

# THE ASYMCHEM EUROPEAN SYMPOSIUM IN LONDON

## ON OCTOBER 9



### A Platform for Connection and Growth

The event received highly positive feedback from participants, who praised the excellent venue, well-balanced agenda, and opportunities for in-depth discussion.

The symposium concluded with a **cocktail and canapé reception**, providing a warm setting for networking and collaboration. The event reaffirmed **Asymchem's commitment to advancing innovation and sustainability** in partnership with the global pharmaceutical community.

### Exploring Innovation and Sustainability in Pharmaceutical Development

Under the theme “Sustainable Synthesis Reimagined: The New Horizon through High Throughput Experimentation, Flow Chemistry & Biocatalysis,” the event brought together leading experts from academia and the pharmaceutical industry to discuss the latest advancements shaping the future of sustainable synthesis.

Distinguished speakers delivered insightful presentations on integrating advanced technologies to improve efficiency and sustainability in pharmaceutical R&D and manufacturing. A dynamic panel discussion further explored how sustainability is evolving into a true source of competitive advantage.

**Sandwich, UK, marks a major milestone, showcasing our commitment to sustainable pharmaceutical process development through advanced chemistry and automation.”** Dr. Guoxi Zheng, SVP, Sandwich Site Operations, Asymchem

Closing the event, **Dr. Cheng Yi Chen**, Asymchem's Chief Technology Officer, remarked:

“The symposium proved to be a resounding success. We look forward to reconvening next year to continue building partnerships and driving innovations.”



## ADVANCING DRUG PRODUCT DEVELOPMENT THROUGH INNOVATIVE TECHNOLOGY PLATFORMS

We are pleased to highlight the capabilities of our **Advanced Drug Product Technology Platform**, which has established an impressive track record with 800+ projects, 27 NDA projects, and partnerships with 300+ clients worldwide. Our drug product capabilities are supported by a successful regulatory history, including multiple passes of FDA and PMDA pre-approval inspections, and a growing portfolio of international projects.

We have comprehensive expertise in the development of oral solid, topical, and parenteral formulations, including tablets, capsules, pellets, granules, oral solutions/suspensions, gels, creams, emulsions, injections (vials, pre-filled syringes, cartridges), lyophilized powder, eye drops, nasal sprays, inhalation solution, liposomes, LNPs, and other complex formulations.

### Spotlight on Advanced Technology Platforms

In response to the growing demand for advanced formulations, we have established multiple cutting-edge technology platforms:

**Nano-medicine**

- Liposomal formulation effectively reduces toxicity and improves in vivo exposure

**Long-acting Injectable**

- Successfully developed long-lasting GLP-1 treatments with dosing every 4 to 12 weeks

**Lipid-nanoparticle (LNP) for Oligonucleotides**

- Reduces empty LNP rate, enhancing therapeutic efficacy
- Extrahepatic targeting delivery
- Co-delivery of multiple nucleic acids

**Oral Macromolecular Drugs**

- Breakthrough Oral Drug Delivery Technology
- New excipients without patent restrictions for oral peptide formulation

These cutting-edge technology platforms and our past experience demonstrate our consistent ability to deliver scientifically advanced solutions across global markets.



