April 10, 2024

NIPRO CORPORATION

Nipro Pharma Odate Plant Receives U.S. Food and Drug Administration (FDA) Certification as a Manufacturing Site

NIPRO CORPORATION is pleased to announce that Nipro Pharma Corporation (Head Office: Settsu City, Osaka; President: Kenichi Nishida)—one of its pharmaceutical manufacturing subsidiaries—has received certification from the U.S. Food and Drug Administration (FDA) for compliance with Good Manufacturing Practice (GMP) regulations at its Odate Plant in Odate City, Akita Prefecture, Japan, on April 3, 2024.

In operation since 2002, the Odate Plant is NIPRO's main plant for injectable drugs and manufactures pre-filled syringes and highly active pharmacological drugs. Nipro Pharma has been working to develop a production line for supplying contract-manufactured lyophilized injectable antibacterial agents for the U.S. market and, following an on-site inspection in January of this year, the plant received certification from the FDA for production of the agents. This makes the Odate Plant the second Nipro Pharma plant to receive FDA certification after the Kagamiishi Plant (Kagamiishi, Fukushima).

Given the limited number of FDA-certified contract drug manufacturing and development (CDMO) companies in Japan—and even fewer with FDA certification for sterile preparation—Nipro Pharma recognizes the significance of the achievements of its Odate Plant.

This certification is only the latest accomplishment in the NIPRO Group's effort to strengthen its quality assurance and production systems in line with global standards, and to help contribute to the supply of pharmaceutical products that can be used with confidence by patients in both Japan and overseas.