

BILFINGER

now!

we create

Digitalization in the process industry – success factors for SMEs

we care

COVID-19 vaccine:
Successfully executing the complex conversion of production plants

we can

INTELLIGENT PLANTS IN THE LIFE SCIENCE SECTOR

We talk to Professor Christoph Herwig (Vienna University of Technology) about a new gene therapy and about digital twins in production



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A hand wearing a blue nitrile glove holds a clear glass vial with a black cap. The vial has a white label with the text 'Vaccine COVID-19' in bold black letters. In the background, a medical syringe is visible. The entire scene is set against a light background with faint, stylized green line art of a virus particle. A vertical green bar is on the left side of the image.

**COVID-19 VACCINE:
A RACE AGAINST TIME**

SUCCESSFULLY EXECUTING THE COMPLEX CONVERSION OF PRODUCTION PLANTS

Many pharmaceutical and biotech companies are currently working on the production of Corona virus vaccines. Pressure to get this done quickly is enormous: many people are still infected, the global economy is suffering and hundreds of thousands of people have lost loved ones. Although vaccinations have already begun in many countries, it will take time to produce a sufficient number of vaccine doses for everyone who needs one.



Given the shortage of vaccine, what is needed now more than anything else is greater speed in production. Bilfinger helped a pharmaceutical company quickly convert its plant for the industrial production of Corona vaccines.

Fast deployment and assembly under tight deadlines

In a short period of time and under tremendous pressure, the Bilfinger team delivered and installed systems, valves and piping for the conversion of a plant for a well-known customer in the pharmaceutical industry. The equipment had previously been used to manufacture other biotech industry products.

“As a long-standing partner of the pharmaceutical industry, we are proud to contribute to the fight against the Corona pandemic with this project,” says Christian Gebetsberger, Managing Director/Head of Operations at Bilfinger Industrietechnik Salzburg GmbH. “Thanks to our experienced team and a resilient network of suppliers, we were able to provide and assemble the required plant components at very short notice. This was critical to the success of the complex conversion – because time is the decisive factor in vaccine production.”

The team from Austrian subsidiary Bilfinger Industrietechnik Salzburg delivered and installed equipment, valves and piping. Various media required for vaccine production will flow through these pipes. Bilfinger won the order at very short notice and performed the work within just a few months.

The biggest challenge was to quickly purchase the required parts in a very short period of time, get them on site and assemble them. Due to the extreme time pressure, planning and construction were carried out simultaneously on the construction site.

Expertise in plant engineering

Bilfinger assumes responsibility for the design, manufacture and assembly of process units and plants for the biotechnology and pharmaceutical sectors in countries all over the world. The range of services covers the entire lifecycle of a plant.

We provide project management, engineering, process technology as well as qualification and offer piping construction as well as tank and apparatus engineering, E/I&C (electrical, instrumentation and control), automation and much more.

“As a long-standing partner of the pharmaceutical industry, we are proud to contribute to the fight against the Corona pandemic with this project.”

CHRISTIAN GEBETSBERGER, MANAGING DIRECTOR/HEAD OF OPERATIONS AT BILFINGER INDUSTRIE-TECHNIK SALZBURG GMBH

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SUCCESSFUL WITH INTELLIGENT PLANTS

Dwindling margins as a result of generic pharmaceuticals and the potential presented by a promising new cell and gene therapy from the USA: In an interview with Bilfinger now!, Christoph Herwig, Professor of Biochemical Engineering at the Vienna University of Technology, talks about trends in the pharmaceutical and life science industries and what digital twins have to do with them.

What trends are currently most prominent in the industry?

As I see it, there are two major trends. The first is cost pressure – something that the biopharmaceutical industry hadn't previously encountered to any significant extent. This cost pressure comes from generics, which are basically copies of pharmaceuticals with the same active ingredient that are already on the market and whose patent protection has expired. Generics do not require major investments in research and development because the efficacy has already been proven by the original medication and the risk of failure in a clinical trial is much lower. This makes generics an affordable alternative. With "normal" tablets such as ibuprofen, for example, it is therefore extremely difficult for manufacturers to make any money.

The second trend is cell and gene therapy – a new procedure developed in the USA that is now being transferred to Europe. It involves taking blood from a patient, purifying the cells, modifying them and putting them back into the body to cure cancer, for example. Gene therapies seek to cure diseases by replacing the missing or defective version of a gene in a patient's cells with an intact gene. These therapies are very complex and are currently among the most expensive drugs in the world.

