



PRESS RELEASE

Biomay Offers Lipid-Nanoparticle Formulation Services for RNA Pharmaceuticals

Vienna, March 4th, 2025. Biomay today announced to offer GMP services for lipid-based nanoparticles (LNPs). With this, the company has completed its end-to-end platform for manufacturing of GMP-grade mRNA drugs from scratch. A comprehensive list of LNP-specific and GMP-conform analytical assays support that service offering.

Those services are comprised in Biomay's LNP platform:

- GMP manufacturing of LNP-formulated mRNA
- Process development (e.g. integration of custom-specific lipids)
- Development of analytical assays for LNPs
- Aseptic filling of LNPs for clinical or research use
- Analytical characterization and release testing of LNPs

Lipid-based nanoparticles are complex and spherical structures of sub-microscopic size (typically smaller than 100 nm – therefore „nano“). The characteristic LNP structure protects the RNA active ingredient from degradation, facilitates its cellular uptake and provides higher efficacy to the drug or the vaccine. LNPs are composed of a set of different types of lipids, some of which are rather generic (such as cholesterol). Other lipid compounds are highly project- or client-specific (such as ionizable lipids). Biomay's LNP platform is flexible in order to incorporate any customized lipids into the particle.

Biomay has in-house in place a powerful set of LNP-specific analytical assays to perform GMP-conform quality control, including for instance:

- Dynamic light scattering / DLS to determine LNP size and polydispersity
- Fluorometric determination of encapsulation efficiency and mRNA content
- LC/MS to determine identity and content of the lipids
- Capillary electrophoresis for mRNA integrity
- Rapid sterility testing

With its latest LNP services, Biomay is now one of only a few CDMOs worldwide being able to offer the whole processing chain for mRNA, essentially without subcontracting. The platform begins with template DNA preparation, continues with mRNA manufacturing and LNP formulation, and ends with aseptic filling. Besides mRNA, the LNP platform can also be applied for other (non-coding) RNA formats, such as micro RNA, small-interfering RNA or guide RNA.

About Biomay:

Biomay AG is a fully integrated Contract Development and Manufacturing Organization (CDMO) based in Vienna, Austria. Founded in 1984, the expression of recombinant proteins in *E. coli* has been Biomay's business focus yet from its beginning. Today, Biomay offers cGMP services for manufacturing of messenger RNA (mRNA), circular plasmid DNA, linear IVT-template DNA and therapeutic recombinant proteins. Biomay operates a dedicated mRNA Competence Center for cGMP manufacturing and QC testing of mRNA drug substance and drug product (clinical, commercial). The company's scope of services comprises process and analytical development, cell banking, R&D material supply, cGMP manufacturing, lipid nanoparticle / LNP formulation and aseptic filling. Biomay's facilities are inspected by the US FDA.

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See more details on [Biomay's GMP mRNA services](#)