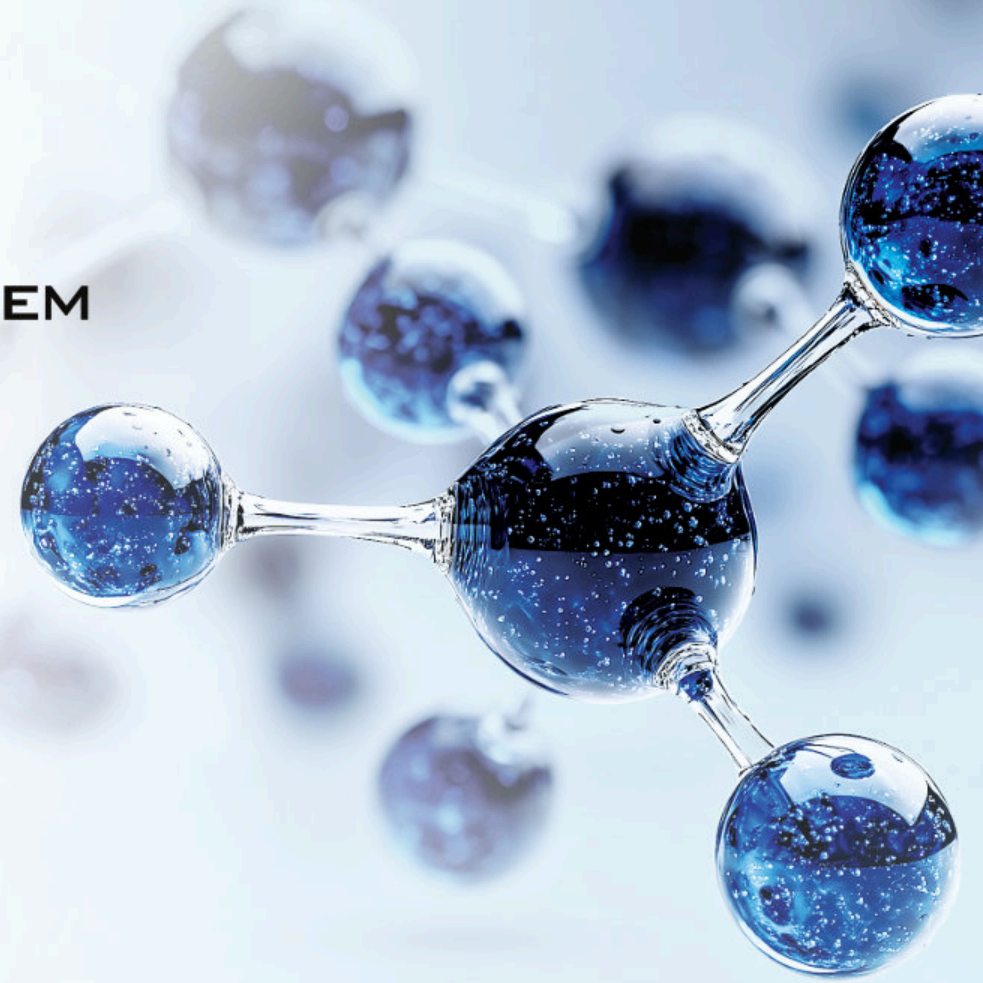
ASYMCHEM



SMALL MOLECULE CMC SOLUTIONS

www.asymchem.com

Stock Code:002821.SZ / 6821.HK

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01
Preclinical to Commercial Services

Asymchem provides integrated CDMO solutions with seamless project management to enable your success. Our streamlined development & manufacturing process ensures timely milestone delivery, effective budget management, and robust regulatory strategies.



Preclinical Stage Projects

- Route Design & Scouting
- Process Development & Optimization
- Pre-Tox & Tox Batches
- IND Filing

Clinical and Late Phase Projects

- Clinical Trial Material Manufacturing
- Regulatory Filing Strategy and Support
- QRA Studies
- Analytical Method Development and Validation
- PPQ Studies
- NDA Filing

Commercial Projects

- Commercial Manufacturing
- Localized Manufacturing
- Life Cycle Management and Optimization
- Global Compliance Assurance
- Raw Material Supply Chain

Proven Track Records

7 USFDA Approved API

10 NMPA Approved API

2 NMPA Approved Drug Product

150+ PPQ Campaigns (DS and DP)

Multinational Market Filing

- 15 USFDA Inspections
- 3 TGA Inspections
- 2 MFDS Inspections
- 2 Health Canada Inspections
- 60+ NMPA Inspections
- 4 PAI Waivers from USFDA

Summary of Projects



Commercial Project Summary



The number of commercial API projects has been steadily increasing since 2019.

