

The Wacker logo is a white rectangular box with the word "WACKER" in bold, black, uppercase letters. The background of the entire slide is a deep purple with various scientific motifs: DNA double helices in white and pink, circular molecular structures, and a central white line-art hand holding a glowing circular object containing a DNA helix. The overall aesthetic is clean and futuristic.

**WACKER**

CREATING TOMORROW'S SOLUTIONS

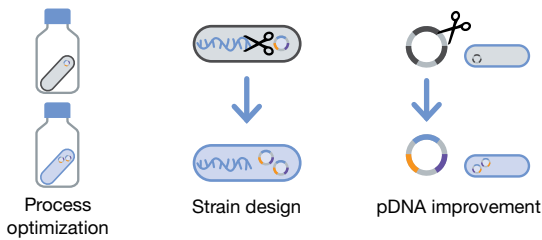
BIOPHARMACEUTICALS

**WACKER BIOTECH –  
ENGAGE THE EXPERTS IN  
pDNA, mRNA AND LNP**

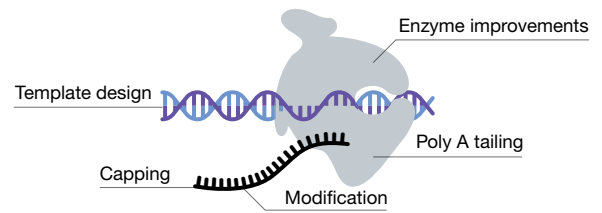
# YOUR NEEDS ARE DRIVING OUR INNOVATION!

4 Labs Working on Process Innovations in pDNA, mRNA and LNP

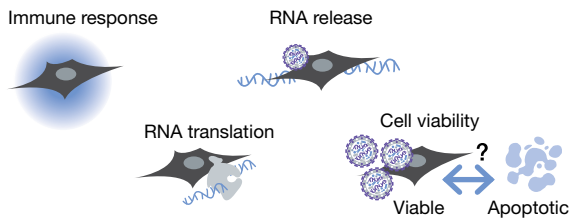
## Plasmid DNA Research



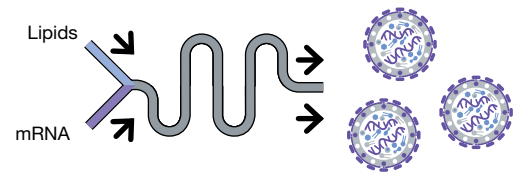
## mRNA Manufacturing (Analytical Methods)



## Functional Analysis



## Nucleic Acid Formulation



In close collaboration with universities and research institutions, WACKER's corporate R&D team of over 200 researchers continuously develops new production platforms and technologies for all types of biopharmaceuticals including pDNA, mRNA and LNPs. Competitive, outstanding solutions are our trademarks.

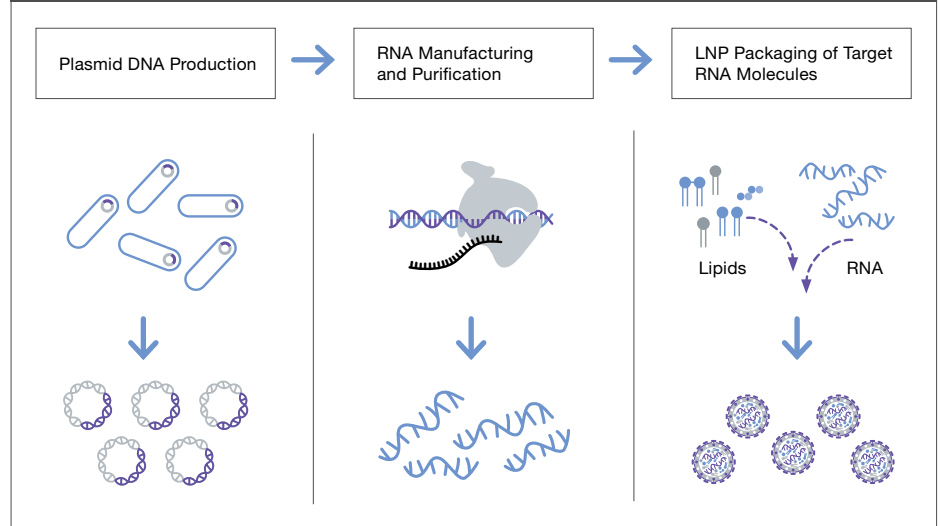
To offer our clients the best support with these advanced medicines, production platforms, and technologies, our R&D team in Munich is leveraging strong know-how and experience in:

- pDNA manufacturing – development of new proprietary cell strains and plasmids
- mRNA production – novel RNA synthesis pathways (mRNA, saRNA, circRNA)
- LNP formulation – academic collaborations to develop novel LNPs
- Analytical development to strongly advance methods for CQAs (e.g., capping efficiency, poly-A tail length, encapsulation efficiency, dsRNA (quantitative and in cells), cellular function of LNPs and mRNA)

Wacker Biotech clients can be assured they will have access to the newest state-of-the-art processes and process platforms through this R&D team and many related academic and industrial collaborations.

