WuXi Biologics
Global Solution Provider

Clinical Manufacturing

Flexible and Robust Clinical Manufacturing Service

- Clinical GMP facilities for drug substance and drug product production where you need it
- Streamlined technology transfer at any stage of your product life-cycle
- Integrated services and dedicated project management support for efficient execution

GMP Manufacturing Where and When You Need It

WuXi Biologics operates multiple advanced clinical-scale cGMP facilities for both drug substance and drug product production, utilizing mammalian and microbial expression systems. With different process platforms and manufacturing paradigms, we offer flexible, economical solutions tailored to client needs. All manufacturing operations adhere to our comprehensive global Quality System that has passed audits by multiple regulatory agencies.

Drug Substance (DS)

- **1,700+** DS Batches
- **99.8%+** Success Rate

Drug Product (DP)

- **2,100+** DP Batches
- **99%+** Success Rate

Track Record

- **1,400+** Audits/Inspection Passed* (*Since 2013)
- **550+** INDs Supported* (*As of FY 2023)

Company-Wide Data

Keys to Our Clinical Manufacturing Success

Minimal Contamination Risk	Technology Platforms to Reduce CoGs	Flexibility	One Global Quality System
Single-use systems, coupled with standardized cleaning procedures and a globally compliant quality system, mitigate contamination risk	Built upon WuXi Biologics' technological platform, diverse strategies formulated to optimize cost of goods (CoGs) including material substitution, titer improvement, and process optimization, offer further opportunities for systematically enhanced productivity through their combined implementation	Dual-site strategy enabling us to effectively cater to diverse customer needs and seamlessly support projects at any stage, offering personalized solutions tailored to their specific goals while leveraging our expertise and resources	Clinical manufacturing sites adhere to the same high-quality standards as commercial sites, utilizing a three-tier quality system approach for consistency, and offering efficient audit support services for both onsite and remote audits to enable global partners

Multiple Bioprocessing Platforms for Maximum Flexibility

We possess extensive experience in biologics production utilizing a range of highly flexible and adaptable manufacturing platforms, all designed to deliver higher productivity, higher titer, and lower costs of goods.

	Traditional fed-batch operating modes in either a scale up or scale out strategy
WuXiUI™	Ultra-intensified fed-batch strategy for even greater benefits compared to standard IFB processes
WuXiUP™	Fully integrated continuous process capable of generating ~6 g/L/day productivity and delivering over 60 kg protein per batch from a 1,000 L single-use bioreactor

Highly integrated into all our biologics development platforms and near ready-to-use in design, our bioprocessing platforms are unmatched in performance

- **Capacities ranging from 50 L to 2 x 2,000 L**
- **Similar processes, equipment, facilities, and quality systems across sites for fast and efficient tech transfer to regional clinical & commercial sites**

Streamlined Technology Transfer & Process Development

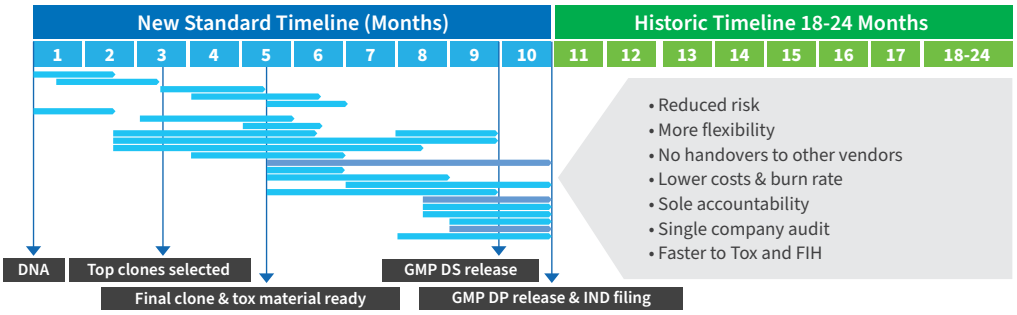
Drawing upon our vast experience and track record of successful technology transfers, we developed workflows to accelerate the transfer of your biologics process at any stage of the product life-cycle. With the aid of our tech transfer, risk assessment and project scoping toolboxes, we streamline the upfront work to maximize the chances of successful operations and regulatory filing. Our on-site process development and optimization support spans the full range of upstream, and downstream processes along with complete analytical and QC functions.

