Capabilities Overview

CRDMO

Contract Research, Development & Manufacturing Organization

RESEARCH
From Target to Lead Identification

DEVELOPMENT
10 Months from DNA to IND

MANUFACTURING
Global Dual Sourcing

A true single-source platform for biologics and vaccines from concept to commercialization

Scan the QR code to learn more:

WuXi Biologics
Global Solution Provider

WuXi Biologics

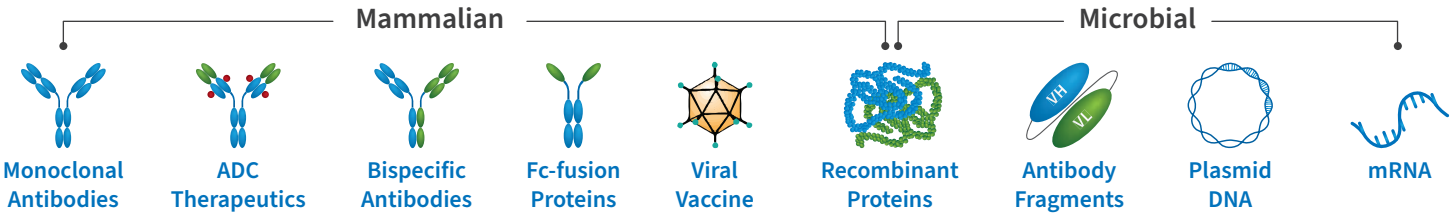
WuXi Biologics is a global Contract Research, Development and Manufacturing Organization (CRDMO) with leading open-access biologics technology platforms. We offer end-to-end solutions that enable our partners to discover, develop, and manufacture biologics from concept to commercialization for the benefit of patients worldwide. With a total estimated bioreactor capacity for biopharmaceutical production planned in five countries at >580,000 L after 2026, WuXi Biologics will provide its biomanufacturing partners with a robust and premier-quality Global Dual Source supply chain network.

WuXi XDC, a subsidiary of WuXi Biologics, is a CRDMO organization for bioconjugated products including ADC's. The company's expert-driven, high-quality services include discovery R&D, CMC development and GMP manufacturing of ADCs' or other bioconjugates, chemical payloads and linkers, and the bioconjugated Drug Substance (DS) and Drug Product (DP).

WuXi Vaccines, a subsidiary of WuXi Biologics, enables the success of global partners in bringing new, effective vaccines to market worldwide.

Our company history and achievements demonstrate our commitment to providing a true one-stop service offering and strong value proposition to our partners and clients.

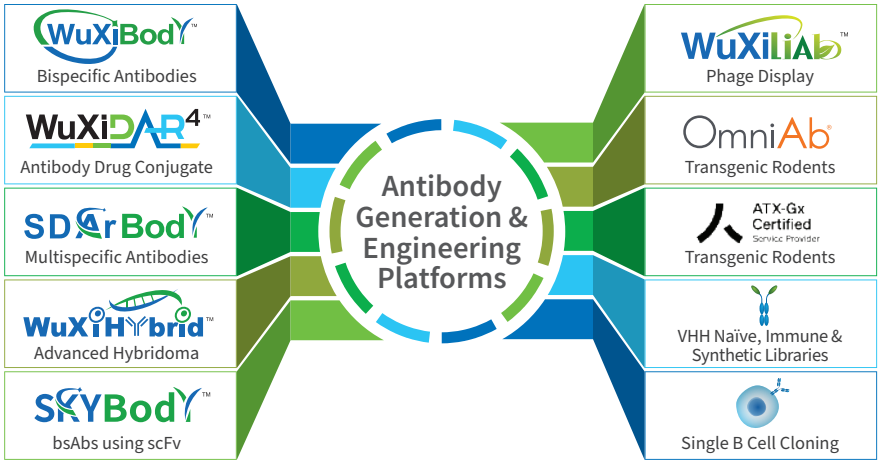
We provide single-source platforms for a variety of biotherapeutics and vaccines produced from mammalian cell culture and microbial fermentation systems.



