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ASIA EDITION

WuXi STA Shanghai & Changzhou Facilities Pass USFDA Inspections

24 July 2019 | News

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STA Pharmaceutical Co., Ltd., (WuXi STA) – a subsidiary of WuXi AppTec – announces that its Analytical Service Unit (ASU) in Shanghai and active pharmaceutical ingredient (API) process R&D and manufacturing facility in Changzhou, have successfully passed two inspections from the U.S. Food and Drug Administration (FDA) within the same week, with no Form 483s issued. This not only marks a milestone for WuXi STA on running a continual state of regulatory readiness, with real time GMP monitoring and an ingrained internal quality culture, but also shows its commitment on providing integrated R&D and manufacturing services with the highest quality standard for customers.

Mei Hao, Vice President of Quality at WuXi STA said, “It’s a point of great pride that our quality systems allow us to be inspected at short notice by any applicable regulatory agency in the world. In this case, we received two separate inspection notices from FDA only seven days and five days in advance of the inspections, respectively. It’s an endorsement of the real time monitoring and quality culture we run across all parts of the company. It’s another key example of the rigorous nature of our global standard quality systems. It is also another milestone for our platform, and in our efforts to have geographically integrated capabilities for both drug product and drug substance.”

Dr. Minzhang Chen, CEO of WuXi STA said, "WuXi STA takes high priority on building quality system meeting global regulatory standards. These successful FDA inspections to ASU and Changzhou facility reflects WuXi STA's commitment to ‘quality first’. We will continue to enhance our platform with highest quality service to better enable our customers to bring better medicines faster for patients.”

WuXi STA has now successfully passed seven inspections from the U.S. FDA since 2013, producing branded drugs marketed in 95 countries. Its Analytical Service Unit provides clients with a full spectrum of analytical method development, validation and testing services from preclinical to commercial. The Changzhou facility with over 1,700,000 square feet has established a variety of new technology platforms such as spray dried dispersion, continuous processing (flow chemistry), oligonucleotides and peptides. It successfully completed the first U.S. FDA inspection in 2018.