

FORMULATION

CASYMCHEM

CARBAPENEMS

ENZYMES

GMP & NON-GMP

COMPLIANCE

BIOCATALYSIS



KNOW.

What We KNOW Makes Us Better.

HOW.

HOW We Innovate Makes Us Different.

Let's go straight to what makes us different.

Hao Hong, Ph.D.
CEO & Chairman



To see what the CDMO of the future will look like, look at Asymchem today.

We are a leader in green chemistry and invest in novel technologies to accelerate development, improve quality and boost effective yields.

We provide comprehensive support services across the entire drug lifecycle at multiple state-of-the-art, large-scale facilities capable of gram-scale to tonne-scale production.

We hold more than 120 significant patents and readily collaborate with major pharma and academia to pioneer new development and production methods.

We serve our clients from a US-based operations center and European presence, and extend a western ethos of quality across our entire manufacturing domain.

Our China-based manufacturing facilities are operated at the highest standards and regularly inspected by the USFDA and other regulatory bodies.

In short, we know how to get things done: no other CDMO can get your product to market with greater speed, less internal bureaucracy and higher yields for your investment.

In the following pages, you'll see how we translate this KNOW-HOW into innovation that makes a difference – and makes Asymchem an exceptional CDMO partner.

INNOVATION LEADERSHIP

Meaningful Ways We Are Increasing CDMO Value

Our scientists and technologists are driven by curiosity and a desire to explore frontiers beyond the reach of the typical CDMO.

THE BEST OF ALL WORLDS

Efficient Capacity That's Globally Regulated

We combine the cost-efficiency of manufacturing sites in China with the best practices and rigorous standards of US and European models.

A SINGLE SOURCE

Services You Can Trust Every Step of the Way

Analytics, compliance, IP protection, supply chain assurance – we're a one-stop shop for everything you need.

GREEN CHEMISTRY

Not a Trend, a Cultural Commitment

Sustainable and environmentally sound methods and materials. Faster, more efficient and less costly synthesis. (It's not a choice. It's both-and.)

DUE DILIGENCE AT EVERY TURN

Attention to Detail

Crossing every t, dotting every i: ironclad security, unimpeachable record-keeping, assiduous analytics and obsessive compliance.

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NOVEL TECHNOLOGIES

Advances for Every Development Stage

From custom R&D to biologics, we see every development challenge as an opportunity to find a better way.

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Your Single Source.

Services for Every Step of the Way.

Driven by curiosity and the desire to break new ground, leading scientists and technologists are attracted to Asymchem's culture of innovation. It's a culture built on operational agility and flexibility, a willingness to invest and share risks, and demonstrated expertise in strategic collaboration and partnership.

Working from this forward-leaning posture, Asymchem successfully supports products at every stage of the lifecycle from preclinical to large-scale manufacturing, with custom development services ranging from investigational new drug (IND) support to Phase III clinical trials and technology transfers for commercial supply.

You'll also get the support and advice you need when preparing the necessary registration documentation to simplify your pathway to market.



A willingness to invest and share risks.

Asymchem Full Lifecycle Support Services*

PRECLINICAL	CLINICAL			MARKET		
Investigational New Drug (IND)	Phase I	Phase II	Phase III	Phase IV		
Route Development				NDA Review / Approval		
Process Research & Development						
Solid State Chemistry						
Process Design						
		Process Optimization API Scale up				
Preformulation	Formulation Development	Tech Transfer / Scale up				
	Clinical Trial Materials Production, Packaging & Distribution					
		Registration Batch Mfg.			Commercial Mfg.	Next Gen Process
	Analytical Development, Qualification & Validation		Analytical Support Quality Control Testing			
	Stability Services					
			PV-Enabling Work	Process Validation		
Regulatory Support						

*Information subject to change due to project scope modifications or other reasons.



An innovative culture requires curiosity, the desire to break new ground and an ability to make the right investments at the right time – anticipating trends and developments rather than reacting to them.

– Rui Yang, Chief Operating Officer

KNOW. HOW.

No Molecule Left Behind.

We leverage our experience in everything – from R&D to process innovation to navigating the complex global regulatory arena – to help clients efficiently develop and manufacture quality products, including monoclonal antibodies, complex proteins and recombinant proteins.

