

Innovative chemistry for a better future

# PharmaBlock

**An Integrated CDMO to Advance Your Molecule from Development to Commercial**

Jun 2022

[www.pharmablock.com](http://www.pharmablock.com)  
[product.pharmablock.com](http://product.pharmablock.com)

**PharmaBlock**

# PharmaBlock Footprint


Started Operation  
BB Design and Process R&D



IPO  
(SZSE:300725)



Established PharmaBlock Zhejiang  
API Manufacturing Site



2000+ Employees  
800+ Well-trained scientists  
100+ PhDs  
\$189M Revenue (2021)

2008.10

2012.5

2016.1

2017.11

2017.12

2018.9

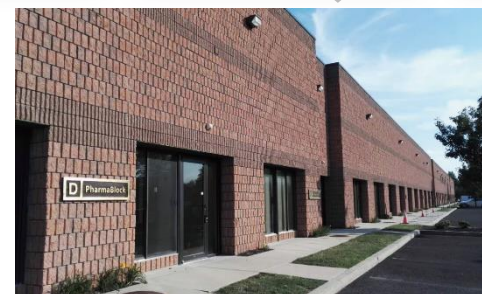
2021.9



Established PharmaBlock US  
in California  
BB Sales



Established PharmaBlock Shandong  
Manufacturing Site of Intermediates



Pennsylvania, US  
BB Sales & Process R&D

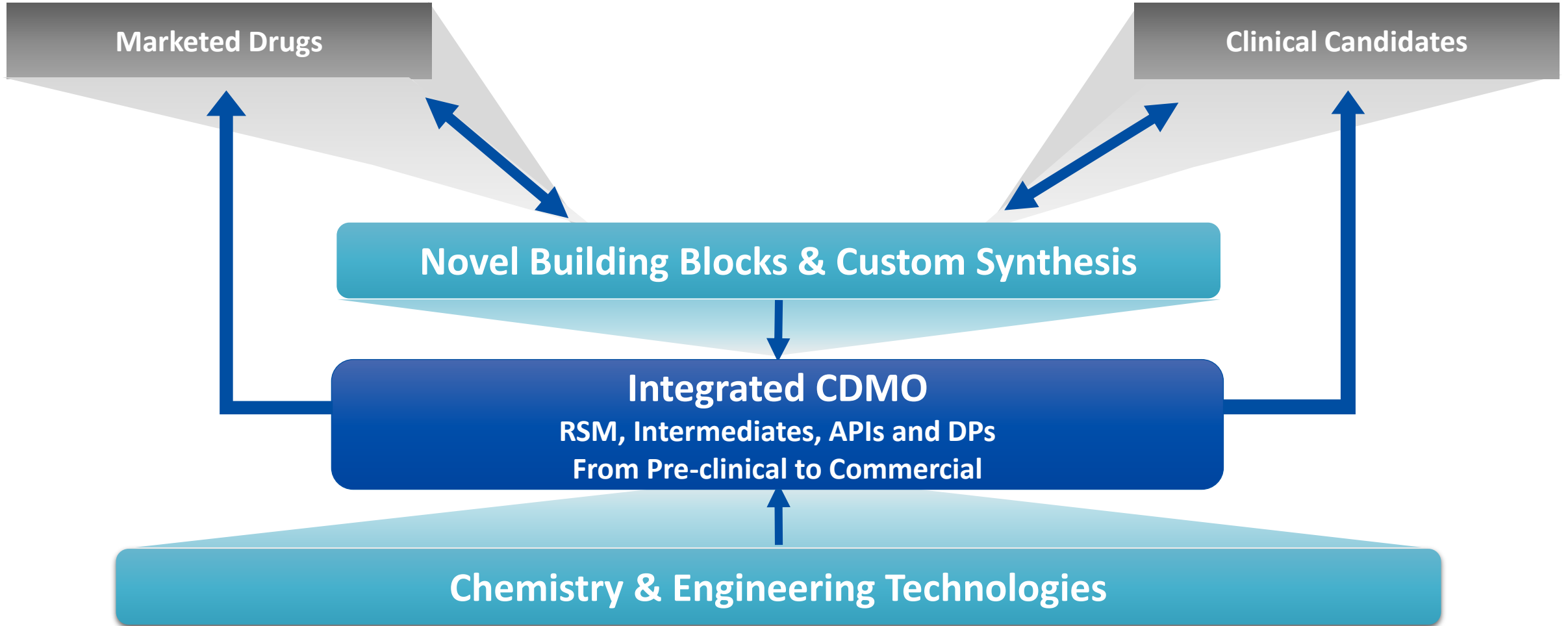


PharmaBlock Shandong  
DP Manufacturing Site

\*BB: Building Block

# Business Strategy

From the drugs, for the drugs



# Fully Integrated CMC Platform



**BBs  
Intermediates  
APIs**

Process R&D, Solid State Research  
BBs, RSMs, Intermediates and APIs Manufacturing

