

# PLASMITEC®: PLUG-AND-PLAY PLATFORM FOR PLASMID DNA GMP MANUFACTURING

The demand for nucleic acid-based gene therapies, novel vaccines, innovative therapeutic agents including messenger RNA (mRNA) and viral vectors is high. Plasmid DNA (pDNA) is the basis for all these advanced therapies. Wacker Biotech's versatile plug-and-play platform PLASMITEC® is based on decades of hands-on experience in pDNA manufacturing for both early stage and Phase 3 clinical trials. A combination of innovative technologies and quality systems, outstanding experience and the ability to efficiently perform GMP (Good Manufacturing Practice) production for both clinical studies and future commercial purposes make Wacker Biotech the partner of choice for contract manufacturing of pDNA.



As a CDMO, Wacker Biotech operates a dedicated GMP production facility focusing on pDNA.

The Wacker Biotech production site in San Diego serves as the location for cGMP manufacturing operations and is equipped with 43 L single-use bioreactors and 650 L stainless steel fermentation vessels, including scalable cell lysis. We specialize in pDNA-based technology and provide contract development and manufacturing organization (CDMO) services to suit various customer needs. The team is supported by staff members with several decades of experience in pDNA production (GMP) ranging from clinical startups to commercial product companies.

## Client Applications

Wacker Biotech manufactures high-quality GMP pDNA for various client applications:

- Viral vectors (AAV, lentivirus)
- DNA vaccines
- CAR-T cell therapy
- Gene editing
- mRNA production

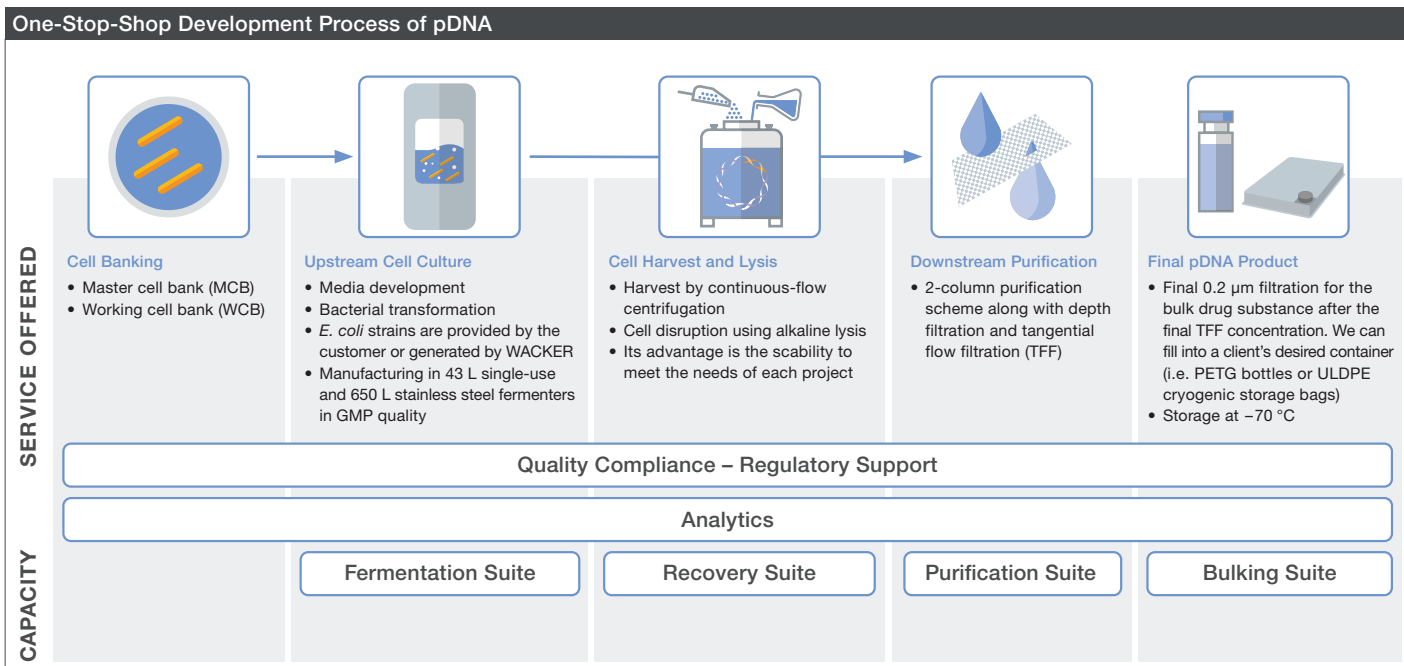
## High Service Level

As a CDMO, Wacker Biotech supports its customers throughout the entire product lifecycle, right up to commercialization. Our services include:

- Generation and selection of the best-performing strains for the production of supercoiled/linearized pDNA
- A dedicated process development lab to support feasibility, optimization, tech transfer and comparability
- Process characterization and validation
- Master cell bank and working cell bank production
- GMP manufacturing for clinical trials or commercial supply, including:
  - Fermentation on 43 L and 650 L scale
  - Scalable lysis suited for large-scale production
  - Dedicated lines for chromatographic purification
  - Analytical portfolio for product release, cell-based assays and stability studies
  - Storage at -70 °C
  - QC and QA release in-house

## Outstanding Experience

- Accumulated experience of more than 18 years in manufacturing plasmids as DS and DP for all stages of clinical studies, including but not limited to late phases (P3s)
- Fully equipped to produce GMP-grade pDNA to meet the highest quality standards and regulatory compliance
- Extensive know-how in cutting-edge pDNA production technologies including fully scalable processes due to scalable lysis approach
- Over 100 GMP pDNA batches produced
- More than 10 different products



Wacker Biotech's team of senior scientists ensures the quality, consistency and integrity of manufacturing campaigns.

**Project Examples**

- GMP pDNA for Helixmith's Phase III Engensis® clinical trials
- CMV vaccines
- Pandemic influenza vaccines
- Other prophylactic and therapeutic agents

**Regulatory Experience**

- 17 INDs filed
- 4 master files
- Orphan (#4), fast track (#2), qualified infectious disease product (#1)

**About Wacker Biotech**

Wacker Biotech is the microbial CDMO – your all-in-one partner of choice for full-service contract manufacturing of therapeutic proteins, live microbial products (LMPs), pDNA and vaccines based on microbial systems. Our portfolio extends from strain/process development and analytical testing through to GMP manufacturing for clinical and commercial supply.

Wacker Biotech, a WACKER subsidiary, maintains four GMP-compliant production plants with several production lines (up to 1,500 L). Our network includes sites in Jena and Halle in Germany, San Diego in the United States and Amsterdam in the Netherlands.

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