PharmaBlock

A Fully Integrated CDMO Focused on Innovative Chemistry and Low Carbon Manufacturing

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

www.pharmablock.com
product.pharmablock.com

Our Global Footprint

Hatfield, PA
CDMO Process R&D
GMP Kilo-lab
Customer Service

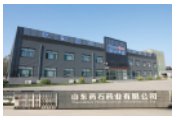
West Chester, PA
CDMO Process R&D
GMP Kilo-lab
(Q4 2022)

Sunnyvale, CA
Customer Service

Nanjing
CDMO Process R&D
- Drug Substance
- Drug Product

Zhejiang
Manufacturing
- Drug Substance

Shandong
Manufacturing
- Drug Product
- Intermediate



2008	2017	2600+	200+
Started	IPO	Employees	Global Partners

Fully Integrated CMC Platform to Accelerate Drug Development and Commercialization

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

Drug Substance Development and Manfuacturing

1500+ projects delivered in 2021

1200+ 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.

Chemistry and Engineering Technologies

Flow Chemistry

210+ projects	30+ 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

Micropacked Bed Technology

300+ 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

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

Heterogeneous catalysis

- > 200 bead-supported fixed-bed hydrogenation catalysts (built in-house and purchased)
- Cartridge catalysts used in flow process
- Powder supported catalysts used in batch process
- Heterogeneous Pd catalysts (coupling reactions and borylation reactions)
- Customized and specialized catalysts
- Catalyst screening

Biocatalysis

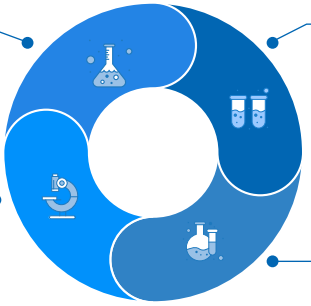
- > 500 enzymes in stock (commercial and in-house)
- Fermentation: up to 100 L
- Screening and process development
- Directed evolution

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

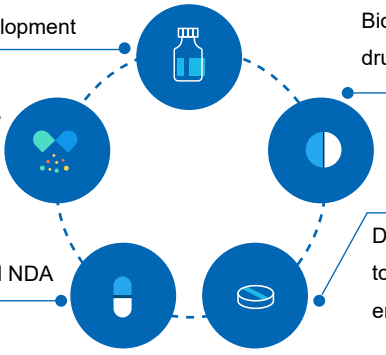
Preclinical formulation

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/tables, etc.

Process Development and Manufacturing

Development: wet/dry granulating, tableting, coating

Beads drug layering/coating, lyophilization

Bioavailability enhancement of new drug candidate substances

Development covering both IND and NDA

Enabling Technologies:

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

Quality & Regulatory Excellence

July 2019
FDA GMP inspection
no Form 483s

Oct 2021
NMPA PAI
no critical/major findings

40+
Clients GMP audits in 2021

40+
IND submissions and approvals by 2021

9+
DMF / NDA / ANDA submissions and approvals by 2021

IP

National Standard
GB/T 29490-2013 implemented

ISO 27001 implemented

- 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

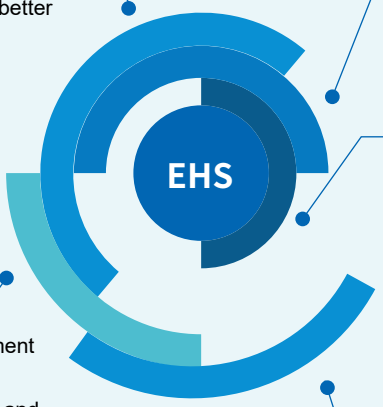
EHS

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

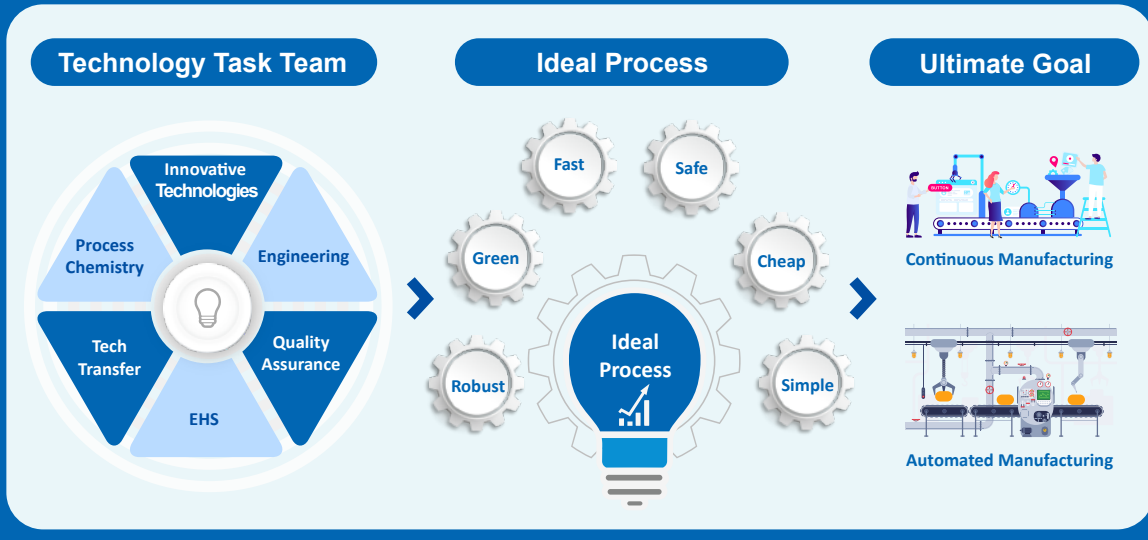
A Reliable Partner to Tackle Your Challenges

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 is a fully integrated CDMO focused on innovative chemistry and low-carbon manufacturing. Its core businesses includes a rationally designed building blocks collection, supplying from discovery, development to commercialization; development and GMP manufacturing of RSMs, intermediates, APIs, and drug products for drug development and commercialization. PharmaBlock's evolving mission is leveraging top-notch expertise and innovation in chemistry and new technologies to support partners in accelerating drug discovery and market integration. The company has partnered with most of the top 20 pharmaceutical companies and hundreds of small to medium-sized biotech companies worldwide.

PharmaBlock (USA), Inc., located in the Greater Philadelphia Area, is a subsidiary of PharmaBlock Group. The company opened its first US facility in the Bay Area of California in 2012, and established US headquarters in Pennsylvania in 2017. PharmaBlock USA is providing process R&D services using new technologies such as flow chemistry and micropacked bed hydrogenation to bring greener, safer, innovative and cost efficient solutions to pharmaceutical industry.

PharmaBlock

Innovative chemistry for a better future

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