### A TOP-TIER INTEGRATED CDMO GLOBALLY

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# ASYMCHEM

## ASYMCHEM'S CPHI WW HIGHLIGHTS

### TRUSTED CDMO PARTNER IN THE SPOTLIGHT



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## ACCELERATING GROWTH THROUGH R&D AND MANUFACTURING EXPANSION

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| <h3>SUZHOU R&amp;D CENTER</h3> <p>Construction is progressing steadily, with infrastructure and interior work advancing in parallel.</p> <p>Focused on synthetic biology, TIDES, and formulation development, the center serves as a technology innovation hub in the Yangtze River Delta with global reach.</p> | <h3>TIANJIN4 SITE</h3> <p>Core facilities are expanding at full speed to strengthen capacity for strategic growth areas.</p> <p>Forward deployment of key resources ensures high operational agility to meet the increasing number of TIDES and formulation partnerships.</p> | <table><tr><td><b>Capacity by EOY 2025:</b><br/>Peptide SPPS: 44,000L<br/>Oligonucleotide SPPS: 1,500kg</td><td><h3>TAIXING SITE</h3><p>Phase I construction is progressing swiftly to build large-scale capacity for conventional small molecule APIs and highly potent compounds, supporting the growing demand for localized services in Eastern China.</p></td></tr></table> | <b>Capacity by EOY 2025:</b><br>Peptide SPPS: 44,000L<br>Oligonucleotide SPPS: 1,500kg | <h3>TAIXING SITE</h3> <p>Phase I construction is progressing swiftly to build large-scale capacity for conventional small molecule APIs and highly potent compounds, supporting the growing demand for localized services in Eastern China.</p> |
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## PIONEERING SUSTAINABLE TIDES SOLUTIONS

### Sustainable Pathways to Greener Peptide Synthesis

Asymchem has been continuously improving its green peptide synthesis processes in response to the industry's growing focus on sustainability and process efficiency.

**Green Solvent Substitution:** Replacing solvents like DMF with sustainable alternatives to cut regulatory risk and environmental impact.

**PAT for Process Efficiency:** Implementing real-time Process Analytical Technology (PAT) to slash washing steps and solvent waste.

**Kinetic Modelling for Robustness:** Using predictive models to accelerate development, optimize processes with fewer experiments, and enable data-driven precision.

**Tag-Assisted Peptide Synthesis (TAPS) & Flow Chemistry:** Combining TAPS with continuous flow reactors to enhance mixing, speed reactions, lower reagent use, and ease scaling.

### MCSGP Continuous Chromatography Capabilities



Asymchem's MCSGP platform delivers high-efficiency purification through continuous chromatography with impurity recycling, significantly boosting yield and purity while cutting solvent use. Its integrated lab-to-production equipment ensures seamless scale-up, and model-based development accelerates optimization.

Proven in **GLP-1 peptide manufacturing**, it consistently achieves around 90% yield and enables over twofold productivity gains within a 2-month development cycle, with reliability confirmed over 35 validation cycles.

### Process Evolution: Enhancing Oligonucleotide Ligation Efficiency and Purity

Asymchem has advanced its **fragment + enzymatic ligation technology**, developing a **second-generation process** that enhances efficiency while reducing impurities. The new approach **eliminated traditional purification**, instead achieved higher purity through optimized fragment synthesis, improved enzymatic ligation, and refined **UF/DF operations**.

In the current phase, fragment synthesis purity has reached **over 90% after desalting**, and the **enzymatic ligation concept** has been successfully validated with duplex purity up to 90%. Ongoing optimization continues to drive higher yields and greater process robustness, paving the way for scalable, cost-effective oligonucleotide manufacturing.

### Asymchem Efficiently Drove World's First GCG/GLP-1 Dual Agonist to Market

Asymchem played a pivotal role in the successful approval of Mazdutide, the world's first GCG/GLP-1 dual agonist for weight control. Leveraging deep expertise in complex peptide API manufacturing, **Asymchem delivered a rapid timeline:** completed Pre-PPQ and PPQ within 12 months, NDA dossier preparation and submission in 6 months, and successfully passed a dynamic PAI inspection within 6 months. The process achieved high purity (>98.5%) and a remarkable single-batch output of over 5 kg. This collaboration highlights Asymchem's capability to accelerate innovative drugs from development to commercialization with **speed, quality, and scale**.

### Peptide Solvent Recovery: Turning Waste into Value for a Sustainable Future

Asymchem has leveraged industry-leading distillation capabilities, developing multi-column extractive distillation and membrane-coupled distillation technologies. These innovations have successfully achieved preparation-grade acetonitrile recovery and high-purity DMF regeneration, both meeting project solvent reuse standards. This breakthrough has driven peptide production toward a greener, more economical, and environmentally sustainable future!