Biologics

- Pre-Formulation
- Clinical Supply
- Tech Transfer
- Process Development
- Product Development
- Formulation Development
- Scale-Up
- Validation
- Analytical Methodology
- Commercial Manufacturing
- Packaging

APIs & Intermediates

- Small Molecules
- Carbapenems
- Glycans
- Peptides
- Oligonucleotides
- Enzymes

100+ Clients

Integrated Service Ecosystem

20+ Years Experience

Greater Capacity and Synergy.

Excellence has no borders.

Built from the ground up to stringent US and European standards, our eight state-of-the-art manufacturing sites offer powerful production capacity and synergies.

Located throughout northeast China, each site features experienced technical teams to ensure rapid and seamless transfer of your production process – from laboratory or pilot scale to full tonne-scale commercial production. These on-site teams work hand-in-hand with the project managers and client liaisons located in our US and Europe-based offices.



Single quality management system utilized across all manufacturing sites.

Manufacturing Capabilities and Capacities

Purpose	Capacity & Equipment		
API Manufacture	173.15 m ³	5-80 L 200-8,000 L	Glass-lined Reactor Glass-lined/ Hastelloy/ Stainless Steel/TiS Reactor
cGMP Pilot/ Commercial Manufacture	817.40 m ³ 350.5 m ³	50-20,000 L 500-12,500 L	Glass-lined/Stainless Steel/ High Pressure/ TiS Glass-lined/Stainless Steel Reactor (Penem Intermediates)
Non-GMP Pilot/ Commercial Manufacture	687.8 m ³	100-20,000 L	Glass-lined/Stainless Steel/High Pressure
High Potency	5.3 m ³	5-80 L 200-1,000 L	Glass Reactor Glass-Lined/Stainless Steel Reactor
Continuous Production	Pipe Reactors for Diazotization, Ozonization, Cryogenic Reaction, High-temperature and Other Regular Reactions by Asymchem Design		
Biotransformation	4×50 L, 4×500 L, 2×5000 L, Reactor		
Total	2,034.15 m ³ (71,835.33 ³ ft)		

Our facilities are located in China, but built for both US and European standards. We use a single quality management system, and all sites are regularly inspected by the FDA and other regulatory bodies.

– Elut Hsu, President



KNOW. HOW.

Using less to do more.

Backed by computer modeling and lab experiments, process intensification uses fewer inputs to get more outputs, thereby reducing production time, improving yields and ensuring safer processes.

Asymchem is also recognized for our extensive use of automatic process interlocks, safety instrumented systems and automated data capture systems.

Technology

- Flow Chemistry
- Biocatalysis
- Fermentation
- Chiral Synthesis
- Hazardous Reactions
- Low Temperature
- Highly Potent
- Non-Precious Metal Catalysis
- High-pressure Chemistry
- Electrochemistry
- Photochemistry

1900+
Scientists

Commercial &
Clinical Supply
Manufacturing

8
R&D and
Manufacturing
Sites

The Case For Going Green.

Safer. Faster. Less costly. More sustainable.

Stringent environmental standards are becoming universal. Asymchem anticipated this shift more than a decade ago and began intensive investment in green chemistry.

Whether you are a biotech looking to create the most attractive drug package to buyers, or a pharma company seeking global acceptance of your new drug, embracing green chemistry minimizes environmental impact and reduces toxic waste posing safety concerns and requiring costly remediation.

If you expect to pay a penalty for this, prepare to be surprised: green chemistry typically lowers the bottom-line costs of drug commercialization by providing quicker workup and cycle times, greater yields and higher purity – all at lower cost.

Advanced flow chemistry delivers on the promise of green chemistry while offering improved safety, quality, space savings and product capacity.

Green methods also use more easily obtainable raw materials that don't stress supply lines, lower regulatory exposure and help insulate costs against oil market price and supply fluctuations, thus reducing risks related to trade disputes, politicization of supply lines and pandemic-related disruptions.

900+ Enzymes and Counting

Asymchem has invested in a complete bio-enzyme catalysis technology platform supporting a library of more than 900 enzymes, many used in the production of statins, glitazones, penem antibiotics and other high-value compounds.