DISCOVERY

WuXi Biologics offers industry-leading expertise, state-of-the-art facilities, and multiple antibody generation technology platforms for the discovery of novel monoclonal, bispecific and multispecific antibodies, immunocytokines and other biologics. We tailor solutions to best suit your technical and budget requirements to ensure you achieve your key drug development milestones.

Our antibody discovery team comprises about 400 highly-trained scientists for the generation, selection, optimization, and characterization of antibodies or other biologic molecules utilizing advanced *in vitro* and *in vivo* approaches. We provide one-stop services from concept to IND filing or modular approaches and flexible business models.



DEVELOPMENT

Utilizing one of the world's largest and highly-trained development teams, we have the manpower and expertise to assist your program in the most efficient and cost-effective manner. Our leading DNA to IND and late-stage development timelines are designed to meet your IND and BLA submission goals.

- Upstream cell culture / fermentation and downstream purification development
- Analytical and bioassay method development
- Drug product / formulation development (liquid & lyophilized)
- Full spectrum and tailored CMC development for bioconjugates and ADCs, including conjugation and purification process development, formulation and drug product process development and analytical development

WuXian™ Custom Protein Generation Services	WuXiUI™ Ultra-Intensified Fed-Batch Manufacturing Platform
WuXia™ Cell Line Development Platform	WuXiHigh™ High Concentration and High Throughput Drug Product Development Platform
WuXiUP™ Continuous Manufacturing Platform	

DS MANUFACTURING

Designed for flexibility and with bioreactor options to meet your program's needs on a campaign basis, WuXi Biologics offers extensive Non-GMP/GMP Drug Substance (DS) manufacturing for a variety of biologics using single-use/disposable bioreactors and our "scale-out" manufacturing paradigm.

- Technology transfer
- GMP cell banking and storage
- Pilot, clinical and commercial-scale
- Mammalian and microbial systems
- Fed-batch, intensified fed-batch and perfusion cell culture options
- Over 280,000 L bioreactor capacity across 14 facilities
- Multiple facilities in 4 countries
- Dedicated GMP facilities for ADCs/Bioconjugates manufacturing, as well as high potency payload linker manufacturing

DP MANUFACTURING

WuXi Biologics has 9 Drug Product (DP) facilities for clinical and commercial-scale cGMP manufacturing. We provide GMP formulation and fill services for both liquid and lyophilized dosage forms utilizing a variety of container closure systems including combination products and vial configurations ranging from 2R to 50R.

- Multiple fully-automated, isolator-based high-throughput fill lines
- Drug product fills via fully-robotic, programmable and gloveless Vanrx systems
- Biologics, vaccines, and aqueous parenterals
- Vials, prefilled syringes (PFS) and ready-to-use (RTU) container closure systems (CCS)
- Up to 100,000 vials/batch
- Dedicated facility for ADCs/bioconjugates
- Labeling and packaging for commercial products

TESTING

We offer a wide array of analytical, molecular, in vitro and in vivo methodologies and provide a full range of services to help take your product from discovery to commercialization and guide you in designing testing programs for global regulatory acceptance.

- Analytical method development
- Product and reference standard characterization
- Bioassay and biological characterization
- Extensive LC-MS capabilities
- In-house testing services (GMP lot release and stability testing)
- Forensic analysis (e.g., particulate(s) ID, material characterization)
- In-house biosafety testing services (e.g., cell line characterization, unprocessed bulk lot release and viral clearance)

