WuXi Biologics
Global Solution Provider

Early Stage CMC Development Capabilities

Expediting Your Path to IND

Proven, expert-driven, cost-effective solutions for biologics

- A true single-source provider from gene synthesis to IND filing in 10 months or less
- Expertise across all CMC functions and activities
- World-class quality systems and project management support
- High quality global supply chain network

Scan the QR code to learn more:

Our Experience and Track Record

WuXi Biologics provides a true, one-stop, integrated CMC product development platform, top-tier quality and unparalleled expertise to speed critical biologics into the clinic and beyond for our clients and partners.

150 / Year
Capacity to perform DNA to IND integrated projects

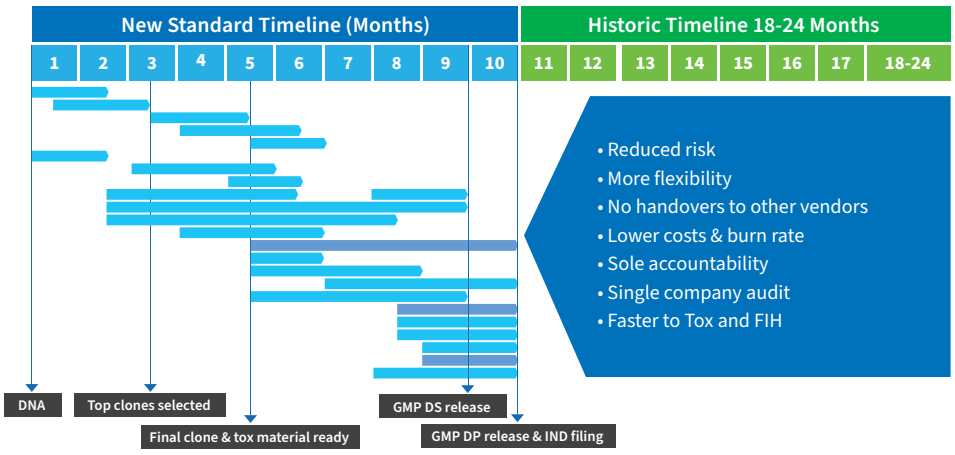
550+ INDs
Enabled globally

740+
Integrated CMC projects enabled for our clients

~600
Global clients

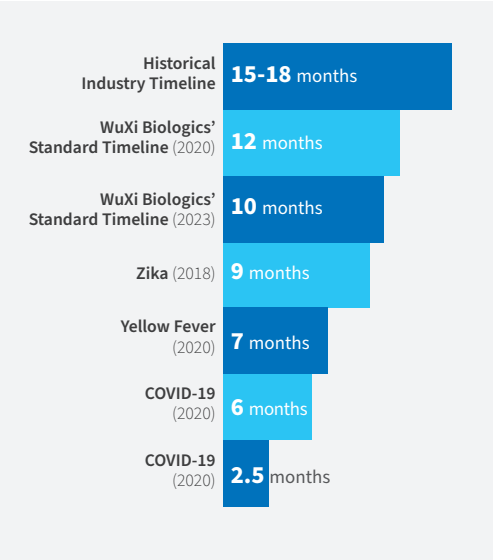
The WuXi Biologics Difference: Expedited DNA to IND Timelines in 10 months or less!

WuXi Biologics' one-stop DNA to IND biologics development platform provides our clients a streamlined 10-month gene synthesis to IND filing program for multiple biologic product types produced from mammalian expression systems. This highly-vetted and integrated development timeline includes not only cell line, process, analytical and formulation development but also drug substance (DS) and drug product (DP) GMP manufacturing and release along with one month of drug product stability data and CMC dossier preparation. We have enabled hundreds of biologics to enter clinical trials for our partners and in specific instances have conducted, in record breaking fashion, DNA to IND programs in a remarkable 2.5 to 6 months.



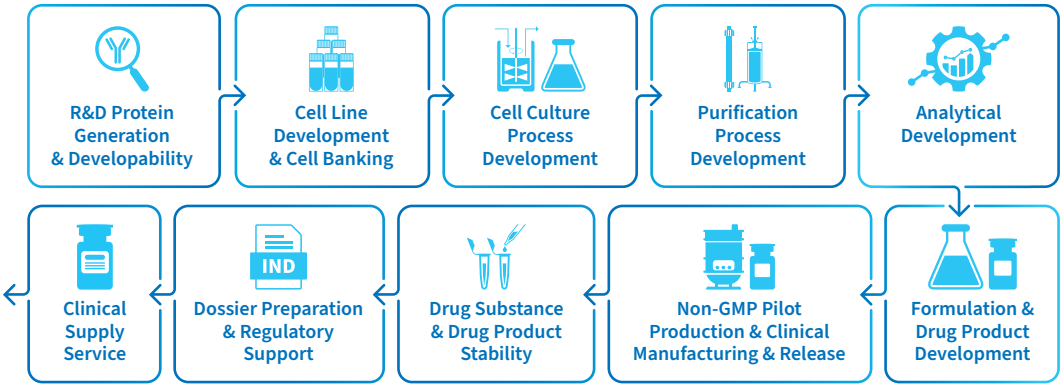
WuXi Biologics Record Breaking Timelines for mAbs from DNA to IND