**Drug Products**

Pre-formulation and Formulation R&D  
Drug Products Manufacturing

**Analytical R&D**

Analytical R&D, QC, Stability Studies

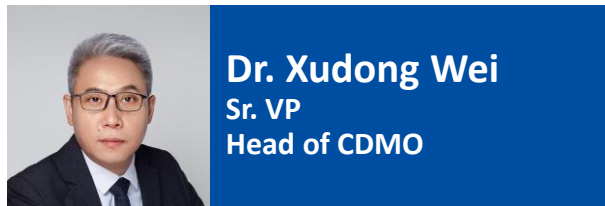
**Regulatory  
Affairs**

Global Regulatory CMC Filing Support

# CDMO Leadership Team-Industry Veterans



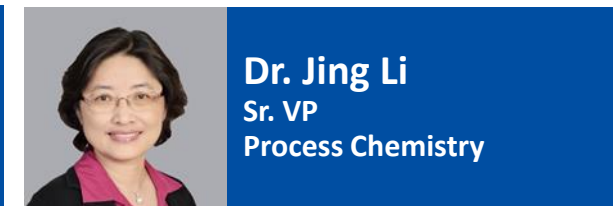
- 20+ yr experience in CMC development, Quality & RA
- PhD at Texas Christian University
- VP/Senior VP at WuXi STA, Pharmaron,
- Principle Scientist at GSK drug development



- 20+ yr experience
- PhD at Nanjing University
- Postdoctoral at Tübingen, York and Emory
- API leader, 15 yr at Boehringer-Ingelheim
- VP at Pharmaron
- 80+ articles, 16 patents



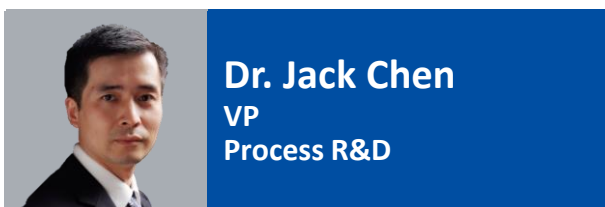
- 25+ yr experience
- PhD at Emory University
- CMC Director at Agios
- Advanced 2 compounds from preclinical to commercial
- 40+ articles and patents



- 20+ yr experience in new drug research and process development
- PhD at Nanjing University
- Postdoctoral at UTSW Medical Center
- Assoc. Director at Merck
- 40 articles and patents, including 18 international patents



- 20+ yr experience
- PhD at Columbia University
- VP at Theravance
- P&G, GSK, 3M
- Led over 10 new drug development projects, 5 were approved for market



- 20+ yr experience
- PhD at Michigan University
- VP at Clariant
- Pfizer, GSK, Asymchem, DSM
- 20+ articles and patents



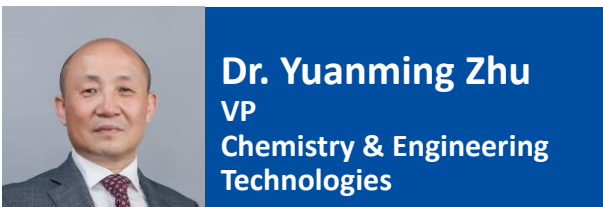
- 25+ yr experience
- PhD at Mississippi University
- TWi, Anbison, Yangzijiang
- Developed 12+ FDA approved DP, including 6 first-time generic drugs, avoid 100+ patent risks



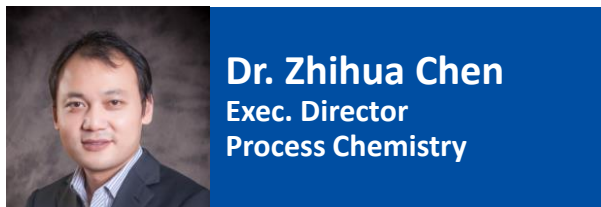
- 10+ yr experience in process chemistry, supply chain management and production operation
- PhD at Beijing Institute of Technology
- 20+ articles and patents

# Project Delivery Team-Talented and Motivated

PharmaBlock



- 20+ yr experience
- PhD at Duquesne University
- Postdoctoral at Colorado State University
- Head of Adama R&D Center (China)
- 40 international patents



- 15+ yr experience in process R&D
- PhD at Lanzhou University
- Postdoc at Purdue University
- 20+ SCI publications and patents



- 20+ yr experience in drug development, and CMC management
- Master at University of Montreal
- CMC leader at GSK
- 10+ publications and patents



- 15+ yr experience in crystallization
- PhD at Tianjin University
- Served at Novartis R&D Center, Porton
- 10+ SCI publications and patents



- 15+ yr experience in PPQ process development
- PhD at Zhengzhou University
- Served at Hansoh, CTTQ Pharma



- 12+ yr experience in regulatory affairs
- Master at China Pharmaceutical University
- Served at Hansoh (top pharma in China)



- 10+ yr experience
- PhD at Nanjing University of Science and Technology
- 10+ SCI publications



- 8+ yr experience
- PhD at University of Minnesota
- B.S. Chemistry & Economics, Peking University
- 6 SCI publications

# Quality & EHS & IP- Our Top Priorities

## Complete Quality, EHS, IP manual and training system

- ❑ cGMP compliant at Zhejiang (US FDA/China NMPA audited), Shandong and US sites
- ❑ ISO 9001 certified at other sites



- ❑ ISO 14001, ISO 45001 certified from lab to manufacturing
- ❑ Benchmark in the industrial park
- ❑ One of the first CDMO process safety labs certified by CNAS

