Cambrex High Point Completes FDA, PMDA and TGA Pre-Approval Inspections, Advancing Commercial Manufacturing Capabilities

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EAST RUTHERFORD, N.J., Aug. 25, 2026 /PRNewswire/ â?? Cambrex, a leading global contract development and manufacturing organization (CDMO), today announced the successful completion of three Pre-Approval Inspections (PAIs) at its High Point, North Carolina facility by the U.S. Food and Drug Administration (FDA), Japanâ??s Pharmaceuticals and Medical Devices Agency (PMDA), and Australiaâ??s Therapeutic Goods Administration (TGA). The completion of all three inspections enables High Point to manufacture approved active pharmaceutical ingredients (APIs) for the United States, Japan, and Australia, establishing the facility as the newest commercial manufacturing site within the Cambrex global network.

PAIs are conducted by regulatory agencies to assess a facilityâ??s quality systems, manufacturing processes, data integrity, and operational controls before commercial products can be approved for manufacture at the site.

The milestone follows Cambrexâ??s $38 million expansion of the High Point facility completed in 2023, which added analytical and chemical development laboratories, clinical manufacturing suites, and commercial manufacturing operations with reactors up to 2,000 liters. The site is designed to support lower-volume commercial products, including orphan drugs, precision medicines, and other specialized therapies serving smaller patient populations.

â??Successfully completing these inspections demonstrates the strength of our quality systems and the dedication of the High Point team,â?• said Thomas Loewald, Chief Executive Officer, Cambrex. â??As more therapies are developed for targeted patient populations, the industry increasingly requires commercial manufacturing capacity at smaller scales. High Point was purpose-built to meet that need, providing customers with an efficient and flexible path from development to long-term commercial supply.â?•

High Point complements Cambrexâ??s global development and manufacturing network by providing customers with a seamless path from process development and clinical manufacturing through commercial production. The addition of commercial manufacturing capabilities in North Carolina further expands the companyâ??s ability to support customer programs throughout the product lifecycle.

About CambrexCambrex is a leading global contract development and manufacturing organization (CDMO) that provides drug substance development and manufacturing across the entire drug lifecycle, as well as comprehensive analytical services.

With over 45 years of experience and a team of 2,000 experts servicing global clients from North America and Europe, Cambrex offers a range of specialized drug substance technologies and capabilities, including continuous flow, controlled substances, peptide synthesis, solid-state science, biocatalysis, material characterization, complex synthetics, and highly potent APIs.

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