

PRESS RELEASE

Number 13

WACKER Expands Production Capacity for Biopharmaceuticals in San Diego

Munich/San Diego, May 6, 2024 - As part of its growth strategy for the BIOSOLUTIONS life-science division, WACKER is increasing capacities in the field of biopharmaceuticals for advanced therapies. Wacker Biotech US, a subsidiary specializing in the fermentative production of plasmid DNA (pDNA), is expanding its mRNA and protein production. As a contract manufacturer (CDMO) located in San Diego, USA, Wacker Biotech is committed to the strict quality and regulatory standards of Current Good Manufacturing Practices (cGMP) of the US Food and Drug Administration (FDA).

Driven by developments in the field of gene therapy, demand for CDMOs offering end-to-end services supplying different components for nucleic acid-based gene therapies has risen sharply in recent years.

Wacker Biotech US Inc, a wholly owned subsidiary of Wacker Chemie AG, specializes in the microbial production of pDNA. As a CDMO located in the strong biotech hub of San Diego, the company offers several fermentation lines with a capacity of up to 650 liters fermentation and subsequent downstream processing steps.

Now, Wacker Biotech US is creating additional development and production capacities in the field of advanced therapy medicinal products to offer comprehensive solutions on the US market. By putting new laboratories into operation, Wacker Biotech US is expanding its bioprocess development capabilities for pDNA, mRNA, and recombinant proteins to support research and pre-clinical development. This service ideally complements the nucleic acid expertise of this site. At the same time, Wacker Biotech US successfully demonstrated that pharmaceutical proteins can be produced at 650 L cGMP scale at the San Diego facility.

Due to the capacity expansion and the associated transfer of decades of experience from Wacker Biotech's European sites to San Diego, messenger RNA (mRNA) and recombinant proteins can now be produced to meet the demands of research and clinical development.

General Manager of Wacker Biotech US, Dr. Philippe Cronet, says: "We have strong local expertise in the production of pharmaceutical proteins and benefit from the many years of experience of the global Wacker Biotech Team. Our site is ideally located in one of the most important biotech hubs, allowing us to serve the local and broader USA market but also worldwide."

WACKER's subsidiary Wacker Biotech has been producing therapeutic proteins, live microbial products, vaccines and mRNA for clinical development and commercial supply at its sites in Jena, Halle, and Amsterdam for decades. Wacker Biotech US' proprietary pDNA technology complements WACKER's portfolio as a contract manufacturer for the pharmaceutical industry. With the San Diego

site, WACKER has been present in the important US market for biopharmaceutical products since 2021. WACKER is continuously investing in its biopharma business.

**Visit WACKER at the BIO International Convention,
3-6 June 2024, San Diego Convention Center, Booth 5050.**



As a CDMO, Wacker Biotech US Inc. operates microbial fermentation lines with a capacity of up to 650 liters for cGMP compliant production and purification of pDNA as well as pharmaceutical proteins (Photo: WACKER).

Image available at: <http://www.wacker.com/pressreleases>

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The Company in Brief:

WACKER is a global company with state-of-the-art specialty chemical products found in countless everyday items, with applications ranging from tile adhesives to computer chips. It has a worldwide network of 27 production sites, 22 technical competence centers and 48 sales offices with some 16,400 employees and annual sales of around €6.4 billion (2023).

WACKER operates through four business divisions. The chemical divisions WACKER SILICONES and WACKER POLYMERS supply products (silicones, polymeric binders) for the automotive, construction, chemical, consumer goods and medical technology industries. WACKER BIOSOLUTIONS, the life sciences division, specializes in bioengineered products such as biopharmaceuticals and food additives. WACKER POLYSILICON produces hyperpure polysilicon for the semiconductor and photovoltaic industries.