Blockbuster Drug Involvement

5 Drugs with $1 billion sales

2 Drugs over $10 billion sales

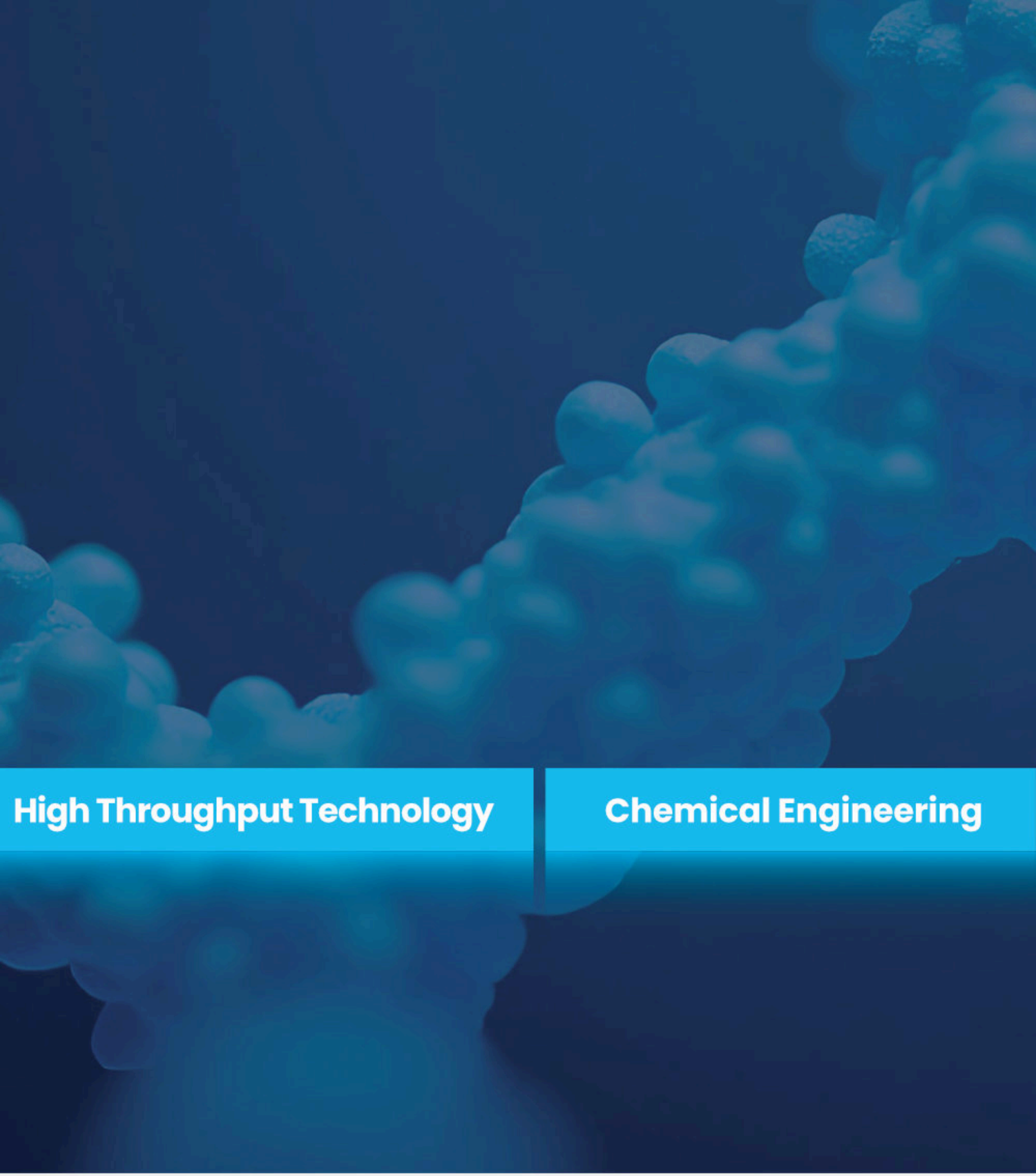
Asymchem's Advantages

- Stable and experienced project execution team
- Transparent, real-time communication
- Successful deliveries of larger number of projects
- Cutting-edge equipment
- High level synchronization across the team
- Well-recognized late phase strategy for R&D and manufacturing