This is because only very small amounts of blood can be taken at any one time, limiting the number of possible tests, and the pressure to succeed is intense. The biggest challenge is that the testing material, such as blood, differs from person to person. Establishing a standard process is therefore difficult. A well-known pharmaceutical company had a license to manufacture a product, but cannot bring it to market because it does not work the same way in all people. There are companies that are already successful with cell and gene therapy, but there is definitely room to expand in this area.

About Professor Christoph Herwig:

Christoph Herwig, bioprocess engineer from RWTH Aachen, worked in industry in the design and commissioning of large chemical facilities prior to entering his interdisciplinary PhD studies at EPFL, Switzerland in bioprocess identification. He subsequently positioned himself at the interface between bioprocess development and facility design in biopharmaceutical industry. Since 2008, he has been full professor for biochemical engineering at the Vienna University of Technology. The research area focuses on the development of data science methods for integrated and efficient bioprocess development along PAT and QbD principles for biopharmaceuticals.

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How should companies in this industry position themselves for success in the market?

Companies must optimize their methods in development and production, and manufacturing must become more predictive. It is important to determine which products are suitable for which patient groups. To do this, data from individual batches must be collected, combined, evaluated and made available as platform knowledge as early as the development phase.

Companies also need to do a better job of analyzing their processes. They need a stable process if they are to obtain a good-quality end product. The quality of the raw material must be measured so that the production process can be adjusted more precisely.

Time-to-market is also a decisive factor, which means shortening the process development time and thereby increasing productivity. Whoever gets to the market fastest is the winner, as currently demonstrated by the race for the development and approval of COVID-19 vaccines.

How can Bilfinger help?

Bilfinger is there to help pharmaceutical and biopharmaceutical companies make the best possible use of their facilities. Plants are best used when production is continuously improved – already during the manufacturing process. But there is one condition: the customer's hardware must become intelligent, meaning that a plant module must be linked to a digital solution. This is made possible, for example, using Bilfin-

ger's Qubicon® software. It enables customers to significantly improve the effectiveness of their process development. In the future, product quality will be ensured during the manufacturing process through the application of mathematical models.

Another possibility for better plant utilization is the digital twin that Bilfinger offers its customers. In addition to the real plant, there is a digital image that runs in real time parallel to the actual process. Maintenance and production data are combined via the digital platform and evaluated in a forward-looking manner. The data can be used to identify where there is potential for using the plants more efficiently. Digital twins have great promise and could also be used for cell and gene therapy.



Hardware at pharmaceutical and biopharmaceutical companies must become intelligent and the process must become more predictive. In practical terms, this means that plants must be digitalized. Bilfinger helps its customers do just that."

**PROFESSOR CHRISTOPH HERWIG,
VIENNA UNIVERSITY OF TECHNOLOGY**

ENSURING SMEs CAN KEEP PACE

DIGITALIZATION IN THE PROCESS INDUSTRY

Hidden champions are the engine of Germany's economy and employment machine. They are the driving force behind countless innovations and a strong partner for companies around the world. To ensure they remain competitive in the future, many companies are forging ahead with the digital transformation. The importance of digitalization was again clearly demonstrated with the onset of the Corona pandemic. A large number of companies had to shift to remote operations within a very short period of time and were uncertain about how to digitalize their processes and systems.

"SMEs are in danger of losing their status as hidden champions if the digital transformation is not dealt with in a sustainable manner," says Franz Braun, CEO of Bilfinger Digital Next. In his opinion, the following success factors are key to the implementation of digitalization in the process industry:

- **Digitalization is not an end in itself:** It must deliver added value for the customer, through reduced costs, for example.
- **Digitalization requires leadership:** The main parameters for the digital strategy must be clearly developed and defined by senior management.
- **Digitalization is 50% technology and 50% organizational development:** Employees are often forgotten when it comes to digitalization. They need to be integrated and given relevant training.

"To date, SMEs in particular have managed to postpone digitalization or they have been unable to successfully implement pilot projects," Braun explained in his **presentation** at the Festival INDUSTRY forward Expo, a digital conference on industry-related topics held from February 23 to March 16, 2021. "With Bilfinger's digital solutions, we are addressing the needs of SMEs in the process industry."

Bilfinger Digital Next focuses on the area that has the greatest leverage for the process industry: Operations 4.0, the digitalization of all production-related activities in the process industry. In addition to actual production, this also includes topics such as energy and CO2 optimization, engineering, plant documentation, maintenance and knowledge management. And we cannot overlook corporate organization and culture – they are of course interconnected in a variety of ways.

Advantages for customers include productivity increases of 10, 15 or even 30 percent. Unscheduled downtime can be reduced by up to 25 percent, maintenance costs can be cut by up to 10 percent and quality improvement can be enhanced by up to 7 percent.