Solvent Recovery

When we capture, recycle or reuse solvent, we increase process intensification and reduce the environmental impact – often even eliminating the need for solvent incineration. Ultimately that means our customers are getting the most value out of every input.



Not a trend,
a cultural
commitment.



Asymchem was one of the first companies elected as a "Green Factory" by the Ministry of Industry and Information Technology of China.

– James Gage, Chief Science Officer

KNOW. HOW.

Leadership from Lab Bench to Boardroom.

Continuous flow production methods can provide eye-opening improvements in cycle times and yields, with related cost reductions. For instance, compared to batch production of carbapenem, Asymchem's continuous flow technology:

- reduces the production cycle from 20 days to 1.5 days
- reduces process mass intensity (PMI) by 50 percent
- avoids the treatment of thousands of tons of waste solvents generated in rhodium recycling, with consequent reduction in energy consumption.

We're All in This Together

Our **NPMC Consortium** brings together professionals with interest in more sustainable alternatives to metal-catalyzed, cross coupling reactions and rapid uptake of greener technology for the public domain.

Since 2009, Asymchem has held **Green Chemistry Symposiums and Roundtables**, as a forum to exchange ideas with experts in the pharmaceutical CMC arena. A diverse group from academia and the pharmaceutical industry participate to shape and promote the future of Green Chemistry.



Beyond the Status Quo.

We thrive on asking, What's next?

At Asymchem, we simply don't do silos. From the production of raw materials to small molecule and macromolecule R&D, from the development of novel engineering technologies to the acceleration of commercial synthesis, our culture rewards selfless cooperation over territorial egos.

We are continuously expanding our suite of technologies and capabilities to meet our client's needs. If a technology doesn't exist, we'll bring together our best minds to create one. If an ingredient is problematic, we'll find another; if a raw material is scarce, we'll make it ourselves. Our Center for Process Science works hand in glove with our Project Process Development Center, Center for Early Phase Pharmaceutical Development and Chemical Engineering Department to improve process R&D design, optimization, scale up, production and technology transfer with a streamlined efficiency that is the definition of seamless.

Whether the final form is a solid oral dosage, injectable or preformulation, every team is on mission to ensure your product enjoys both medical and commercial success.



If a **technology** doesn't exist, we'll create one.

Technology Suite

- Flow Chemistry
- Biocatalysts
- Fermentation
- Chiral Synthesis
- Hazardous Reactions
- Spray Drying

Biologics

- Commercial Licensed Cell line
- Cell Culture Process Development
- Downstream Purification Process Development

API Solutions

- Small Molecules
- Highly Potent
- Carbapenems
- Glycans
- Peptides
- Oligonucleotides
- Enzymes

Through close collaboration with our clients, we anticipate future needs and provide technology solutions that foster mutually advantageous, long-term partnerships.

– Anne Vogt, Executive Director Business Development



KNOW. HOW.

Flow chemistry catalyst screening.

We tackle problematic synthetic conversions – so you get more efficient processes, more control and more savings.

Our Flow Modalities

- Electrochemical Reaction
- Diazomethane Reaction
- Dibal-H Reaction
- High-temperature Reaction
- Low-temperature Reaction
- Curtius Rearrangement Reaction
- Continuous Catalytic Hydrogenation Reaction
- Continuous Reaction With High-energy Reagents
- Ozonolysis

No other CDMO can get your product to market with greater speed

20+

Publications Documenting Our Innovations

Rigorous Attention To Detail.

We play by the rules – and the results speak for themselves.



Asymchem's Quality Policy and Management System ensures compliance with cGMP and ICH Q7/Q8/Q9/Q10/Q11 guidelines. As a result, we meet or exceed regulatory requirements of the USFDA, the EU, China and other countries.

Things can move fast at Asymchem. But we don't cut corners and we don't game the system. As a fully integrated provider, we have the comprehensive policies, systems and safeguards to ensure compliance and responsible manufacturing.

We inform our regulatory affairs work with the full constellation of our combined knowledge base – scientific, business and legal – to ensure your project meets the expectations of regulatory bodies worldwide.

IP Protection

Integrity is an essential ingredient in every Asymchem project: all intellectual property developed as a service by Asymchem under a client CDA or MSA is the property of the client and protected by both national law and company agreements.

