

WuXi Biologics Quality Milestones

Total Quality and Regulatory Achievements

As of April 30, 2021



4 drug regulatory agencies' accreditations for the manufacture of biologics



5 GMP certificates from the EMA



12+ inspections from global regulatory agencies



370+ GMP audits from global clients

Regulatory Achievements in April

01 FDA U.S. FOOD & DRUG ADMINISTRATION

Our manufacturing facilities in Wuxi, including MFG1, MFG2 and DP1, completed the Pre-License Inspection and routine GMP inspection by the U.S. FDA.



02 EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH

Our MFG4 site in Wuxi, the first GMP facility to use the industry's largest disposable bioreactor (4,000L), is certificated by EMA for GMP manufacturing.



03 EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH

Our biosafety site in Suzhou, one of the largest third-party biosafety testing providers in the Asia-Pacific region, completed another GMP inspection by EMA.



04 国家药品监督管理局 National Medical Products Administration

Our manufacturing facilities in Wuxi, including MFG1, MFG2 and DP1, as well as the GMP cell banking facility and Analytical Science labs in Shanghai passed Pre-Approval Inspection by China NMPA.



05 HSA

Our DP4 site in Wuxi, the first robotic aseptic filling facility in China, receives GMP conformity assessment from the Singapore HSA.