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With Bilfinger's digital solutions, we are addressing the needs of SMEs in the process industry."

FRANZ BRAUN, CEO OF BILFINGER DIGITAL NEXT GMBH

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“ENSURING QUALITY AS EARLY AS THE PRODUCTION PHASE”

Bilfinger's **Qubicon® software** for enhanced process monitoring and control in pharmaceutical manufacturing has successfully passed the first industrial beta test. The test was performed by global biotechnology company **Ichnos Sciences SA** in Switzerland. The software had previously successfully undergone extensive alpha and beta testing phases in academic institutions, and the beta test was conducted to confirm its usability in real-world production and purification conditions.

**“Quality-by-Control” approach:
flexible process monitoring and control
in real-time ensure product quality**

Qubicon® automatically collects and processes all data in real time from connected equipment such as bioreactors and analytical instruments. The software thereby eliminates the need for time-consuming and error-prone manual data acquisition and processing. As an enhanced process monitoring system, it also continuously delivers information on the current status of the production process. The software has features that include “live” data comparison with reference runs (e.g. “golden batch”) and normal distributions as well as the calculation of soft-sensors and critical quality attributes (CQAs) in real time. This allows users to identify possible product quality defects during the production process and to initiate suitable control strategies in response. As opposed to the “Quality-by-Testing” approach, where inadequate product quality is normally revealed only after the production process and extensive testing, Qubicon® focuses on “Quality-by-Control”.

“With the beta test conducted by Ichnos, we undertook the final optimizations to Qubicon® and prepared it for industrial use. Qubicon® will enable our customers to vastly improve the effectiveness of their process development. Additionally, with the use of suitable mathematical models in Qubicon®, product quality can be ensured during the manufacturing process in the future.”

**GERALD BERGHAMMER, HEAD OF RESEARCH & DEVELOPMENT
AT BILFINGER INDUSTRIE-TECHNIK SALZBURG GMBH**

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END-TO-END SERVICE PACKAGE FOR THE LIFE SCIENCE SECTOR

Cost pressure, competition and the struggle to be the first to obtain market approval: Lars Malter, Managing Director at Bilfinger GreyLogix GmbH, and Claudia Nachbur, Sales Director at Bilfinger Industrietechnik Salzburg GmbH, discuss the challenges facing the pharmaceutical industry and how Bilfinger can help its customers meet these challenges.

What kinds of challenges is the life science industry currently facing in the area of plant engineering and production?

Claudia Nachbur: Cost and competitive pressures in the pharmaceutical and biotech industries are intense. The industry faces three major challenges: the first of these is time-to-market. In other words, the speed with which vaccines or other therapeutic substances reach the market is critically important. The company that is the first to obtain approval for its active ingredient has a competitive advantage. Secondly, products must be available in the highest quality and meet the strict production, safety and quality requirements of the regulatory authorities. Third, companies face the challenge of competitively pricing their products.

Lars Malter: As a trusted partner of the life science industry for many years, we are seeing a trend toward process optimization, digitalization and increased ef-

ficiency. This is where our range of services has an important role to play. With our new Life Science business line, which combines the process engineering expertise of Bilfinger Industrietechnik Salzburg with the excellent digital expertise of Bilfinger GreyLogix, we provide the industry with an end-to-end package covering all the disciplines they need to maintain control of their technical production processes. And all of it comes from a single source. Our portfolio includes services and engineering as well as technology development, consulting for optimization, qualification and validation of production processes. For us, it is vital to establish the highest possible degree of customer focus using teams that ensure long-term support directly on site.

Have the requirements of the industry changed in the course of the Corona pandemic?

Lars Malter: The pressure of getting to market with a vaccine faster has increased as a result of the Corona



