Biomay Announces Expansion of GMP-Facilities to Offer mRNA Manufacturing and Aseptic Filling Services

Monday 13 November, 2023

Biomay expanded its biomanufacturing facility in central Vienna, 9th district, by adding clean rooms, laboratories, and warehouse premises in the Vienna Competence Center building. Besides the 4000 sqm main site in Vienna 22nd district, Biomay now operates an additional 2000 sqm integrated biomanufacturing facility, equipped with five GMP-commissioned clean rooms for upstream and downstream processing and aseptic filling. Furthermore, the site features comprehensive laboratories for quality control, process and assay development.

A New Center of Excellence for mRNA

The upgraded site will serve as Biomay's Center of Excellence for end-to-end Contract Development and Manufacturing Organization (CDMO) services, specifically for messenger RNA (mRNA) manufacturing. The GMP service offerings for mRNA include plasmid cell banking, circular plasmid and linear DNA template manufacturing, in-vitro transcription (IVT) of mRNA drug substance, and aseptic filling of mRNA drug product. Biomay employs cutting-edge enzymatic run-off transcription based on linear DNA templates for mRNA processing, offering various options for 5´-capping, 3´-poly-adenylation, and nucleotide modification as per client requirements.

Notably, Biomay has a strong track record in GMP production of linear DNA templates, supplying significant amounts of these templates during the COVID-19 pandemic for the manufacturing of a COVID-19 mRNA vaccine. The company has also gained extensive experience in GMP manufacturing of DNA templates for other clinical indications, such as oncology.

Aseptic Filling Capacities

Biomay's aseptic filling capacities include a seven-glove isolator equipped with an automated processing line for aseptic filling, vial capping and crimping, primarily serving clinical-stage investigational medicinal products (IMPs). Dr. Angela Neubauer, the Site Head of the facility and Biomay's Senior Vice President Client Business, emphasized the company's evolution from being a drug substance and API manufacturer to offering drug product aseptic filling, testing and release services. She highlighted Biomay's strategic goal of establishing itself as a leading player in the mRNA CDMO field, alongside its existing expertise in proteins and plasmids.

About Biomay

Founded in 1984, Biomay AG is a fully integrated CDMO with a focus on microbial based GMP services for manufacturing therapeutic proteins, plasmid DNA and mRNA. The new site complements Biomay’s main manufacturing site in Vienna Seestadt (22nd district, Ada Lovelace-Strasse), established in 2021.

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