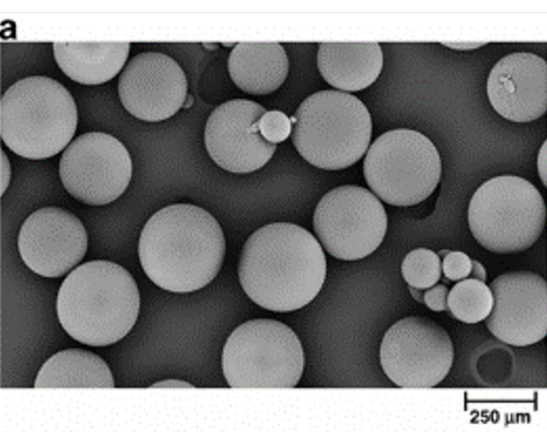
# POWERING YOUR INNOVATION: SCALABLE IMMOBILIZED ENZYMES & RECOMBINANT PROTEINS FROM THE CENTER OF SYNTHETIC BIOLOGY TECHNOLOGY (CSBT)

## Unlock Scalable Biocatalysis with Enzyme Immobilization

Enzyme immobilization is a cornerstone of sustainable industrial biocatalysis. It overcomes critical barriers—such as poor enzyme stability, limited reusability, and high enzyme loading—to enable robust and cost-effective processes. As protein engineering delivers novel enzymes, a scalable and effective immobilization platform becomes essential for their commercial success.

We provide end-to-end expertise in enzyme immobilization, seamlessly transitioning processes from gram-scale R&D to ton-scale production. Our capabilities ensure optimal integration into both batch and continuous flow manufacturing.

- Why Partner with Us?**
- **Proven Track Record:** Over a decade of experience, with more than 100 processes scaled up from grams to tons.
  - **End-to-End Integration:** From in-house enzyme production to advanced platforms like co-immobilization and whole cell immobilization.
  - **Operational Flexibility:** Expertise in applying immobilized enzymes in both batch and continuous flow modes.
  - **Reliable Delivery:** Committed to delivering robust processes on schedule.
- Leverage our expertise to develop scalable, cost-effective immobilized enzyme solutions that accelerate your path to market.



## Dedicated and segregated production line for GMP & GMP-like compliance, offering one-stop fermentation services



With a fermentation capacity of ~900,000 liters and a lyophilization capacity of 10,000 kg, the facility supports efficient scale-up and commercialization of diverse bioproducts including enzymes, cytokines, nanobodies, antibiotics, and fusion proteins.

Backed by strong expertise and advanced facilities, CSBT-TJ4 has successfully completed over 100 clinical phase projects across multiple scales (50–5000 L), providing reliable and scalable biomanufacturing solutions for global partners.

### Nanobody Platform – A Proven Success

#### Rich Experience

- Platform fermentation process with high cell density
- Efficient induction strategy
- Efficient design of DSP

#### High Purity and Yield

- High titre of nanobody
- High purity > 98%
- Low endotoxin < 1 EU/mg
- Low HCP/ HCD

#### High Expression

- Completed 10+ nanobody projects from 5 L to 500 L scale
- GMP-grade supply for Phase I clinical trials

#### Troubleshooting

- Production and purity issues
- Impurity characterization
- Timely delivery

### Nanobody Platform

## Advancing Enzyme Evolution: An AI-Driven Automated High-Throughput CFPS Platform

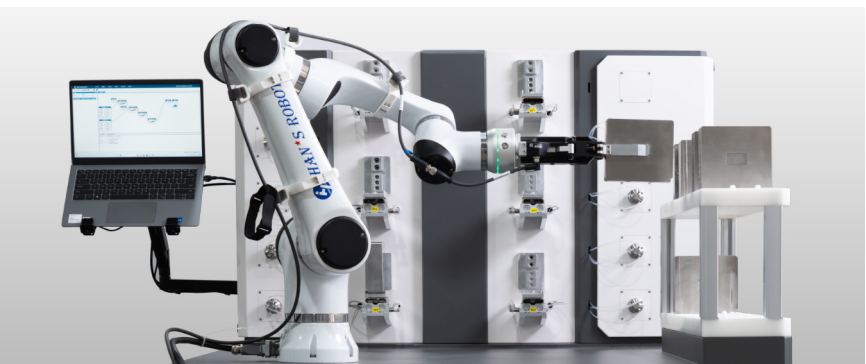
Asymchem has integrated artificial intelligence with four core technologies: Cell-Free Protein Synthesis (CFPS), Enzyme Evolution, High-Throughput Screening, and Automation Platforms into **China's first high-throughput automated platform dedicated to CFPS-based enzyme evolution**. By incorporating machine learning into the closed-loop Design-Build-Test-Learn (DBTL) cycle, the advanced platform enhances enzyme evolution efficiency by approximately 2 to 3 times, revolutionizing enzyme engineering by delivering high precision, efficiency, and scalability.

