

BILFINGER SE




BILFINGER

PHARMACEUTICALS AND BIOPHARMA PROJECTS: WE MAKE IT WORK

FROM ENGINEERING AND TECHNOLOGY TO FABRICATION, CONSTRUCTION AND MAINTENANCE





PHARMACEUTICALS AND BIOPHARMA PROJECTS: WE MAKE IT WORK

We design, manufacture and assemble process units and complete plants. We take responsibility for engineering, project management, qualification and process technology and offer sterile, clean room and ultra-pure media technology, piping construction, equipment engineering, EI & C installations, automation and much more. And of course we also provide comprehensive maintenance services.



1

2



- 1 Superskids
- 2 Bioreactors and preparation skids
- 3 Clean water loops
- 4 Water Filtration Unit
- 5 Process Vessels in clean rooms
- 6 Bilfinger Building Information Modelling (BIM)



FROM THE CORE PROCESS TO THE COMPLETE BIOTECH UNIT

PAT SOFTWARE SOLUTION FOR BIOREACTORS

Together with a well-known university, Bilfinger has developed an innovative software solution for a QbD/PAT-compliant production in biopharmaceutical processes.

The software combines data acquisition and advanced analysis tools for cell culture production. As such, it delivers sophisticated mathematical process models, leading to an innovative Quality by Control (QbC) approach and a consistent process performance monitoring. This PAT software solution is a benchmark solution to manage the quality of the product already during the production process. It creates a real added value for biotech production processes as a superior solution for increasing production efficiency and limiting batch production losses.

SUPERSKIDS FOR UPSTREAM PROCESSING

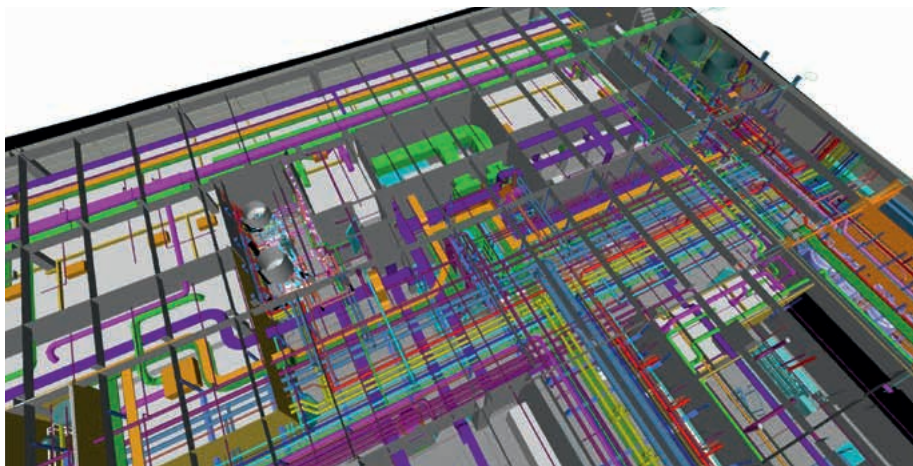
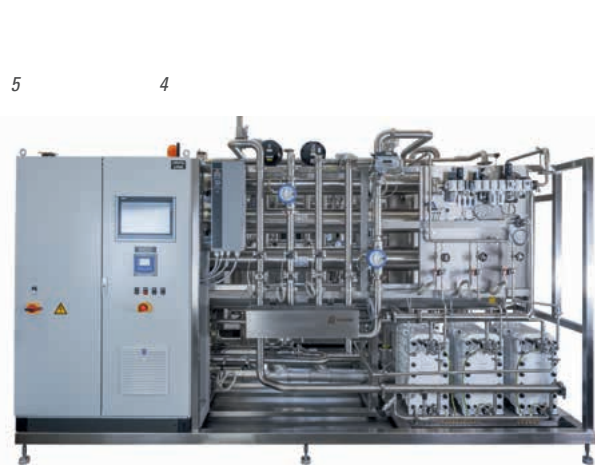
Bilfinger has unique know-how in providing modular concepts for the supply of pharmaceutical processing units and Media- & Buffer Preparation Units – from design to in-house manufacturing. We are able to fully assemble complete sub-modules in our workshops and perform the corresponding FAT. We then dismantle the modules and transport them for re-assembly to the customer site. The concept is based on a “plug and play” model, ensuring premium quality of the delivered units while at the same time significantly reducing construction time for the customer.

