

PRESS RELEASE

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WACKER Invests in Jena Biotech Site

Munich and Jena, September 13, 2018 – In Jena, the Munich-based chemical group WACKER has enhanced its production facilities for biopharmaceuticals – also known as biologics – with new equipment. Furthermore, an inspection by the Brazilian health authority ANVISA assessing the site’s quality standards was a major success. Both developments increase the appeal of the Jena site and offer benefits to customers.

“In recent years, we have been continuously expanding our contract manufacturing capacity for biopharmaceuticals in Jena. The new, modern production equipment has further enhanced the site, making our company fit for the future,” explained Dr. Guido Seidel, managing director Operations of the wholly-owned WACKER subsidiary Wacker Biotech GmbH. The company invested €2.5 million in, among other things, a fully automated fermentation plant including a new bioreactor with a capacity of 350 liters, a new separator for efficiently isolating cells and a new GMP cell-bank suite. The suite enables independent cell-bank production and expands storage capacity for customer cell banks. Furthermore, analytical capacities were expanded with a new microbiology laboratory and equipment for process and product characterization. A modern eDMS system now enables the automatic handling of GMP documentation. As a result, Wacker Biotech’s Jena site is fully equipped to supply the fast-growing market for biologics. Future-oriented therapeutic agents now make up 25 percent of the global pharmaceuticals market.

Another positive signal came with the recent visit from the Brazilian health authority ANVISA. After a five-day inspection of the production facility in April 2018, the ANVISA team confirmed that the Jena site complies with the Good Manufacturing Practice (GMP) principles and standards for the production of high-quality active ingredients. The health authority not only praised the GMP system itself, but also the outstanding organization and the professionalism of the WACKER employees.

The pre-approval inspection by ANVISA experts was arranged, because one of WACKER's customers intends to market its cancer medication in Brazil. Wacker Biotech has been producing the active ingredient using a new, efficient, recombinant method since 2016. "We already received approval from the European Medicines Agency (EMA) in February 2016. With the successful ANVISA inspection, we now have further confirmation from a respected authority that we are able to provide our customers with outstanding products and efficient production processes," emphasized Dr. Susanne Leonhartsberger, managing director of Wacker Biotech GmbH. "This positive assessment makes Wacker Biotech an expert and certified partner for all customers who want to sell their products on the Brazilian market."

About Wacker Biotech

Wacker Biotech GmbH is a full-service contract manufacturer of biopharmaceutical proteins based on microbial systems. The company's services range from molecular biology, analytical services and process development through to the GMP-compliant manufacture of clinical test samples and pharmaceutical actives for the commercial market at the GMP-compliant, FDA and EMA-certified production plants in Jena and

Halle, Germany. Above all, Wacker Biotech offers proprietary technologies that satisfy market needs for cost-efficient production and maximum quality. Wacker Biotech is a wholly-owned WACKER subsidiary.

For further details, visit the following website:

<https://www.wacker.com/biologics>



A cleanroom for producing biologics at WACKER's Jena site. Bacteria in the fermenters help produce active proteins for medications used, for example, to treat cancer and multiple sclerosis.

(Photo: Wacker Chemie AG)

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The Company in Brief:

WACKER is a globally-active chemical company with some 13,800 employees and annual sales of around €4.9 billion (2017).
WACKER has a global network of 23 production sites, 21 technical competence centers and 50 sales offices.

WACKER SILICONES

Silicone fluids, emulsions, rubber grades and resins; silanes; pyrogenic silicas; thermoplastic silicone elastomers

WACKER POLYMERS

Polyvinyl acetates and vinyl acetate copolymers and terpolymers in the form of dispersible polymer powders, dispersions, solid resins and solutions

WACKER BIOSOLUTIONS

Biotech products such as cyclodextrins, cysteine and biologics, as well as fine chemicals and PVAc solid resins

WACKER POLYSILICON

Polysilicon for the semiconductor and photovoltaic industries