WuXi Biologics
Global Solution Provider

Microbial-Derived Product Services

Comprehensive CMC Development and cGMP Manufacturing of Microbial Fermentation-Derived Products

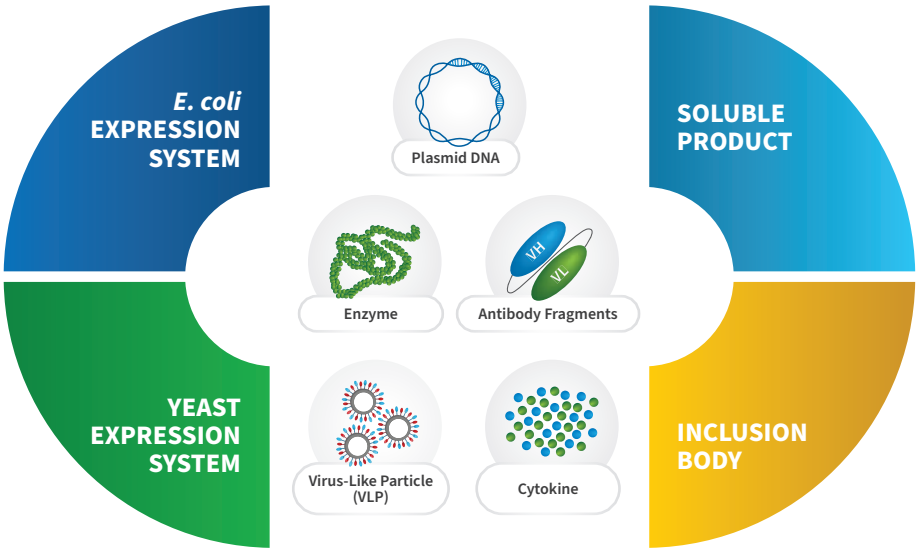
Scan the QR code to learn more:

WuXi Biologics Microbial Platform

WuXi Biologics provides comprehensive CMC development and cGMP manufacturing services for a wide range of biotherapeutics, bioreagent and vaccines produced from microbial-based systems. We have built world-class facilities and established an expert, highly-trained team to provide end-to-end services from strain development to regulatory filing and beyond. Centralized development & cGMP activities for microbial fermentation-derived products can be offered by a dedicated business unit in Hangzhou, China, to streamline and expedite product development.

Comprehensive, End-to-end Microbial Services

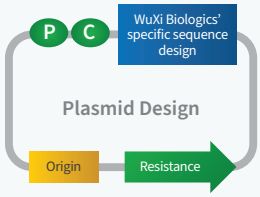
We support, through microbial fermentation, the production of an array of products that include but are not limited to plasmid DNA, enzyme, cytokine, virus-like particle (VLP), antibody fragment and other recombinant protein. Our cGMP services include a Drug Substance (DS) manufacturing facility with up to 2,000 L scale fermenter and state-of-the-art robotic aseptic filling systems for Drug Product (DP) manufacturing.



Strain Development

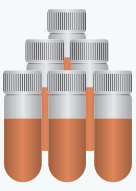
- Innovative engineered *E. coli* and Yeast host systems
- Optimized expression vector construction
- Sequence optimization and signal peptide screening
- Rapid strain development process
- In-house cGMP cell banking and characterization
- Zero royalty fees from research to commercialization

Proprietary host strains and plasmid backbones for protein and pDNA expression



- Vector construction
- Sequence optimization

- High-expressing *E. coli*/Yeast
- Genetic stability
- Productivity stability



- cGMP cell banking
- Cell bank characterization

Our end-to-end, comprehensive microbial platform offers a single-source solution from strain development through CMC dossier and regulatory support by our well-trained staff and global quality system that has continually passed multiple rigorous regulatory inspections.

- Vector Construction
- Cell Line/Strain Development
- cGMP Cell Banking
- Strain Characterization
- Fermentation Process Development
- Purification Process Development
- Analytical Development
- Drug Product Development
- GMP Manufacturing (DS and DP)
- Batch Release & Stability Study
- CMC Dossier & Regulatory Support

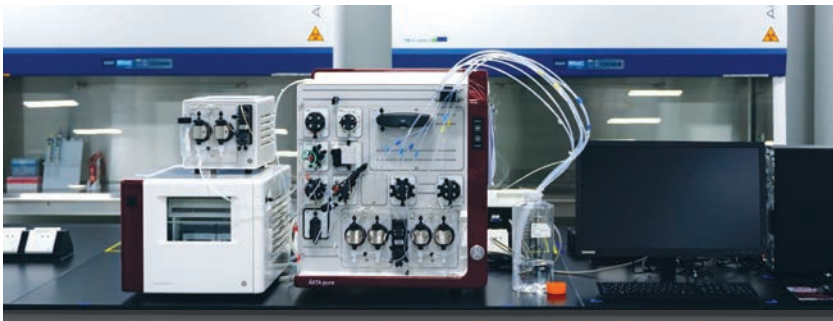
Fermentation (Upstream) and Purification (Downstream) Process Development

We offer state-of-the-art microbial fermentation and purification process development laboratories as well as a non-GMP pilot plant specializing in the process development, process characterization, technology transfer and process scale-up for successful cGMP manufacturing.

