

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**
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, 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).



08 **Health Canada**

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