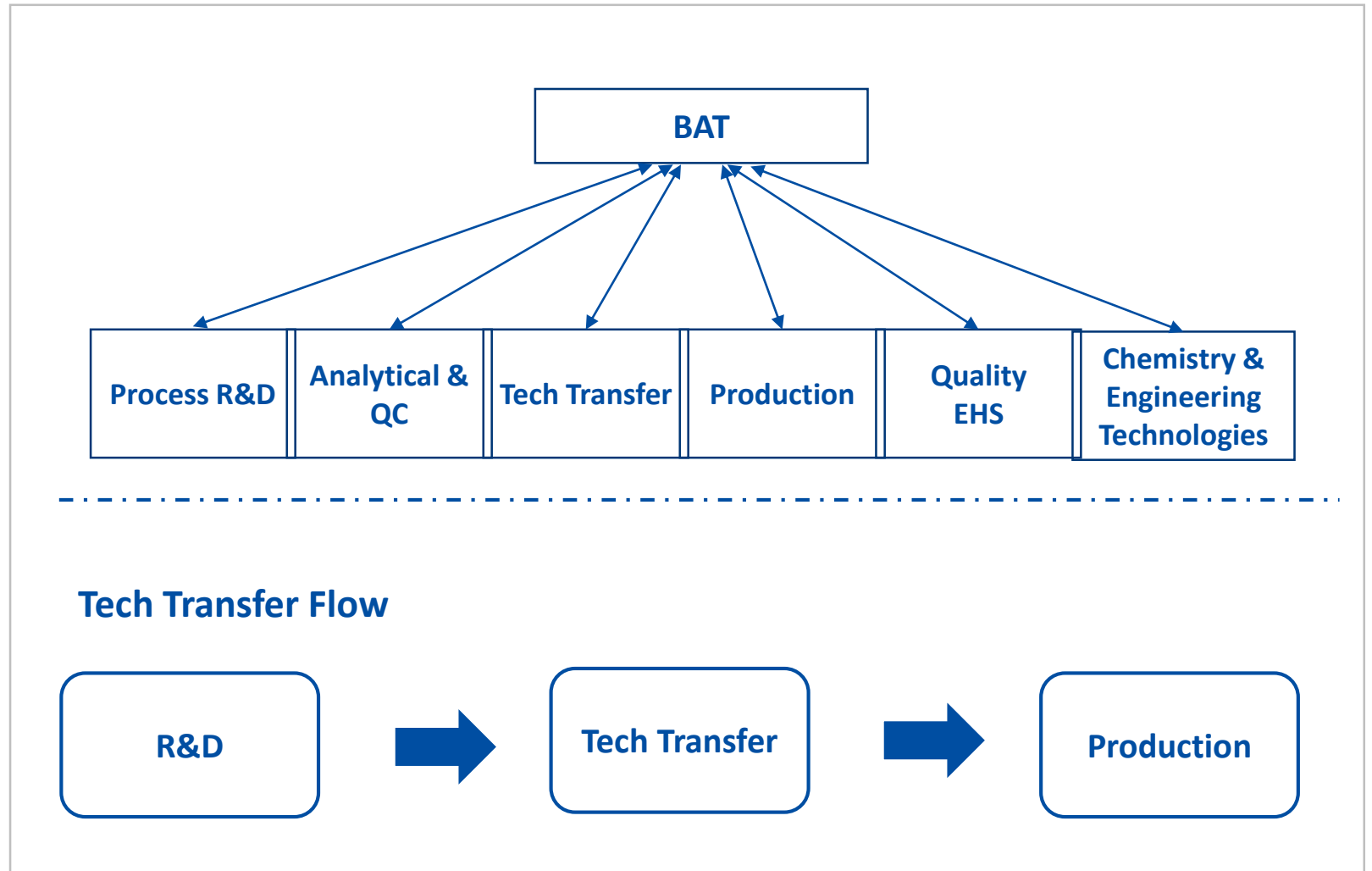
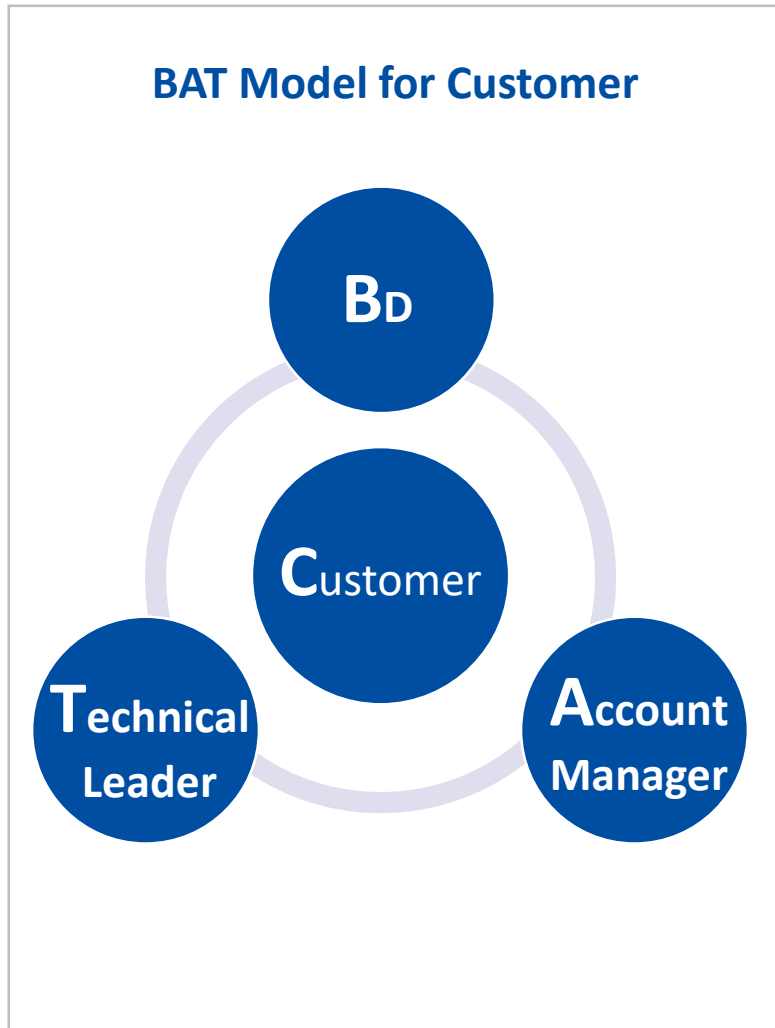


