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WuXi STA, CFDA and Jinshan Government to co-host Marketing Authorization Holder regulatory summit in Shanghai

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Industry and regulators combine to run afternoon congress on the implications of regulatory changes

STA Pharmaceutical Co., Ltd. (STA) a WuXi AppTec subsidiary and the leading open-access capability and technology platform for small molecule pharmaceutical development and manufacturing will co-host with the Shanghai Municipal Food and Drug Administration and the government of Jinshan District of Shanghai a special summit on the Marketing Authorization Holder (MAH) pilot program currently being implemented in 10 regions across China.

The event will be held on June 22, 2017 at the Jumeirah Himalayas Hotel in Shanghai.

The MAH has huge implications for international pharma and biotech companies, as it will expedite market access to the world's second largest pharmaceutical economy by allowing license holders of a drug to sell in China using a contract manufacturer. Ultimately, this pilot will boost local innovation and enable a shorter time to market for drugs.

China's State Council has approved the pilot program in 10 provinces and municipalities: Beijing, Shanghai, Tianjin, Hebei, Guangdong, Jiangsu, Zhejiang, Fujian, Shandong, and Sichuan.

Yet despite this large opportunity, many foreign companies are yet to harness the growth potential and are unsure how to register or work with a local provider in the country. The symposium will provide a forum for the CFDA, US FDA, pharma/biotech companies, and CMOs to discuss latest policy updates, share their experiences and best practices.

Together, senior leaders from the CFDA and Jinshan government will explain in detail the process of registering an office in a pilot region, the execution of working with a local manufacturer, and post-market supervision. The Assistant Country Director from US FDA China Office will provide FDA perspectives on risk management as it relates to contract manufactures. Finally, a panel discussion including executives from multi-national pharma companies and domestic innovative drug development companies, CFDA and CDMO representatives will share case studies and answer questions from the audience.