WuXi Biologics
Global Solution Provider

Late Stage Development and Commercialization Services

Redefining Your Speed from IND to BLA

Comprehensive, High-quality, Late-stage Services

- Extensive experience & expertise
- Unparalleled capacities & resources
- One-stop highly-vetted development platform

Scan the QR code to learn more:

Expediting your path to BLA

WuXi Biologics provides one-stop, high-quality late-phase development and manufacturing services for companies looking to bring biologics and vaccines to the market. We have streamlined our highly-vetted development platforms to accelerate your product through all aspects of late phase process, assay and formulation development, optimization, characterization and validation. We also provide the necessary GMP manufacturing capacities through our extensive global drug substance and drug product supply network. Whether you are developing products from mammalian cell culture, microbial fermentation or via in vitro methodologies (e.g., for RNA-based vaccines), let our experienced teams help you meet your critical BLA filing milestones.

Our Experience and Track Record:

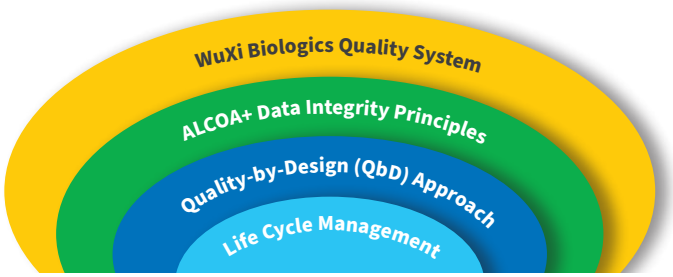
132 Ongoing Late-stage (Phase II / III) Programs

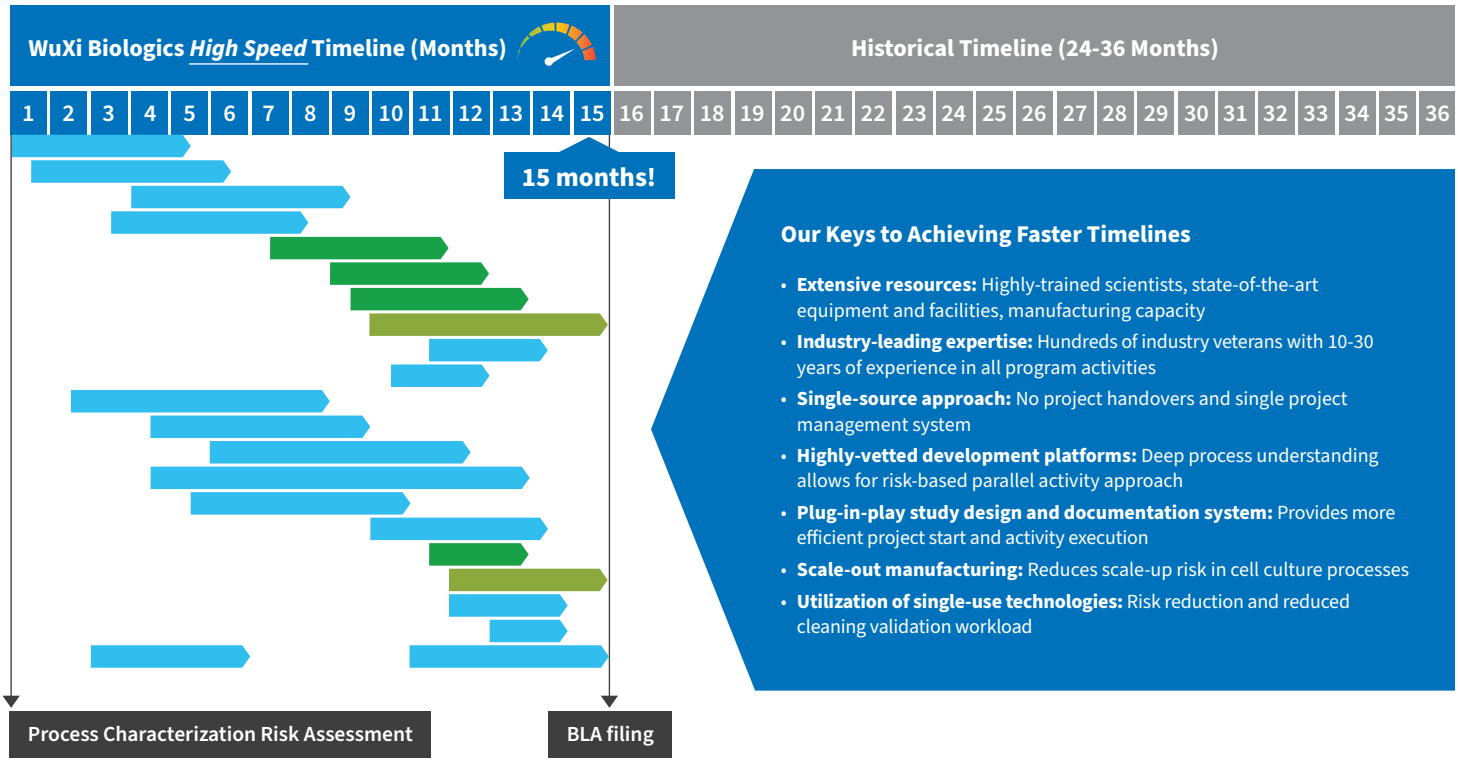
65 Licenses Approval from Global Regulatory Agencies (FDA / EMA / NMPA / Others)

