PharmaBlock

A Fully Integrated CMC Platform Focused on Innovative Chemistry and Low Carbon Manufacturing

PharmaBlock (USA), Inc.
PharmaBlock Sciences (Nanjing), Inc.

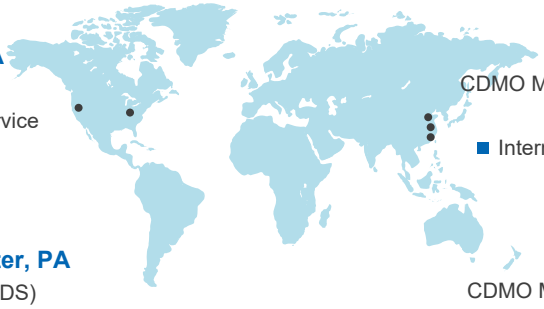
www.pharmablock.com
product.pharmablock.com

Our Global Footprint

Sunnyvale, CA
Customer Service

Nanjing
Headquarters
BB & CRO
CDMO PRD(DS & DP)

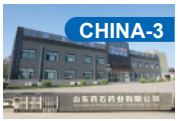
Hatfield, PA
BB & CRO
Customer Service



Zhejiang
CDMO Manufacturing
- BB & RSM
- Intermediate & DS

West Chester, PA
CDMO PRD (DS)
GMP Kilo-lab

Shandong
CDMO Manufacturing
- BB & RSM
- DP



2008	2017	2500+	600+
Started	IPO	Employees	Global Partners

Fully Integrated CMC Platform to Accelerate Drug Development and Commercialization

	Preclinical	Phase I	Phase II	Phase III	Commerical Stage
	IND			NDA	
Drug Substance Drug Product Analytical R&D Regulatory Affairs	■ Preliminary process R&D ■ Synthesis for tox study ■ Method development & validation ■ Pre-formulation ■ DS and DP Manufacturing ■ Stability & degradation studies ■ Documentation and IND filing	■ GMP manufacturing for clinical supply ■ Process validation enabling (DOE) ■ Process validation and continuous improvement ■ Final formulation & modification ■ Method development & validation ■ Stability & degradation studies		■ NDA filing ■ Production risk mitigation ■ Post approval changes ■ Litigation support	

Drug Substance Development and Manfuacturing

1500+ chemists

505m³ total reactor volume

190m³ to add in 2023

Early Phase Development

- FFS/FTE for process R&D of drug substances
- Fit-for-purpose process development
- PMI & COG oriented, implementing cutting-edge technology
- Extensive experience in most modern organic reactions

Late Phase Development

- Robust, green and cost efficient
- Study unit operation of each step (NORs, PARs) and define CPPs
- Develop control strategy for RSMs, intermediates and APIs
- Perform process risk analysis

Manufacturing

- GMP manufacturing facilities (FDA GMP Inspection; NMPA PAI)
- Reactors of different sizes (50 L to 8,000 L), supply materials for pre-clinical, clinical development, and commercial projects
- Multiple operation units to undertake a broad range of chemistries at all scales
- Process safety must be assessed for each scale-up project before moving into the workshop
- Special capabilities including: HP kilo-lab; GMP micropacked bed hydrogenation; spray dry, etc.

Green Chemistry and Low Carbon Technologies

Flow Chemistry

400+ projects	40+ reaction types	kilo to metric ton scale

Application in safer, more stable, higher-yield processes

- High temperature/pressure
- Highly energetic
- Cryogenic
- Highly reactive and air-sensitive
- Toxic and/or stinky agents
- Unstable intermediates
- Oxidation and/or ozonization
- Diazotization
- Sulfonation
- Esterification
- Halogenation
- Reduction

Micropacked Bed Technology

450+ projects	kilo to metric ton scale	commercial and GMP projects

Reactions applied at manufacturing scale

- Deprotection
- Nitro reduction
- Nitrile reduction
- Diazo reduction
- Reductive amination
- Phenyl ring reduction
- Selective dehalogenation
- Pyridine ring reduction
- Oxime reduction
- Asymmetric hydrogenation
- Olefin/acetylene reduction

