

Biomay Announces Expansion of its GMP-Facilities to Offer mRNA Manufacturing and Aseptic Filling Services (Vienna, October 2023)

Biomay, a Vienna based biotech manufacturer, announced a facility extension and is now able to expand its GMP-facilities, to offer mRNA manufacturing and aseptic filling services. Biomay is a one-stop-manufacturer of plasmid DNA, mRNA and recombinant proteins.

Facility Extension

Biomay announced the recent extension, reconstruction and commissioning of its GMP biomanufacturing facility in central Vienna, 9th district. Earlier this year, the company has acquired additional clean rooms, laboratory and warehouse premises in the Vienna Competence Center building. After adaptation, Biomay meanwhile operates a total floor space of 2000 sqm at that site. The fully integrated biomanufacturing facility comprises five GMP-commissioned clean rooms for upstream and downstream processing and aseptic filling. Furthermore, the new site consists of extensive laboratories for quality control and process and assay development.

A New Center of Excellence for mRNA

At the upgraded site, Biomay will offer end-to-end CDMO services for manufacturing of messenger RNA (mRNA). The list of GMP service offerings for mRNA comprises: 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. Those manufacturing activities are backed by a fully operative quality control lab employing a sound set of mRNA specific analytical assays, and a dedicated team focused on manufacturing science and technology (MSAT).

For mRNA processing, Biomay applies enzymatic in-vitro run-off transcription based on linear DNA templates. Depending on client's needs, several options can be offered for 5'-capping (co-transcriptional, enzymatic), 3'-poly-adenylation and nucleotide modification. The mRNA process is fully GMP qualified (including all starting and raw materials), is free of animal components and employs a high rate of single-use equipment.

As a particular feature of Biomay's scope of services, the company has meanwhile a strong track record in GMP production of linear DNA templates for mRNA IVT. During the Corona pandemic and as published earlier, Biomay produced and supplied big amounts of linear DNA template used for manufacturing of a Covid-19 mRNA vaccine. In the meantime, Biomay has gained comprehensive experience in GMP manufacturing of DNA templates for other clinical indications, such as oncology. At its newly adapted manufacturing site, Biomay will continue in supplying DNA start templates for mRNA IVT.

Aseptic Filling Capacities

Biomay's site comprises premises for aseptic filling services which are offered for mRNA, plasmids and recombinant protein drugs. The core unit consists of a seven-glove isolator (clean room class A in C) equipped with an automated processing line for aseptic filling, vial capping and crimping (batch volume around 1500 vials). The facility has been inspected yet by the Austrian health authority AGES. Biomay will utilize its aseptic filling facility primarily for clinical-stage investigational medicinal products (IMPs).

Dr. Angela Neubauer is Site Head of the updated facility, and is Biomay's Senior Vice President Client Business. *"We are excited that we could extend our service portfolio with this site investment," she stated. "So far, Biomay has been a drug substance and API manufacturer. It is a big and important step for us now to offer drug product aseptic filling, testing and release services for our clients."* Commenting on Biomay's new mRNA Center of Excellence, Dr. Neubauer said: *"We are happy that our mRNA services are now concentrated at this site. It is Biomay's strategic goal to become a major player in the mRNA CDMO field, as it is the case already for proteins and plasmids. Furthermore, we are proud that we are able to offer the whole mRNA GMP processing chain, including the associated DNA templates. There are not too many CDMOs in the field being capable of producing both DNA and mRNA, respectively. By this investment, Biomay has become a real one-stop-shop."*

About Biomay

Biomay AG is a privately owned and fully integrated Contract Development and Manufacturing Organization (CDMO). Founded in 1984, the expression of recombinant proteins by utilizing *E. coli* has been Biomay's business focus yet from its beginning. Today, Biomay offers microbial-based cGMP services for manufacturing of therapeutic proteins, plasmid DNA and messenger RNA. Biomay operates two independent manufacturing sites in Vienna: the greenfield-invested headquarter facility in Vienna Seestadt (22nd district, Ada Lovelace-Strasse) which was built and set into operation in 2021; and the original and extended facility in central Vienna (9th district, Lazarettgasse), the latter has now become the company's mRNA Center of Excellence.

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