Technology Transfer (TT) Workflow

<table>
<tr><th>Questionnaire for Initiation & Quick Evaluation</th><th colspan="2">TT Toolbox for Achieving New Product Introduction and GMP Readiness</th><th>Accelerating Time to GMP Run</th></tr>
<tr><td rowspan="2">• Cell and raw materials
• Equipment
• Process details
• Historical data review</td><td>Materials
• Gap assessment
• Material equivalence
• Risk assessment</td><td>Process
• Lab scale confirmation (3 L/5 L)
• Optimization for higher quality/ productivity</td><td rowspan="2">• Achieve GMP vial thaw in as little as 4 weeks from process lock
• Achieve GMP vial thaw in as fast as 3-4 months from external cell line transfer</td></tr>
<tr><td>Environment
• EHS
• Microorganism test
• Contamination/cross-contamination control</td><td>Equipment
• Applicability evaluation
• Platform-based parameter amplification and optimization
• Cleaning confirmation/verification</td></tr>
</table>

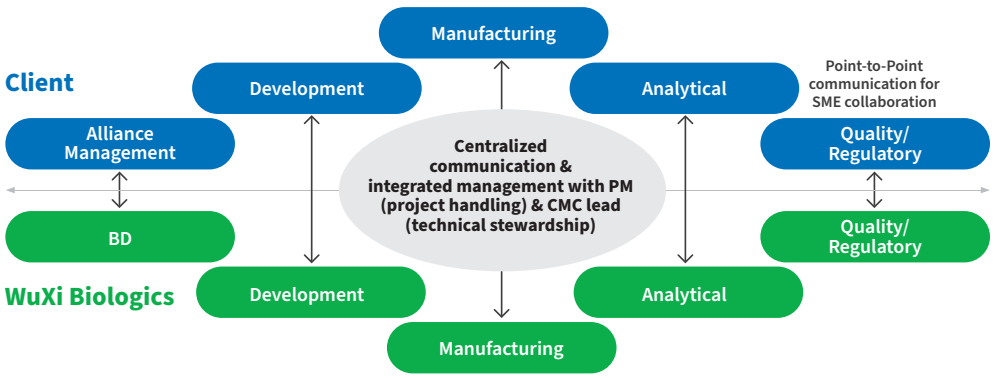
Clinical manufacturing integrated into our streamlined DNA to IND platforms

Our well-established, high-quality, flexible and robust platform across all IND-enabling project phases and CMC activities provide our clients a true, one-stop service offering. As one of the key activities in our integrated, highly vetted and streamlined DNA to IND platforms, our clinical manufacturing services have expedited and enabled over 280 products to achieve IND filing.