In response to public health emergencies, we have been pursuing, along with our clients and the global regulatory agencies, ever-faster speeds, without compromising product quality to get critical life-saving antibodies into the clinic. In a COVID-19 neutralization mAb DNA to IND program, we successfully reduced DNA to IND timeline from conventional 12-18 months to 2.5 months, which is one of the fastest global programs on record. These expedited timelines have also been utilized on a case-by-case basis for many non-COVID projects.



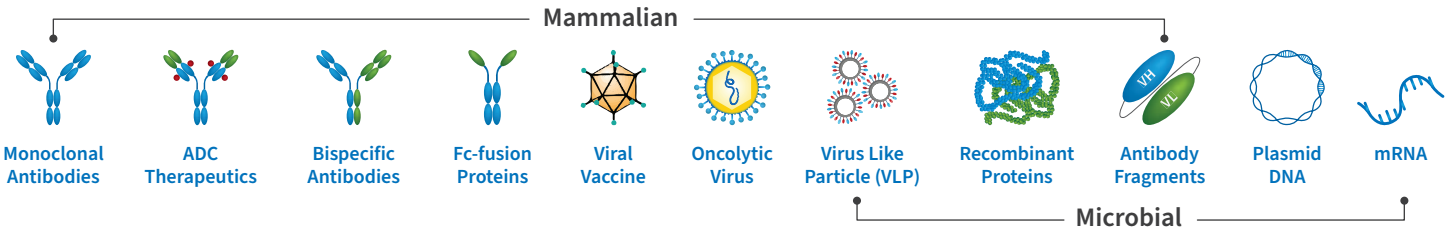
Advanced Development Capabilities from Concept to IND

Our expedited DNA to IND timelines are achieved due to our comprehensive CMC development capabilities and capacities. Clients can choose to use our fully integrated end-to-end product development platform, or start from any point in the CMC continuum, or take advantage of our expertise and use us for a standalone development service.



Expertise Available for Various Modalities

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



Cutting-Edge Technologies & Development Platforms

WuXi Biologics offers multiple proprietary technology platforms for the efficient development of biologics.

WuXian™	WuXia™	WuXiUP™	WuXiUI™	WuXiHigh™	Analytical Centers of Excellence
Customized Protein Production	Cell Line Development Platform	Ultra-High Productivity Continuous Bioprocessing Platform	Ultra-Intensified Fed-Batch Bioprocessing Platform	High Concentration & High Throughput Drug Product Development Platform	Bioassay, Forensic Analysis, Process Residuals & Mass Spectrometry

WuXia™

Starting from client-provided DNA or amino acid sequences, we utilize our robust host cell library to provide high yielding (up to ~11 g/L) stable monoclonal cell lines of superior quality for subsequent process development and GMP production. The WuXia™ CHO-K1 cell line development platform utilizes a highly optimized and engineered host cell line coupled with our proprietary expression vectors to generate top clones with desired product quality attributes. Our CLD platform takes advantage of advanced technologies including:

- Proprietary codon optimization program
- NGS-guided clone selection
- High throughput automated clone screening
- In-well imaging for monoclonality determination
- CRISPR/Cas-9-based engineering

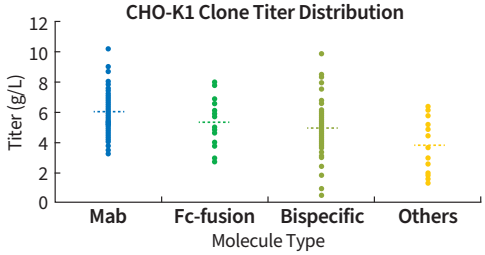
In addition, over 150 stable cell lines can be generated per year, one of the largest capacities in the world.

