

WuXi STA receives PAI from the US FDA

07 May 2018 | News

This is the first time that WuXi STA's Changzhou facility has been inspected by the FDA



STA Pharmaceutical Co., Ltd., (WuXi STA), announces that its active pharmaceutical ingredient and manufacturing facility located in Changzhou, China has, secured Pre-Approval Inspection (PAI) for two APIs from the U.S. Food and Drug Administration (FDA). This is the first time that WuXi STA's Changzhou facility has been inspected by the FDA.

A subsidiary of WuXi AppTec, WuXi STA is the first CMC platform (including both APIs and drug product) in China to have passed FDA inspection for new chemical entities. It is also the first CDMO in China that is approved to supply APIs and GMP intermediates for branded commercial drugs by regulatory agencies in the USA, China, EU, Canada, Switzerland, Australia, and New Zealand.