

BIA Separations and Biomay collaborate on production and purification of large DNA plasmids (16 May. 2018)

Press release
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Celebrating 20 Years of Innovation

Collaboration enables high yield, high purity supercoiled plasmid DNA manufacture for therapeutic application

Ajdovščina, Slovenia and Vienna, Austria, 16 May 2018: BIA Separations, a leading biochromatography development and manufacturing company, and Biomay, a contract manufacturer of cGMP biopharmaceuticals, today announced a collaboration on the high-yield production of large DNA plasmids. The companies have co-developed an economical production system for double-digit gram-scale production and purification of plasmids larger than 20,000 base pairs (20kbp) achieving high recovery of 95% supercoiled DNA. The new manufacturing process addresses a major challenge in the scaled manufacture of plasmid DNA and represents a significant step towards the wide application of large DNA plasmids in cell and gene therapy.

The collaboration combines Biomay's experience in the production of GMP-conform ultrapure pDNA with BIA Separations' CIM® (Convective Interaction Media) monolithic chromatographic columns. Monoliths support effective purification for plasmids up to at least 60 kbp and are able to maintain high capacity and resolution at high flow rates regardless of the size of the molecules being separated.

The system is commercially available to clients through Biomay's GMP service offerings.

Aleš Štrancar, CEO of BIA Separations commented: "Monoliths have been well-established for some time as the best purification tools for smaller single-gene plasmids and we are pleased to now adapt them to the purification of larger pDNA molecules. By working with Biomay, we are removing a major obstacle in the field which will allow product developers to proceed with an unlimited array of multi-gene clinical candidates."

Dr Hans Huber, COO of Biomay added: "The combination of our know-how in pDNA production with BIA's monolithic columns represent a key enabling step for us to meet our customer's needs for fast and economic production of large DNA plasmids, such as AAV starting vectors, in quantities required for the clinical development and early market supply of their gene therapy products."

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About BIA Separations www.biaseparations.com

BIA Separations is the leading developer and manufacturer of CIM® (Convective Interaction Media) monolithic chromatographic columns for production, purification, and analytics of large biomolecules. The company has research and production facilities in Slovenia, with sales offices and distributors throughout the world.

BIA Separations mission is to develop and produce CIM® monolithic columns of highest quality and provide superior research and method development services for purification and analytics of biomolecules. In addition the company aims to provide unique in-process control tools to better understand and control the bioprocesses.

About Biomay AG www.biomay.com

Biomay is a cGMP contract development and manufacturing organization (CDMO) for microbially derived DNA plasmids and recombinant proteins. In the past years, Biomay has positioned itself as a technology and innovation oriented one-stop-shop for manufacturing of DNA plasmids (applied as APIs or critical starting material), offering flexible and cost effective CDMO services to its clients.