



**BILFINGER**

## Press Release

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### **Bilfinger's Qubicon® software passes industrial field test: advanced process control in the biotech industry**

- **First industrial beta test phase of Qubicon® successfully completed**
- **“Quality-by-Control” approach: flexible process monitoring and control in real time ensure product quality**
- **Central processing of all lab data increases efficiency and data integrity**

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

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".

Gerald Berghammer, Head of Research & Development at Bilfinger Industrietechnik Salzburg: "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."



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The focus of the industrial beta test was to assess the integration, processing and management of all data generated in upstream (cell culture production) and downstream (purification) lab operations at Ichnos. The creation of a centralized database will enable the identification of previously unknown process correlations, thereby deepening the understanding of the entire process chain. With this data, industrial users of the software will be in a position to enhance real time monitoring and advance process control.

Prior to the creation of Qubicon<sup>®</sup>, there was a gap in the market for automated solutions that seamlessly integrated data from upstream and downstream process development. Ichnos worked with Bilfinger to assess the software and provided input for the further development of the product.

[Bilfinger Industrietechnik Salzburg](#) has been developing the Qubicon<sup>®</sup> software for four years now. As part of a joint research project, the University of Natural Resources and Applied Life Sciences in Vienna, Austria, delivered the scientific fundamentals. With its “Quality-by-Control” approach, Bilfinger is moving beyond the much-discussed concepts of “Quality-by-Design” (QbD) and PAT. Qubicon<sup>®</sup> monitors critical quality features and process states in real time and enables straightforward enhanced control strategies.

Bilfinger Industrietechnik Salzburg designs, manufactures and installs piping, plants and systems for the biotech and pharmaceutical sectors. The scope of services covers the entire life cycle of a plant - from the idea through installation and commissioning to maintenance. With progressive products such as Qubicon<sup>®</sup>, Bilfinger Industrietechnik Salzburg is expanding its range of services toward the intelligent bioprocess technology of tomorrow.

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Bilfinger is a leading international industrial services provider. The Group enhances the efficiency of assets, ensures a high level of availability and reduces maintenance costs. The portfolio covers the entire value chain from consulting, engineering, manufacturing, assembly, maintenance and plant expansion to turnarounds and also includes environmental technologies and digital applications.

The company delivers its services in two service lines: Engineering & Maintenance and Technologies. Bilfinger is primarily active in Europe, North America and the Middle East. Process industry customers come from sectors that include chemicals & petrochemicals, energy & utilities, oil & gas, pharma & biopharma, metallurgy and cement. With its ~ 30,000 employees, Bilfinger upholds the highest standards of safety and quality and generated revenue of €3.5 billion in financial year 2020.

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