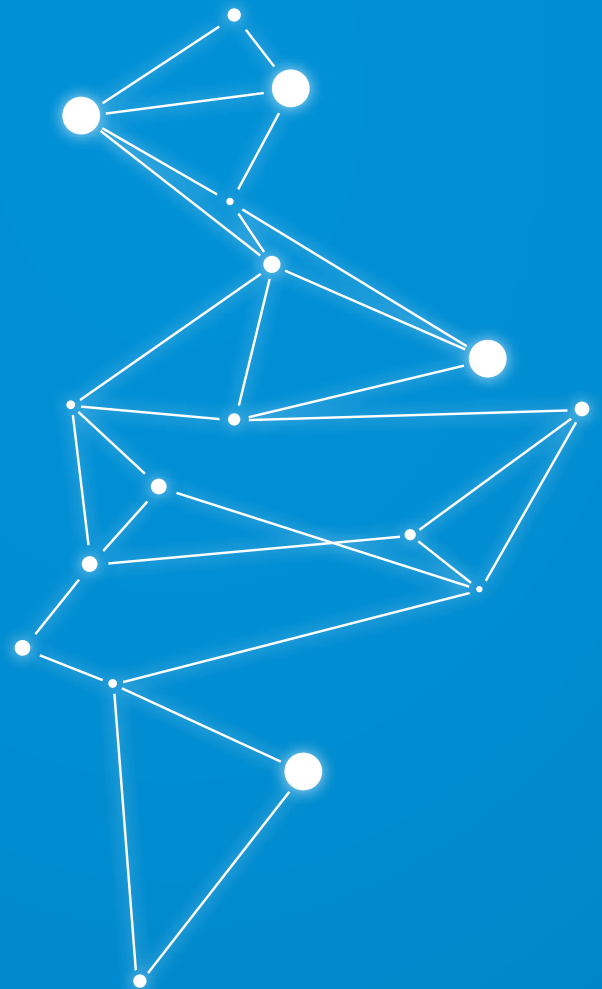




QUALITY BY CONTROL

QUBICON[®]

**THE SOFTWARE SOLUTION
FOR ADVANCED PROCESS
MONITORING AND CONTROL**



KEY FEATURES AT A GLANCE

Data management and processing



- › Client-server architecture with unlimited access points
- › Libraries as main access to comprehensive database including meta information
- › Supports various communication interfaces and data protocols
- › Combines equipment in a flexible way
- › Integrates, processes and manages all process data
- › Imports complete data sets, single values or sampling data

Process comparison



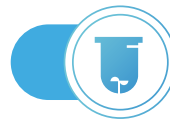
- › Calculates and depicts deviations from other processes in real time
- › Golden batch comparison
- › Alerts if values differ from the reference range
- › Time offset functionality
- › Imports complete data sets
- › Depicts data from several processes in one chart

Data visualization



- › Data shown in real time
- › Wide range of visualization options
- › Rapidly accessible process overview
- › Process- and project-related chart organization
- › Up to five y-axes in one chart

