WuXi Biologics
Global Solution Provider

Drug Product Development, Manufacturing and Supply

Your Single-Source Drug Product CRDMO

from Preclinical to License Application

→ Liquid, Frozen, Lyophilized Dosage Forms

→ Vials, Prefilled Syringes, Safety Devices, Auto-injectors

Scan the QR code to learn more:

WuXi Biologics Drug Product Development, Manufacturing & Supply

WuXi Biologics provides industry-leading, state-of-the-art drug product (DP) development, fill and clinical supply services for our global partners. Our expert teams specialize in the development of liquid, frozen and lyophilized clinical and commercial dosage forms and processes. We have extensive experience with multiple container closure systems (CCSs) that include vials, prefilled syringes (PFS), safety PFS and auto-injectors. Extending beyond GMP manufacturing, our services provide clinical labeling, secondary packaging, cold chain transportation, storage, global logistics & distribution, clinical returns & destruction and comparator sourcing services to provide our customers a true one-stop experience.

Extensive Drug Product (DP) Development Experience

Utilizing cutting-edge instrumentation and high-throughput automation tools throughout our DP development activities, we have provided end-to-end DP development for hundreds of DP now in clinical trials or in commercial use. Formulation expertise is available for a wide variety of protein, viral, and nucleic acid-based therapeutics shown below.

- Monoclonal Antibodies
- ADC Therapeutics
- Bispecific Antibodies
- Fc-fusion Proteins
- Viral Vaccine
- Oncolytic Virus
- Virus Like Particle (VLP)
- Recombinant Proteins
- Antibody Fragments (VH, VL)
- Plasmid DNA
- mRNA

End-to-End DP Development Capabilities

Under quality by design (QbD) principles, we perform formulation, DP process development, comprehensive analytical assessment, combination product development, and post-launch continuous improvements as part of our life-cycle management program to ensure we meet your needs and specifications.

- Strong expertise in protein formulation with concentration as low as 1.5 µg/mL and up to 200 mg/mL
- High concentration development based on WuXiHigh™ platform

IND Filing — BLA Filing

R&D → Toxicology → Phase I → Phase II → Phase III → Commercialization

Formulation Development
- Developability
- Formulation development

Process Development
- Scale down models for thawing, mixing, filtration, filling, etc.
- Technology transfer

Other IND-filing Supporting Studies
- Clinical in-use compatibility
- Forced degradation study
- Reconstitution stability
- Matching placebo development

Commercial Formulation & Robustness
- Formulation risk assessment (FMEA)
- Commercial formulation optimization
- Formulation robustness (DoE)

Process Characterization & Control Strategy
- Process risk assessment (FMEA)
- Process characterization
- Process control strategy

Drug-Device Combination Product Development
- Drug-container compatibility
- Primary packaging and assembly control strategy
- Design History File (DHF)
- Human factor studies

Other BLA-Enabling Studies
- Shipping simulation study
- Extractables & leachables (E&L)
- Filter validation

Life-Cycle Management

Formulation Development

Regardless of your development phase, our scientists design the ideal formulation for your product within the container closure system of your choice. Some of the specialized services include:

- Formulation development using design of experiment (DOE) or one factor at a time (OFAT) approach
- High-throughput screening utilizing biophysical methods, such as dynamic light scattering (DLS), differential scanning calorimetry (DSC), and differential scanning fluorimetry (DSF), Uncle, Reosense meter and Low Field-Nuclear Magnetic Resonance (LF-NMR) amongst others
- Molecular Dynamics Simulation for molecule stability prediction

WuXiHigh™

- Advanced development strategy for formulation, process and combination product based on expertise from 70+ high concentration projects
- High-throughput & automated instruments, e.g. LF-NMR, HT-DLS, and Uncle
- Novel viscosity reduction methodology utilizing in-house intellectual property

We also have significant expertise in the development of special modalities such as nanoparticles and liposomes, and the development of co-formulations.

DP Manufacturing Process Development

To expedite your path to clinical or commercial DP manufacturing, our team of DP development experts leverage our state-of-the-art technologies and offer a variety of process development and technology transfer services including:

- Advanced process development and characterization from drug substance thawing through formulation mixing, filtration, filling, stoppering and capping to final visual inspection
- Process development for RABS (Restricted Access Barrier Systems), and isolator-based filling line, including fully-automated Vanrx systems
- Lyophilization cycle development and optimization
- Combination product process development

Pilot Plant Production

Pilot plant production is available for non-GMP DP fill and lyophilization services for pre-clinical toxicology studies, non-GMP stability studies and scale-down process development.

- Three DP production lines for vials and PFS
- Supporting worldwide IND applications and process characterization in the late phase

Drug Product Development Service Features

Clinical Supply Service

- Labeling & secondary packaging
- Cold chain & storage global logistics & distribution
- Return & disposal
- Comparator sourcing

Lyophilization

- Lyophilization process development
- Process/appearance optimization
- Tech transfer/scale-up for lyo

Extractables and Leachables (E&L)

- E&L risk assessment and toxicology risk assessments (TRA)
- Controlled / simulated extraction studies
- Leachable studies
- Method development & validation
- Trace organic analysis

Co-Formulation

- Co-formulation development (mAb+mAb, mAb+Enzyme)
- Analytical methods development
- Stability analysis and characterization

Combination Product

- Drug-container compatibility
  - PFS functionality test methods
  - Silicone oil distribution
  - Dimensional measurements
  - Container closure integrity test
- Combo product development and documentation
- Automated PFS GMP filling
- Safety device and auto-injector assembly
- Partnership with global syringe and device market leaders

PFS & Safety PFS
(Prefilled Syringe & Prefilled Syringe with Needle Safety Device)