- ❑ National Standard GB/T 29490-2013 implemented
- ❑ Strict SOPs covering HR, access, IT security and document control



# Project Management-BAT Model for Customer

Orchestrated efforts to advance your project at full speed





## Strong Chemistry Experience

**800+** scientists, **100+** PhDs, **400+** Masters

**1500+** projects delivered in 2021

## New Technologies

Flow chemistry

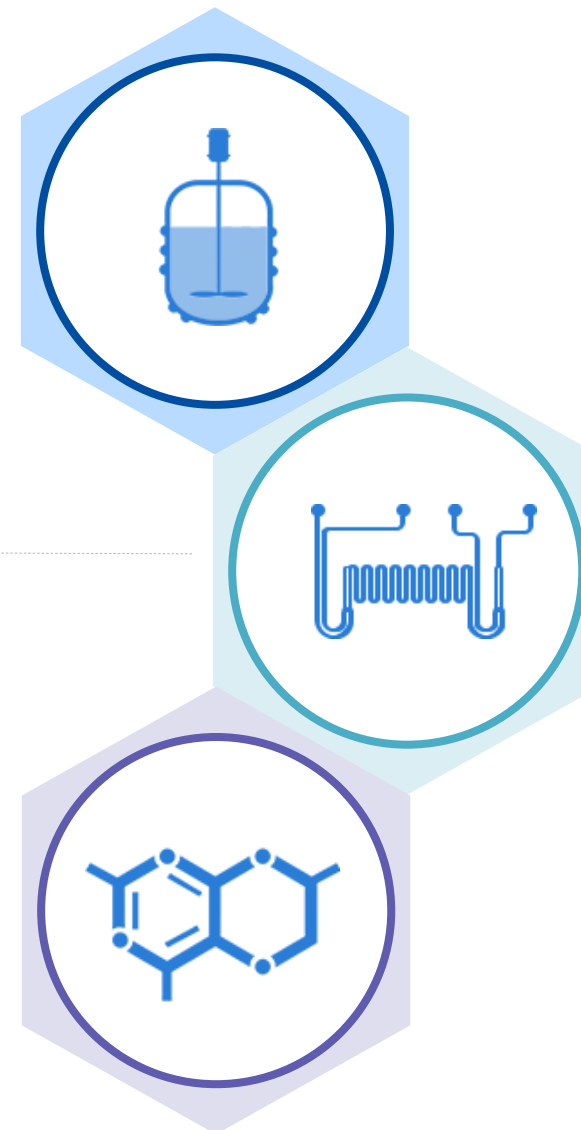
Micropacked bed hydrogenation

Biocatalysis; Heterogeneous catalysis

## Building Blocks Accumulation

**150,000+** BB profiles

**5,000+** with scale up process



### Nanjing-1



New CDMO Process R&D Center, 679,000 ft<sup>2</sup> \ 1000+ hoods

### Nanjing-2



CDMO Process R&D, 58,000 ft<sup>2</sup>



### Nanjing-3



Building Block R&D for Drug Discovery, 38,000 ft<sup>2</sup>

# Process R&D Center-USA Site

- ✓ Greater Philadelphia area (Hatfield, PA)
  - 15,000 ft<sup>2</sup> of offices, labs and warehouse:
  - ISO9001 certified
  - cGMP API Kilo-lab for clinical supply
- ✓ Capacity Expansion (West Chester, PA):
  - 29-30K sqf usable space
  - 3 GMP kilo lab suites (up to 250L)
  - 2 Clean rooms
  - 3 Process labs with 25 fume hoods



Hatfield (PA) Site since 2017



West Chester (PA) Site  
target operational Q4 2022



Chemistry lab at Hatfield  
9' fume hoods (5X)



Analytical lab  
LCMS & UPLC, HPLC, GC, KF, DSC, NMR



Kilo lab  
8' walk in hoods (2X)

# DS Manufacturing Capabilities



PharmaBlock Zhejiang established in **Sep. 2018** by acquisition from Porton  
Facility established in **2014** (Porton Zhejiang)  
Production started in **Dec. 2015**  
FDA inspected in **Jul. 2019**