Real-time monitoring



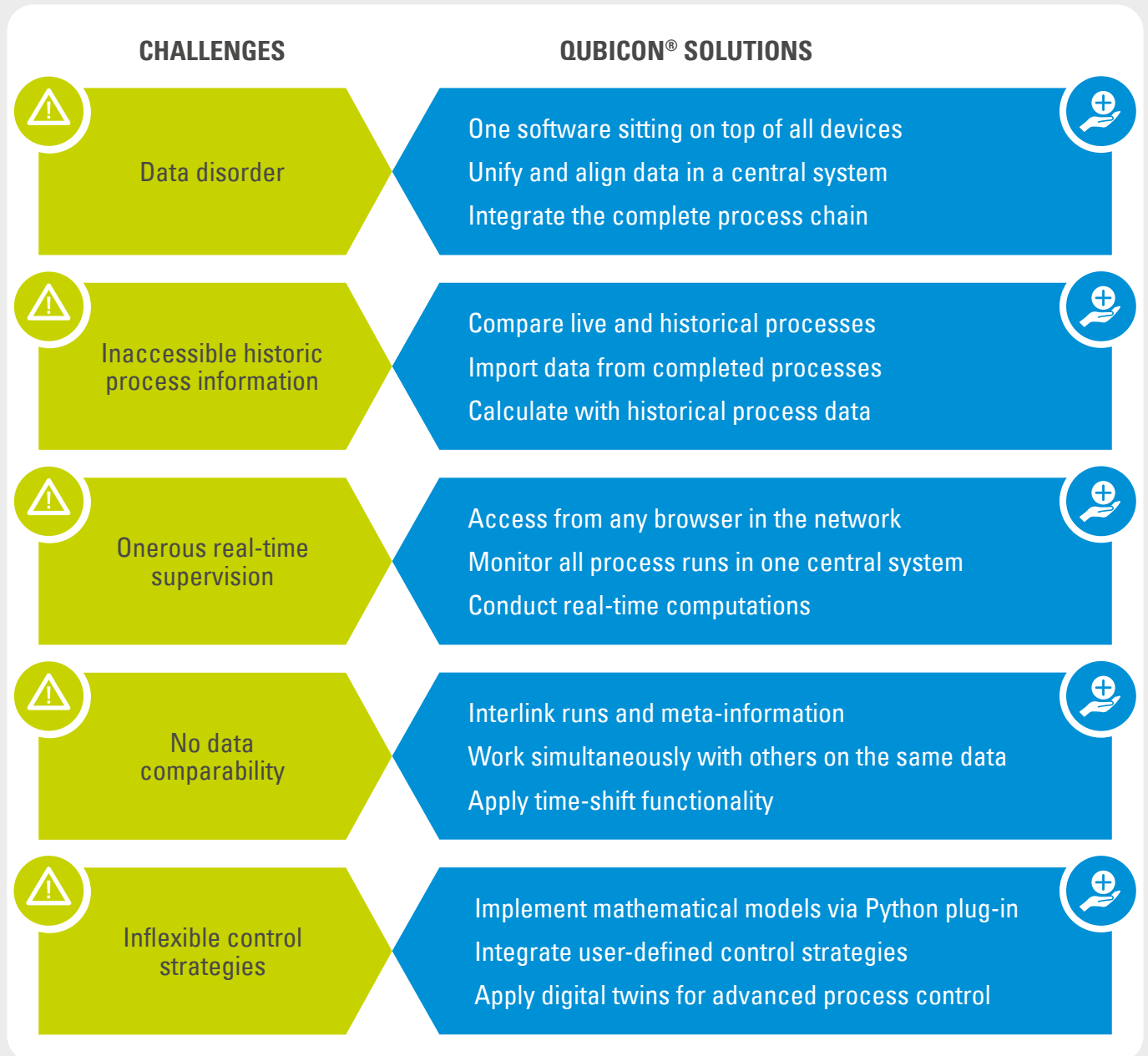
- › Online data from process units or additional analysers
- › Equipment is directly connected via OPC UA or via PAT-Box
- › Prevents batch rejection
- › In-process product quality control
- › Dynamic manufacturing processes

Advanced process control



- › Real-time and retrospective individual calculations
- › Soft-Sensors, key performance indicators (KPIs), setpoints, process alerts
- › Model based and predictive control
- › State-of-the-art control strategies such as feed on demand