02
Process Development

Flow Chemistry

Biotransformation



High Throughput Technology

Chemical Engineering

Flow Chemistry

Comprehensive and Whole Process Customization Service for Flow Chemistry

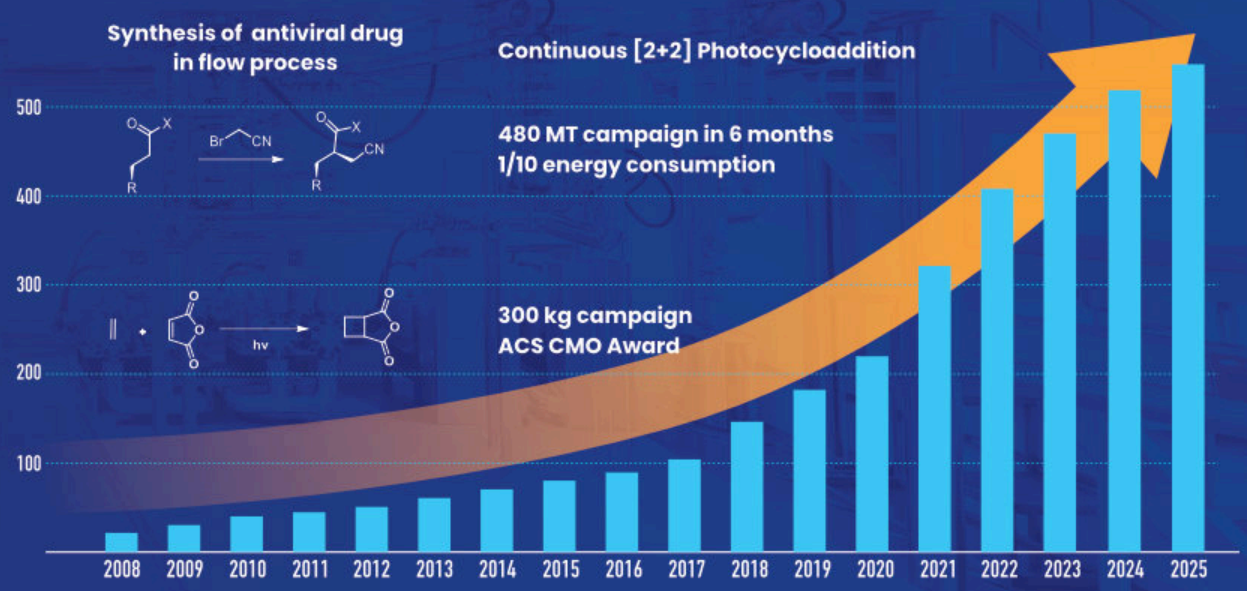
Reaction Types	Capacity	Reaction Types	Capacity
Cryogenic Reactions	900 kg/d	Halogenations	200 kg/d
Diazotization	120 kg/d	Supported Enzyme Catalysis	200 kg/d
Nitrations	330 kg/d	Azidation	420 kg/d
Ozone, Oxygen Oxidation	330 kg/d	Continuous Distillation	300 kg/d
Photochemistry	500 kg/d	Coupling Reaction	580 kg/d
Electrochemistry	10 kg/d	Hydrolysis	200 kg/d
High Temperature Reactions	160 kg/d	Grignard Reagent	5000 kg/d
Heterogeneous Hydrogenation	200 kg/d	Ring-opening Polymerization	500 kg/d
Supported Catalysis	300 kg/d		

Large-Scale Production Solutions (Up to 1,000 Tons)

300+ Experienced Flow R&D Scientists and Engineers

8,200 m² Dedicated Flow Manufacturing Space

Custom Equipment Optimizes Flow Processes



"CMO Excellence in Green Chemistry Award"



Biotransformation

Enzyme Engineering

- **Enzyme Discovery & Cell-Free Protein Synthesis High-throughput Enzyme Screening**
- **In-house Enzyme Library:**

