



Strengthening **Stability Study Capabilities** to Support Drug Development

Asymchem Boston has successfully acquired **new stability chambers** for the Analytical Development and Quality Control Laboratories.



Expanded Service Capabilities:

These state-of-the-art chambers expand our capacity to support ICH-compliant stability studies across a wide range of conditions, ensuring the generation of reliable and reproducible data throughout the drug substance lifecycle.

Project Execution Readiness:

Installation and qualification activities are currently underway to support the upcoming Phase I stability study program.

This equipment enhancement further reinforces Asymchem Boston's service capabilities in drug stability studies. We remain committed to upholding the highest **global standards of regulatory compliance** and **data integrity**, providing robust and reliable data support to our clients throughout the full lifecycle of drug development.



USA
BOSTON



Asymchem's Pre-filled Syringe Workshop Reaches Full cGMP Operational Status for Global Supply

Asymchem's dedicated pre-filled syringe (PFS) workshop achieved **full GMP compliance and the first project was successfully executed in December 2025.**

Documentation:

Supported by 90+ finalized documents and records covering all procedures and manuals.

Qualification:

Successfully executed 120+ GMP-related validation activities, including water systems, HVAC, core production equipment, and associated facilities.

Aseptic Process Simulation:

Completed media fill test (MFT), confirming robust aseptic processing capabilities.

Production Capacity:

The PFS line operates with a batch size of up to 150,000 units and an annual capacity of 45 million units.

This milestone further solidifies our commitment to delivering seamless, end-to-end injectable solutions, empowering our global partners with a more resilient and responsive supply chain.



CHINA
TIANJIN

Asymchem Announces **New GMP Laboratory** to Strengthen European Service Capabilities

Asymchem is advancing **a new GMP laboratory** at its Sandwich site in the UK to expand localized development and manufacturing support in Europe. The lab is designed as a flexible, modular platform and is expected to achieve phased operational readiness from **Q2 2026**.

Phase 1: Core Capabilities

A suite of 15 L, 30 L, and 60 L small-molecule reactors equipped with RX-10 reactor control systems:

- 15 L and 30 L reactors scheduled for installation and validation between February and April 2026.
- Cryogenic 60 L reactor (-70°C to $+180^{\circ}\text{C}$) scheduled for delivery and installation in June 2026.

This investment will directly benefit our clients by enabling faster project cycle times and providing strategic flexibility through a truly localized, full-spectrum service capability in Europe.

Phase 2: Modular Expansion

The laboratory's modular design allows for future integration of specialized capabilities

- Modular flow (PFR, CSTR)
- Separations (Prep-HPLC, Flash Chromatography)
- Hydrogenation
- OEB 5 Containment