Catalysis

500+ heterogeneous catalysts	400+ biocatalysis projects	kilo to hundred-kilo scale

Heterogeneous catalysis

- > 500 bead-supported fixed-bed hydrogenation catalysts(built in-house and purchased)
- Consistent performance and releasing on real substates
- Contract reseach and custimized catalysts
- >40 cats have been used in kilo projects or larger
- Various metals: Pd, Pt, Ru, Rh, Fe, Co, Ni, Cu
- Catalysts characterization, design, screening, and continuous optimization.

Biocatalysis

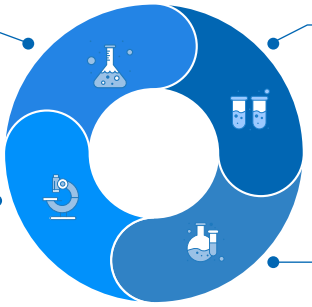
- > 500 enzymes in stock (commercial and in-house)
- Fermentation: up to 5 ton, using Various microbes
- Creening and process development
- Enzyme discovery and enzyme engineering

Drug Product Development and Manufacturing

Pre-formulation

Physicochemical properties: solubility, pKa, logP, hygroscopicity

Screening: polymorph, salt, cocrystal, amorphous dispersion



Solid state/solution stability: heat, humidity, light, pH, oxidation

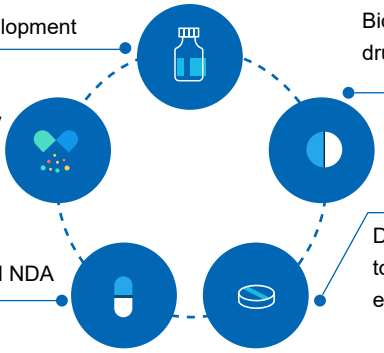
Preclinical formulation

Formulation

Oral solid dosage form design, development

Drug/excipient compatibility, stability

Development covering both IND and NDA



Bioavailability enhancement of new drug candidate substances

Dosage forms include but not limited to hydrogel matrix, osmotic pump, enteric coated pellets/tablets, etc.

Process Development and Manufacturing

Development: wet/dry granulating, tableting, coating

Beads drug layering/coating, lyophilization

Tablet and capsule production lines (5–100 kg, flexible for project changes)

Bottle and blister packaging lines

Enabling Technologies:

- Spray Dried Dispersion (SDD)
- Hot Melt Extrusion (HME)
- Micro-emulsions
- Emulsions
- Nanosuspensions
- Solid lipid nanoparticles
- SMEDDS

Quality & Regulatory Excellence

July 2019
FDA GMP inspection
no Form 483s

Oct 2021
NMPA PAI
no critical/major findings

>80
Clients GMP audits
by June 2023

>50
IND approvals,
submissions, and support
with submission by June 2023

>10
DMF / NDA submissions
and approvals by June 2023

IP

National Standard
GB/T 29490-2013 implemented

ISO 27001 implemented and certified

- Strict enforcement to protect our partners' intellectual property is our top priority
- Audited by a number of global pharmaceutical companies
- Comprehensive strategy and practices are implemented, covering employee management, project management, information management, supplier management, and material management

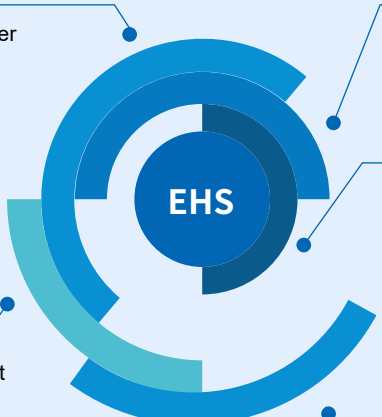
EHS

ISO 14001 certified

ISO 45001 certified

CNAS certified process safety lab

Our strong commitment to the environment, health and safety underpins all that we do at PharmaBlock