Experience and Expertise

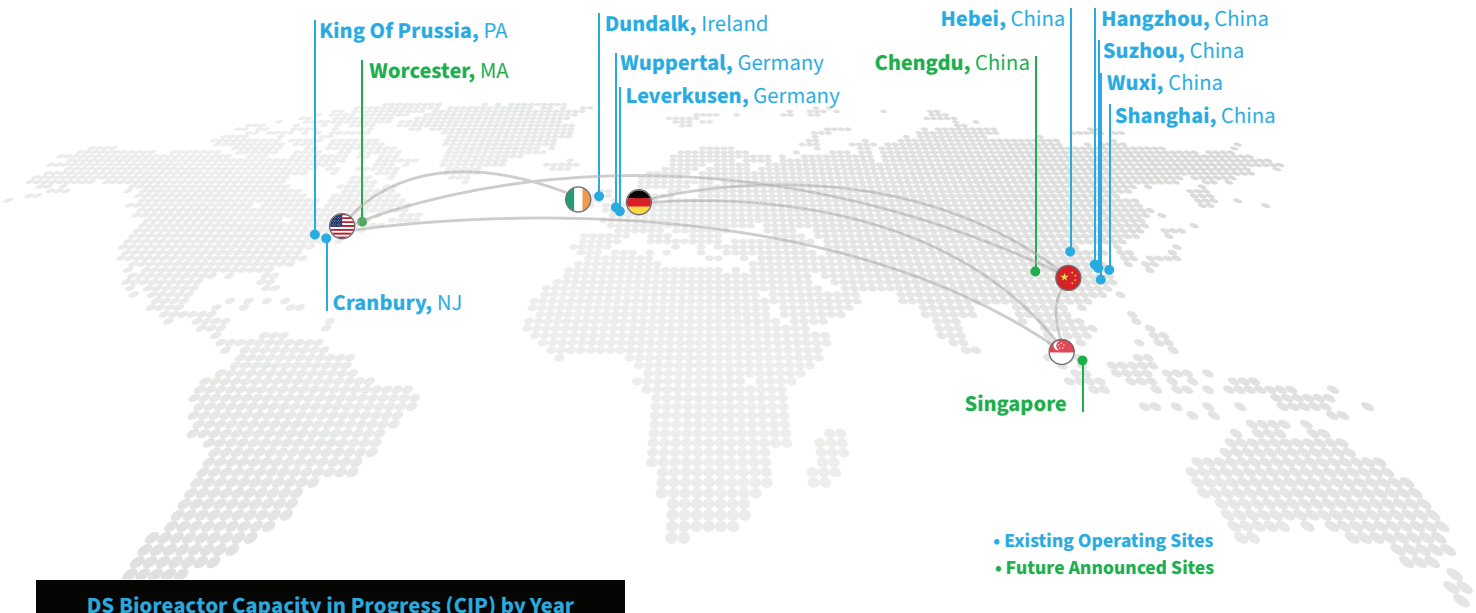
Our leadership team consists of over 650 scientists with 15-20 years of experience working at the forefront of the biologics industry. While at WuXi Biologics this team has enabled 69 MAAs, BLAs and EUAs and 540+ worldwide IND submissions in the last few years. Our expertise covers all facets of drug development from discovery to GMP manufacture of final drug product.

Commitment to Quality

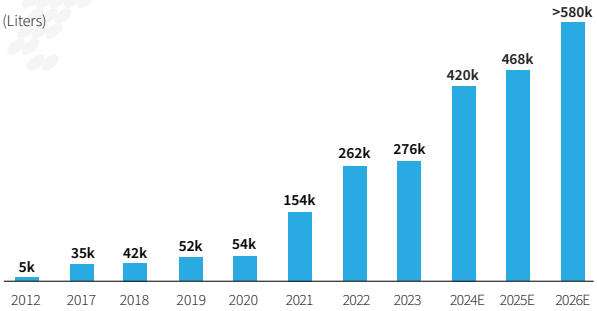
We provide a quality system and operations that meet worldwide regulatory guidances. Our audit track record demonstrates our commitment to meeting worldwide regulatory standards as validated by GMP manufacturing accreditations from the U.S. FDA, EMA, NMPA, ANVISA, PMDA, Health Canada, MFDS and HSA. We have also successfully passed >1,000 quality audits by our global clients or Qualified Persons.

Unparalleled Capacity and Capabilities

Utilizing ten biologics discovery platforms, over 12,000 highly trained employees, multiple R&D labs, and several of the world's largest cGMP biologics manufacturing sites using disposable bioreactor technology, we provide you with the necessary expertise and capacities to meet your drug development needs.



DS Bioreactor Capacity in Progress (CIP) by Year



Future Expansion Plans and Global Dual Source Network

WuXi Biologics will be adding even more biologics discovery and development capabilities and extensive clinical and commercial GMP manufacturing capacity. After 2026 we will provide >580,000 L of disposable bioreactor capacity using our scale-out manufacturing strategy and multiple drug product facilities across five countries to provide our partners a Global Dual Source manufacturing supply chain network.

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

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