WACKER

CREATING TOMORROW'S SOLUTIONS

BIOPHARMACEUTICALS I CONTRACT MANUFACTURING

WACKER BIOTECH: THE MICROBIAL CDMO

YOUR BIOLOGICS CONTRACT MANUFACTURER OF CHOICE

Wacker Biotech is THE MICROBIAL CDMO – your partner of choice for contract manufacturing of therapeutic proteins, vaccines and live microbial products.

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* 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 or live microbial products.

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 and live microbial products 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 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 and rounded off our portfolio by acquiring SynCo Bio Partners B.V. in 2018.

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 and Japan. 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 proprietary technologies for efficient, cost-effective production of biologics

ESETEC®: *E. coli* Secretion Technology

Wacker Biotech's unique 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 secretion. The technology has been successfully used for the production of a broad variety of recombinant proteins, including therapeutic Fabs, scaffolds and single domain antibodies with yields up to 14 g/L. Fast strain development and a nearly 3-fold reduction in the cost-of-goods make ESETEC® a better alternative to mammalian systems for non-glycosylated proteins.

FOLDTEC®: *E. coli* Folding Technology

While Wacker Biotech's own ESETEC® technology has proven highly efficient in producing soluble proteins via secretion, poorly soluble biologics form aggregated inclusion bodies within the cell.
Here protein refolding is a key production stage in order to achieve the desired active properties.

FOLDTEC® technology is based on proprietary *E. coli* strains optimized for high-quality inclusion bodies and superior yields (up to 12 grams per liter). 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. In synergy with Wacker Biotech's high-cell-density fermentation systems, FOLDTEC® provides unique refolding solutions for sophisticated biopharmaceuticals manufacturing.

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. For example, PASylated Fabs can be produced with yields > 4 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.

EMA/FDA APPROVED GMP FACILITIES

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

Five manufacturing lines are equipped with stainless steel fermentation vessels ranging in size from 270 to 1500 liters, as well as single-use bioreactors and WAVE bags. These are complemented by primary recovery, downstream and fill-finish capabilities meeting various customer needs across the development path (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. All three GMP production facilities are approved for commercial manufacturing by the EMA, FDA and/or ANVISA.

Services at Glance – Key Facts

Drug Substance
- Stainless steel: **270 L, 350 L, 2 x 1,500 L**
- **20 L** to **200 L** disposable WAVE bioreactors
- **250 L** SUB (single-use bioreactor)
- BSL 1 and 2
- 1100+ 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

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