

BeOne Medicines
Global Manufacturing Capabilities

BeOne

OCT 2025

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



SUS/SS
Flexible manufacturing capabilities

PD/CMC
End-to-end Bio dev platform (IND to commercial)

Platform standardization allowing efficient tech transfer and shared world-wide resources

MST Lab
Capabilities each on-site for PD support

QC Lab
Capabilities each on-site for testing support

Notes: * Mammalian production system; SUS, Single-Use System; SS, Stainless Steel; PFS, Pre-filled Syringes; ADC, Antibody Drug Conjugates.

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

Biologics Campus

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



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

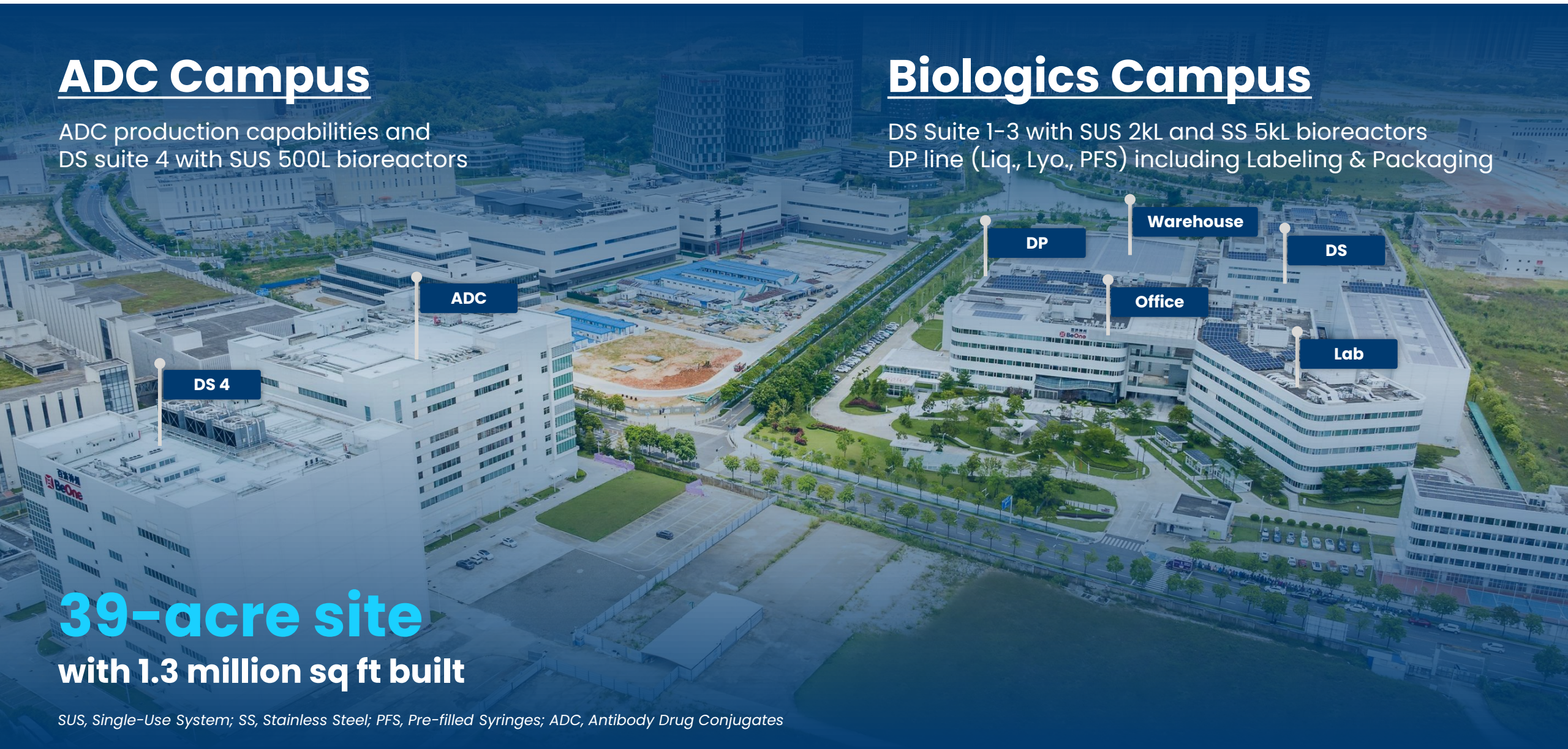
Guangzhou, CN Site | Clinical & Commercial Bio & ADC Campus