  30+ Enzymatic Reaction Types

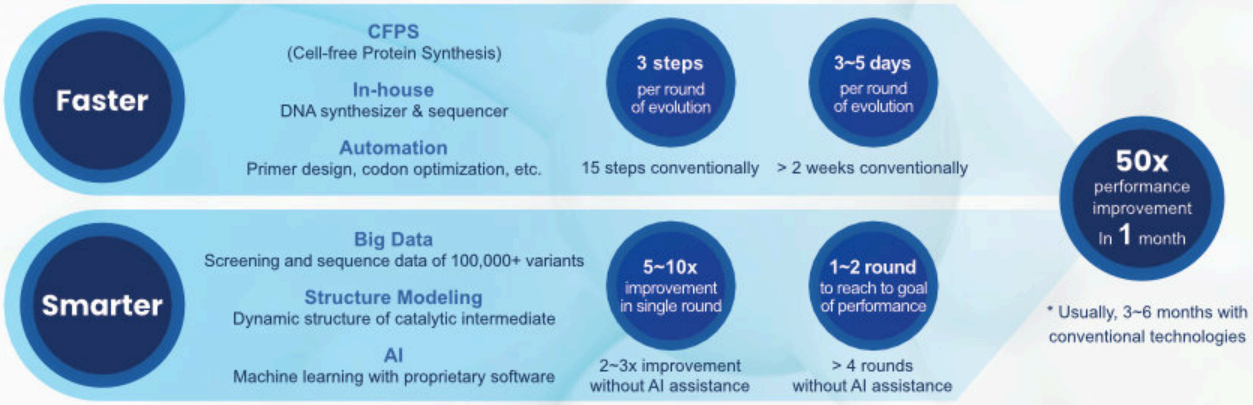
  300,000+ Proprietary Enzymes
- **20 Enzyme Kits**
- **500+ Scalable Biotransformation Processes**
- **Enzyme Immobilization & Continuous Flow Synthesis**

Enzyme	Asymchem Library	Kit	Enzyme	Asymchem Library	Kit
Transaminase	644	92	Proline Hydroxylase	69	20
Ketoreductase	272	72	Threonine Aldolase	35	25
Hydrolase	197	50	Arylmalonate Decarboxylase	25	20
Imine Reductase	212	50	Tyrosine Phenol Lyase	21	20
Amino Acid Dehydrogenase	85	50	Hydroxynitrile Lyase	20	20
Nitrilase	38	28	Monoamine Oxidase	30	20
Ene Reductases	130	42	Amidohydrolase (Amidase & Acylase)	54	30
Baeyer-Villiger Monooxygenase	151	42	Styrene Monooxygenase	65	30
Phenylalanine Ammonia Lyase	41	33	Unspecific Peroxygenase	35	18
α-Amino Acid Ester Acyltransferase	159	30	Other Enzymes	1075	0
Purine Nucleoside Phosphorylase	89	20			

Enzyme Evolution

- **CFPS simplify the enzyme evolution procedures, reducing the lead time of a round of evolution to 3~5 days.**
- **Our bioinformatics AI further accelerates such process, improving enzyme activity/selectivity by 5~10x in a single round.**
- **Combining the both, we can enhance enzyme performance by ~50x within 1 month (which is 3~6 fold faster than average).**

Enzyme Evolution Procedures



Enzyme Production

- **Strain development & cell bank establishment**
- **High density fermentation**
- **High throughput and continuous fermentation**
- **Scalable separation and purification systems**
- **Gram-to-ton scale production**

High Throughput Technology

HTP & HTP-DoE Technologies

Reactors for Screening

- 24/48/96 well plate for fast screening
- 6-well plate or EasyMax for confirmation
- 10 sets of high-pressure HTP equipment

Error Control

- Weighing: Error ＜3%
- Loss of Solvent: All lost ＜3%
- Workflow: Ensuring results are consistent with traditional DoE

Capacities

- ~2000 Reactions / day
  Temperatures: -20 to 130°C
  Conditions: water-free or oxygen-free
- For Pressure Reaction:
  ~800 Reactions / day
  Temperature: RT~250℃
  Pressure Range: up to 10 Mpa

Screening Library

- Metal Precursors
- (Chiral) Ligands
- Acids / Bases
- Heterogeneous Catalyst
- Other Reagents
- Salts

Auxiliary Equipment

- Multi-port Glove Box
- Labconco CentriVap
- Liquid/Solid Handling Tool
- Mettler Easymax
- 20 Parallel Autoclaves

Dedicated Team's Capabilities



R&D Capabilities Enabled by HTP Technologies

Route Development

Rapid Exploration

HTP methods allow for the rapid screening and evaluation of multiple reaction conditions, enabling the exploration of a wide range of possibilities in a shorter timeframe.

Increased Success Rate

The ability to screen a large number of reactions simultaneously increases the chances of discovering viable routes, improving the success rate of route development.

Cost Reduction

HTP experimentation minimizes manual labor, the consumption of expensive reagents and material, significantly increasing throughput while reducing resource requirements.