24 Commercial Manufacturing Programs

Essential Program Activities

We utilize life cycle management and Quality-by-Design principles as outlined by the ICH guidelines as the fundamental backbone to all our process development (PD), process characterization (PC) and process validation (PV) activities and couple that with ALCOA+ data integrity principles to provide you the highest quality late-phase development program.





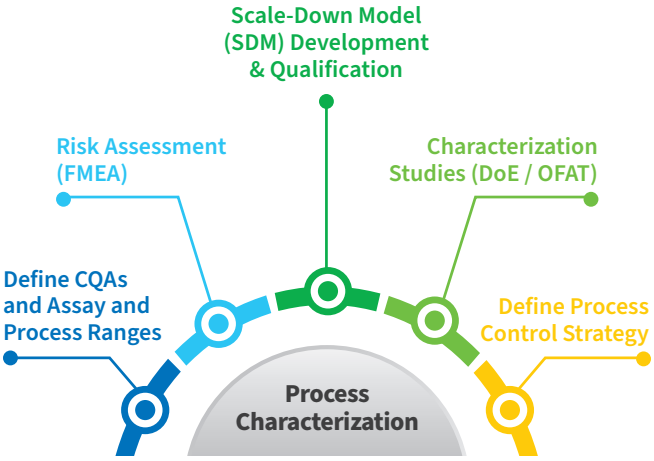
Our Keys to Achieving Faster Timelines

- **Extensive resources:** Highly-trained scientists, state-of-the-art equipment and facilities, manufacturing capacity
- **Industry-leading expertise:** Hundreds of industry veterans with 10-30 years of experience in all program activities
- **Single-source approach:** No project handovers and single project management system
- **Highly-vetted development platforms:** Deep process understanding allows for risk-based parallel activity approach
- **Plug-in-play study design and documentation system:** Provides more efficient project start and activity execution
- **Scale-out manufacturing:** Reduces scale-up risk in cell culture processes
- **Utilization of single-use technologies:** Risk reduction and reduced cleaning validation workload

Critical Process Characterization Elements

WuXi Biologics late-stage development program adheres to rigorous scientific standards and a highly-detailed methodology in order to meet the eventual regulatory scrutiny upon BLA filing.

