

MES Digital Transformation at Tianjin Sites

Since mid-June, Asymchem has launched its **Manufacturing Execution System (MES)** digital project at its Tianjin sites. Built on the International Society of Automation Batch Control Standard (ISA-88), the solution integrates IT and OT, constructing an **all-in-one digital platform** covering process design, weighing & dispensing, production execution and batch record review. It realizes **deep interconnection between the Distributed Control System (DCS) batch module and Electronic Batch Record (EBR)**.

The project connects cross-system data and business workflows. Process data from the **DCS synchronizes to EBR in real time**, eliminating manual data entry and securing authentic, complete source data to meet global pharmaceutical compliance standards. **EBR seamlessly links with DCS, Enterprise Resource Planning (ERP) and intelligent weighing equipment**, connecting end-to-end production and material workflows to eliminate data silos. A **triple closed-loop verification** based on barcode, batch number and expiry date is deployed during material dispensing to prevent material mixing risks. Production data from all procedures is automatically archived and associated with raw materials, equipment, operators and process parameters, substantially boosting **overall operational efficiency and compliance management**.

The system generates full batch genealogy to support **instant traceability**, supplying complete and credible data for global regulatory audits. Powered by the **Review-by-Exception workflow**, deviations and OOS results are resolved through digital closed-loop management to drive early quality control. QA teams are freed from repetitive line-by-line record checking and can focus on core risk assessment. Comprehensive rollout of **EBR drastically shortens batch record review and product release lead times**, lowers manual transcription errors and audit observations, and builds a transparent, unified online quality management system.

This digital transformation surpasses simple paperless upgrades. It condenses more than 20 years of Asymchem's practical experience in pharmaceutical quality management and global customer service into a **verifiable, scalable and continuously iterable core digital asset** for long-term inheritance.

High-Throughput SPPS Process Screening Platform

The Center of Excellence for Process Science (CEPS) has established a high-throughput screening platform for solid-phase peptide synthesis (SPPS) to accelerate process development while minimizing material consumption. Leveraging proprietary reaction modules and fit-for-purpose workflows, the platform enables comprehensive, end-to-end evaluation of critical SPPS unit operations, including **resin swelling, coupling, washing, deprotection, and cleavage**.



Operating at reaction scales as low as **10 mg of starting material** per experiment, the platform supports efficient, data-driven process optimization in early development. For individual process steps, it can reduce screening timelines from the **conventional 1-2 weeks to as little as 1-3 days**. Already deployed across multiple peptide programs, the platform delivers high-quality experimental data, shortens optimization cycles, and strengthens process understanding, significantly enhancing R&D productivity for peptide manufacturing.



SHANGHAI
CHINA

AsymBio Kicks Off Construction of Fengxian R&D Building to Establish a Full-Cycle, One-Stop Biologics Service Ecosystem

The construction of AsymBio's new R&D building has officially broken ground at the Shanghai Fengxian site. The project marks a pivotal infrastructure step in strengthening AsymBio's biologics CDMO capabilities and reinforcing the Fengxian site's role as a core **development-and-manufacturing hub**.

With full completion and official commissioning slated for the second half of 2027, the eight-story building will occupy a site of approximately **2,500** square meters, provide nearly **20,000** square meters of gross floor area, and be constructed in full compliance with green and low-carbon construction standards.

As a key R&D hub within Asymchem Group's integrated GxP ecosystem, the newly established R&D building will further strengthen synergies across the Group's global resources, including the Zhangjiang CBTI Science and Technology Center, Jinshan manufacturing site, and Fengxian commercial manufacturing facility.

By leveraging the complementary capabilities of Asymchem Group, together with AsymBio, Yugen Medtech, and Asymchem Clinical (Clin-nov), the integrated platform will deliver a seamless end-to-end solution spanning lead identification and optimization, preclinical evaluation, CMC process development, clinical research, and regulatory submission. This ecosystem will further enhance AsymBio's capabilities in early-stage drug development, antibody therapeutics, ADCs, and next-generation conjugates such as NDCs.



Asymchem Launches **Next-Generation Biocatalysis Platforms**

Asymchem has launched **Zymora** and **Nucenova**, two complementary technology platforms designed to advance sustainable, scalable innovation across biocatalysis and nucleic acid manufacturing.

The Zymora logo features the word "Zymora" in a white, sans-serif font. The letter "o" is replaced by a stylized circular icon containing a grid of dots, resembling a molecular structure or a data matrix. The background of the logo area is dark blue with a faint, glowing grid pattern.

Zymora is Asymchem's **AI-driven biocatalysis enzyme development platform**. Integrating cell-free protein synthesis (CFPS), artificial intelligence, and high-throughput automation, Zymora provides an end-to-end Design-Build-Test-Learn (DBTL) workflow for enzyme discovery, engineering, screening, and optimization. By eliminating cell-culture bottlenecks and enabling high-throughput screening of tens of thousands of samples, the platform can compress conventional multi-week development cycles into days. In multiple projects, Zymora has delivered 10- to several-thousand-fold improvements in enzyme activity, selectivity, or stability within 2-8 weeks. The platform supports applications spanning green biomanufacturing, ADC bioconjugation and glycoengineering, peptide and oligonucleotide synthesis, and novel biosynthetic pathways.

The Nucenova logo features the word "Nucenova" in a white, sans-serif font. The letter "N" is stylized with a flowing, wave-like line extending from its top, suggesting a DNA double helix or a chemical pathway. The background of the logo area is dark blue with a faint, glowing DNA double helix structure.

Nucenova is an **all-enzymatic, de novo oligonucleotide synthesis platform** for next-generation nucleic acid manufacturing. It integrates enzymatic nucleoside monomer synthesis and oligonucleotide chain assembly, creating an end-to-end route from natural or modified nucleoside starting materials to target sequences. Powered by enzyme engineering, directed evolution, automated experimentation, and intelligent process optimization, Nucenova enables efficient production of modified monomers and their precise incorporation at defined positions. The platform expands manufacturing possibilities for complex, multi-site modified, and customized oligonucleotides while reducing dependence on conventional chemical synthesis, reagent consumption, and waste generation.

Together, Zymora and Nucenova reinforce Asymchem's leadership in enzyme engineering and Tides innovation, advancing differentiated solutions from molecular design to scalable manufacturing.



Dunhua 2 Site Successfully Completes its First FDA Inspection

Asymchem's dedicated carbapenem API manufacturing facility (Jilin Asymchem Pharmaceuticals Co. Ltd., also known as "DH2") **successfully completed its first USFDA inspection on June 22, 2026** for the Pre-Approval Inspection (PAI) which occurred between April 27 and 30, 2026.

This PAI inspection was conducted in support of a commercial API using continuous raw material feeding and reaction technology, **marking a first regulatory milestone for the DH2 carbapenem site commissioned in 2020.**

Asymchem's DH2 facility provides custom carbapenem APIs to support both clinical and commercial supplies. The site houses cutting edge continuous flow ozonolysis capabilities which were in-house designed and built **with capacity up to tonnage scale.** Implementing continuous flow chemistry across all Asymchem sites is a priority to ensure operational safety while reducing the carbon footprint.