To get the most out of your process, you can also connect multiple bioreactor superskids with our PAT Software Solution to optimize predictive control of the production.

PURIFICATION UNITS FOR DOWNSTREAM PROCESSING

Bilfinger has strong capabilities in the integration of purification technology covering both filtration steps and low, medium and high pressure chromatography. We deliver columns as well as filtration systems including buffer-preparation, storage and distribution systems.

Using the most efficient technology, we design and manufacture such purification units in-house, fully matching the needs of our customers and their individual processes. We can also provide an integrated end-to-end solution, reducing complexity for the customer and optimizing production.



BILFINGER BUILDING INFORMATION MODELLING

Bilfinger has developed a comprehensive Building Information Modelling (BIM) software solution, utilising multidisciplinary design input and capabilities.

The BIM solution software is a multi-layer engineering database that manages all data related to layouts, engineering, construction, operation and maintenance of a plant, eliminating clashes during design and offering great value for our customers from capex to opex.

Based on our strong process know-how in biotech pharmaceutical processes, Bilfinger incorporates preliminary design of the process equipment into the BIM model from the early design phase of the plant, thus eliminating design iterations and delivering superior design value for our customers and also saving them time.

Moreover, the BIM can be easily integrated with smart engineering data solutions such as "COMOS".

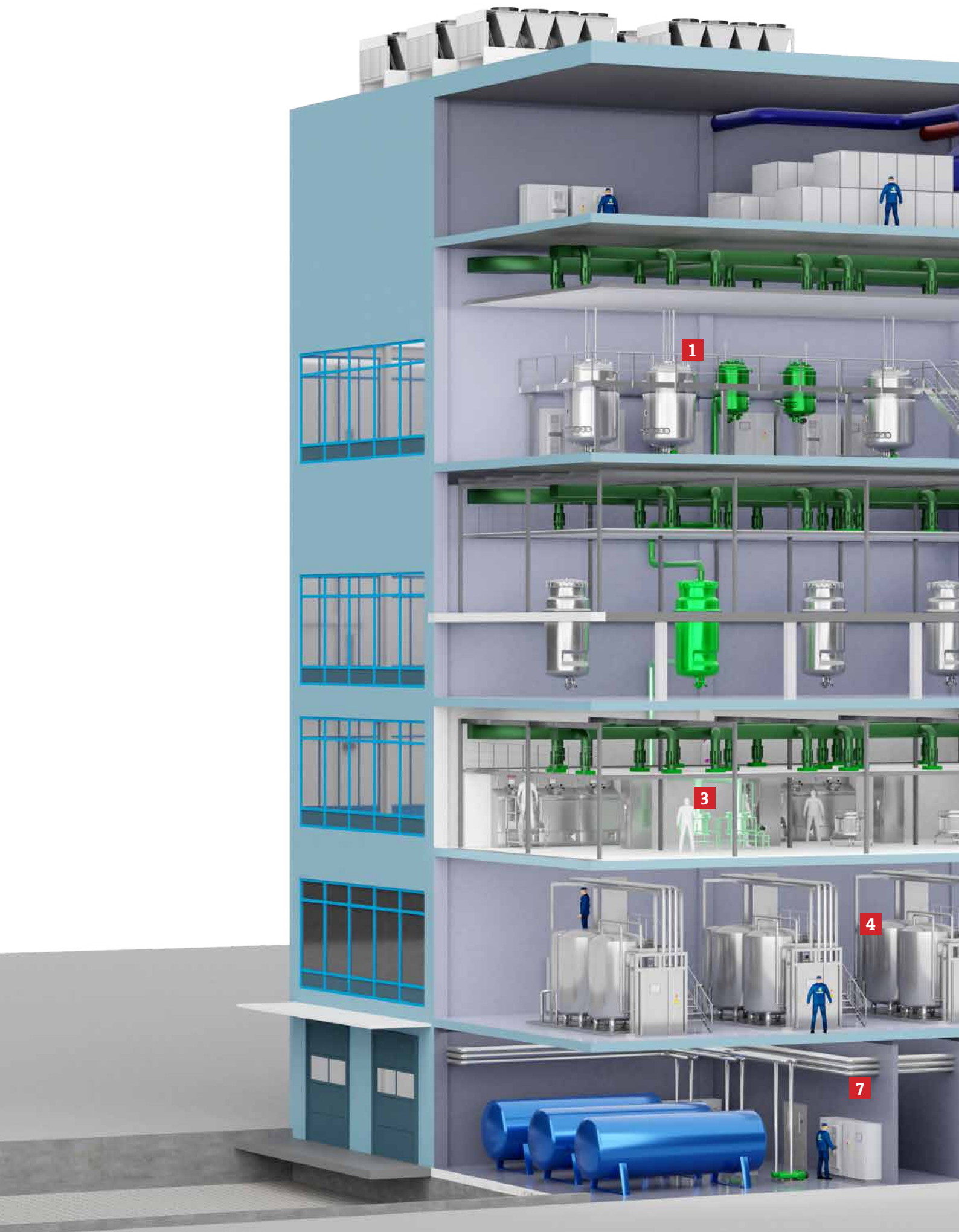
CLEAN WATER SYSTEMS

Bilfinger is one of Europe's largest suppliers of pure media generation and distribution systems. We design and deliver the complete range of clean water generators including ion exchangers, reverse osmosis, EDI and distillation units. We have developed a PW / HPW generator method that could save as much as 25% of feed water and energy consumption, thereby substantially reducing operation costs for our customers.

Our very experienced field construction management group and highly qualified construction staff can install clean piping systems up to and over 10 km long, ranging from DN 15 up to DN 300. We ensure all clean piping media is delivered at the right quality at every point of use in the plant.

FULL CONTRACTING SOLUTIONS

