WuXi Biologics
Global Solution Provider

Commercial Biologics Manufacturing Capabilities

Your Global Dual Source for World-Class Late-Stage and Commercial GMP Production

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to learn more:

World-Class, High Quality Commercial Supply Where and When You Need It

WuXi Biologics, as a leading Contract Research, Development and Manufacturing Organization (CRDMO) operates multiple state-of-the-art, premier quality, commercial-scale cGMP drug substance (DS) and drug product (DP) facilities in Ireland, Germany, and China for the production of a wide array of biologics. With 14 DS facilities worldwide, our GMP drug substance manufacturing capacity is over 280,000 L and expanding over the next few years to include one of the world's largest single-use bioreactor manufacturing facilities in Tuas, Singapore and a next-generation manufacturing facility in the U.S.

We currently maintain 9 drug product facilities capable of conducting liquid or lyophilized fills into a variety of container and closure system (CCS) configurations that include vials, prefilled syringes and other combination products. All of our manufacturing operations are overseen by our comprehensive global quality system that has passed inspections from 10+ regulatory agencies.

24 Ongoing Commercial Manufacturing Programs

50 BLA/MAA/NDA Approvals (**+ 16** EUAs)

37 Passed Regulatory Agency Inspections

14 Certified Facilities

We provide large-scale GMP manufacturing for a wide variety of biologics produced from mammalian cell culture and microbial fermentation systems.

Mammalian

- Monoclonal Antibodies
- ADC Therapeutics
- Bispecific Antibodies
- Fc-fusion Proteins
- Viral Vaccine
- Recombinant Proteins

Microbial

- Antibody Fragments
- Plasmid DNA
- mRNA

Key Advantages to the WuXi Biologics Global Dual Sourcing Manufacturing Model

- Harmonized facilities, equipment, MSAT and quality systems for rapid transfer of projects through all clinical and commercial phases and across geographic regions
- Highly efficient and well-vetted project management and technology transfer protocols and systems
- Risk-reducing scale-out manufacturing paradigm for cost-effective and highly flexible scale-up or scale-down of processes throughout the product life-cycle
- Advanced digitalized manufacturing execution systems (MES), process / plant information (PI), and data management platforms for efficient, high-quality production from raw material receipt to DP release
- GMP manufacturing integrated with development to support late-stage process validation, fit and process performance qualification (PPQ) runs prior to BLA filing
- Focus on quality, timely and right-the-first-time execution that has lead to an outstanding track record

Drug Substance

1,700+ Batches Completed

98% Success Rate (Since 2020)

Completed 185 x 12,000 L batches and achieved a 99.5% success rate in 2023

Drug Product

2,100+ DP Batches Completed

100% Success Rate (Since 2020)

Conducted 100+ media fills at a 100% success rate

Comprehensive Support from Late-Stage Development and Throughout Product Lifecycle

GMP manufacturing operations are fully integrated with all late-stage development activities to ensure successful transition of process and product and will continue to work with you throughout the product lifecycle to ensure efficient, cost-effective manufacturing at the highest achievable quality levels.

PTM Runs

Phase 2b Trial

Supports late phase process transfer to commercial site, and provides clinical trial material.

Pre-PPQ Runs

Phase 3 Trial

Supports process characterization, control strategy and PPQ readiness and provides clinical trial material.

PPQ Runs

Prepare for BLA

Conducts process and cleaning validation activities and supports CMC dossier preparation for BLA filing.

PLI

Prepare for PLI

Reviews cGMP compliance-related deviations and change controls and process controls on personnel, facility, equipment, materials, methods, procedures and environment.

Lifecycle Mgt.

Post-Approval

Commercial product lifecycle management and support of post-marketing changes.

Extensive Global DS and DP Manufacturing Network

Implementing next-generation facility designs for multi-product facilities, a “scale-out” single-use bioreactor production scheme and production in either traditional fed-batch, intensified fed-batch or continuous bioprocessing modes, WuXi Biologics has become a leading global biologics supplier for our partners and clients.