Process Development

Accelerate Process Development

This approach enables rapid screening of multiple variables, facilitates swift evaluation of experimental conditions, and identifies optimal process parameters.

Comprehensive Parameter Space Exploration

HTP-DoE efficiently explores a large parameter space, considering multiple variables simultaneously. It identifies critical parameters and optimizes systems or processes by systematically varying factors.

Drive Innovation

The methodology empowers researchers to efficiently explore potential solutions, validate multiple hypotheses through experimentation, and accelerate discovery of novel industrial applications.

PV Enabling Work

Enhanced Process Understanding

HTP-DoE systematically explores process parameters and their interactions, providing comprehensive insights into API production. This understanding supports the development of effective control strategies.

Robustness and Reliability Improvement

HTP-DoE evaluates process robustness by testing different variables and their interactions. Critical parameters and acceptable ranges are identified to develop control strategies, enhancing reliability and reducing deviations.

Risk Mitigation

HTP-DoE mitigates risks by understanding the impact of process parameters on quality attributes. Risks related to impurity formation, yield variability, and product quality deviations are identified and minimized through control strategies.

Chemical Engineering

Chemical Engineering Science

- Process engineering evaluations for process scale-up & technology transfer
- Optimization for unit operations
- Process safety calculations

Process Engineering Technology & Design

- Solvent recovery & product purification
- Process engineering strategic technologies
- Manufacturing continuous improvement
- Engineering design

Crystallization Engineering

Crystallization process development and optimization with support of process analytical technology (PAT)

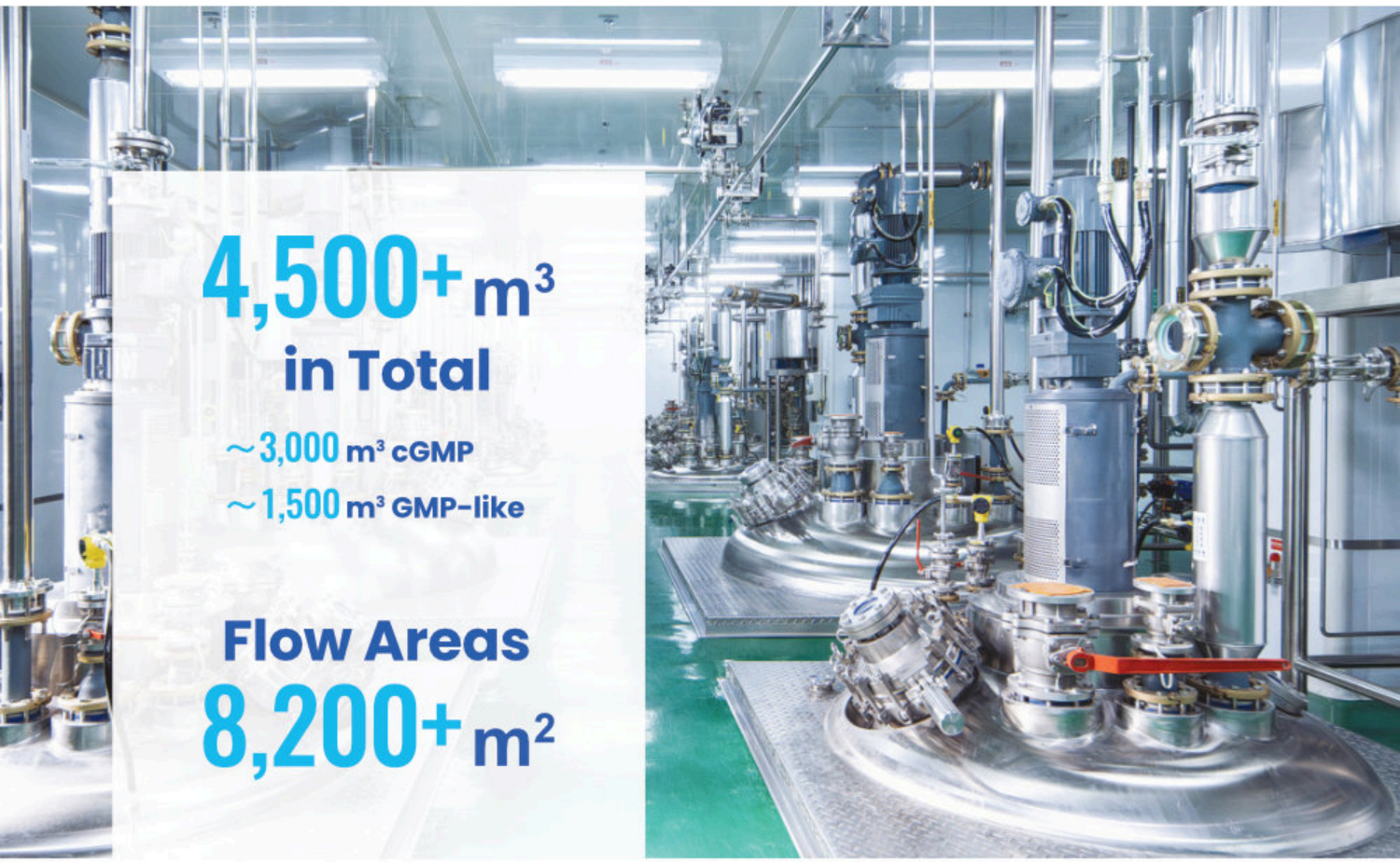
Center of Intelligent Manufacture Technology