Optimal route design for better PMI control

New technologies application for greener and efficient process and manufacturing

Process safety assessment for intrinsic safety. One of the first CDMO process safety labs certified by CNAS

Strict process and equipment management, along with scientific waste treatment and recycling use for cleaner production

Corporate wide efforts and lean operation for energy savings and emission reduction

About PharmaBlock

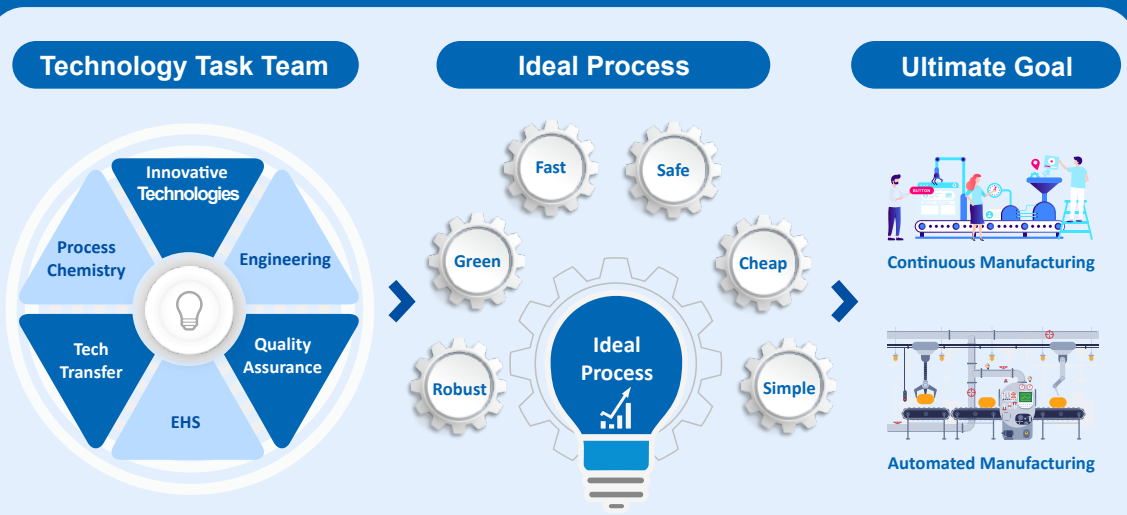
A Reliable Partner to Tackle Your Challenges

Fast Delivery of Challenging Molecules
Strong chemistry accumulated

DS & DP Bundle, All The Way to Commercialization
Integrated CMC services with multi-purpose capacity

Efficient, Green, and Safe Process and Production
Innovative technologies

Flexible Supply Management and Cost Control
Back-integration of key raw materials



PharmaBlock (Stock Code: 300725.300725) is a global, fully integrated CRDMO in the pharmaceutical R&D and manufacturing industry. Its core businesses include a collection of rationally designed building blocks, supplying from discovery to development and commercialization; building block-enhanced hit generation and hit-to-lead optimization services and solutions; and development and manufacturing of RSMs, intermediates, APIs, and drug products for drug development and commercialization.

Throughout the product lifecycle, PharmaBlock integrates innovative and enabling technologies, such as flow chemistry, micropacked bed technology, chemo-catalysis, bio-catalysis, and equipment R&D, to proactively explore greener, safer, and more intelligent manufacturing and service models in the biopharmaceutical field, and promote the sustainable development of the industry.

Officially operated in 2008, PharmaBlock has partnered with almost all of the top 20 pharmaceutical companies, as well as hundreds of small to medium-sized biotech companies around the world. Its mission is to provide better products and services through innovation of chemistry and low-carbon technology in R&D and manufacturing, and help partners improve the efficiency of new drug discovery and development, and accelerate the project launch process at full speed.

PharmaBlock

Innovative chemistry for a better future

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Official Website

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