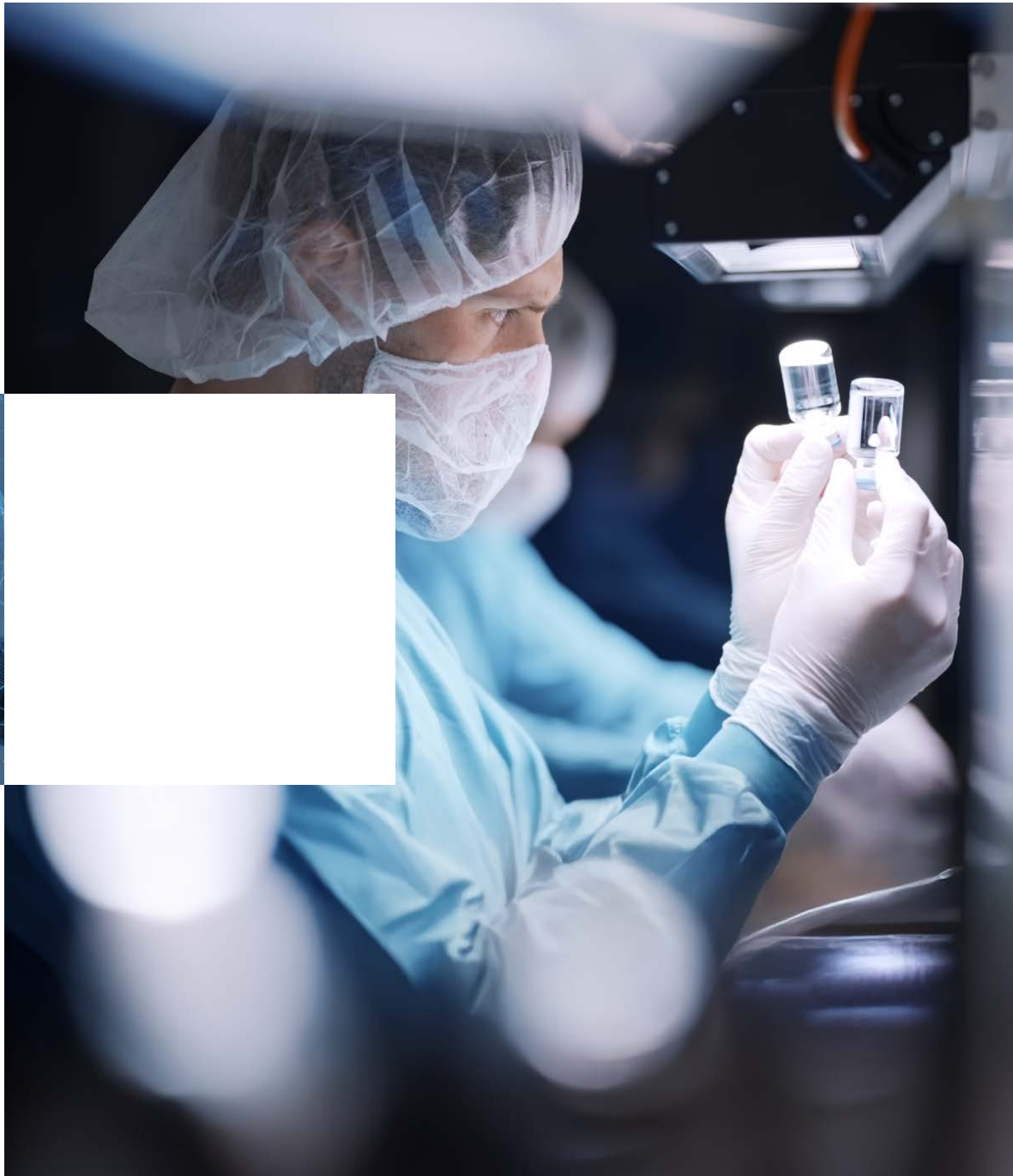


# EVERY BIOLOGIC CAN BE MADE

Single-source **CRDMO** services from  
concept through commercial



[wuxibiologics.com](http://wuxibiologics.com)

# Translating Possibility into Progress

As a leading CRDMO, WuXi Biologics integrates biologics services from concept through commercialization, delivering quality at every stage. We perform under the most demanding conditions, advancing programs at unmatched speed with expertise and assurance.