~700 employees

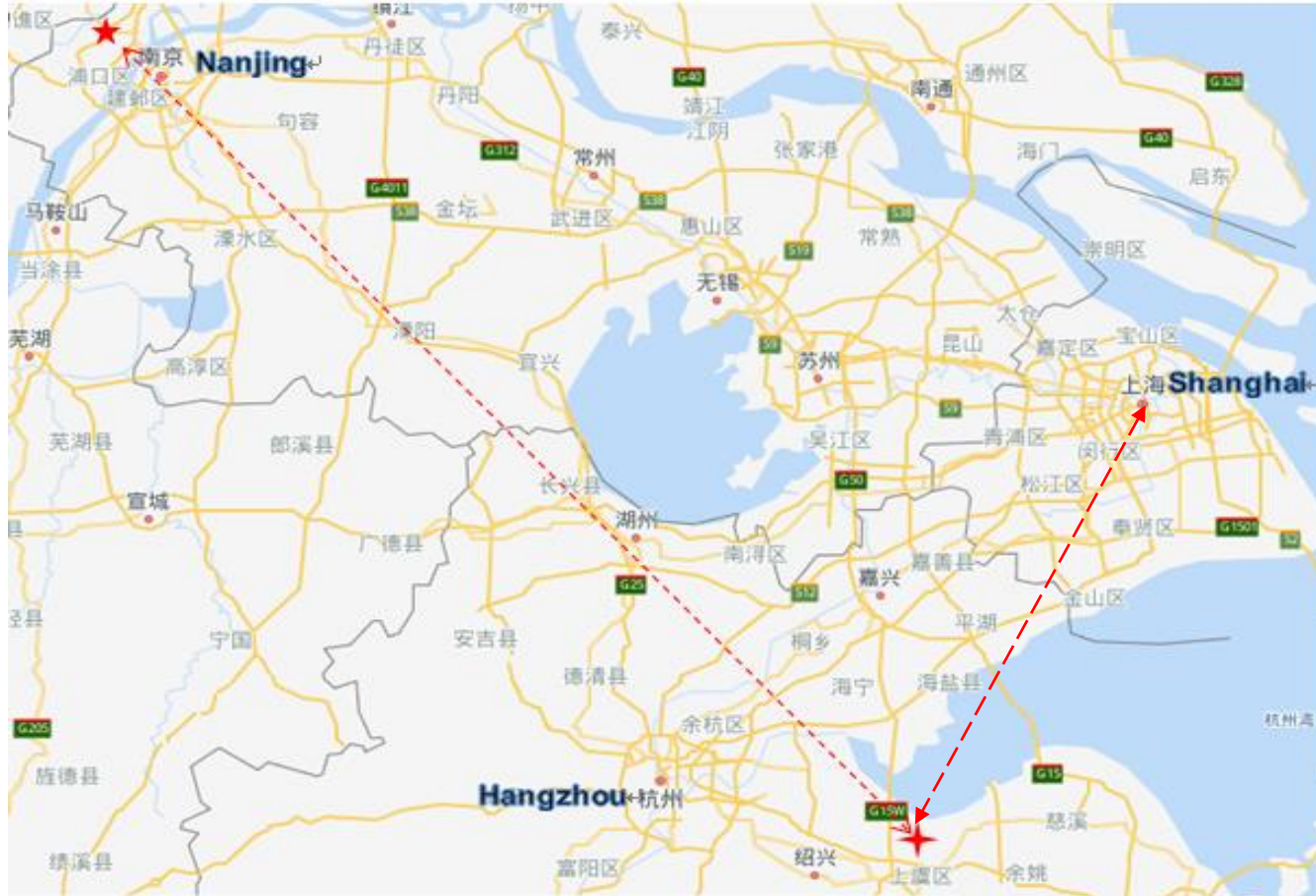


**Total area: 1,436,000ft<sup>2</sup> (~133,400m<sup>2</sup>)**  
**Building area: 1,052,000ft<sup>2</sup> (~97688m<sup>2</sup>)**



Production of **building blocks, RSMs, GMP intermediates, and APIs**  
Support **preclinical, phase I-III, and commercial-scale** needs

