

WACKER

CREATING TOMORROW'S SOLUTIONS



ESETEC®

FOLDTEC®

LIBATEC®

PLASMITEC®

BIOPHARMACEUTICALS | CONTRACT MANUFACTURING

**WACKER BIOTECH –
ENGAGE THE EXPERTS IN
ADVANCED THERAPIES**

Your Needs Are Driving Our Innovation!

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



CUTTING-EDGE TECHNOLOGIES

Wacker Biotech offers efficient and cost-saving technologies for production of biologics.

ESETEC®

***E. coli* Controlled Secretion Technology**

Allowing for high yields of correctly folded proteins secreted in the fermentation broth.

FOLDTEC®

***E. coli* Refolding Technology**

Unique solutions for the sophisticated manufacturing of biopharmaceuticals by refolding.

LIBATEC®

Platform for GMP Production of Live Biotherapeutic Products

Suitable for a wide range of LBPs and fermentation regimes including anaerobic cultivation.

VACCINES

Extensive GMP Manufacturing of Vaccines incl. mRNA

Expertise in process development and manufacturing of a variety of vaccine products.

mRNA

mRNA Manufacturing

mRNA production incl. LNP formulation under one roof.

PLASMITEC®

Plasmid DNA Manufacturing

Versatile plug-and-play platform for manufacturing of pDNA for advanced therapies.

PASylation®

Extending the Plasma Half-Life of Biopharmaceuticals

Collaboration with XL-protein GmbH to produce high yields of PASylated biologics.

PEGylation

Extending the Plasma Half-Life of Biopharmaceuticals

Expertise in developing and performing the PEGylation step.

ESETEC®, FOLDTEC®, LIBATEC® and PLASMITEC® are registered trademarks of Wacker Chemie AG.



Learn more about our technologies:
www.wacker.com/biologics

100 YEARS OF RELIABILITY, 20 YEARS OF EXPERIENCE IN BIOLOGICS, OVER 200 PROJECTS, 4 COMMERCIAL PRODUCTS AND SATISFIED CLIENTS.

Here is what they say about us:

“We are very pleased with the high technical competence, reliability and support of the WACKER team to bring our lead candidate into the clinic as planned – WACKER is a true partner in this project.”

Juha Yrjänheikki, CEO Aurealis Therapeutics

“A partnership with WACKER, one of the world’s leading microbial drug CDMOs, provides a significant boost to Helixmith. Having a strong partner like WACKER provides us with additional confidence as we pursue our global blockbuster pipeline.”

Seungshin Yu, CEO Helixmith

“In WACKER we have found a highly competent partner for ensuring that we have a secure supply of raw materials for our industrial scale production.”

Dr. Wolfram Strobl, General Manager Fresenius Medical Care

“This approval represents a significant milestone in Chiesi’s work to bring Retavase® back to the US market. WACKER is a proven leader in microbial technology. The collaborative effort and partnership have been outstanding.”

Alan Roberts, Senior Vice President, Scientific Affairs at Chiesi

“We selected WACKER among competing CMOs because their proprietary bacterial expression technology provides a significant yield of fully refolded PAS-nomacopan, and we believe working with WACKER provides the best path to GMP manufacturing of long-acting PAS-nomacopan for use in GA clinical trials. WACKER has proven to be an exceptional contract manufacturing partner for the parent drug nomacopan, and we look forward to our continued relationship with them.”

Dr. Miles Nunn, Chief Scientific Officer at Akari

Customer Proximity From
Research to Delivery

Wacker Biotech expertly
delivers on a broad
range of service offerings,
ready to fulfill your
demand for clinical and
commercial supply.

Products

- Recombinant proteins
- Vaccines
- Live Biotherapeutic Products
- Plasmid DNA
- mRNA incl. LNP formulation

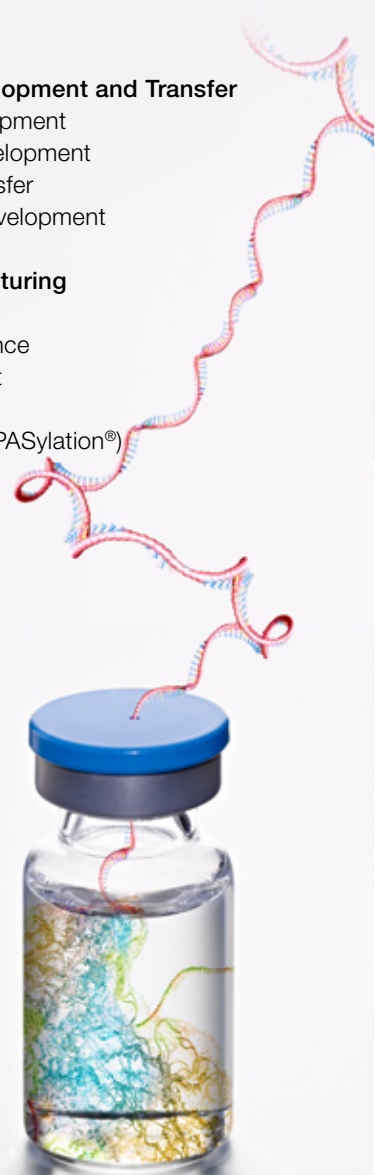
Services

Process Development and Transfer

- Strain development
- Process development
- Process transfer
- Analytical development

GMP Manufacturing

- Cell banking
- Drug substance
- Drug product
- Conjugation
(PEGylation/PASylation®)



GLOBALLY OPERATING GMP FACILITIES FOR ADVANCED THERAPIES

pDNA

San Diego, USA

- 43 L stirred single use bioreactor
- 650 L stainless steel stirred fermenter
- pDNA process development
- QC/QA for pDNA on site
- Cell banking
- CA FDA licensed



San Diego (CA), USA

mRNA

Halle (Saale), Germany

- mRNA competence center
- Production of pDNA and mRNA incl. LNP formulation
- 4 production lines (Class C)
- 2 x 30 L, 2 x 3 L IVT scale
- g to kg scale within a few months
- Flexibility based on fast-track supply of raw materials
- Facility for pandemic preparedness



Halle (Saale), Germany

Amsterdam, the Netherlands

- Production of pDNA and mRNA incl. LNP formulation
- 350 L stainless steel stirred tank fermenter
- Flexible to accommodate customized mRNA processes
- Center of Excellence in process development of mRNA-based processes



Amsterdam, the Netherlands

GMP FACILITIES FOR PROTEINS, LIVE BIOTHERAPEUTIC PRODUCTS & VACCINES

Proteins

Jena, Germany

- 350 L stainless steel stirred tank fermenter
- Recombinant **protein** manufacturing
- **Strong process development**
- Cell banking
- **Commercial** and **clinical** supply
- **EMA** and **FDA** approved



Jena, Germany

Halle (Saale), Germany

- 1,500 L stainless steel stirred tank fermenter
- Recombinant **protein** manufacturing
- **Strong process development**
- **mRNA** Center of Excellence
- **Commercial** and **clinical** supply
- **EMA** and **FDA** approved



Halle (Saale), Germany

Proteins, Live Bio-therapeutic Products and Vaccines

Amsterdam, the Netherlands

- 250 L stirred single use bioreactor
- 1,500 L stainless steel stirred tank fermenter
- **Live bacteria, proteins, vaccines** incl. mRNA
- **Cell banking**
- **Fill & finish**
- **Commercial** and **clinical** supply
- **Biosafety Level 2** certified
- **EMA** and **FDA** approved



Amsterdam, the Netherlands



Take a virtual 360° tour through
our production sites:
<https://biologics-plant-tour.wacker.com>





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