Multi-modality discovery generates development-ready assets built for continuity. A growing pipeline supports over 660 IND approvals and 25 commercial manufacturing programs. DNA reaches IND in as little as 6 months.



## Built to Deliver Since 2010

**12,000+**  
Employees

**945**  
Cross-functional projects

**1,000+**  
Global clients

**90+**  
Market authorizations supported

**1,800+**  
Quality audits passed



## Regulatory excellence across all major global markets

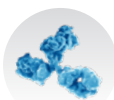
**46**  
regulatory inspections

**136**  
facility license approvals

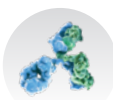
Sites in  
**6 countries**  
with continued global expansion



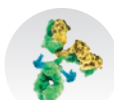
## Mammalian Expression



Monoclonal Antibodies



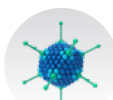
Bispecific Antibodies



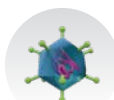
Antibody-Drug Conjugates



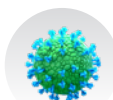
Fc-Fusion Proteins



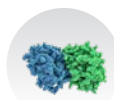
Viral Vectors



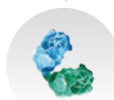
Oncolytic Virus



Virus-Like Particles



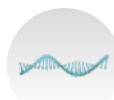
Recombinant Proteins



Antibody Fragments



Plasmid DNA



Messenger RNA

## Microbial Expression

# Integrated Strength across Biologics Services

Research, development, and manufacturing unite into a single-source solution, eliminating external handoffs and minimizing cost and risk. Quality, regulatory, and testing are all in-house.



## RESEARCH

- Antibody discovery
- Protein production and engineering
- Protein characterization
- *In vitro* assays
- *In vivo* pharmacology



## DEVELOPMENT

- Cell line development
- Cell culture process development
- Cell banking and characterization
- Downstream process development
- Pilot production and scale-up
- Analytical development
- Biosafety testing
- Formulation and drug product development
- Commercial process development
- Process characterization and process performance qualification (PPQ)
- BLA-enabling studies
- IND and BLA filing support



## MANUFACTURING

- Drug substance GMP manufacturing
- Drug product GMP manufacturing
- Quality control lot release and stability



RESEARCH



DEVELOPMENT



MANUFACTURING

# Advance and De-Risk

Start strong with a data-driven approach aligned to downstream success.



## Modular platforms from discovery to translational insights

Guide development-ready candidate selection and reduce late-stage risk.



## Quality built for scale and transfer

Deliver premium research materials with fast turnaround and seamless transition into CMC.



## One unified framework for diverse biologics

Advance T-cell receptors, miniproteins, and other modalities with consistent workflows, timelines, and quality.



## Extensive drug development expertise

Experienced scientists, proven processes, and a global track record empower biologics research.



## Drug development expertise empowering research services for biologics

### Research Capabilities

- Antibody discovery
- Protein production and engineering
- Protein characterization
- *In vitro* assays
- *In vivo* pharmacology



RESEARCH



DEVELOPMENT



MANUFACTURING



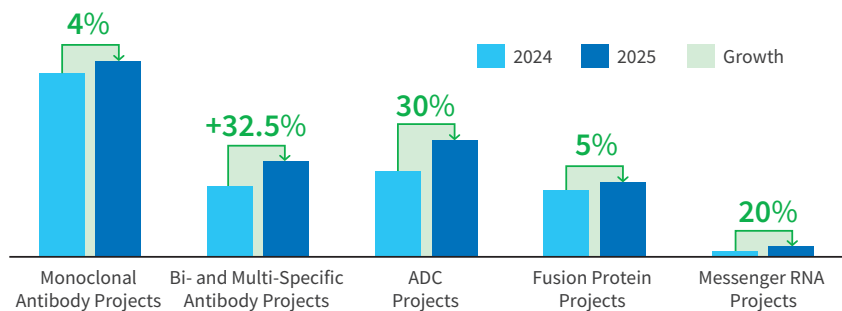
# Streamline and Accelerate

Advance biologics development with expertise, rigor, and efficiency.

