ASYMCHEM

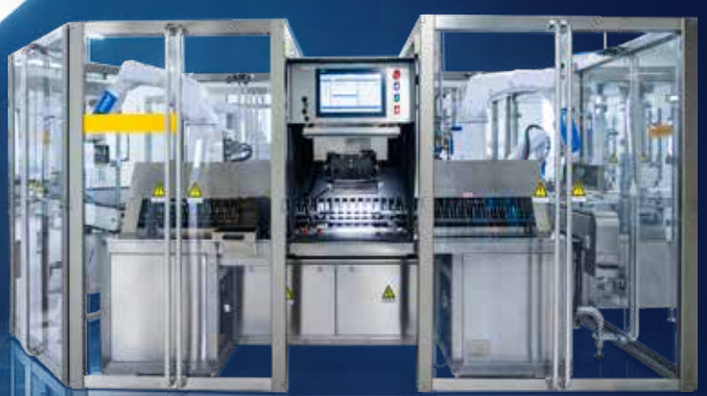
CHINA
TIANJIN

Asymchem Expands Sterile Manufacturing Excellence with New Cartridge Line

Asymchem has reached a significant milestone in the expansion of its **parenteral production capacity**. The newly constructed sterile manufacturing facility at the TJ4 site is strategically designed to support the growing demand for **oligonucleotide and peptide drugs (TIDES)**.

By integrating high-containment, large-scale aseptic processing lines, Asymchem is uniquely positioned to provide global partners with seamless supply assurance from clinical development through commercial launch.

Pre-filled Syringe (PFS) Line



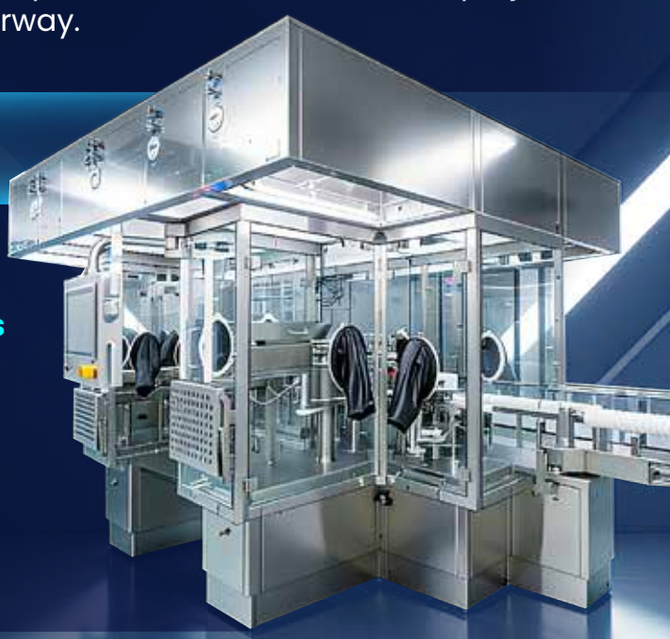
Compliance: Achieved full GMP status in December 2025.

Throughput: Features a batch capacity of **150,000 units** and a total annual capacity of up to **50 million units**.

Track Record: The line has already successfully delivered multiple clinical batches and completed process validation for a key project.

Current Status: Multiple clinical and commercial projects are currently underway.

Advanced Cartridge Line



Timeline: Scheduled to achieve full GMP compliance in Q2 2026.

Scale: Engineered for high-volume production with **330,000 units** per batch and an annual capacity reaching **100 million units**.

Market Demand: The line has already secured commercial orders and is currently the subject of active negotiations with several global partners.

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UK

SANDWICH

Accelerating the Path from Early Development to Commercialisation through API Development Workflows

Asymchem Sandwich seamlessly integrates **High Throughput Experimentation (HTE)**, **engineering**, **process chemistry**, **analytical science** and **cGMP manufacturing** into comprehensive API Development Workflows—delivering speed, quality, and regulatory compliance from pre-clinical to commercial launch.

	Pre -clinical	Phase 1	Phase 2	Phase 3	Process Validation	Commercial Launch
Process		Mitigate early-stage manufacturing risks for target compounds.	Identify and demonstrate the most efficient, cost-effective synthetic routes.	Advance synthetic routes into commercially viable manufacturing processes.	Execute late-stage development packages to support RSM designation, CPP identification, FMEA/HAZOP, control strategy and, regulatory submissions.	
		ENABLING MANUFACTURE	ROUTE SCOUTING/DESIGN	DATA-CENTRIC PROCESS DESIGN	PROCESS VALIDATION READINESS	
Analytics		Ensure method quality by thorough screening for fast, phase-appropriate development.	Apply orthogonal analytical methodologies to enable rapid decision-making in route selection.	Ensure robustness through in-silico method development and structure elucidation to understand quality attributes.	Determine impurity genealogy and establish a robust control strategy with appropriate specifications to meet regulatory expectations and support smooth technology transfer.	

By delivering a robust, end-to-end solution that accelerates time-to-market, mitigates risks, and ensures quality, Asymchem provides a solid foundation to advance projects from pre-clinical to commercialization.