



PRESS RELEASE

Biomay Expands DNA Manufacturing Portfolio with Cell-free Enzymatic DNA Synthesis

New technology expands Biomay's DNA portfolio while complementing its established plasmid DNA manufacturing capabilities

Vienna, Austria – October 26, 2026. Biomay, a fully integrated contract development and manufacturing organization (CDMO) based in Vienna, Austria, is expanding its DNA manufacturing portfolio with the introduction of **cell-free, enzymatically synthesized DNA**. As the result of focused internal research and development, the company has filed a patent application earlier this year. Biomay is now implementing the technology for GMP manufacturing, with the first GMP batches completed by end of this year.

The new platform results in a **linear DNA molecule**, optionally **protected by a closed hairpin loop** at one or both ends. The **cell-free enzymatic in-vitro process** combines rolling circle amplification (RCA) with a proprietary procedure for forming closed hairpin loops, followed by downstream purification, aseptic filling and quality control. The enzymes required for synthesis of the DNA are recombinantly made in-house by Biomay.

Expanding the range of DNA solutions for advanced therapies

Enzymatically synthesized DNA offers a complementary approach to established plasmid DNA technologies and has the potential for **applications across a wide range of advanced therapy and nucleic acid platforms**. Biomay's new platform enables the production of three distinct DNA formats:

DNA Format	Fields of Application
Linear closed DNA	DNA vaccine / gene therapy Starting DNA for viral vectors (AAV, LV)
Linear semi-closed DNA (3' open)	Template DNA for in-vitro transcription of mRNA
Linear open DNA	Donor DNA for gene editing (homology-directed repair, HDR)

As a cell-free manufacturing approach, the technology eliminates the need for bacterial fermentation and avoids bacterial plasmid backbones. This may offer advantages in process design, impurity management and manufacturing lead times, with potential benefits for cost of goods (COGs) and personalized manufacturing applications.

"Biomay's expansion into enzymatically synthesized DNA is a natural and logical next step in the development of our DNA business," said Dr. Hans Huber, CEO of Biomay. "Biomay's goal is to provide our customers flexibility in terms of DNA technologies to choose from, within one end-to-end integrated CDMO platform. Different applications and manufacturing requirements call for different solutions. We believe that both established plasmid DNA and emerging enzymatic DNA technologies will have an important role to play in the future."



Complementing technologies, one integrated DNA portfolio

Biomay's entry into enzymatically synthesized DNA does not signal a departure from its established plasmid DNA business. Plasmid DNA will remain a core modality of the company's offering and an important manufacturing technology for the foreseeable future.

With decades of clinical experience and broad acceptance in the biopharmaceutical industry, plasmid DNA offers a well-established manufacturing pathway. Its advantages include scalable production, established master cell bank-based processes, extensive manufacturing experience and the ability to deliver highly purified material with controlled impurity profiles. Finally, the plasmid's characteristic supercoiled structure is a crucial and beneficial quality attribute for efficacy and stability.

Rather than positioning enzymatically synthesized DNA as a replacement for plasmids, Biomay aims to combine the strengths of both technologies. This approach enables the company to support customers with different DNA formats and manufacturing strategies while building on its existing expertise, infrastructure and quality systems.

Building on decades of bioprocessing and GMP experience

Biomay brings more than 40 years of experience in the bioprocessing of recombinant modalities, including more than 15 years of DNA-related track-record, and nearly 20 years of GMP manufacturing experience. This established foundation provides a strong basis for the implementation of enzymatically synthesized DNA and its integration into Biomay's existing service portfolio.

About Biomay

Biomay is a fully integrated CDMO based in Vienna, Austria. Biomay offers cGMP services for the manufacturing of mRNA, circular and linear DNA (plasmid-based or synthetic/enzymatic), and therapeutic recombinant proteins (clinical and commercial). The company's services include process and analytical development, cell banking, R&D material supply, cGMP manufacturing, LNP formulation, and aseptic fill-finish. Biomay's manufacturing facilities are multiple times inspected by the U.S. FDA.

Contact:

Dr. Arnd Dankesreiter, Vice President Business Development Europe; request@biomay.com
Biomay AG, Ada Lovelace-Str. 2, A-1220 Vienna, Austria; www.biomay.com
See more details on www.biomay.com/products/enzymatic-dna-synthesis