Speed:
9-10 weeks from DNA to MCB creation

Quality:
No sequence variants at genetic level

Productivity:
Average mAb titer **6.0 g/L**

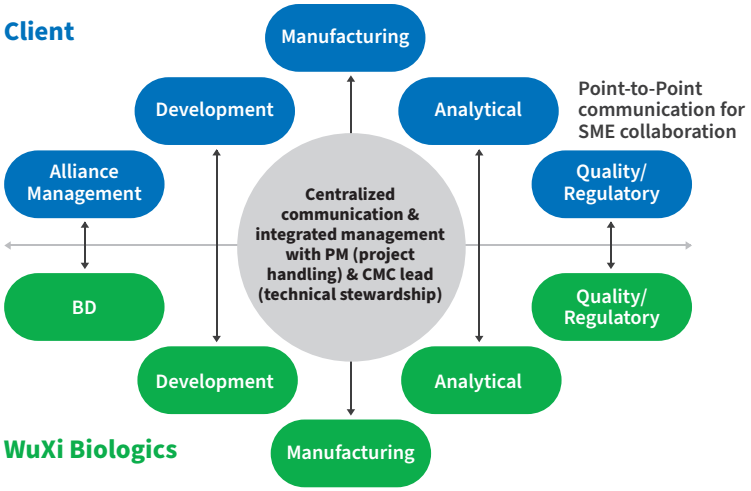
Stability:
>98.8% clone stability (titer maintains >/= 70%)



The WuXia platform has been applied to >900 cell lines, including 5 commercial products

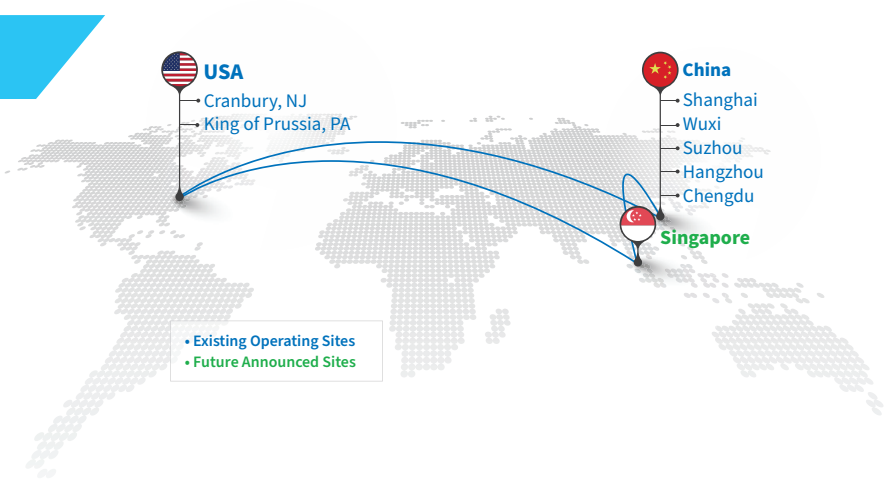
CMC Project Management

Critical to achieving our expedited timelines is the assignment to every integrated project, a highly experienced CMC technical lead and an extensively-trained and dedicated project manager. Both the CMC lead and project manager (PM) plan and work closely with all functional and technical teams from both the client and our organization to move the program efficiently through the various project phases. Our teams utilize widely-recognized industry project management tools and secure information sharing platforms to make communications efficient and timely. In addition, for our clients convenience, we have CMC technical leads available throughout North America, Europe and Asia.



Located Globally for Your Convenience

For ultimate project execution efficiency, all DNA to IND or other early stage development activities can be conducted within minutes or just 1-2 hours drive of each other in China, thus providing an unprecedented timeline advantage. Likewise, projects can be synchronized across our R&D and GMP manufacturing facility network around the globe to meet specific client needs or geographic preferences.



The WuXi Biologics Difference

The following key elements are the backbone to every service we provide and are the reasons we have enabled over 465 products for our clients to enter the clinic in just the past few years. We can do the same for you. Let's get started.

Execution:
Excellent IP Protection and project execution, via operational excellence has won trust from global customers

People:
Highly-trained, expert, world-class talent; 650+ experienced industry veterans; one of the largest biologics development teams worldwide

Quality:
Outstanding audit track record and U.S. FDA, EMA, ANVISA, PMDA, NMPA, Health Canada, MFDS & HSA Inspected Quality Systems

Speed:
Leading the industry by shortening the time from DNA to IND including record-breaking pandemic drug/vaccine development timelines

Technology:
Single-source, state-of-the-art technology platforms from discovery to commercial manufacturing streamline your path to IND and BLA

Flexibility & Agility:
Intense, company-wide focus on customer service and customer satisfaction

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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