



BeOne Medicines Global Manufacturing Capabilities

BeOne Established Integrated Global Technical Operations with Dual Site Supply for China and US

1600+
GTO Employees

73kL
Biologics
MFG Capacity

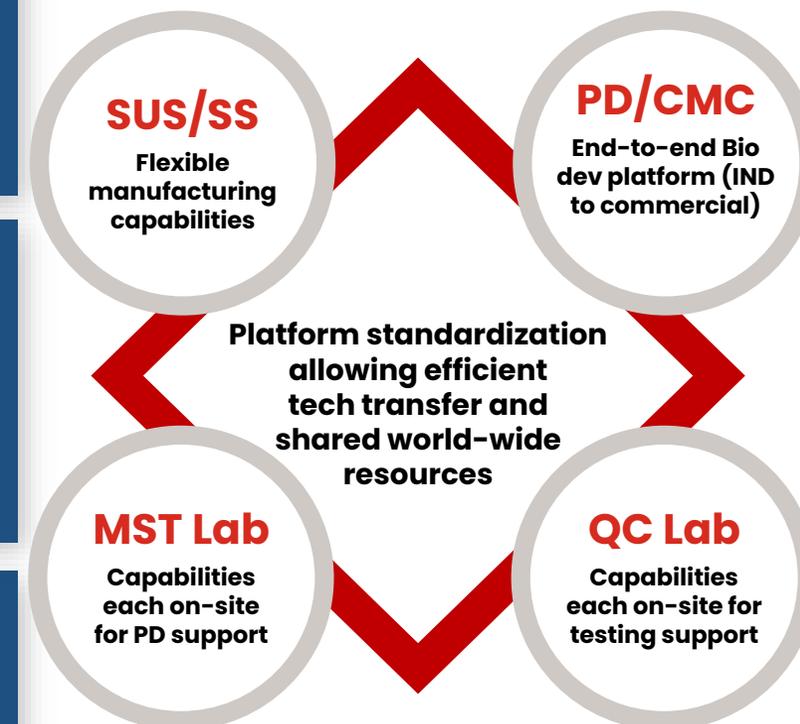
600M+
Small Molecule
MFG Capacity

16
Approved
Commercial Assets

40+
Clinical &
Commercial Assets



Our Global Manufacturing Capability Enables End-to-end Bio Dev from Pre-clinical to Commercialization, for Both DS and DP



Hopewell, NJ Site | Our First U.S. Biologics Manufacturing Facility

Biologics Campus

DS Suite with SUS 2kL bioreactors
DP line (Liquid & Lyophilized vials)

An aerial photograph of the Hopewell, NJ Biologics Campus. The image shows a large, modern industrial facility with a mix of brick and glass facades. A parking lot with several cars is visible in the foreground. The facility is surrounded by greenery and a road. Callout boxes with white lines pointing to specific buildings are labeled: 'Lab' (a large glass-walled building), 'Warehouse' (a large brick building), 'DS' (a smaller brick building), and 'DP' (another smaller brick building).

Lab

Warehouse

DS

DP

42-acre site
with 400,000 sq ft built

Expandable to Small Molecule & ADC

Hopewell: Flagship U.S. Biologics Manufacturing and Clinical R&D Facility at the Princeton West Innovation Campus



Drug Substance

Manufacturing Capabilities

- Total 8kL Cell Culture Capacity
 - Single-use System (4 x 2kL)
 - Batch, Fed-batch, and Perfusion
- 2nd line cell culture (4x2KL) **Expansion Plan**
- ADC conjugation suite



Drug Products

DP Production Lines

- Isolators
- Liquid vials (clinical & commercial)
- Lyophilized Vials (clinical & commercial)
- Labeling & Packaging

Small Molecule

- DP manufacturing **Expansion Plan**
- DP packaging



Warehouse

Equipped with Latest Technology

- ASRS (Automatic Search & Retrieval System)
- Storage Conditions: 2 - 8°C, -20°C, -70°C



Guangzhou, CN Site | Clinical & Commercial Bio & ADC Campus

ADC Campus

ADC production capabilities and
DS suite 4 with SUS 500L bioreactors

DS 4

ADC

39-acre site
with 1.3 million sq ft built

SUS, Single-Use System; SS, Stainless Steel; PFS, Pre-filled Syringes; ADC, Antibody Drug Conjugates

Biologics Campus

DS Suite 1-3 with SUS 2kL and SS 5kL bioreactors
DP line (Liq., Lyo., PFS) including Labeling & Packaging

DP

Warehouse

DS

Office

Lab

Guangzhou: A Versatile, High-efficiency Facility with 65,000L Capability Designed to Meet Diverse Partner Requirements




Drug Substance

Versatile and high-efficiency capabilities

- Total 65kL Cell Culture Capacity
 - Single-use System (2 x 500L, 12 x 2kL)
 - Stainless System (8 x 5kL)
 - Fed-batch cell culture and purification



Drug Products

End-to-End DP Production Lines

- Liquid Vials (clinical & commercial)
- Lyophilized Vials (clinical & commercial)
- Pre-filled Syringes (clinical & commercial)
- Labeling and Packaging



