Delivering Quality with Speed for European Market

WuXi STA Pushes ahead with the Expansion of its Global R&D and Manufacturing Network

WuXi STA, a division of WuXi AppTec, a Global R&D and manufacturing services provider (CRDMO) for the pharmaceutical and healthcare industry, is increasing its regional footprint in Europe. Currently, the division operates facilities in the UK, Switzerland and Germany. CHEManager spoke with Jinling Chen, Head of WuXi STA's drug product business and Jamie Andrews, Site Head of the Couvet manufacturing site — a facility that the company purchased from Bristol-Myers Squibb in 2021 — about the strategy and goals of the European expansion.

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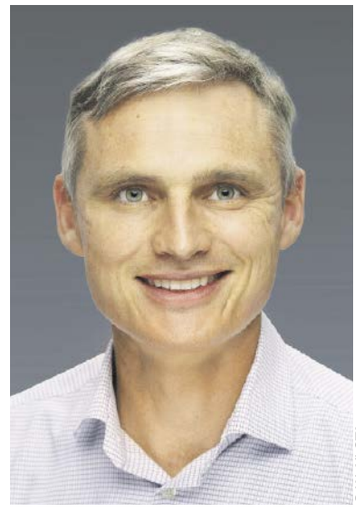
Jinling Chen, Head of Drug Product business, WuXi STA



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Jamie Andrews, Site Head of Cuvet facility, WuXi STA

CHEManager: WuXi STA's footprint in Europe starts from the facility in Switzerland. When and how was the facility added to the WuXi STA map?

Jinling Chen: The site was acquired from Bristol-Myers Squibb in August 2021 as a drug product manufacturing site and was already fully operational when purchased. It was quite a modern facility—the site was constructed between 2016 – 2018 and is installed with top-class equipment. Despite its 'young age', the Couvet facility had already passed multiple inspections from the FDA, EMA, SwissMedic, and Japanese PMDA. It was also designed with industry-leading energy efficiency and environmental standards with a few industry awards received for this. Looking forward, we foresee its potential as an increasingly important node in our global CRDMO network of 14 sites across Asia, the US and EU.

What are the core capabilities of this site?

Jamie Andrews: The Couvet site is a manufacturing facility for oral solid drug product at both clinical and commercial scales, with best-in-class equipment including automated visual inspection and fully integrated IT systems. In addition, the site has deeply customizable packaging and labeling lines for both primary and secondary packaging. The Couvet site has the annual capacity of one billion units of oral dosage forms, supplying eight key markets globally, including the US, EU, UK, Switzerland, Australia, New Zealand, Canada, and Japan.

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What are the company's growth prospects in Europe?

J. Andrews: WuXi STA expects the Couvet site to become a key drug product supply hub in Europe. In order to achieve this goal, we will continue to enhance Couvet capabilities. New manufacturing, packaging and labeling capabilities are under construction, which will double the capacity once fully operational. Additionally, a larger warehouse implemented with an automated environment control system is also part of the near-future expansion plan to handle increasing logistics and supply demands.

> *"WuXi STA expects the Couvet site to become a key drug product supply hub in Europe."*

J. Chen: We have also connected other nodes of our facilities for our European clients. Our drug product manu-

facturing site in Wuxi city, China, passed the EMA inspection last year and is currently supporting our European clients. We keep the same standards across all the sites within WuXi STA, so our clients can receive the same high-quality product from any site with a robust supply chain. This is also a demonstration of our dual-sourcing strategy.

For several years, WuXi has been pursuing a dual sourcing strategy. How has this worked for WuXi STA?

J. Chen: With a dual sourcing strategy, one manufacturing task can be assigned to multiple manufacturing sites. For European clients, their drug products can be manufactured at both the Couvet site in Switzerland and the Wuxi city site in China. We offer this dual-sourcing strategy to ensure robustness of supply. In case of any disruption at one site, the other can immediately step in to maintain productivity. We can guarantee the continuation of supply through our global network, providing an added layer of reassurance with increased efficiency.

WuXi STA has invested heavily in building and expanding its high potent (HP) manufacturing capabilities. What are the reasons for engaging and investing in this field?

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J. Chen: The need for HP drug development continues to increase driven by a growing demand for oncology drugs. To better serve our global customers, we opened our first HP (<1 µg/m³) oral dosage drug product manufacturing facility in the Wuxi city site last year. And this year, we will open our first HP injectable drug product manufacturing line. Together, with the well-established HPAPI development and manufacturing facilities in the Changzhou and Jinshan sites, we now offer a one-stop solution for both early and late stages to clients with HP drug outsourcing needs.

> *"With a dual sourcing strategy, one manufacturing task can be assigned to multiple manufacturing sites."*

What other capabilities can European clients expect from other WuXi drug product facilities?

J. Chen: WuXi STA has recently invested in the injectable drug product platform including the opening of two wholly automated manufacturing lines in fully enclosed isolators. Our facility supports multiple parenteral dosage forms and in different filling formats. From a new technology perspective, we opened a new lipid nanoparticle (LNP) manufacturing facility that provides new solutions to deliver more complex molecular modalities such as oligonucleotides.

How much increase in demand and subsequently in supply are you expecting to see in the near future and how do you plan to meet it?

J. Andrews: We are well set for growth, and the Couvet site is well prepared with its existing available capacity, significant expansion plans, as well as having the leverage of the global CRDMO network it connects to.

J. Chen: Speed and quality are customers' top priorities. Leveraging WuXi STA's strong capability in both API and drug product, our integrated CRDMO platform can provide fast, flexible, and high-quality solutions—particularly when we support customers with both API and drug product.

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