Bilfinger fully manages the design and construction of small biotech pharmaceutical production plants on an EPC basis. We can team up with capable partners for the building construction, HVAC and clean rooms. With our in-house capabilities in engineering, construction and overall project management, we ensure seamless project execution while providing lower complexity and contracting costs to customers.





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

LIFE CYCLE VIEW

1. PROJECT CONSULTANCY

Bilfinger provides the full range of consultancy services to support the pharmaceutical industry in developing their investment projects. Our services cover project development from the initial concept, feasibility studies as well as safety-environmental and sustainability studies including (c)GMP services and CQV (Qualification and Validation).

We also offer a full range of EPCm services including engineering, project management, project services, procurement services and multidisciplinary construction management. Our plant engineering is supported by our BIM software that allows an easy multidisciplinary optimization of all design phases and is a superior baseline for plant construction including plant operation and maintenance.

5. CLEAN WATER LOOPS

We can design your clean water loops by running through the various scenarios of production, using our software to simulate operation of the water loop. These simulations also take into account requirements resulting from standby operation during holidays or maximum demand situations. We design the production capacity, storage and distribution of WFI, HPW and PUW according to cGMP standards including the design and in-house manufacturing of clean water generation units. We assemble and test all pipe runs on site and provide a reliable end-to-end solution to our customers.

Project
Consultancy

Engineering

Procurement/
Fabrication

Construction/
Commissioning/
Startup

2. PROCESS DESIGN FOR BIOTECH UNITS

Bilfinger develops the concept design and basic engineering for biotech production lines and clean media systems. Our decades-long experience allows us to rely on various best practices with regard to the process design of plants, packages and skids as well as the design of process equipment including DQ. We self-perform all the engineering activities from concept design to detailed mechanical design and from fluid-flow analysis to automation software programming. Our engineers perform both the subsequent FAT/ SAT efforts and also the following IQ/OQ performance.

