



WACKER

CREATING TOMORROW'S SOLUTIONS

BIOPHARMACEUTICALS | CONTRACT MANUFACTURING

WACKER BIOTECH: THE MICROBIAL CDMO



EMA/FDA APPROVED GMP FACILITIES

Wacker Biotech's sites in Jena, Halle (Germany), Amsterdam (the Netherlands) and San Diego (U.S.) provide a complete range of services for the development and GMP-compliant manufacturing of biopharmaceuticals using microbial hosts.

Several manufacturing lines are equipped with stainless steel fermentation vessels ranging in size from 30 to 1,500 liters, as well as a single-use bioreactor. These are complemented by primary recovery, downstream and fill-finish capabilities meeting various customer needs across the development path (biosafety level (BSL) 1 and 2).

Wacker Biotech holds biomanufacturing certificates from the relevant authorities for all of its sites, and follows the ICH Q7A guidelines for GMP-compliant production of active pharmaceutical ingredients (APIs) and drug products (DPs). Our quality systems are continuously assessed by a combination of internal, customer and official audits. Our GMP production facilities are approved for commercial manufacturing by the EMA, FDA and/or ANVISA.

Services at a Glance – Key Facts

Drug Substance

- Stainless steel: **30 L, 350 L, 500 L, 2 x 1,500 L**
- **250 L SUB** (single-use bioreactor)
- BSL 1 and 2
- 1,200+ GMP batches released

Fill/Finish into Vials:

- DIN 2R to 20R vials established
- Others upon request
- Liquid/lyophilization up to 20,000 vials/lot
- 500+ DP GMP batches released

Bulk Lyophilization

- Lyoguard trays™ up to 65 L per lot

YOUR BIOLOGICS CONTRACT MANUFACTURER OF CHOICE

Wacker Biotech is THE MICROBIAL CDMO – your partner of choice for contract manufacturing of therapeutic proteins, vaccines, Live Microbial Products (LMPs) and plasmid DNA (pDNA).

Integrated Service Portfolio

Wacker Biotech's services cover cell banking, process/analytical development, and GMP manufacturing of biologics for clinical and commercial supply. We offer our customers added value with outstanding *E. coli* and Live Microbial technologies that significantly increase bioprocess efficiency and thus reduce the cost of goods. In addition, we have extensive experience with a broad range of bacterial hosts for generating vaccines, proteins, pDNA or LMPs.

From Scratch to Commercial Batch

Wacker Biotech has an established track record and more than 20 years of experience in process design, process transfer and manufacturing of therapeutic proteins, vaccines, LMPs and pDNA for a vast number of customers – from small biotechnology companies to big pharmaceutical corporations. Our experience covers everything “from scratch to commercial batch,” i.e., projects from preclinical development to drug substance and drug product manufacturing for commercial supply. We have completed more than 200 projects for our customers across the globe.

Services at a Glance – Key Facts

Process Development and Transfer

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

GMP Manufacturing

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

More than 20 Years of Experience

Founded in 1999 as a spin-off from the Hans-Knöll Institute in Jena, we have been a 100% subsidiary of Wacker Chemie AG since 2005. Biopharmaceutical manufacturing in Jena had already started in the early nineties. In 2014, we acquired Halle-based Scil Proteins Production GmbH. SynCo Bio Partners B.V. from Amsterdam followed in 2018. In 2021, we rounded off our portfolio by acquisition of the US-based Genopis Inc. in San Diego.

BIOPROCESS DEVELOPMENT

Process development is the link between research and subsequent commercial production of biopharmaceuticals. Its goal is to develop a cost-effective, robust manufacturing process that can be validated and that maximizes yields of high quality product – all while complying with process and product specifications.

With more than 20 years of experience and more than 200 successfully accomplished projects, Wacker Biotech has the expertise to develop processes that meet customers' demands for rapidly available clinical materials with an eye to the long-term demands on commercial production processes. We serve EU and US customers, along with customers from other regions such as Korea, Japan and Brazil. Our bioprocess development department, which has more than 50 full-time employees (the vast majority of whom hold academic degrees), is focused solely on process development, material supply for preclinical trials, strain/analytical development, process transfer and process characterization.

We carefully document all of the process development work involved. By integrating project management at an early stage and establishing project core teams, we streamline bioprocess development in an efficient and transparent way.

Bioprocess development always starts with selecting the right expression system, followed by fermentation and downstream process development, along with intensive and comprehensive process and product analysis. For late-stage projects we offer comprehensive process characterization.



For more information, please visit our website
www.wacker.com/biologics



CUTTING-EDGE TECHNOLOGIES

Wacker Biotech offers innovative technologies for efficient, cost-effective production of biologics.

ESETEC®: *E. coli* Controlled Secretion Technology

Wacker Biotech's unique controlled secretion system allows for high yields of correctly folded proteins in the culture broth. The system includes engineered *E. coli* K12-based host strains, a set of proprietary plasmids, and a genetic toolbox to increase and control secretion. The technology has been successfully used for the production of a broad variety of recombinant proteins with yields up to 14 g/L.

FOLDTEC®: *E. coli* Folding Technology

FOLDTEC® technology is based on proprietary *E. coli* strains optimized for high-quality inclusion bodies and superior yields (up to 12 g/L). Complemented by our years of experience in refolding and a tailored screening approach, FOLDTEC® offers improved efficacy, smaller folding volumes and fully scalable manufacturing processes – with no need for antibiotics or undesired phage components.

LIBATEC®: Live Bacterial Technology

LIBATEC® is Wacker Biotech's efficient, comprehensive production platform suitable for a wide variety of live microbial strains with an intended therapeutic or prophylactic effect in humans, for several routes of administration, including parenteral. The technology is based on Wacker Biotech's long experience in LMPs process development and optimization, both in clinical and commercial GMP manufacturing applications. The platform

offers integrated drug product production, including lyophilization and a closed production system (monoseptic processing).

Experience in Plasma Half-Life Extension

PASylation®

Wacker Biotech works with XL-protein GmbH to produce PASylated biopharmaceuticals using ESETEC®. The resulting synergies generate high yields of PASylated biologics, with titers of several g/L.

PEGylation

Wacker Biotech has extensive expertise in developing and performing the PEGylation step in the production of biologics and synthetic peptides at our GMP facilities.

Plasmid DNA

The San Diego site is supported by staff members with several decades of experience in pDNA production (GMP) ranging from clinical start-ups to commercial product companies. Fermentation, downstream purification including continuous lysis as well as pDNA quality control are part of our proprietary platform.

Vaccines

Our expertise extends to the process development and manufacturing of a variety of vaccine products, including live attenuated, inactivated, (conjugated) polysaccharide and protein-based vaccines. Wacker Biotech has produced and released more than 650 GMP vaccine batches for clinical (phase I to III) and commercial applications. In 2020, Wacker Biotech entered into a manufacturing partnership with CureVac for its mRNA-based COVID-19 vaccine candidate.



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 (United States)
Phone: +1 858-875-4700

info.biologics@wacker.com
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.