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WuXi Biologics pre-filled syringes (PFS) commercial production to expand global footprints

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Secures FDA PLI approval for five facilities, First for commercial PFS line ever

WuXi Biologics, a leading global Contract Research, Development and Manufacturing Organization (CRDMO), announced that five manufacturing facilities successfully passed the Pre-License Inspection (PLI) by the U.S. Food and Drug Administration (FDA), with no critical issues or data integrity findings. This achievement further affirms WuXi Biologics' strong track record of regulatory compliance—a 100% success rate passing PLIs.

The FDA's inspection covered WuXi Biologics' quality management system and the entire production processes of multiple facilities, including two drug substance facilities (MFG1 and MFG5) and three drug product facilities (DP1, DP2 and DP5) in Wuxi, China. Passing the initial regulatory inspection by the FDA for DP5, the company's first commercial pre-filled syringes (PFS) manufacturing facility, will allow WuXi Biologics to provide high-quality PFS manufacturing solutions to clients.

Dr. Chris Chen, CEO of WuXi Biologics, commented: "At WuXi Biologics, our unwavering commitment to the highest global quality standards is embedded in everything we do. Maintaining a 100% success rate for regulatory inspections is a true reflection of our relentless pursuit of excellence in building a world-class quality system that not only meets but exceeds global regulatory requirements. WuXi Biologics will continue—with speed and efficiency—to enable global partners in delivering life-saving treatments, with the ultimate goal of benefiting patients worldwide."

As of late 2024, WuXi Biologics has successfully passed 42 regulatory inspections, including 22 by the EU EMA and the FDA. Additionally, the company has received 97 license approvals from regulatory agencies around the world.