ADCs

Conjugation and Fill Finish Production

- ADC Conjugation (up to 500L, SU & SS reactors)
- Purification with Chromatograph & UF/DF
- DP liquid and Lyophilized Vials
- Labeling & Packaging



Warehouse

Equipped with Latest Technology

- ASRS (Automatic Search & Retrieval System)
- Storage Conditions: 15-25°C, 2-8°C, -20°C, -40°C, -70°C



Suzhou, CN Site | Clinical & Commercial Small Molecule Campus

Small Molecule Campus

OSD Production – 300M Tablet & 300M Capsule
Small Molecule CMC Lab

CMC Lab &
Shared Office

Warehouse

OSD DP

QC Lab &
BIO PD

Office

12.4-acre site
with 460,000 sq ft built

百济神州
BeOne

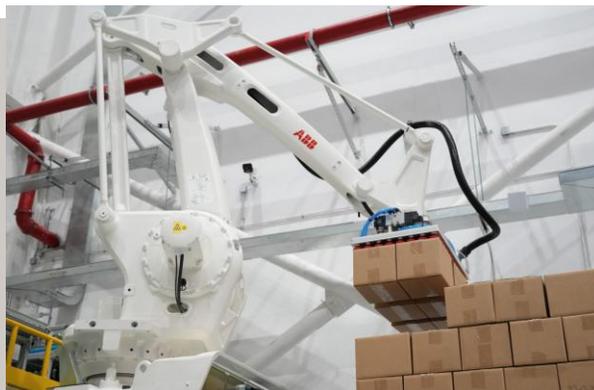
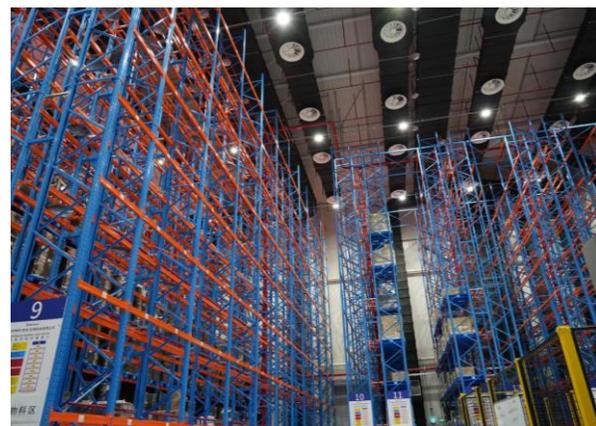
Suzhou: Small Molecule Production Base for Drug Candidates and Commercial Medicines



Oral Solid Dosage

Flexible Manufacturing Capabilities

- 600M Capsule & Tablet Production Capacity (Expandable to 1B)
- Primary Packaging (bottle & blister)
- Labeling & Packaging



Warehouse

Supports various product types

- Storage Conditions: 15-25°C, 2-8°C



Capability: Highest Standards for Quality Management

**Benchmarking ICH and US, European, and Chinese GMP standards
to provide accessible and affordable good drugs for patients around the world**

**Quality System:
Internationally Recognized Top Standards**



**30+ Approvals And Inspections In 5+ Years
(US FDA, EMA, TGA, China NMPA, ANVISA, and more)**



**US
FDA**



**Europe
EMA**



**Brazil
ANVISA**



**China
NMPA**



**Australia
TGA**

- **Successful Regulatory Approvals**
- **Inspections With 0 Critical Observations**



Capability: QC Lab – Comprehensive Testing Capabilities

Global Stability Center

**Global Reference
Standard Management
Center**

Global Sterility Assurance



MST Lab

Established BeOne's Global Testing Platform

Focuses on Analytical Method Validation/Transfer and QC Testing

**Raw
Material**

**In-Process
Control (IPC)**

**DS/DP
Release**

DS/DP Stability

**Environmental
Monitoring**

**Utility
Monitoring**

**Reference
Standard
Management**

***Globalized Quality System enables the quick and efficient biologics CMC development
Phase-appropriate strategy which meet international GMP regulatory requirement***



Capability: Bio PD/CMC and MST Capabilities



Bio PD & CMC

Established Large Molecule Development Platform
End to End (IND to Commercial)

Cell Line & Process Development

- Cell Line Development
- Upstream & Downstream Development
 - Incl. ADC conjugation & purification PD
- Analytical Development
- Formulation Development (Liquid, Lyo, PFS)
- Media Development
- Proprietary Media (2x Titer output)

mAbs,
BsAb/TsAb,
ADC,
Fabs,
Fusion,
Recombinant
protein

CMC Strategies and Management

- Fast to IND, BLA Strategies
- Ensure Timeline and Meet BLA Requirement (Global HA)
- Internal & External Programs Management

Linker and Payload Process Development underway to internalize supply in future



MST Lab

Established BeOne's Global Lab Capabilities
Well-equipped MST Lab With Expansion Opportunities

Technical Support

- Tech Transfer
- Process Validation
- Continuous Process Verification
- On The Floor Support

Lab Capability

- Deviation Analysis



Thanks!

