

ChemExpress Subsidiary 2Y-Biopharma Completes U.S. FDA Pre-Approval Inspection with No Form 483 Observations

ChemExpress' drug product GMP site, 2Y-Biopharma, completed a U.S. FDA PAI with no Form 483 observations and received its EIR.

SHANGHAI, SHANGHAI, CHINA, August 18, 2026 /EINPresswire.com/ -- 2Y-Biopharma, a wholly owned subsidiary of Shanghai Haoyuan [Chemexpress](#) Co., Ltd. (SSE: 688131, "ChemExpress") and a drug product GMP manufacturing site, has successfully completed a Pre-Approval Inspection (PAI) conducted by the U.S. Food and Drug Administration (FDA), with no Form 483 observations.



ChemExpress

The FDA inspection was conducted from June 22 to 26, 2026. Following the inspection, 2Y-Biopharma received the Establishment Inspection Report (EIR). The completion of the PAI with no Form 483 observations represents an important milestone in the continued development of ChemExpress's global quality and compliance system for its drug product business.

A Regulatory Milestone for 2Y-Biopharma

"We are pleased to have received the EIR following the successful completion of the FDA Pre-Approval Inspection with no Form 483 observations," said Mr. Wensheng Tang, Co-founder and General Manager of 2Y-Biopharma.

"This positive inspection outcome further strengthens the regulatory compliance foundation for our drug product business as we expand into the U.S. market, while also enhancing the global competitiveness of our drug product capabilities."

The successful completion of the FDA PAI and receipt of the EIR mark an important regulatory milestone for 2Y-Biopharma. The achievement also strengthens ChemExpress's integrated CDMO capabilities across regulatory starting materials, novel building blocks, intermediates, reference compounds, active pharmaceutical ingredients (APIs), biologics, and drug products. Through these integrated capabilities, ChemExpress supports clients across the drug

development and manufacturing process, from process development through commercialization, while continuing to expand its services for the global pharmaceutical market.

Strengthening Drug Product Development and Manufacturing Capabilities

2Y-Biopharma supports drug product development and manufacturing across different stages of the product lifecycle, from registration and clinical supply to commercial production.

Its formulation platform includes specialized technologies for poorly soluble drugs, such as spray drying, hot-melt extrusion, lyophilization, and fluidized-bed amorphous solid dispersion (ASD).

The company also has capabilities in modified-release formulations and topical semi-solid formulations.

These capabilities enable 2Y-Biopharma to support pharmaceutical programs from formulation development and scale-up through GMP manufacturing and commercialization, further strengthening ChemExpress's integrated CDMO offering.

About ChemExpress

Founded in 2006, Shanghai Haoyuan ChemExpress Co., Ltd. (SSE: 688131, "ChemExpress") is a CRO & CDMO that provides services for pharmaceutical and biotechnology companies. The company focuses on small molecules, biologics, and new modalities such as ADCs/XDCs, peptides, and PROTACs. Its comprehensive platform supports the research, development, manufacturing, and supply of regulatory starting materials, novel building blocks, intermediates, reference compounds, APIs, biologics, and drug products. ChemExpress supports client programs from early drug discovery and process development through commercialization. For more information, please visit www.chemexpress.com.

About 2Y-Chem and 2Y-Biopharma

Founded in 2003, 2Y-Chem, Ltd. is a CDMO that provides pharmaceutical development and cGMP manufacturing services to leading innovative biotechnology and pharmaceutical companies, for regulatory applications in the United States, Europe, and China. With more than 20 years of dedicated CC experience, 2Y-Chem has served more than 200 NME projects worldwide, ranging from preclinical and clinical to commercial stages. 2Y-Chem is a member of ChemExpress Group, a company listed on the SSE. The wholly owned cGMP drug product manufacturing plant, 2Y-Biopharma, Ltd., was established in 2017. In the past 5 years, 2Y-Chem and 2Y-Biopharma have supported 14+ MAH clients in obtaining the marketing approval of innovative or generic drugs and have been entrusted with their commercial production. 2Y-Chem and 2Y-Biopharma are committed to excellence in drug development and contract manufacturing services, accelerating drug innovation from laboratory to pharmacy and benefiting patients around the world. For more information, please visit <https://www.2ychem.com/>.

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