ADC Campus

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

Biologics Campus

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



39-acre site

with 1.3 million sq ft built

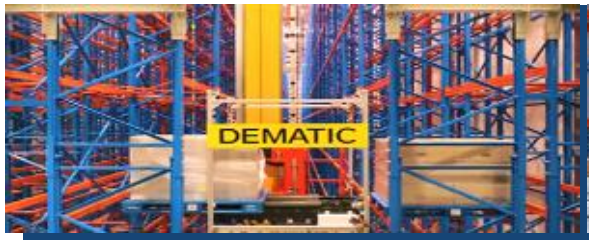
SUS, Single-Use System; SS, Stainless Steel; PFS, Pre-filled Syringes; ADC, Antibody Drug Conjugates

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

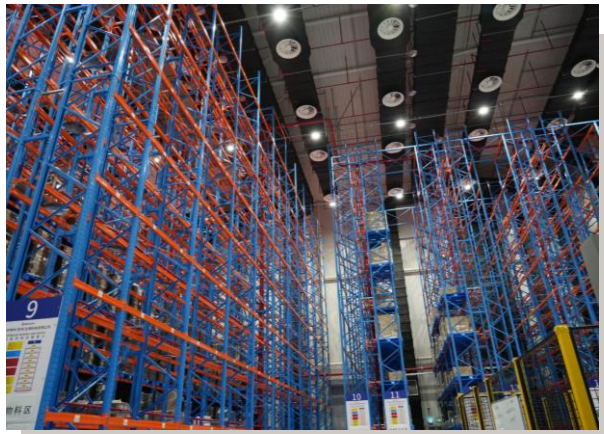


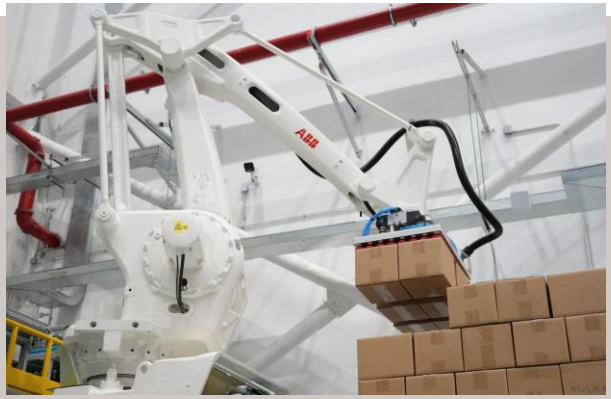
12.4-acre site
with 460,000 sq ft built

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

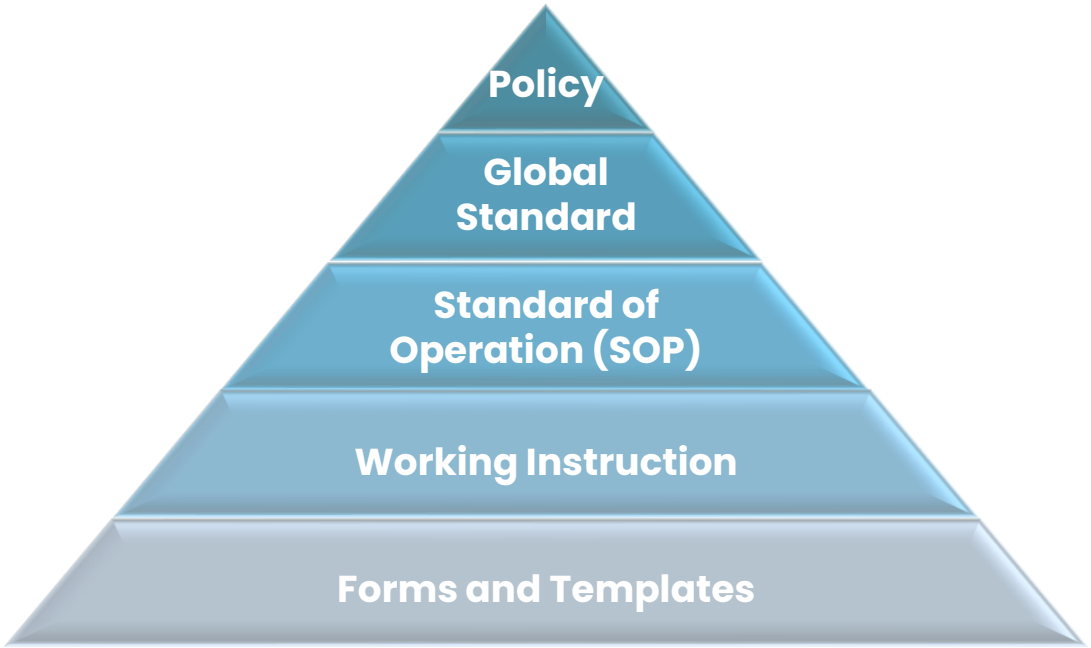
Supports various product types

- 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

QC 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

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

Linker and Payload Process Development underway to internalize supply in future

Thanks!