DP FACILITIES

Wuxi, China

DP1

- Approved for commercial production by FDA & EMA, up to 6 million dose/year
- GMP ready in 2014 / liquid & lyo / vials

DP2

- Isolator-based IMA filling line, up to 10 million dose/year
- GMP ready in 2021 / liquid & lyo / vials

DP4

- HSA and NMPA GMP-certified Vanrx robotic aseptic fill system
- GMP ready in 2019 / liquid / vials and PFS

DP5

- Isolator-based Syntegon filling line, up to 17 million dose/year
- GMP ready in 2022 / liquid / Prefilled Syringe (PFS)

DP9

- Isolator-based IMA filling, up to 6 million dose/year
- GMP ready in 2021 / liquid & lyo / vials and PFS (in 2024)

Leverkusen, Germany

DP7

- Annual fill capacity of 10 million doses
- GMP ready in 2021 / liquid and lyo / PFS in 2025

DS FACILITIES

Wuxi, China

MFG1
- First site approved for commercial production by FDA & EMA
- GMP ready in 2012 / 15,000 L

MFG2
- First large scale facility for commercial production
- GMP ready in 2016 / 28,000 L / 4,000 L

MFG4
- First biologics site in China to use 4,000 L single-use bioreactor
- GMP ready in 2019 / 11,000 L

MFG5
- Quality-by-design facility hosts two complete production lines
- GMP ready in 2021 / 60,000 L

MFG9
Future Announced Site

Dundalk, Ireland

MFG6/7
- Two suites for fed-batch and continuous manufacturing
- GMP ready in 2022 / 48,000 L / 6,000 L

Wuppertal, Germany

MFG19
- This site just a short distance from our Leverkusen drug product site
- GMP ready in 2024 / Total 24,000 L

Hebei, China

MFG8
- Multi-product facility, designed as a modern “Green” factory
- GMP ready in 2022 / 48,000 L

Hangzhou, China

MFG20
- First Kubio module facility at Wuxi Biologics
- GMP ready in 2021 / 8,000 L
- Additional 15,000 L (by end of 2024)

Singapore

Future Announced Site

Digitizing Manufacturing Operations For Optimized Performance

Throughout all of our manufacturing sites, we have systematically upgraded and implemented LEAN concepts coupled with automation and digitalization to reduce risk and increase efficiency and quality – all in alignment with global GMP requirements.

Enterprise Systems

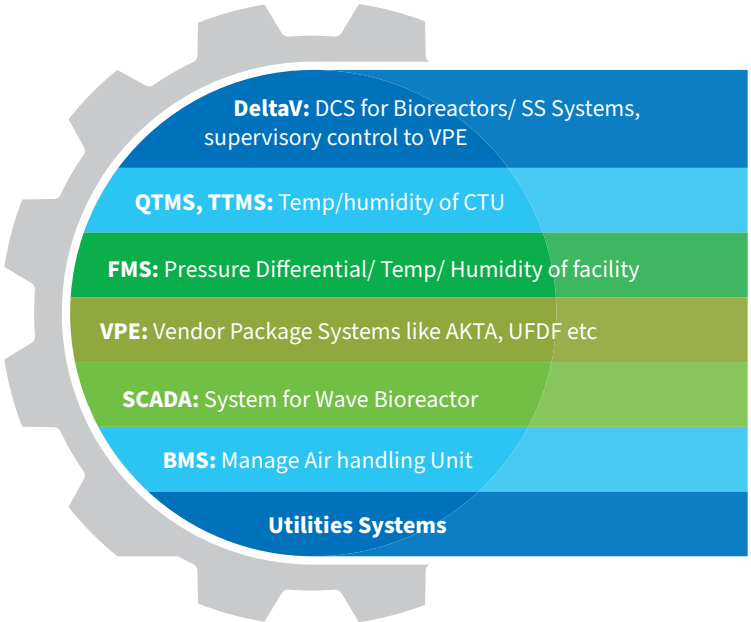
Business Logistics	Quality Assurance (QA)	Quality Control (QC)	Engineering	Business Support
SAP: Enterprise Resource Planning	**MasterControl:** SOP and Training **Trackwise:** Deviation/ CAPA/ change control, audit **GMP BPM:** Records Management/ Controlled Copies	**LIMS:** Sample and Testing Results Mgt **LES:** Support lab operations/ Workflows **Empower:** Data Management HPLC/GC	**Maximo:** Asset Management	**GMP BPM:** Data Recording

Specialized Applications

- **Smart Writing:** Smart Document Generation
- **Dr Bio:** Audit Q&A Database
- **PI Smart Applications:** Support Manufacturing Engineering Operations