- Advanced control technology
- Intelligent manufacturing technology
- Laboratory automation and information management

Process Safety Lab

- Process safety assessment
- Reaction kinetics modelling

03 Manufacturing Capacity



Item	Capacity
API Manufacturing	20 - 80 L GL Reactors 200 - 8,000 L GL / Hastelloy / SS / TiS Reactors
cGMP Pilot/ Commercial Manufacturing	5 - 20,000 L GL / SS / Autoclave / TiS Reactors 500 - 20,000 L GL / SS / Hastelloy Reactors
Non-GMP Pilot/ Commercial Manufacturing	20 - 20,000 L GL / SS / Autoclave
High Potency	HP Kilo Lab (Class D): 6 Isolators, 2 - 20 L Glass Geactors (-80 -150℃)
	HP Plant (Class D): 200 - 1,000 L GL Reactors / Stainless Steel Reactors (-20 -120℃); 2 - 20 L Glass Isolators (-80 -150℃)
Challenging Reactions	Cryogenic Reaction (Low as 110°C) High Temperature Reactions (> 200°C) High-pressure Reactions (> 100 atm)
Fermentation	50 - 5,000 L (CNC+D+A Grade) Reactors
Penem Intermediates	50 - 20,000 L Reactors

In-house Production Guarantees Raw Material Supply

In 2003 Asymchem began in-house bulk production of raw material (RM) and regulatory starting material (RSM). Since then, Asymchem has established consistent track records of on-time delivery with efficient management of impurity profiles and costs.

Internal Supply Network

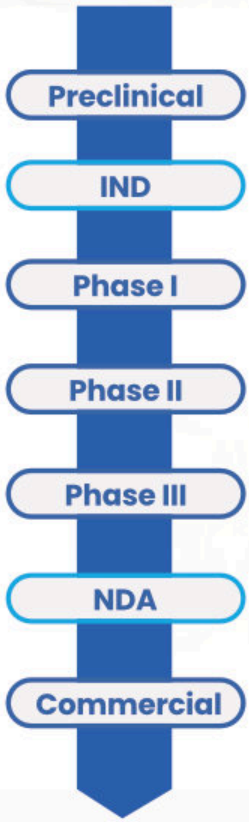
- Advanced backend integration for a reliable, efficient and sustainable supply chain
- Leverage Asymchem's advanced technologies for minimized cost

External Supplier Audit System

- Continuous and rigorous supplier auditing for delivery, QA and EHS
- Data collected by survey and on-site visits by Asymchem auditors
- Broad and growing network with adaptability

04
Analytical Services

Asymchem delivers comprehensive, phase-appropriate analytical services to support process development and manufacturing. By accelerating your advancement from preclinical to commercial phases, we ensure quality through rigorously characterized data to enable global regulatory approvals.



- Initial establishment of analytical method for RSMs and intermediates
- Simple establishment and validation for API methods
- Structure elucidation for API
- Characterization of reference standards involved in methods
- Stability study to support IND
- Materials release testing base on initial methods

- Further analytical method optimization with process development and production
- Release testing for the clinical materials

- Analytical method development corresponding to QRA study
- Method validation for RSMs, intermediates and IPC, etc.
- API analytical method development and validation
- Stability study
- Physicochemical study
- Structure elucidation
- Cleaning validation

- Lifecycle optimization combined with the process and production

We have developed a versatile analytical platform with expanded scope, immediate usability, and a broad spectrum of equipment, complemented by a seamless One-Stop analytical service that spans the entire CMC life cycle.

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