

The Microbial CMO

Process Development and Manufacturing of Biologics

Wacker Biotech is “The Microbial CMO” — partner of choice for process development and contract manufacturing of biopharmaceuticals (proteins, vaccines, and live microbial products) using microbial hosts. WACKER’s integrated service portfolio covers molecular biology, process/analytical development, and GMP manufacturing of biologics for clinical and commercial supply.

WACKER operates three state-of-the-art GMP facilities located in Europe (Germany and Netherlands). Manufacturing lines with two 300-L and two 1,500-L stainless steel fermentation vessels, single-use fermentation lines, matching downstream processing scales and fill and finish capabilities are available to suit all possible customers’ needs (BSL 1 and 2).

WACKER holds biomanufacturing certificates from the relevant authorities for all sites and follows the ICH Q7A guidelines for GMP-compliant production of biologics. The facility in Halle has been EMA and FDA approved for the commercial production of Reteplase (trade names Rapilysin® and Retavase®), a thrombolytic drug that is indicated to treat acute myocardial infarction. In 2016, the Jena plant received EMA approval for manufacturing of the approved product Spectrila®, a recombinant L-asparaginase for treatment of childhood leukemia.

WACKER rounds out its offering with outstanding *Escherichia coli* technologies that can significantly increase the bioprocess efficiency and thus reduce cost of goods.

SERVICES PORTFOLIO

Project Management: We work in close collaboration with our customers. Projects are managed by dedicated project managers supported by cross-departmental teams. Depending on our customers’ requirements, we have the flexibility to perform the whole process development or to transfer projects at various stages.



WACKER

Cell Line Engineering:

- Construction and optimization of host/vector systems
- Production and characterization of master and working cell banks

Process Development and GMP Manufacturing:

- Efficient process development and optimization
- Process transfer
- Process scale from 20 L to 1,500 L
- GMP-compliant production
- Process validation
- Aseptic fill and finish

Quality Control:

- Development of analytical methods
- Assay qualification and validation
- Release testing
- ICH-compliant stability testing

Quality Assurance:

- Ensured regulatory compliance in all aspects of manufacturing and quality control
- Batch release by qualified person
- Support with dossiers (e.g., IND or IMPD)

COST-SAVING TECHNOLOGIES

ESETEC® — *E. coli* Secretion Technology: WACKER’s secretion system allows for high yields of correctly folded proteins in a culture broth. It consists of an engineered *E. coli* K12-based host strain, a set of proprietary plasmids, and a genetic toolbox to increase secretion. The technology has been used successfully to produce a broad variety of recombinant proteins, including therapeutic Fabs and scaffolds.

FOLDTEC®: Using rational experimental design with a proprietary expression vector portfolio, WACKER provides solutions for complex and challenging in vitro folding processes. Better folding efficiencies and smaller folding volumes render fully scalable manufacturing processes with superior productivity.

PASylation® — Innovative Technology for Extension of Plasma Half-Life: In collaboration with the German company XL-protein GmbH, WACKER offers the production of PASylated biopharmaceuticals using ESETEC® technology. Recently, PASylated Fabs were produced with yields >4 g/L. 🌐

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WACKER

CREATING TOMORROW'S SOLUTIONS

THE MICROBIAL CDMO – YOUR ALL-IN-ONE PARTNER

Fill & Finish

Process
Development

Contract
Manufacturing



SynCo
Bio Partners

NOW PART OF WACKER

WACKER is now your truly all-in-one partner for manufacturing biologics, vaccines and live microbial products. By acquiring SYNCO BIO PARTNERS, we doubled our GMP capacity and now offer CDMO activities ranging from initial development to fill and finish. From strain development through to technology transfer and manufacturing in our EMA-/FDA-approved GMP facilities, we are able to cover the whole process for pre-clinical, clinical and commercial supply. On top of that, our unique microbial technologies help you to manufacture your protein extremely cost-effectively. You can put your trust in our experience!

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