3. BIOREACTORS

Having built the first bioreactors in the 1980's, Bilfinger has gained extensive experience in designing and manufacturing these systems. Our expertise has stood us in good stead in developing our own bioreactor line, covering a range from 15 l laboratory size up to 4,000 l, which we designed on a modular basis. Whether for bacterial or cell culture cultivation, it offers the right solution. We also design and manufacture tailor-made individual fermenter solutions for special applications ranging up to 40,000 l.

4. MANUFACTURING AND SKID ASSEMBLY OF BIOTECH PROCESS UNITS

Bilfinger builds large and complex skid-mounted biotech process units in various workshops throughout Europe. These modules are assembled to conduct a complete FAT, leading to easier and faster integration at the customer's site. Combining fully-computerized logistics and inspection of received goods with lean manufacturing management and state-of-the-art welding and inspection technologies, high-quality manufacturing is ensured and fully tracked. We also perform tests with water and other fluids already in our workshops.

6. PLANT CONSTRUCTION

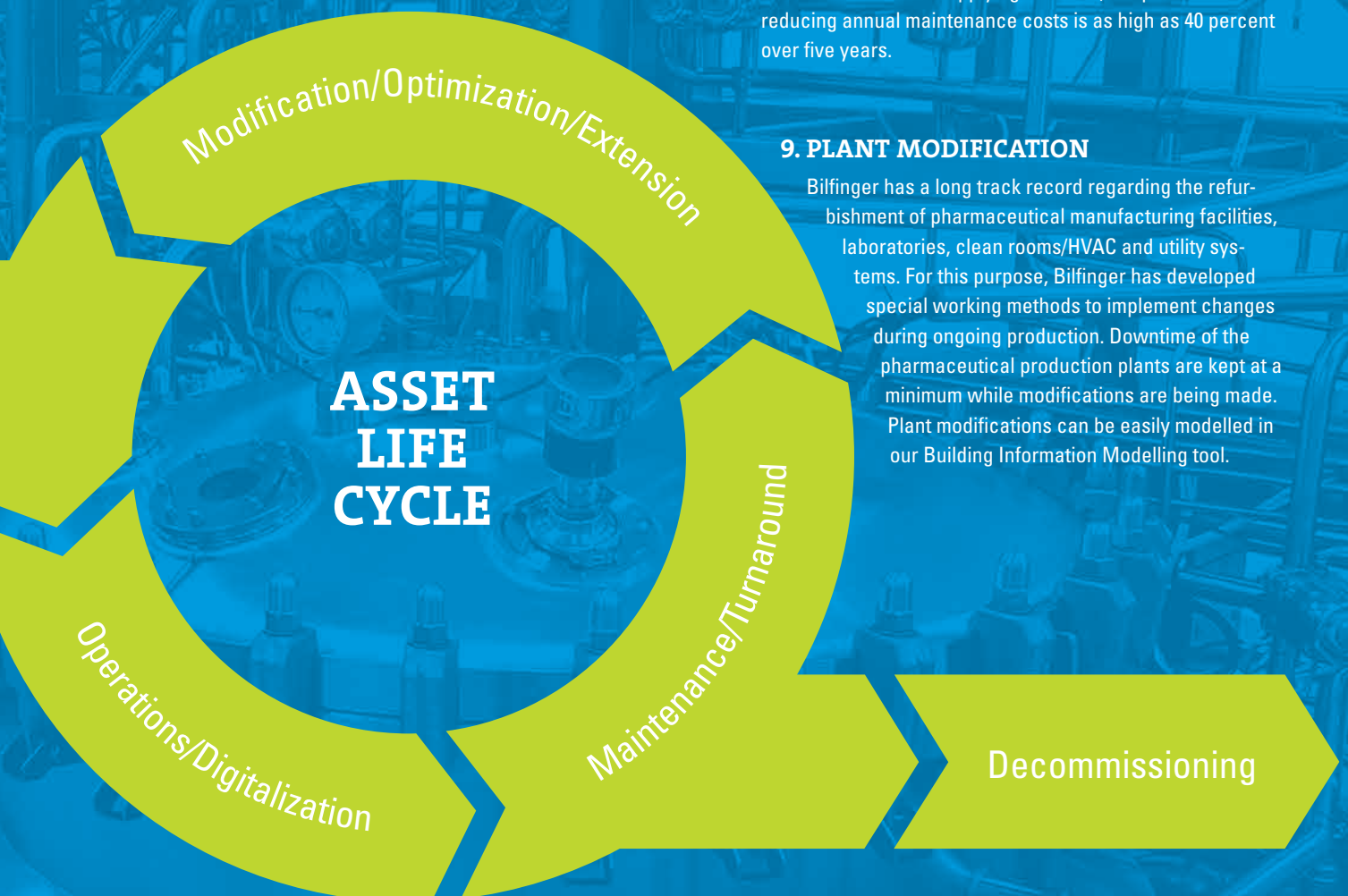
Bilfinger has extensive experience in installing laboratories, complete simple biotech plants and large processing units in complex biotech facilities. We conduct most of the work for field construction with our own resources, including equipment setting, welding, cabling and the installation of all instrumentation and control equipment. Our project management systems combined with our strong construction management capabilities ensure the proper control of schedule and costs as well as quality of the field installation work. Our engineers can also team up with the customer's teams to perform all the SAT activities through to the OQ.