Strong Development Capabilities:

- Well defined dual-affinity tag system to facilitate expression and purification of enzymes
- High-performance platform process for quick plug-in and optimization
- High throughput screening technologies (integration with DoE) to accelerate process development for challenging molecules
- Fermentation tool-box for titer/quality improvement
- Flexible purification tool-box (Endotoxin/HCP/HCD removal) to expedite process development of various modalities
- Rich process development experience in Virus-Like Particles/ Inclusion Bodies
- Successfully scaled-up from 10 L to 50/200/500/2,000 L

Separate room and equipment are dedicated to *E. coli* and Yeast fermentation. Different types of bioreactors support fermentation development at scales ranging from 200 mL to 10 L.



A variety of equipment, depending on your needs, can be utilized for controlling low-temperature purification processes.

Additional Key CMC Development Services

Analytical Development

The analytical method development team supports many CMC activities including strain development, fermentation, purification, and formulation development. These include:

- Development of in-process, release and stability-indicating methods
- Product biochemical, biophysical, and biological characterization, comparability and similarity assessment
- Forensic and analytical investigation/troubleshooting for GMP manufacturing-related issues
- Lot release and stability studies of non-GMP products
- Reference standard generation and characterization
- Tech transfer to quality control (QC)

	Identity	Purity	Impurity	Potency	Safety	Structure
pDNA	✓ pDNA sequencing ✓ Restriction enzyme digestion	✓ Supercoiled percentage ✓ A260/280 by UV absorbance ✓ pDNA segment by electrophoresis/ HPLC/CE	✓ Residual host cell protein by ELISA/ LC-MS ✓ Residual host cell DNA/RNA ✓ Residual solvent ✓ Residual antibiotics by ELISA	✓ *In vitro* gene of interest expression by cell-based assay (CBA) ✓ Gene of interest or product functionality by CB	✓ Sterility/Bioburden ✓ Phage ✓ Endotoxin	✓ Intact/ reduced mass ✓ Sequence coverage by LC-MS/MS ✓ PTMs ✓ Peptide mapping ✓ SEC/FFF-MALS ✓ AUC ✓ Secondary and higher order structure ✓ Size distribution and zeta potential
Protein	✓ Peptide mapping ✓ Western Blot	✓ SEC-HPLC ✓ Charge variant by AEX-HPLC or cIEF ✓ CE-SDS (Reduced & Non-Reduced) ✓ RP-HPLC				

Formulation and DP Process Development

- 500 m^2 labs with processing and physicochemical testing ability
- Pre-formulation and formulation development
- Liquid, frozen liquid and lyophilized dosage form development
- Forced degradation studies
- Container closure selection/evaluation including vials and prefilled syringes (PFS)
- Clinical in-use compatibility
- Adjuvant selection and evaluation

cGMP Manufacturing of Drug Substance and Drug Product

We provide high flexibility for your needs to support the complex drug filling processes of biotherapeutics, bioreagents and vaccines.

We can support cGMP manufacturing of both DS and DP to efficiently and cost-effectively meet your preclinical, clinical and commercial supply needs.

Microbial Fermentation DS cGMP Manufacturing

Our microbial-based large-scale manufacturing facility was designed and constructed based on U.S., EU and China cGMP requirements. The site utilizes the same comprehensive quality system utilized by all of our global GMP facilities.

Site Details:

- Over 3,000 m^2 cGMP manufacturing space
- 3 stainless steel lines scaling up to 2,000 L
- Multiple single-use bioreactors scaling up to 300 L
- Flexible downstream lines with single-use technologies
- Temperature control processing
- One DS fill line

Drug Product Manufacturing

A dedicated suite with robotic aseptic filling systems for liquid DP manufacturing is available in Hangzhou.

System Features:

- Highly-automated with high flexibility, and advanced aseptic assurance
- Grade A isolator under Grade C environment background
- Up to 20,000 units per batch, satisfying clinical manufacturing needs of various dosage forms
- Supporting special processing requirements
  - Equipped with aseptic formulation isolator for alum-adjuvanted vaccines
  - Equipped with T-junction mixer, UF/DF unit for LNP formulation process
- Ability to fill multiple ready-to-use (RTU) container-closure systems (CCS)
  - Vials (2R, 4R, 6R, 8R, 10R, 20R)
  - Pre-filled syringes (standard/long, 1-3 mL)
  - Cartridges

In addition to our site in Hangzhou, fill of biologics and vaccine drug substance produced via microbial fermentation, including lyophilized dosage forms, can also be performed in our various manufacturing facilities globally.

Quality Control

Our dedicated team of well-trained and experienced professionals allows us to offer:

- Qualified state-of-the-art analytical instrument in compliance with cGMP requirement
- Analytical method transfer, qualification, and validation as per phase-appropriate strategy
- Over 2,000 m^2 of laboratory with dedicated space for Microbiology, Physical and Biochemical tests, and potency assays
- Support environmental monitoring of facilities and utilities
- cGMP testing services for cell bank, production materials, intermediates and products
- Data Integrity promoted with culture and training and ensured via technical and procedural control

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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