Active Method	Passive
Syringe Available	• 1 mL long, 1 mL standard, 2.25 mL & 3 mL syringes • Stacked needle & luer lock
Plunger Stopper Available	• 1 mL long, 1-3 mL plungers • Nested, RTP Bag
Filling Volume	0.15 - 3 mL
Flange Type	• Cut (CF), Round (RF), Small Round (SRF) • Extended Finger Flange
Customization Options (for Safety PFS)	Plunger Rod, extended finger flange: customized colors and materials

Auto-injectors

- Standard design optimized for user experience
- Fully customizable based on client-specific schematics
- Design optimized through AI selection, assembly, and human factor considerations

Drug Product Manufacturing Experience

After technology transfer from our DP development team to our GMP operations, WuXi Biologics leverages its wide-ranging process technology platforms and expertise to provide clients with efficient and cost-effective GMP DP manufacturing solutions. Our global GMP manufacturing facilities provide automated and isolator-based DP production under the current Good Manufacturing Practice (cGMP) conditions as defined by the worldwide regulatory agencies, including:

- United States Food and Drug Administration (U.S. FDA)
- European Medicines Agency (EMA)
- National Medical Products Administration (NMPA)

Backed by our experience supporting clinical and commercial projects for a wide range of biological modalities, we have established a strong reputation with global organizations of all sizes.

500+ Formulations / DP Process

80+ Lyophilized Products

30+ Formulation Robustness

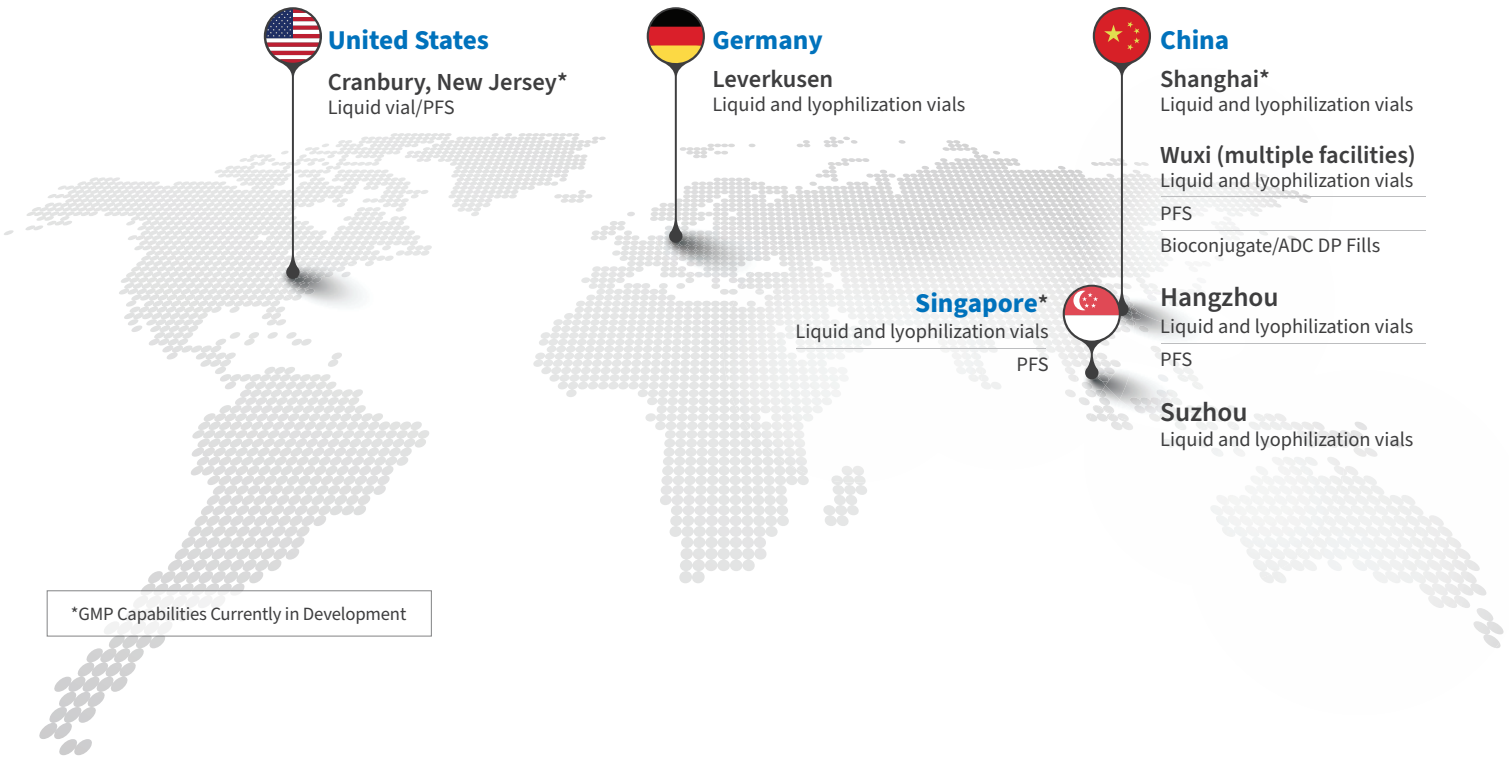
20+ Process Characterization

20+ Extractables & Leachables

10+ Shipping Simulation Studies

Global Drug Product Solutions Network

We currently maintain 9 drug product GMP manufacturing facilities that in total provide an annual capacity of 100+ million vials and 30+ million PFS. In addition, multiple clinical and commercial GMP DP sites in the United States, Europe and China are being constructed to fulfill our client's demands for clinical and commercial supply.



*GMP Capabilities Currently in Development

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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