## ★ PharmaBlock Nanjing



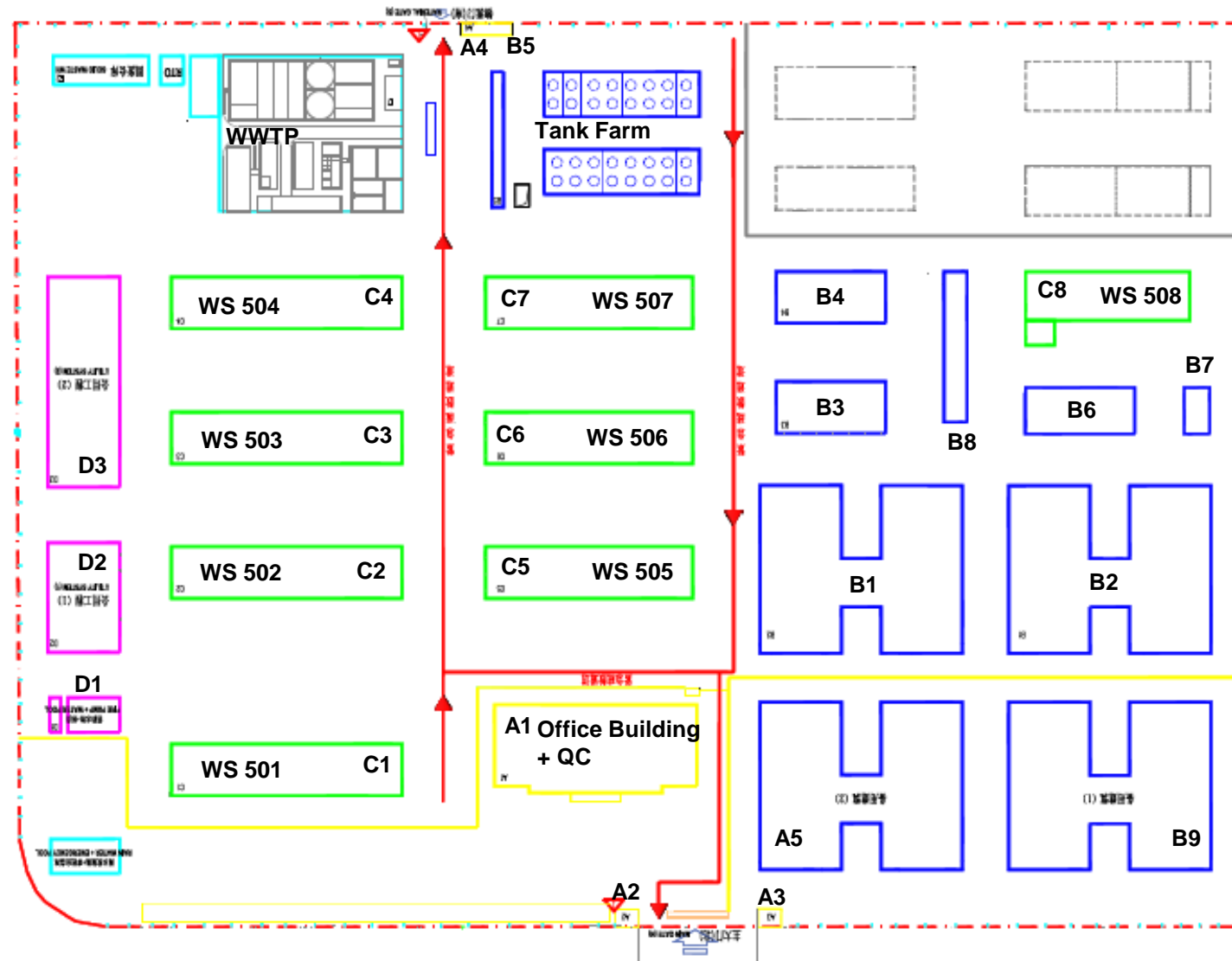
## ★ PharmaBlock Zhejiang



- Located in Hangzhou Bay Shangyu Economic & Technological Development Area, Shaoxing, Zhejiang.
- It is a **national-level chemical industry park**, established in 1998, total area about 275 km<sup>2</sup>.
- ~ 400km from Zhejiang Site to Nanjing HQ
  - ✓ 2 hours by high speed train
- ~200km from Zhejiang Site to Shanghai
  - ✓ 1.5 hours by high speed train
  - ✓ 2.0 hours by driving

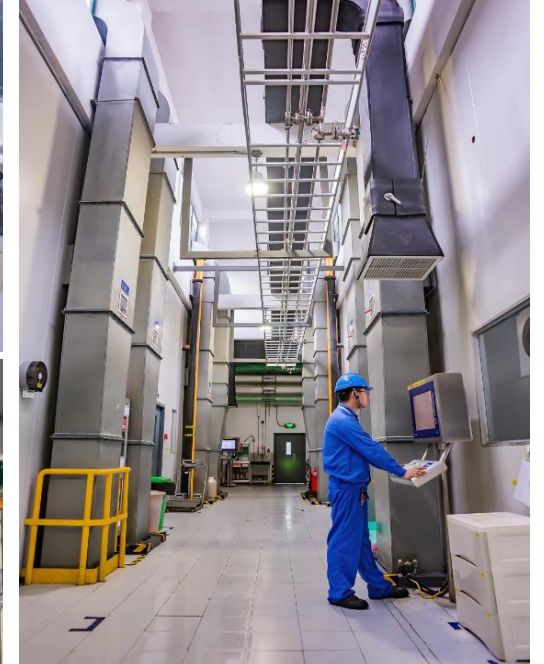
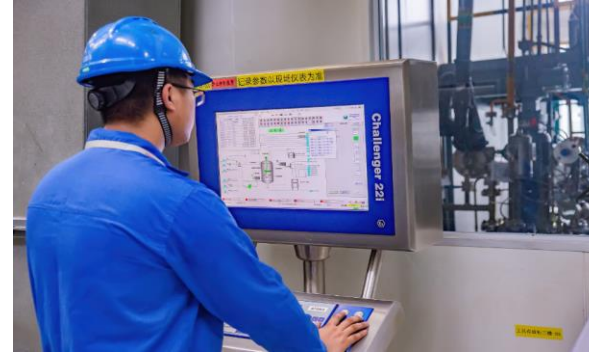
# Site Layout

Building #	Usage / Function
B1	Three floors: - Temperature controlled warehouse - Outer package material warehouse - Inner package material warehouse - Hygroscopic material warehouse - Production consumables warehouse
B2	East side of first floor: - Solid raw material warehouse - Temperature controlled warehouse West side of first floor: - Special raw material warehouse and finished product warehouse for type 3 and 4 products - Temperature controlled warehouse
B3, 4	liquid raw materials warehouse
B5	Tank Farm
B6, B7, B8	Class A warehouses, mainly for the storage of gases, liquids and solid raw materials
B9	Future expansion
C1	Workshop 501 for intermediates
C4	Workshop 504 for intermediates
C7	Workshop 507 for intermediates and APIs
C8	Workshop 508 for hydrogenation
C2, C3	API Workshop under construction
C5, C6	Future expansion
A1	Office Building, including QC
A5	Process development and research, Kilogram Lab
D2, D3	Public system