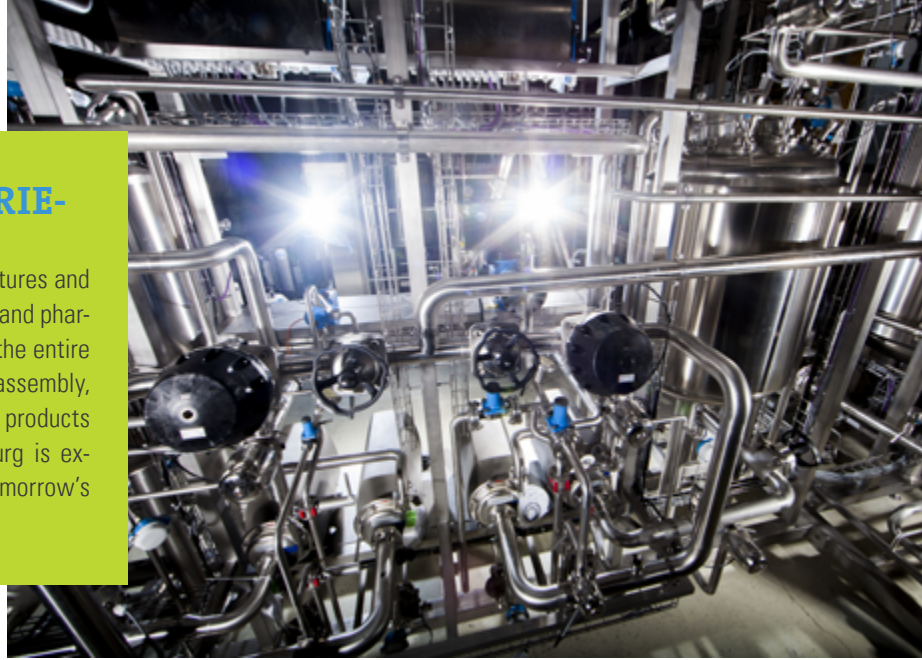
With our new Life Science business line, we provide the industry with an end-to-end service package."

LARS MALTER, MANAGING DIRECTOR AT BILFINGER GREYLOGIX



ABOUT BILFINGER INDUSTRIE- TECHNIK SALZBURG

Bilfinger Industrietechnik Salzburg designs, manufactures and installs pipelines, plants and systems for the biotech and pharmaceutical industries. The range of services covers the entire lifecycle of a plant – from the initial idea through to assembly, commissioning and maintenance. With advanced products such as Qubicon®, Bilfinger Industrietechnik Salzburg is expanding its range of services to meet the needs of tomorrow's intelligent bioprocess technology.



“ We put together a complete production plant for an American pharmaceutical company from scratch.”

CLAUDIA NACHBUR, SALES DIRECTOR AT
BILFINGER INDUSTRIE-TECHNIK SALZBURG

pandemic. We helped a pharma customer convert facilities for the industrial production of a Corona virus vaccine in record time. The support we provided for the conversion of the existing plants not only saved the customer time, but also costs. As a rule, construction of a new production plant takes approximately one to one and a half years.

What key products and services does the industry currently need from Bilfinger?

Claudia Nachbur: Our key services for technical production processes, services and consulting are well-aligned to the needs of the industry. Our services already include the basic conceptual planning of production plants, including bioreactors, plant engineering and construction, commissioning as well as maintenance and optimization of existing plants.

Lars Malter: We are constantly evolving and also cooperating with research institutions such as the Vienna University of Technology or the University of Natural Resources and Applied Life Sciences in Vienna. We have developed the Qubicon software as part of a research project. This program collects and processes – automatically and in real time – all data from connected process devices such as bioreactors

and analyzers. With our operational excellence approach, we follow the trends in the industry so that we can be even more focused on the needs of our customers and, with our portfolio, continue to be the supplier of choice for the pharmaceutical industry in the future.

What project really made an impression on you and why?

Claudia Nachbur: We put together a complete production plant for an American pharmaceutical company from scratch. Starting with the first customer meeting, where the customer gave us the specific volumes and the schedule for completion, we delivered all the services that were critical to the success of the project. We were a partner for the entire process technology, covering all trades and technical disciplines from specification (URS) through to commissioning. This included process design, engineering, automation, manufacturing, installation and documentation. It was truly an ultra-fast-track project: we had just two years to achieve what would normally have required four.

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THREE BILFINGER UNITS TOGETHER UNDER ONE ROOF

GREATER CUSTOMER FOCUS AND COMPREHENSIVE **EXPERTISE**

Bilfinger will be merging large parts of its service portfolio in Germany into one company. As **Germany's leading industrial services provider**, Bilfinger is networking its expertise in the various trades even more closely so that it can offer customers a complete range of services from a single source: from engineering and project execution to integrated services in maintenance and digitalization.

Greater customer focus with about 3,000 employees at more than 40 locations in Germany

The new company will merge the subsidiaries Bilfinger Maintenance GmbH, Bilfinger Peters Engineering GmbH and Bilfinger EMS GmbH into a single organizational unit. With around 3,000 employees at over 40 locations in Germany, Bilfinger will optimize its geographical presence and achieve even greater customer focus. The transfer of knowledge between the teams will also be facilitated, including in the area of digitalization, so that customers at all locations will be able to draw on the full scope of Bilfinger's expertise.

"As Bilfinger Engineering & Maintenance, we can offer our customers comprehensive services throughout the entire lifecycle of their plants," says Niklas Wiegand. Current customer relationships and contact persons will remain in place in the new company, as will the range of customized solutions from individual services to full-service or EPC contracts (Engineering, Procurement, Construction).

