WuXi Biologics
Global Solution Provider

WuXi Biologics Quality Milestones

Total Quality and Regulatory Achievements
As of November, 2021

10 different regulatory agency accreditations

9 certified facilities

19 total inspections from global regulatory agencies

370+ GMP audits from global clients

01 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

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

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, received GMP conformity assessment from the Singapore HSA.

06 Federal Ministry of Health

Our drug product facility (DP7) in Leverkusen, Germany received the License of Manufacturing Permit from the German health authorities.

07 Pmda

Our drug substance facility (MFG2) at Wuxi city, China received the Manufacturing License from Japan's Minister of Health, Labor and Welfare (MHLW).

06 Health Canada

Our drug substance facility (MFG2) at Wuxi city, China completed a remote GMP inspection by Health Canada.