# WACKER BIOTECH – R&D MEETS FULL SERVICE

## Our Offering – from pDNA Production to LNP Packaging



Our customers benefit from Wacker Biotech's R&D and GMP experience, capabilities, and solutions as a full service CDMO for the development and GMP manufacturing of pDNA and mRNA including LNP formulation to meet their clinical and commercial needs.

## Your Benefits

### Trust

- One CDMO partner for the entire manufacturing chain from pDNA and mRNA to LNPs
- Working with experienced, solid partners validated by the German government\*
- Experienced MSAT and manufacturing teams
- Experience in GMP manufacturing of commercial supply for marketed products


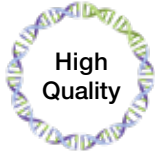
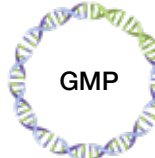
### Flexibility

- Variable production scales
- Flexibility in process design and equipment
- Fast-track supply of raw materials

### Innovation

- Access to the newest nucleic acid technologies supported by WACKER's Central R&D in Munich
- Dedicated 30-person R&D team at WACKER Munich Central R&D for early-stage products on site

# pDNA – RELIABILITY MEETS FLEXIBILITY

Our Offering to Meet the Current pDNA Market Needs		
<p>Research material</p> <p>↓</p>  <p><b>R&amp;D</b></p> <ul style="list-style-type: none"> <li>• Up to 14 L in BPD</li> <li>• High Throughput System*</li> <li>• Up to 2 g pDNA</li> <li>• 2 – 4 weeks</li> </ul>	<p>Critical raw material for AAV, lentivirus, mRNA, cell therapy safety and tox studies</p> <p>↓</p>  <p><b>High Quality</b></p> <ul style="list-style-type: none"> <li>• Up to 43 L in GMP suite</li> <li>• Up to 20 g pDNA</li> <li>• 10 – 12 weeks</li> </ul>	<p>Human clinical studies and commercial supply of pDNA injectable products</p> <p>↓</p>  <p><b>GMP</b></p> <p>In GMP suite:</p> <ul style="list-style-type: none"> <li>• Up to 43 L SUB**</li> <li>• 650 L</li> <li>• Up to 100 g pDNA</li> <li>• 4 – 6 months</li> </ul>

A combination of innovative technologies, quality systems, outstanding experience, and the ability to efficiently perform GMP production of both clinical and commercial material makes Wacker Biotech the partner of choice for the contract manufacturing of pDNA.

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.

## Wacker Biotech Supports Their Customers Throughout the Entire Product Lifecycle

- Committed R&D team to develop innovative, cutting-edge pDNA technologies and processes
- Generation of high-performing strains to produce excellent yields of supercoiled pDNA, with available processing for linearization
- Master and working cell bank production
- Process characterization and validation
- Decades of experience in pDNA GMP production for clinical and commercial manufacturing

