

# Kaneka Eurogentec completes commercial mRNA GMP facility expansion

**Newly accredited GMP facility for commercial manufacturing of mRNA in anticipation of customer BLA submission.**

Kaneka Eurogentec, an FDA, EMA inspected CDMO focused on the production of injectable grade cGMP biopharmaceuticals, including cell and gene therapies, announced the **accreditation of an additional mRNA manufacturing facility** by the Belgian health authorities.

The achievement is highlighted by the successful outcome of the regulatory inspection, with no critical or major observations reported. This confirms that these cGMP mRNA production zones are state-of-the-art for commercial manufacturing.

## Key Accomplishments:

1. Facility is commercial ready for the manufacturing of mRNA for vaccine, protein replacement or gene editing purposes in human and veterinary applications.
2. The additional zones significantly increase the capacity of mRNA production for commercial scales.
3. The new facility benefits from the same streamlined QMS used for other commercial biopharmaceutical products supplied by Kaneka Eurogentec.

Lieven Janssens, CEO of Kaneka Eurogentec, stated "The newly expanded facility represents a significant milestone in Kaneka Eurogentec's commercial manufacturing growth strategy, adding advanced cleanroom space, state-of-the-art equipment, and enhanced quality systems designed to support late-stage clinical and commercial production of mRNA-based therapeutics."

## About mRNA

mRNA has significant potential in:

1. **Vaccine development**, thanks to its rapid production timelines, adaptability to emerging variants, and broad range of applications.
2. **Protein replacement therapies**, by delivering the correct genetic instructions for cells to produce missing or defective proteins in patients.
3. **Gene editing**, to remove, modify or insert genetic sequences in patients with inherited genetic disorders.

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## About Eurogentec

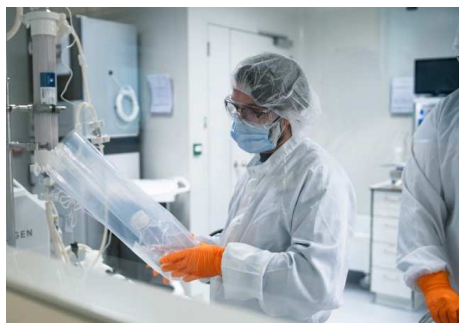
Kaneka Eurogentec SA, part of the Kaneka group, is a contract development and manufacturing organization providing custom products and services to researchers in the biological sciences, diagnostic and biopharmaceutical industries. With a commitment to excellence, the company operates under ISO 9001, ISO 13485 and cGMP quality systems. Eurogentec's business units fully support research, diagnostic and drug development projects from early R&D to commercial phases. Headquartered in Belgium, and with strategically located subsidiaries worldwide, the Eurogentec Group employs a team of 475 people.

## About Kaneka

Kaneka is an innovation-oriented chemical company. Traditionally the company has been active in polymers, fermentation, biotechnology and electronics, as well as other fields. Business activities now span a broad spectrum of markets ranging from plastics, chemicals and foodstuffs to pharmaceuticals, medical devices, electrical and electronic materials and synthetic fibers. The life science related activities are currently one of the strategically important domains for Kaneka. The company has been a pioneer among Japanese chemical companies in establishing overseas operations, beginning in 1970 with a subsidiary in Belgium.

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