News release

FDA Selects Kyowa Kirin for Precheck Pilot Program to Accelerate Manufacturing Timelines and Enhance Supply Chain Resilience

Strategic collaboration at Sanford, North Carolina facility, currently under construction, to optimize cGMP validation, accelerate time-to-market for complex biologics, and shore up U.S. medicine supply

TOKYO AND PRINCETON, N.J. – June 30, 2026 –Kyowa Kirin Co., Ltd. (TSE: 4151, Kyowa Kirin), a Japan-based global specialty pharmaceutical company, today announced the U.S. Food and Drug Administration (FDA) has selected Kyowa Kirin's Sanford manufacturing facility for the FDA PreCheck Pilot Program.

Kyowa Kirin's selection into the program enables the operational acceleration of the state-of-the-art biologics manufacturing facility currently under construction in Sanford, North Carolina. By initiating structured, early-stage regulatory engagement during the facility's build phase, the PreCheck Pilot Program is designed to optimize current Good Manufacturing Practices (cGMP) compliance and validation, accelerate commercial production timelines, and strengthen supply chain resilience for rare disease patients.

"Being selected for the FDA PreCheck Pilot Program is a transformative milestone for Kyowa Kirin as a global organization. The Sanford facility marks our first manufacturing footprint in the U.S., and with this program we have the opportunity to build our quality and compliance framework from the ground up in close collaboration with the FDA — establishing a new standard for how we approach manufacturing. As we continue to expand our pipeline of next-generation antibodies and biologics for rare diseases, strengthening our supply chain resilience through the establishment of a U.S.-based manufacturing site is essential to fulfilling our mission of delivering life-changing value to patients around the world." said Toshiyuki Kurata, Chief Supply Chain Officer of Kyowa Kirin.

The Sanford facility, which broke ground in late 2024 and is on track to be operational by 2027, will serve as a core U.S. hub for manufacturing innovative biologic therapies, with a strong emphasis on next-generation antibodies for rare and orphan diseases.

"One of our primary goals for participating in the FDA PreCheck Pilot Program is the acceleration of the review and approval process to ensure a resilient product supply to patients suffering from rare diseases and other unmet medical needs." said Steve Schaefer, President, Kyowa Kirin North America. "This early engagement with the FDA is invaluable as Kyowa Kirin establishes our first manufacturing facility in the U.S. We are committed to fostering a strong, mutually beneficial collaboration with the FDA to meet the requirements and expectations of both the agency and the patients we serve."

Complex biologics, such as those developed for rare diseases, often require highly specialized, low-volume, high-complexity manufacturing processes that can be vulnerable to regulatory bottlenecks. The FDA PreCheck Program addresses these challenges by replacing sequential reviews with a proactive, two-phase collaborative framework:

Phase 1 (Facility Readiness Phase): Kyowa Kirin will utilize a facility-specific Type V Drug Master File (DMF) to receive real-time technical feedback from the FDA regarding equipment qualification and Pharmaceutical Quality System (PQS) design. This eliminates the risk of post-construction compliance gaps and costly retrofits.

Phase 2 (Application Submission Phase): The partnership shifts to structured pre-submission engagements that streamline Chemistry, Manufacturing, and Controls (CMC) reviews, significantly shortening the timeline between drug application and approval.

About Kyowa Kirin

Kyowa Kirin aims to discover and deliver novel medicines with life-changing value. As a Japan-based Global Specialty Pharmaceutical Company, we have invested in drug discovery and biotechnology innovation for more than 70 years and are currently working to engineer the next generation of antibodies and cell and gene therapies with the potential to help patients affected by a severe or rare disease. A shared commitment to our values, to sustainable growth, and to making people smile unites us across our four regions – Japan, Asia Pacific, North America, and EMEA/International. You can learn more about the business of Kyowa Kirin at www.kyowakirin.com.