- It transforms enzyme engineering by enabling:
- **Innovative CFPS Technology:** Our cell-free system enables protein expression directly from DNA within hours, streamlining a traditional multi-step process into just three key steps for exceptional speed and flexibility.
  - **High-Throughput Capacity:** The platform scales sample processing from hundreds to tens of thousands per week, dramatically increasing output and precision while reducing manual labor.
  - **End-to-End Automation:** Integrated systems create a seamless, automated workflow—from mutant construction to data analysis—enabling continuous 24/7 operation.
  - **Proven Stability & Flexibility:** A dual-redundant architecture with 14 precision instruments ensures exceptional operational stability and flexibility for diverse experimental needs.
  - **Efficient Data Processing:** Automated data pipelines replace manual handling, significantly accelerating processing and enhancing data accuracy.
- This innovation reflects our commitment to providing partners with advanced tools to accelerate discovery and drive industrial transformation.

# NEXT-GENERATION LAB-SCALE CONTINUOUS PROCESSING PLATFORM

## Efficient, Precise, and Visualized — Accelerating the Journey from R&D to Production

- Precision Control**
- ±1% feeding accuracy
  - <100 ms data scanning cycle
- Efficiency & Flexibility**
- Standardized quick-connect interfaces enable rapid equipment setup and changeover
  - One-click switching between multiple processes



**Full Visibility**

- Real-time monitoring and visualization of flow, temperature, and pressure
- Supports traceability, data export, and expandable PAT analysis capabilities

**Broad Applications**

Applicable to various continuous reactions, including nitration and chlorination, as well as downstream operations such as quenching and extraction.

# ROBUST AND EFFICIENT PEPTIDE ANALYSIS

## Redefined Chiral Isomer Determination for Peptide Chiral Impurity Control

- Asymchem has introduced a groundbreaking analytical platform that can perform chiral amino acid analysis for peptides, delivering unprecedented efficiency and reliability.
- To address extended sample preparation in derivatization, we developed a robust liquid chromatography–tandem mass spectrometry (LC-MS/MS) method to:
- **Reduce sample preparation time from 2 days to 6 hours**
  - **Enable a 15-minute detection cycle**
  - **Detect 17 natural and 2 non-natural amino acids with 0.1% sensitivity**
- This innovative approach sets a new industry benchmark, providing partners with an accelerated, precise solution for chiral impurity control that shortens development timelines while guaranteeing drug safety and quality.

- Automated Mass Spectrometry Interpretation**
- Asymchem has developed an intelligent mass spectrometry analysis platform for rapid impurity identification, interpretation, and reporting. This platform can accelerate project timelines, enhance data reliability, and support fast development of synthetic biologic drugs.
- Rule- and List-Based Rapid Identification**
- Standard spectral library for known high-abundance impurities
  - Intelligent deconvolution tool for automated spectral comparison and rapid screening
- AI-Powered Deep Analysis Engine**
- AI-driven mass spectrometry model leverages accumulated data to decode unknown impurities and complex spectra
  - Iterative AI model with a confidence-scoring system drives efficient impurity analysis through a human–machine collaboration loop

## UTILIZE OUR VALIDATED AI PLATFORM TO STREAMLINE CHALLENGING DRUG DEVELOPMENT

- Asymchem has developed an integrated AI platform that combines advanced computational technologies to accelerate macromolecular synthesis and pharmaceutical development.
- Value Delivered by Integrated Platform**
- **Efficiency through Automation:** Our self-developed LC-MS analytics system provides high-quality, standardized data with automated impurity profiling, ensuring both speed and consistency.
  - **AI-Powered Insights:** ML-based prediction of retention time and MS fragments for rapid impurity identification.
  - **Computational Chemistry Expertise:** Molecular dynamics simulations with specialized force fields for API characterization.
- This platform actively accelerates our partners' projects, slashing development timelines and mitigating risk through its data-driven predictability.