Bilfinger Engineering & Maintenance's portfolio covers the entire lifecycle of industrial plants from consulting and engineering to plant construction, assembly, commissioning and maintenance and also includes turnarounds, modifications, expansions as well as the dismantling of plants. Scaffolding, insulation and corrosion protection can also be integrated through the colleagues at Bilfinger Arnholdt GmbH.

The new company has been named **Bilfinger Engineering & Maintenance GmbH**. Customers from the process industry can now easily and efficiently access the comprehensive expertise of Bilfinger's experts via just one interface. "We already work closely together in practice," says Niklas Wiegand, Executive President Engineering & Maintenance Germany at Bilfinger. "We are now also shaping the organizational framework to further lower administrative hurdles and to create a strong and broadly-positioned partner with a comprehensive range of services for our customers."

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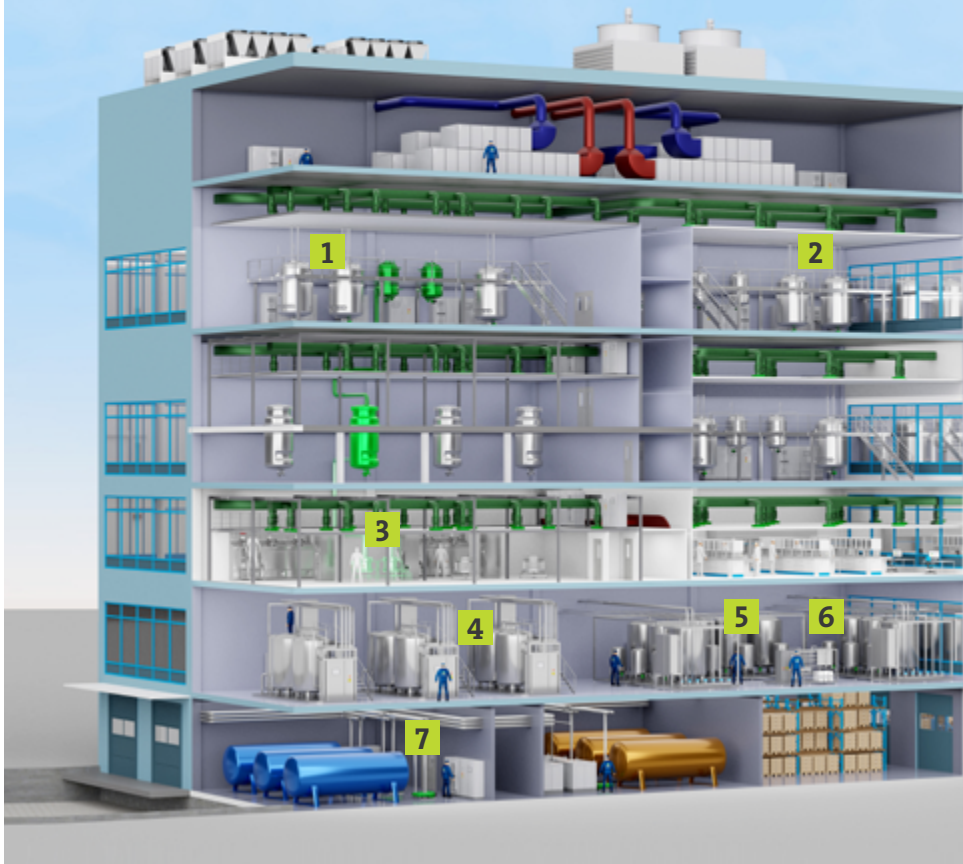
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BILFINGER SERVICES FOR THE CONSTRUCTION AND CONVERSION OF PHARMACEUTICAL PLANTS



- 1 Bioreactor
- 2 Media preparation
- 3 Purification unit
- 4 Cleaning in place station
- 5 Storage unit
- 6 Water generation unit
- 7 Clean water loops

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SEEN IN ...

... Duisburg. Green energy: How can energy companies respond to the challenge of providing a climate-friendly energy supply? Availability of regenerative energies is patchy, and energy generation is not linked to energy consumption. Consequently, in addition to the use of renewable energies, the expansion of district heating networks in combination with industrial waste heat forms the basis for a successful energy transition. One such example is Stadtwerke Duisburg's district heating storage facility which, thanks to a light installation, starts to shine as soon as it gets dark outside. As general contractor, Bilfinger was responsible for the entire storage facility, including construction work as well as basic and detailed engineering for integration into the existing plant. A clear demonstration of how the urban energy transition can succeed.



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