# Facility Design

- Gravity flow design (3 floors)
- DCS system for process control
- Heating and cooling exchange medium: Glycol and heat transfer oil
- Relief system for reactors and tanks
- General ventilation
- Local Exhaust Ventilation (LEV)
- Dedicate area for dispensing in the WS with down flow booth
- Powder charge by PTS and other containment technology





# Current Manufacturing Capacity

Workshop	Bay No.	Total reactor vol.	Reactor No.	Size range	Centrifuges	Dryers	Others
<b>WS 501</b> (Mar. 2022) Multi-Purpose for Intermediates	5	165 m <sup>3</sup>	38	500 L – 8,000L (GL, SS)	9	5	
<b>WS 504</b> (Dec. 2015) Multi-Purpose for Intermediates	8	~ 120m <sup>3</sup>	40	500 – 6,300L (GL/SS/HC)	8	6	
<b>WS 507</b> (Dec. 2015) Multi-Purpose for Intermediates	8	~ 60m <sup>3</sup>	45	300– 3,000L (GL/SS/HC)	9	7	
<b>API Clean Room Area</b> (Jun. 2019) <b>WS 507, 2<sup>nd</sup> Floor</b>	N/A	~ 2.5m <sup>3</sup>	2	500 L, 1000 L (GL)	1	2 (1 spray dryer)	Fixed Crystallizer: 2 Jet Mill: 1
<b>WS 508</b> (Oct. 2019) Hydrogenation Workshop	7	N/A	5	100L (SS), 500L (SS), 1000L (SS/GL), 2000L (SS)	N/A	N/A	Micropacked Bed Hydrogenation Unit: 3 (5L, 10L, 10L)
<b>GMP Kilo Lab–1</b> (Oct. 2020) With One Class D Cleaning Area	N/A	N/A	11	20~100 L(Glass)	N/A	4	Jet Mill: 1

# Capacity Expansion in Zhejiang Site (2022-2023)

Workshop	Total reactor vol.	Reactor No.	Size range	Centrifuges	Dryers	Others
W502 (2022 Q3)	94m <sup>3</sup>	36 Reactor: 31 Cryogenic Reactor: 2 High Temperature Reactor: 3	500-6,300L (GL, SS, HC)	11	9	Continuous manufacturing facilities 3 API lines with 2 jet mill, 3 filter dryers, 1 cone mill, 1 double cone dryer OEB-4
W503 (2023 Q1)	190m <sup>3</sup>	41 Reactor: 36 High Temperature Reactor: 5	500-8,000L (GL, SS, HC)	11	8	2 API lines with 1 jet mill, 1 filter dryer, 1 cone mill, 1 spray dryer OEB-4
GMP Kilo Lab-2 (2022 Q2)	700 L	9	20-100 L	3	4	GMP control, class D cleaning area, for clinical APIs production
HP Kilo Lab (2022 Q4)	220 L	4	20-100 L	2 filter dryers		For high potent API manufacturing OEB-5

Instrument	Brand & Type
GC	Agilent 7890B (Qty.7) Agilent 7820A (Qty.3), Agilent 8860 (Qty. 2), Agilent 8890 (Qty. 2), Agilent 8890+7697A (Qty. 1), Agilent 7890B+7697A (Qty. 1) ( include 4 headspace injection system)
HPLC	Waters 2695 (Qty. 3), Waters Arc (Qty. 5), Waters H-Class (Qty. 2), Agilent 1260 (Qty. 8) Agilent 1260II DAD (Qty. 7), Agilent 1100 DAD (Qty. 4), Agilent 1260 DAD (Qty. 2), Agilent 1260II VWD (Qty. 5)
NMR	Bruker AVANCE III 400MHz
IR	PE SPECTRUM TWO
UV	Shimadzu UV-2700
Potentiometric Titrimeter	Metrohm 905
Water determination apparatus	Metrohm 852+885 (Qty.1), Mettler Toledo V20S (Qty.1), Mettler Toledo V30S (Qty.1)
Halogen moisture analyzer	Mettler HX204
Specific Rotation	JIAHANG M70 (Qty.1), Mettler-Toledo MP90 (Qty.1)
Ultra Purified Water	Integral-5(Qty.1), Mettler - IQ7000 (Qty.2)
Conductivity meter	Mettler S230
TOC	Shimadzu TOC-L CPH
ICP-MS	Nexlon1000
LC-MS	Agilent 1260II DAD+6125C
Ion chromatograph	DIONEX AQUION RFIC
Malvern particle sizer	Malvern 3000
Clarity detector	SC-4000A
Automatic Polarimeter	PA850
Stability chamber	SHH-SSD-2ST, SHH-500SD-2T

## Profile

- Located in the Shandong Provincial Hi-tech Park
- Space: 18.5 acre
- Compliant with ISO9001 & high EHS standards for Intermediate; cGMP compliant for DP

## Capacity (Intermediates)

- 2 workshops; 30 reactors: 200-3,000 L; total reactor vol.: 60 m<sup>3</sup>
- RSM supplier for NCE products
- Delivered 40+ MTs of > 60 products from Phase I to Commercial stage in past 4 yrs

## Capacity (Drug Products)

- 1 workshop and QC labs; 3 workshops to be added
- Tablets and capsules production lines (from 5 kg to 100 kg, flexible for project change)
- Bottle and blister two packaging line