Environmental, Health and Safety (EHS)

Our EHS Policy requires that we operate in a socially responsible manner and continuously evaluate risk to ensure reliable, compliant operations that protect our clients, workers, the community and the environment. Projects are handled at high standards of safety and environmental responsibility.

Supply Chain

Asymchem's purchasing group adroitly navigates China's chemicals market and maintains strong relationships with hundreds of producers to ensure reliable delivery of APIs, intermediates and RSMs. We also have a dedicated facility to produce many of our own raws and RSMs to better control cost.



Trusted collaboration matters: by working closely with a high-tech membrane producer, we developed a continuous-flow process that achieved production runs delivering the target compound at throughputs exceeding 5 kg/day.

– Mark McLaws, VP, CMC & Development

KNOW. HOW.

360° Security Assurance.

Many cyber security and physical security measures must remain confidential, but best practices include:

- Secure VPN for Email Transfers
- Central Document Server (CDS) with Assigned Security Access
- Locked Archive Rooms Under Strict Access Control
- Centralized PM System with Strict Access Control
- Disabled USB Port Access
- Real-time Monitoring
- Information Security Management Platform
- International Backup and Recovery Solution

Analytical Services expertly applied across GMP and non-GMP manufacturing:

- Analytical Method Development and Validation
- Stability Studies
- Structure Identification
- Impurity Preparation and Characterization
- Standard Sample Presentation
- Chemical Properties Characterization
- Cleaning Validation

40+
Successful
Product Validations
<3 years

300+
Successful
Customer Audits



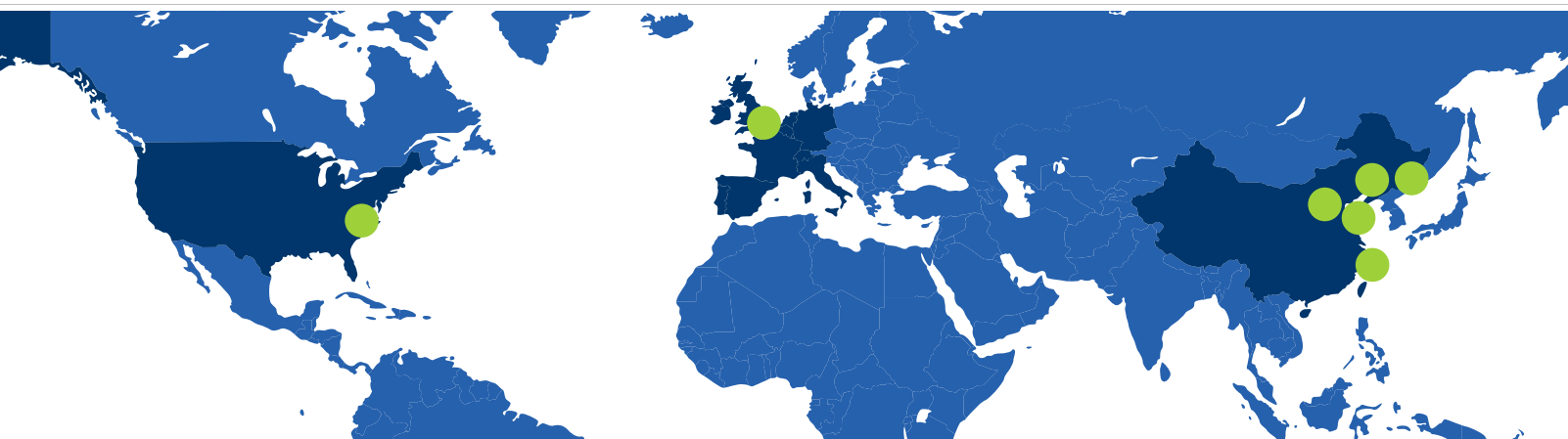
30+
Successful
USFDA, NMPA, TGA
Inspections



A Partner Who's Ready for What's Next

Asymchem offers a superior mix of CDMO solutions today while continually driving new innovations to give you a greater advantage tomorrow.

To see what our KNOW HOW can do for your development needs and learn more, contact us at innovation@asymchem.com



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