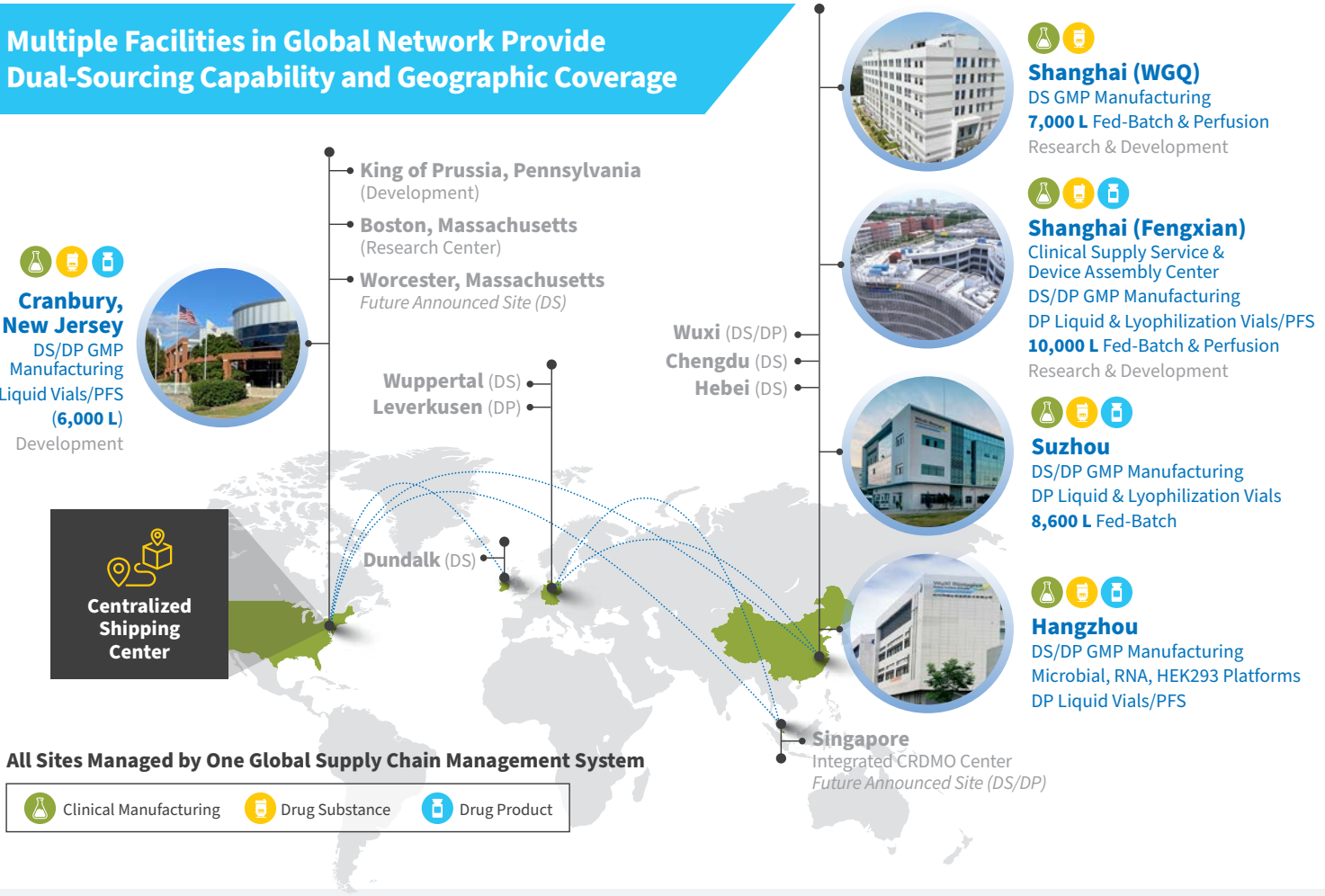


Single-Source Project Management

During all phases of project execution including shipping logistics, clients are supported by a dedicated project manager (PM) and CMC lead to ensure efficient and effective communications. To facilitate project execution, our PMs have extensive import/export experience and can effectively coordinate within the WuXi Biologics network to ensure timely delivery and supply.



Multiple Facilities in Global Network Provide Dual-Sourcing Capability and Geographic Coverage



All Sites Managed by One Global Supply Chain Management System

Clinical Manufacturing | Drug Substance | Drug Product

One Global Quality System

All our clinical manufacturing sites utilize the same world-class quality systems that have been approved at our commercial sites. Our quality teams follow a three tier quality system approach to help unify and drive consistency in our operations. Onsite or remote audits are easily supported via efficient audit support services.

Premier Global Quality and Excellent Track Record

100% pass rate of our clinical manufacturing facilities across **320+** audits from global clients (EU/US/China/APAC)

100% pass rate for agency inspections/QP audits

Remote technology empowers flexible remote access without in-person travel

170+
Remote clinical manufacturing audits supported

Remote Due Diligence	Remote Audit	Remote Person-in-Plant
• Videos on Demand • Presentations • Project Specific Discussions	• Audit Doc Online Review • Audit Paper Live Review	• Surveillance Cameras in Facilities • Live Video Feed via Transmission Box • Access to Process Historian

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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