation of Major Impurities



Solubility, Stability, Lyophilization and Formulation

Industry Leading Comprehensive Services

WuXi Biologics offers an extensive list of CMC services that can be integrated and often conducted in parallel with our cell line development services – all using the same cell line platform.

Sequence Analysis

- Sequence analysis helps identify the hot spots for potential risks in product quality attributes

Material Generation

- WuXian™ Transient with 1.2 g/L productivity within 4 days
- WuXian Express with average titer of 3.8 g/L

Developability Studies

- Developability studies screen candidates and help reduce risk by determining a product's suitability to upstream and downstream processes and the stability of product and formulation

Stability Studies and Analytical Services

- Long-term productivity studies assess protein expression and product quality
- Genetic stability studies provide stability assessments for cell banks
- A full range of requisite product analytical characterization support services are available

Cell Banking, Biosafety Testing and Cell Line Characterization

- EMA, NMPA, and PMDA certified GMP cell banking and global regulatory compliant biosafety testing
- Comprehensive cell line characterization services for late-stage development

Process Development

- WuXi Biologics has one of the world's largest and most experienced process development teams to develop, optimize, and validate upstream and downstream processes for eventual large-scale GMP manufacturing

Development to IND

- The highly qualified, integrated CMC teams at WuXi Biologics can enable our client partners to reach IND submission in as little as 2.5 to 12 months, depending on the project requirements and complexity



Laboratory Data Management System

Lab Data Management System (LDMS) is our proprietary integrated platform to manage the life cycle of data from R&D.

Using biostatistical models and machine learning algorithms, LDMS assists data recoding, analysis, and summary, ensuring data integrity.

About WuXi Biologics

WuXi Biologics is a leading contract research, development and manufacturing organization (CRDMO) that provides end-to-end capabilities to healthcare organizations worldwide. With operations in China, the United States, Ireland, Germany, and Singapore, we enable our partners to effectively and efficiently bring biologics and vaccines to patients worldwide through our comprehensive and high-quality drug development model.

The world's leading global single-source platform from concept to commercialization.

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WuXi Biologics
Global Solution Provider

