

## **WuXi STA Launches New Small-Molecule API Facility; Expands Peptides, Oligonucleotides Capacity; Updates Drug-Product Expansions**

WuXi STA is proceeding with a major multi-site, global expansion plan to enhance its manufacturing capabilities and capacities. Yu Lu, the Chief Business Officer of WuXi STA and Head of WuXi TIDES, detailed the expansion efforts across several key sites at the DCAT Member Company Announcement Forum held on March 18th, 2024, at DCAT Week.

The expansion efforts across several key sites, including the unveiling of its 169-acre active pharmaceutical ingredient (API) manufacturing facility in Taixing, China, alongside existing drug-product manufacturing facilities in Wuxi City, China, and Couvet, Switzerland, and forthcoming sites in Middletown, Delaware, and Tuas, Singapore.

The highlight of the announcement was the introduction of the company's new Taixing site, which spans over 169 acres, making it one of the largest API manufacturing sites globally, according to the company. Phase I of the site, already operational since January 2024, encompasses 81 acres with nine manufacturing plants, three of which are currently operational. The site's expansion aims to bolster the company's total reactor volume for API to 3,773 m<sup>3</sup> by the year's end (2024).

In response to the surging demand in the market, particularly in the glucagon-like peptide-1 (GLP-1) sector, WuXi TIDES has tripled its peptide-manufacturing capacity. With the addition of two new peptide plants in China in Changzhou and Taixing, the company's total solid-phase peptide synthesis (SPPS) reactor volume has reached 32,490 L. The company also plans to further enhance SPPS capacity in Taixing and its upcoming Singapore site. Beyond capacity expansion, WuXi TIDES is deepening its expertise and experience in the peptide field. It currently supports 48 ongoing preclinical to commercial peptide-based therapies.

The presentation also highlighted the expansion of the company's oligonucleotide manufacturing capabilities, with 27 lines currently operational and plans to increase capacity in Taixing and Singapore. WuXi TIDES has experience in over 160 projects for different types of oligonucleotides in all the development phases, ranging from preclinical to commercial, covering all the common modalities such as ASO, siRNA, and PMO, supported by a team of over 600 scientists.

In addition, WuXi STA has fortified its drug-product platform through the integration of CMC (chemistry, manufacturing and control) services. This includes the introduction of a high-potency sterile injectable line and a new high-potency oral solid line for tablets and capsules, both with an occupational exposure limit OEL of 10 ng/m<sup>3</sup>, enhancing its high-potency CMC platform. By the end of 2024, the company will have five aseptic filling lines suitable for sterile injectables, eye-drops, and inhalants. At the company's drug-product site in Couvet, Switzerland, the company plans to double tablet and capsule production capacity, add a parenteral line, a lipid nanoparticle (LNP) platform, and a spray dryer.

The company is further expanding its footprint globally. The company's new site in Middletown, Delaware, is on track and is expected to open in 2025. Phase I construction includes formulation R&D and manufacturing as well as packaging, labeling, and distribution for oral solids. The company is also proceeding with a new site in Singapore for API development and manufacturing. Phase I is expected to open in 2026, which includes an API R&D center and three manufacturing plants for small molecules, oligonucleotides, and peptides and the conjugates.



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