- Mammalian Biologics Development and Manufacturing
- Microbial Manufacturing and Fermentation
- Conjugation and Bioconjugate Development
- Biosafety and Characterization Testing
- Clinical Manufacturing and Product Release
- CMC Strategy and Program Management

## Rich Pipeline across Biologic Modalities

Leadership in bi- and multi-specific antibodies and ADCs



## DNA to IND in 6 Months

Setting a New Standard for Speed

MONTH											
1	2	3	4	5	6	7	8	9	10	11	12

Industry Standard **12 Months**

WuXi Biologics **10 Months**

WuXi Biologics **6 Months**

**65+ INDs**  
delivered within 6 months





RESEARCH



DEVELOPMENT



MANUFACTURING

Our technology platforms synthesize technology, processes, and expertise into a standardized system designed to address specific development needs, unlocking yield, purity, stability, and speed.

### Cell Line Development



Mammalian cell line development with targeted integration

- 6 g/L mAb pool titer
- > 8 g/L mAb clone titer
- > 99% of lead clones are stable
- WuXia RidGS, WuXia CHO-K1, and WuXia293<sup>Stable</sup> and other extensions for specialized capabilities\*



Microbial cell line development

- 15 g/L protein titer
- 1 g/L plasma DNA titer
- 99% purity

### Upstream and Downstream Processing



Ultra-intensified intermittent perfusion fed batch

- 10–35 g/L CHO cell titer
- 60–80% cost of goods sold reduction
- 3–6× productivity gain



Ultra-high productivity continuous bioprocessing

- 20–120 g/L expression levels
- 5–20× productivity gain



Site-specific antibody-drug conjugate (ADC) conjugation

- ≥ 85% single-species ADCs without purification (DAR1 and DAR2)
- ≥ 65% single-species ADCs without purification (DAR4 and DAR6)
- ≥ 95% single-species ADCs with column purification

### Formulation Development



High-concentration drug product development

- ≤ 230 mg/mL concentration
- ≤ 90% viscosity reduction
- ≤ 8-week screening of 24 formulations

## Technology Innovation



77

patent applications



8

granted patents



Explore WuXia extensions at [wuxibiologics.com/capabilities/cell-line-development](http://wuxibiologics.com/capabilities/cell-line-development).



RESEARCH



DEVELOPMENT



MANUFACTURING

# Scale and Finish

Deliver clinical and commercial supply with global quality and reliability.

> 1,300

drug substance batches at  $\geq 98\%$  success

> 2,100

drug product batches at  $\geq 99\%$  success

16

drug substance sites

9

drug product sites

> 350

large-scale ( $\geq 6,000$  L) batches at  $99\%$  success

> 500,000 L

total capacity

## Global Network Security

Globally distributed manufacturing, unified under one quality system, supports dual sourcing and hybrid development-to-manufacturing pathways. Our network boosts flexibility, mitigates risk, and maintains supply continuity.



## Transfer-In at Any Stage

Expert technology transfer to resolve productivity, robustness, and scale-up challenges.

120+

Pre-IND to Phase II

60+

Phase II to PPQ

16

PPQ to Commercial

# Putting the Plus in CRDMO

WuXi Biologics has evolved CDMO to CRDMO, and now CRDMO+. Our plus model raises the standard across 4 pillars, reflecting our commitment to faster, smarter, more comprehensive solutions.



**CLIENT<sup>+</sup>** Enable client success

**GLOBAL<sup>+</sup>** Scale global manufacturing

**INNOVATION<sup>+</sup>** Advance innovation across modalities

**AGILITY<sup>+</sup>** Accelerate speed and execution



## SUBSIDIARIES FOR SPECIALIZED CAPABILITIES



Trust the complexity of ADCs and other bioconjugates to dedicated experts. WuXi XDC merges research, development, and manufacturing into an integrated, end-to-end solution.

[wuxidc.com](http://wuxidc.com)



Overcome bottlenecks and accelerate access to safe, effective vaccines. WuXi Vaccines merges development and manufacturing services for vaccines and prophylactic antibodies to enable rapid responses that scale.

[wuxivaccines.com](http://wuxivaccines.com)



**Despite these unprecedented challenges, you've demonstrated great dedication, excellence, and creativity. We're very impressed and grateful for all of your hard work and creativity... We're proud to have you as our partner.**

– CEO of a top-20 pharmaceutical company



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

WuXi Biologics is a leading CRDMO that provides comprehensive services to healthcare organizations worldwide. Operations in the US, Ireland, Germany, Singapore, China, and Qatar empower efficient, effective delivery of high-quality biologics and vaccines to patients around the world.



Have questions?  
**Contact us**

[wuxibiologics.com](http://wuxibiologics.com)  
[info@wuxibiologics.com](mailto:info@wuxibiologics.com)