- Optimize late phase process
- Tech transfer to commercial facility
- Perform initial Failure Mode and Effects Analysis (FMEA)
- Define presumptive CQAs
- Build scale down model and PC
- Conduct final FMEA, Control strategy, CQA Confirmation before PPQ preparation



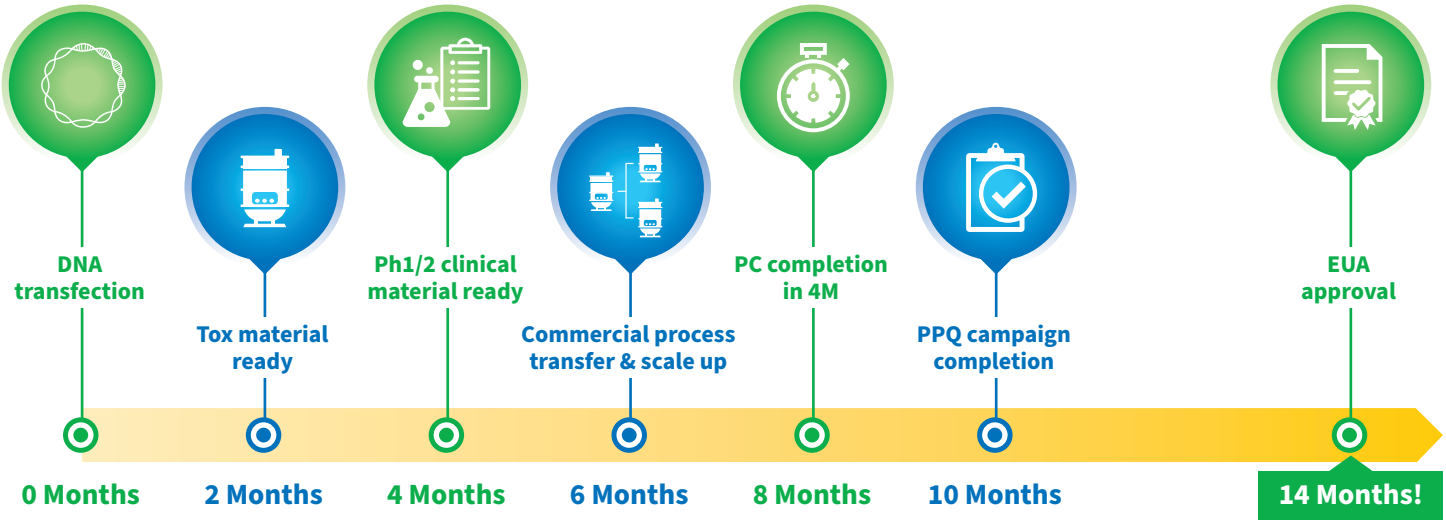
Comprehensive In-house Capabilities

Our one-stop approach includes a myriad of specialized capabilities that include:

- Cell bank characterization on working (WCB) and end of production (EOPC) banks
- Method validation and process/product related impurities characterization
- In-house project specific HCP assay and reagent generation
- Cell-based bioassay development and validation
- Upstream and downstream process optimization and characterization
- Viral clearance validation
- Mixing study
- Cleaning validation
- Microbial hold study
- Formulation development and optimization
- Container and closure systems (CCS) development and validation
- Extractable and leachable assessment
- Simulated shipping studies and shipping validation

COVID-19 Rapid Response

Our extensive resources, expertise and risk-based approach led to an unprecedented expedited timeline from DNA to EUA for a client's late-stage COVID-19 program.



Process Qualification

All critical aspects for PPQ readiness utilizing our extensive in-house qualification and validation programs enable a right-first-time approach including our comprehensive raw materials control system that has passed 30 global regulatory agency audits.

To provide you with a global supply network, WuXi Biologics operates multiple state-of-the-art, premier quality cGMP drug substance (DS) and drug product (DP) facilities across five countries. With 14 DS facilities worldwide, our GMP drug substance manufacturing capacity is over 280,000 L and growing to over 580,000 L across five countries after 2026. We currently maintain 9 drug product facilities capable of conducting liquid or lyophilized fills at varying clinical and commercial scales and utilizing a variety of container and closure system (CCS) configurations that include vials, prefilled syringes and other combination product CCS.

All of our manufacturing operations are overseen by our comprehensive global Quality System that has been audited by multiple regulatory agencies including the FDA, EMA, NMPA, PMDA, MFDS, HSA, ANIVSA, HPRA and Health Canada.

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.

wuxibiologics.com | info@wuxibiologics.com

WuXi Biologics
Global Solution Provider

9-10-2024