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# Expanding High-Potency Manufacturing Capacity at Asymchem

Asymchem has expanded its **OEB5 high-potency manufacturing capabilities** at the TJ4 site with the launch of a new High Potency Pilot Plant, adding five high-potency production lines.

With all five new lines now in operation, the site has **doubled its total production lines from five to ten**. Maximum reactor volume has increased from **1,000 L to 2,000 L**, while purification capability has expanded from **DAC150–DAC450 to DAC600**.

The expanded capacity provides **greater scale and flexibility** to support high-potency manufacturing programs. Asymchem continues to strengthen its high-potency manufacturing capabilities to meet **a broader range of project needs**.

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# New Approaches to Green Solvent Selection for Peptide Manufacturing

Asymchem's Center of Excellence for Process Science (CEPS) is developing new approaches to improve solvent selection and support more sustainable peptide manufacturing.

## Smarter Solvent Selection

The High-Throughput Team has developed a **Solvent Optimization Agent** that analyzes solvent characteristics and uses experimental data to model and predict alternative green or mixed solvent systems. This capability can support solvent selection for **small-molecule API synthesis and DMF replacement in solid-phase peptide synthesis (SPPS)**, helping improve R&D efficiency.

## Supporting DMF Replacement for SPPS

Building on its established high-throughput SPPS screening capabilities, the team has evaluated potential DMF replacement solvents across peptide sequences of different lengths. This work has strengthened the team's R&D capabilities and technical expertise in green solvent selection and peptide synthesis.


Together, these efforts support **more efficient R&D and more sustainable peptide manufacturing**, with the potential to support future peptide projects from development toward commercial production.

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# Breaking Through Formulation Technology Barriers:

## Enhancing the Clinical Value of New Drugs with Advanced Delivery Systems

Following global innovative-drug trends and addressing high-end formulation R&D pain points, Asymchem Formulation Division founded the Center of Drug Delivery and Formulation (CDDF) in 2023. **Since its establishment, CDDF has continued to focus on innovative delivery technologies and build multiple novel formulation platforms**, helping clients overcome traditional formulation bottlenecks to improve bioavailability, enable long acting sustained release, reduce dosing frequency and improve patient tolerability, thereby enhancing the clinical value and market competitiveness of new drug candidates. **To date, our complex formulation platforms have delivered nearly 100 projects,** enabling efficient R&D and fast delivery of IND-enabling programs.

## *Engineering for Complex Formulations*

### *Regulatory Expertise*

**Process Route Selection:** Assess compliance, GMP and submission paths for low-risk, high-feasibility solutions

**Proactive Regulatory Communication:** Engage reviewers proactively to foresee and resolve review risks

### *Production Process Science*

**Upfront CMC Strategy:** Embed CMC in early R&D to guarantee data integrity and clear submission routes

**Systematic Development:** Mechanism-driven design; map links between key process parameters and quality attributes to avoid fragmented trial-and-error

### *Engineering Integration*

**Equipment Scale-up & Modelling:** Predict scale-up performance via engineering models to cut trial-and-error costs

**Engineering Translation:** Transfer lab processes to robust industrial-grade solutions, with automated digital systems integrated with PAT and in-process control

### *Establish LC-MS Methods for Impurities*

**Compliant Manufacturing:** Build GMP-compliant QA and process control systems

**Validation System:** Full-scope validation covering process, cleaning and analytical methods

**Complex formulations scale-up challenges? Variability in batch performance? We have solutions.** As these capabilities continue to develop, CDDF has built a complete engineering-development system. With extensive experience in regulatory submissions for drug products, we advance process R&D and compliance control at early stages. Full-process GMP management connects R&D, pilot testing and large-scale manufacturing. We accelerate complex-formulation projects from pre-clinical research into clinical phases, bringing complex formulations to patients.

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# Asymchem's TJ4 TIDES Manufacturing Site Successfully Passes U.S. FDA Pre-Approval Inspection

The API project manufactured at Asymchem Life Science (Tianjin) Co., Ltd.'s TIDES manufacturing facility, also known as "TJ4", successfully completed **a U.S. Food and Drug Administration (FDA) Pre-Approval Inspection (PAI) from late June to early July 2026**. At the end of August, the site received the **Establishment Inspection Report (EIR) issued by the FDA**, marking another recognition of Asymchem's compliance capabilities by the U.S. regulatory authorities.

This FDA PAI was the **first FDA inspection of TJ4 TIDES manufacturing site**, marking the site's capability to carry out large-scale manufacturing and routine operations using mature, compliant advanced processes. It also demonstrates the site's ability to meet internationally high regulatory standards, laying a solid compliance foundation for the commercial manufacturing of innovative, high-end TIDES APIs.

The inspection was conducted efficiently and rigorously. During the **four-day on-site inspection**, FDA inspectors conducted a comprehensive review of the commercial API registration project, covering the company's quality systems, materials systems, facilities and equipment, production systems, and Quality Control (QC) systems. The manufacturing lines remained in normal operation throughout the inspection, and the site **successfully passed the inspection**.

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# Turning Complex Data into Clear Structures

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At Asymchem's UK Sandwich Site, the **Structure Elucidation (SE) Group** helps address complex analytical questions that arise during pharmaceutical development. From unknown compounds to impurities and degradants, the team applies specialist expertise to help determine structures and provide clear answers.

## Solving Complex Structure Challenges

The SE Group specializes in the elucidation of unknown, related and unrelated compounds, including organic compounds, chiral intermediates and novel chemical entities. Its expertise also covers **impurity identification, extractables and leachables, counterfeit medicine analysis, stereochemistry determination, and impurity fate and purge**. These capabilities support both scientific problem-solving and regulatory requirements.

## Combining Advanced Analytical Expertise

The team uses a broad range of analytical technologies, including **one- and two- dimensional NMR, variable-temperature NMR, qNMR, high-resolution LC-MS and tandem mass spectrometry**. FT-IR and GC-MS provide additional support for functional group confirmation and spectral analysis. Spectroscopic databases and predictive computational tools also support structure determination.

## Supporting Project Teams

Structure elucidation is the team's core role, its support extends beyond individual analytical investigations. The SE Group is **integral within our project teams**, providing problem solving, technical advice, troubleshooting, training and upskilling. This collaborative approach helps address analytical challenges as they arise throughout the project lifecycle.

With **more than 20 years of experience in pharmaceutical structure elucidation and problem-solving**, the UK Sandwich Site's SE Group brings together advanced analytical technologies and practical scientific expertise to turn complex data into clear, actionable insight.


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