Major Automation Systems

- **Batch /Recipe**
- **Continuous Control**



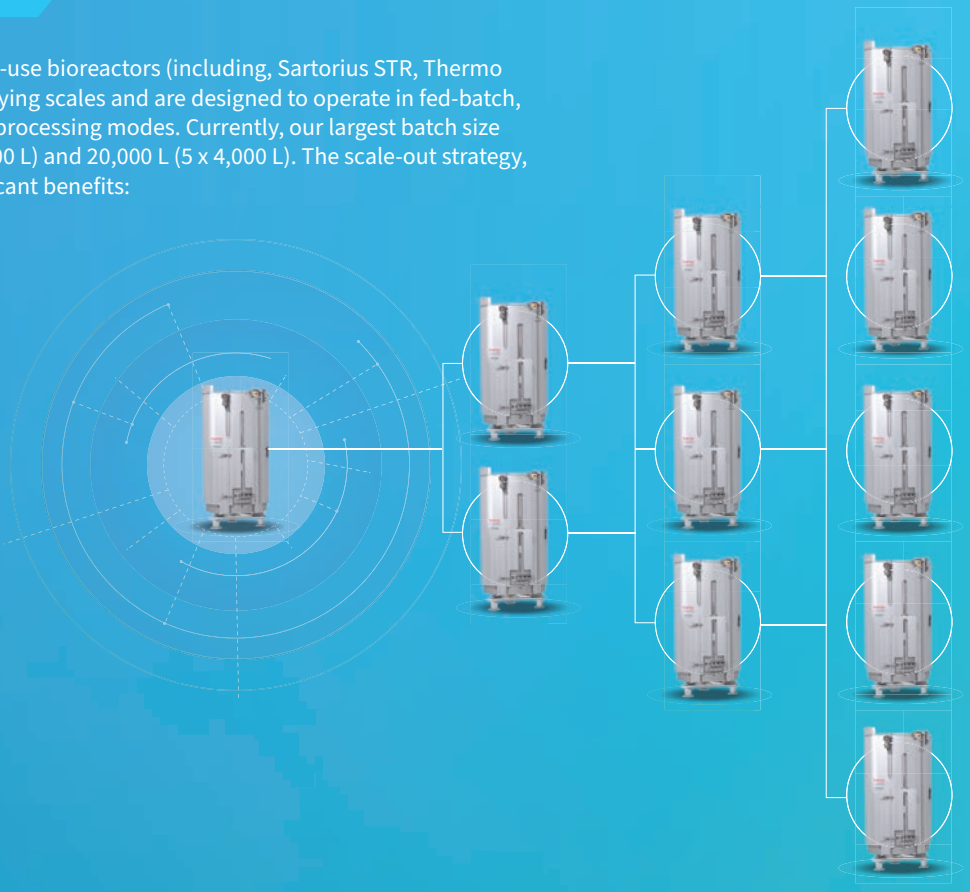
Manufacturing Operations Systems

- **WuXi MAP:** Master Planning
- **Toolbox:** Facility Fit
- **MSAT Database:** Project/Process related parameters
- **Digital CPV:** CPV Calculations
- **Batch End Report:** Supports MFG and QA review by exception

The "Scale-out" Advantage

All of our drug substance facilities utilize single-use bioreactors (including, Sartorius STR, Thermo SUB, Cytiva Xcellerx XDR, and ABEC CSR) at varying scales and are designed to operate in fed-batch, intensified fed-batch or continuous/perfusion processing modes. Currently, our largest batch size using the scale-out strategy is 12,000 L (6 x 2,000 L) and 20,000 L (5 x 4,000 L). The scale-out strategy, harmonized across all of our sites offers significant benefits:

- Eliminates cell culture scale up risks
- Adapts quickly to production demand changes
- Offers highly flexible process design and validation
- Provides faster changeover in multi-use facilities
- Utilizes the benefits of single-use technologies
- Scale-out instead of Scale-up for higher volumes



Comprehensive In-House (QC) Support

Highly-trained personnel oversee all QC operations across our global GMP manufacturing sites. Having successfully passed over 37 inspections from global regulatory agencies, we provide top-quality testing and meticulous oversight of other critical functions, including environmental monitoring, cleaning validations, instrument life-cycle management, and sample/retain management.

Pre-Production

- Raw Material Specifications, Sampling and Testing
- Method Transfer, Qualification, and Validation
- Cell Bank Testing and Characterization

Production Monitoring

- In-Process Controls (IPC)
- In-Process Testing (IPT)
- Unprocessed Bulk (UPB) Release Testing
- End of Production Cell Bank (EOPC) Testing

Post-Production

- Release Testing (Drug Substance and Drug Product)
- Stability Studies (including Photo-Stability)
- Comparability Studies

Environmental Monitoring, Reference Standard and Sample / Retains Management, Instrument & Method Life-Cycle Management and Audit Support

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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