8. BILFINGER MAINTENANCE CONCEPT

Our Bilfinger Maintenance Concept (BMC) ensures that all our customers have access to the same high Bilfinger maintenance standards. We understand maintenance as an integral part of the value chain and have several thousand engineers, technicians and skilled workers in this area. For the customer, this means comprehensive expertise combined with a high degree of flexibility. Because in times when there are less maintenance or repair tasks to carry out, we can assign our employees to other orders and make fixed costs variable. When applying the BMC, the potential for reducing annual maintenance costs is as high as 40 percent over five years.

9. PLANT MODIFICATION

Bilfinger has a long track record regarding the refurbishment of pharmaceutical manufacturing facilities, laboratories, clean rooms/HVAC and utility systems. For this purpose, Bilfinger has developed special working methods to implement changes during ongoing production. Downtime of the pharmaceutical production plants are kept at a minimum while modifications are being made. Plant modifications can be easily modelled in our Building Information Modelling tool.



7. CONNECTED SKID MOUNTED BIOTECH PROCESS UNITS FOR OPERATIONS / DIGITALIZATION

Data management plays a crucial role when it comes to further improving biopharmaceutical production processes. Data generated by our PAT software solution can be linked to other process units in the production process. This way, production

across the whole plant can be measured and stored more accurately. By doing so, production can be improved considerably. Bilfinger complies with all GMP automation regulations such as GAMP and 21CFR part 11



WE ARE BILFINGER

We offer international engineering and local maintenance. Our portfolio covers the entire value chain from consulting, engineering, manufacturing, assembly to maintenance, plant expansion as well as turnarounds. It also includes environmental technologies and digital applications. We increase the efficiency of assets, ensure a high level of availability and reduce maintenance costs.

BILFINGER AT A GLANCE

Our organization along two complementary business segments enables us to accompany our customers along the entire life cycle of their assets: the capex side is covered by our Engineering & Technologies (E&T) segment, while our Maintenance, Modifications & Operations (MMO) segment addresses the opex side. Within E&T, we develop, construct and expand industrial plants. Within MMO, we assume responsibility for industrial maintenance. And while the MMO segment offers its services locally in four core regions, E&T is a project and technology business with an international setup.



Oil & Gas



Chemicals &
Petrochemicals



Energy &
Utilities



Pharmaceuticals
& Biopharma



Metallurgy



Cement

We have a particular focus on six industries:

Oil & Gas, Chemicals & Petrochemicals, Energy & Utilities, Pharmaceuticals & Biopharma, Metallurgy, and Cement. Our 36,000 employees ensure that our customers can focus on what they can do best: their core business.

Bilfinger SE

Engineering & Technologies

Europaallee 1
46047 Oberhausen
Germany

sales.contact@bilfinger.com
www.bilfinger.com