Blister packaging line



Bottle packaging line



Tablets and capsules production lines

# Building Blocks Enhanced CDMO

For fast delivery, reliable & flexible supply chain, better cost control

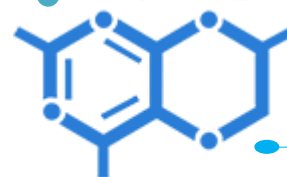


## Novelty & Diversity

- Novel and diverse BBs supplied from drug discovery to development

## Strong Chemistry for Fast Delivery

- Systematically develop chemistry expertise for core structures
- Strong chemistry accumulated for challenging molecules, and ensure fast delivery



## Reliable & Flexible Supply Chain

- Better supply management on BBs as intermediates and RSMs
- Qualified suppliers of raw materials accumulated from BBs synthesis

## Better Cost Control

- Increase flexibility to control the cost by optimizing process of BBs
- BB's scale factor to cut down the cost on raw materials

# Innovative Technologies Enhanced CDMO

For efficient, green, and safe process and manufacturing

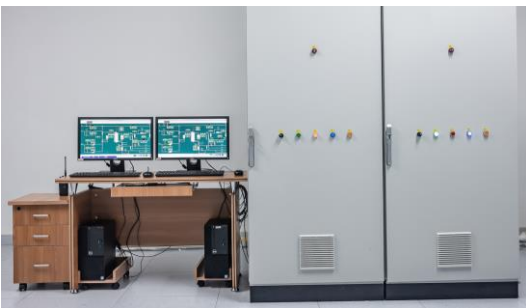
## Flow Chemistry

210+ projects  
30+ reaction types  
kilo~hundred-kilo scale



## Micropacked Bed Technology

300+ projects  
kilo~MT scale  
commercial and GMP projects



## Catalysis

300+ heterogeneous catalysts  
200+ biocatalysis projects  
kilo~hundred-kilo scale



## Solid State & Crystal Engr.

330+ projects



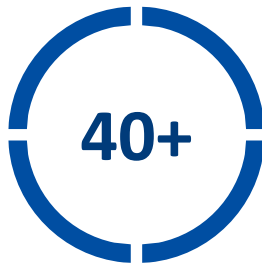


July 2019  
FDA GMP inspection  
no Form 483s

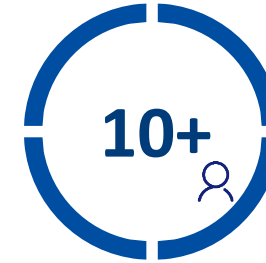


Oct 2021  
NMPA PAI  
no critical/major findings

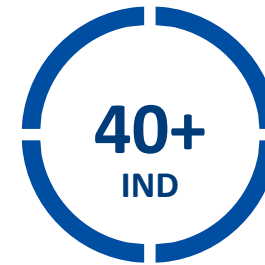
### Clients GMP audits



### Regulatory affairs team



### DMF, ANDA, IND and NDA submission and approval experiences

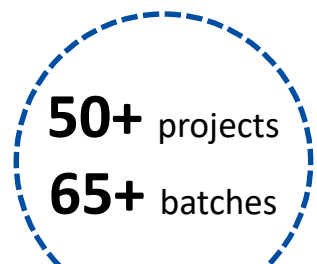


### 10+ regulatory markets including China, US, EU, Japan, etc

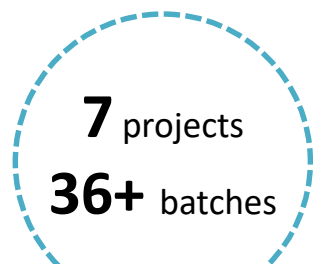


## GMP Experience

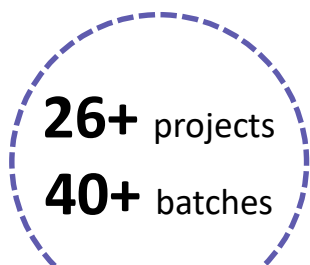
(Since 2019)



API (Clinical)



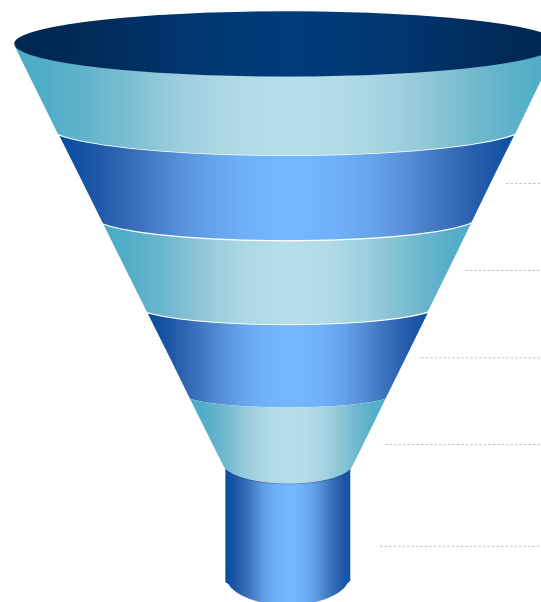
API (Validation)



GMP Intermediates & RSMs (Validation)

## Increasing Projects Pipeline

(2021)



Discovery

10K+ BBs

Pre-clinical

1430+ Projects  
(43 APIs)

Phase I

Phase II

Phase III

45 Projects  
(5 APIs)

Commercial



# Focus on our core competencies

Integrated CMC platform



Top notch leadership team



Strong chemistry  
& new technologies



Flexible supply chain



Efficient delivery



Reduced risk



Cost saving



Sustainability



## Bring customer's molecules to medicines