### Application

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



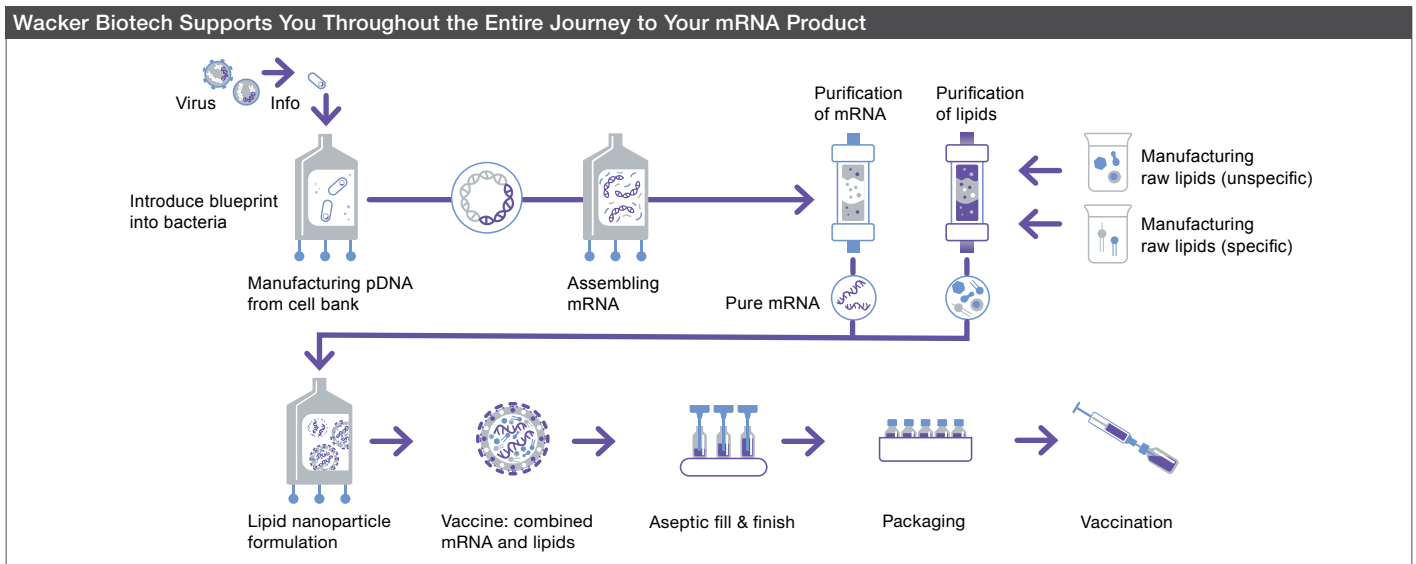
**GMP Facility  
San Diego, US**

### GMP Facility in San Diego, US

43 L single-use bioreactors and 650 L stainless steel fermentation vessels, including scalable cell lysis

\* Available as manual procedure in 2023, as automated system in 2024, 10 µg yield per plasmid targeted.  
\*\* Single-use batch. All yields and times may vary depending on product properties.

# mRNA – KNOW-HOW MEETS PIONEERING SPIRIT



During the Corona pandemic, Wacker Biotech jump-started mRNA manufacturing in Amsterdam, the Netherlands, including large-scale production capabilities for mRNA process transfers, and is now a leading CDMO with hands-on GMP manufacturing experience of mRNA-based therapies including process validation.

Our high-end mRNA Center of Excellence in Halle, Germany, will become operational in Q2 2024 as a GMP competence center for RNA product manufacturing and LNP formulation. It has been validated by the German government for their pandemic preparedness program. As our customer, you benefit from this level of quality!

## Broad Spectrum of Services

- Small to large scale mRNA production
- Transfer of client's processes
- Development of customized processes
- On-hand stock supply of pDNA starting material
- LNP formulation



**mRNA Competence Center Halle (Saale), Germany**

## mRNA Competence Center Halle (GMP)

- 4 GMP production lines (Class C)
- 2 x 3 L and 2 x 30 L disposable bio-reactors for IVT
- Capacity to produce several 100M vaccine doses p.a. in case of a pandemic
- mg to g to kg scale within a few months
- Flexibility based on fast-track supply of raw materials



**mRNA Competence Center Amsterdam, the Netherlands**

## mRNA Competence Center Amsterdam (GMP)

- Flexible to accommodate customized mRNA processes
- Center for excellence in development of mRNA-based processes
- Process development and scale-up of LNP formulation (AI and microfluidics)
- Dedicated R&D team to support customers that have new RNA technologies
- Proprietary analytical panel for RNA products (capping efficiency, poly A tail length, dsRNA)
- Analytical capabilities to test RNAs and LNPs in cell culture





**WACKER**

**Wacker Biotech GmbH**  
Jena and Halle, Germany  
Phone: + 49 3641 5348-0

**Wacker Biotech B.V.**  
Amsterdam, the Netherlands  
Phone: +31 20 750 3600

**Wacker Biotech US Inc.**  
San Diego, CA/USA  
Phone: +1 858-875-4700

[info.biologics@wacker.com](mailto:info.biologics@wacker.com)  
[www.wacker.com/biologics](http://www.wacker.com/biologics)

Follow us on:   



The data presented in this medium are in accordance with the present state of our knowledge but do not absolve the user from carefully checking all supplies immediately on receipt. We reserve the right to alter product constants within the scope of technical progress or new developments. The recommendations made in this medium should be checked by preliminary trials because of conditions during processing over which we have no control, especially where other companies' raw materials are also being used. The information provided by us does not absolve the user from the obligation of investigating the possibility of infringement of third parties' rights and, if necessary, clarifying the position. Recommendations for use do not constitute a warranty, either express or implied, of the fitness or suitability of the product for a particular purpose.