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

Hatfield, PA
BB & CRO
Customer Service

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

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

Zhejiang
CDMO Manufacturing
BB & RSM
Intermediate & DS

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

Drug Substance
- 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 Manufacturing

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 substrates
- Contract research and customized 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
- Screening 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)
- Nanosuspensions
- Hot Melt Extrusion (HME)
- Solid lipid nanoparticles
- SMEDDS
- Micro-emulsions
- Emulsions
Quality & Regulatory Excellence

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

EHS

- 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
- Corporate wide efforts and lean operation for energy savings and emission reduction
- Strict process and equipment management, along with scientific waste treatment and recycling use for cleaner production

IP

- National Standard GB/T 29490-2013 implemented
- ISO 27001 implemented and certified
- GB
- ISO

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
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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