ADDED VALUE TO YOUR PROCESS



THE ALL-IN-ONE SOFTWARE SOLUTION: QUBICON®

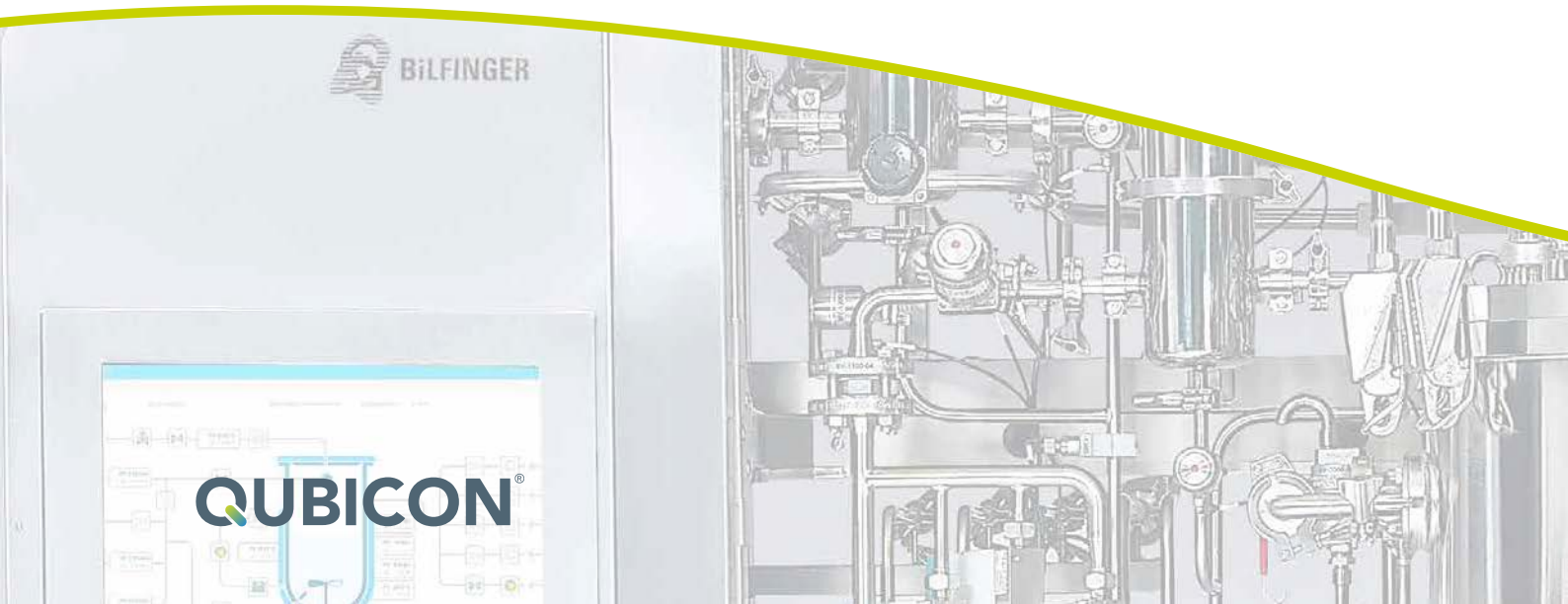
Qubicon® is a software application that offers solutions to common challenges faced in production processes. It has been designed with the industry's priorities in mind, rendering the advanced planning, monitoring and analysis of processes both easy and intuitive. Qubicon®'s modular architecture enables users to customise the actual functionalities needed in the respective workflow. Qubicon® ultimately makes it possible to implement the Quality by Control concept to processes [1].

The heart of Qubicon® is its database, which features data acquisition, integration and management from various input sources. Since Qubicon® is integrated on top of the existing equipment, it has a very wide scope of application possibilities. Almost any device can be connected to the

software to achieve bidirectional data transfer, making it feasible to manage and integrate different process devices.

The web-based software runs on a server infrastructure and is simultaneously accessible for multiple clients. A user gains access to Qubicon® by means of an identification and authentication procedure. Operators can access Qubicon® from any client computer in the entire local network and are able to work on process data at the same time without interfering with each other.

[1] Sommeregger, Wolfgang, et al. "Quality by control: Towards model predictive control of mammalian cell culture bioprocesses." *Biotechnology journal* 12.7 (2017).



ENHANCED REAL-TIME MONITORING

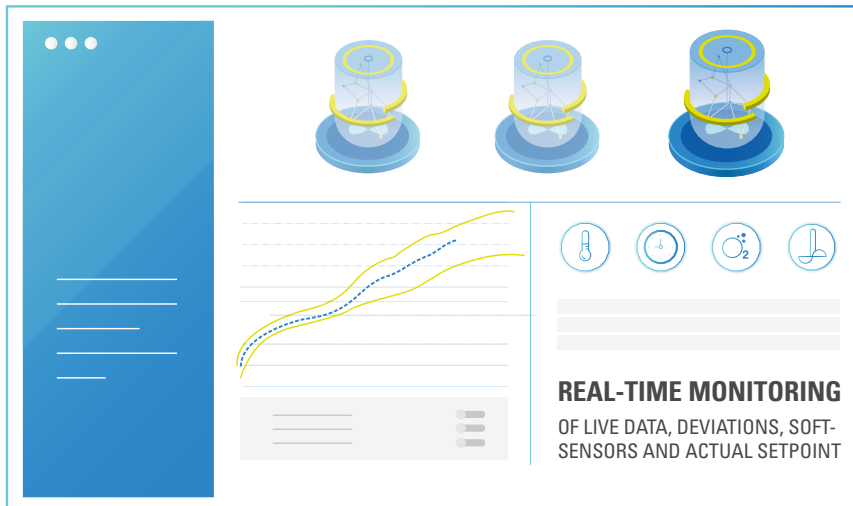
The **Monitor** module represents an essential organization and management tool for all processes, providing the user with a clear overview of all process-relevant data in real time. Meta-information, equipment details or applied control strategies can also easily be visualized directly from this module.

At any time during a running process, calculations can be conducted with real-time data simply by applying a Soft-Sensor. In general, Soft-Sensors supply real-time information for characteristics that cannot be directly measured or critical quality attributes (CQAs) using mathematical models and online sensor data. The **Calculate** module provides the perfect environment for implementing such models using the Python scripting plug-in.

Python is a popular, powerful programming language that enables various calculations to be performed, ranging from basic operations to complex computations. Not

only can calculations in Qubicon® based on mathematical models be executed on historical data, but also on live processes. Once a model is stored in the database, it can be applied as often as needed. Only a few clicks of the mouse are needed to apply the model itself since the desired sensors are simply selected as input variables for the model.

All this means that Qubicon® takes the monitoring of manufacturing processes to the next level by comparing live data to reference runs and calculating key performance indicators in real time, making it possible to compare actual process conditions to desired ones and, ultimately, observe the direction that the process is taking and verify its performance on an ongoing basis. Moreover, individually customizable process alerts mean that it can be seen very quickly if critical process parameters are deviating from the specified operation ranges.

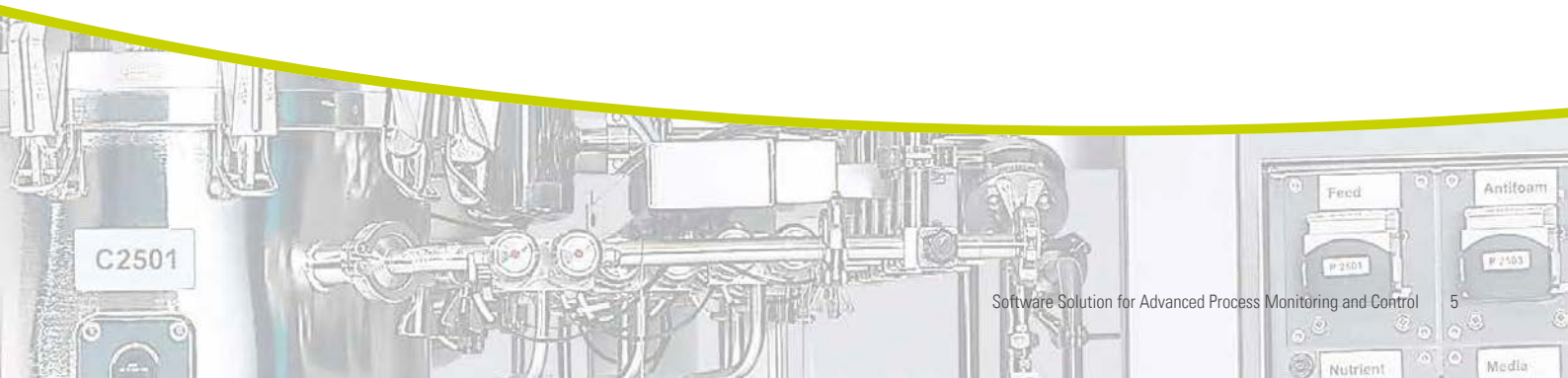


Clear overview of all process data

Alerts if values differ from the reference range

In-process product quality control

Straightforward Soft-Sensor application



IMPROVED PROCESS COMPARISON

Qubicon® uses **Charts** to provide a flexible visualization engine that enables data from various sources to be displayed. The module makes it possible to compare running processes to reference runs (e.g. golden batch) in real time. A time-shift functionality here helps to properly synchronise these processes to achieve a real degree comparability.

There is also the option of visualizing several processes simultaneously by placing data of interest within one chart or positioning up to four different charts in the same frame so as to make it easier to compare and maintain sight of the big picture. Identical physical quantities are grouped to one axis per default and up to five different y-axes are supported in one diagram.

A navigator below each chart facilitates orientation and enables the user to navigate quickly through the whole process in zoom mode. Various flexible view options also enable process data to be inspected in a quick and straightforward way.

In addition to these diverse visualization options, the **Calculate** module offers numerous ways of conducting cross-process calculations within Qubicon®. The results of such computations can then again be incorporated as input variables for use in additional calculations. As such, Qubicon® provides an extensive but highly flexible range of process comparison options.

- 🔍 Trending of live and historical data
- 🔍 Comparison to reference runs
- 🔍 Time-offset functionality
- 🔍 Cross-process visualizations and calculations



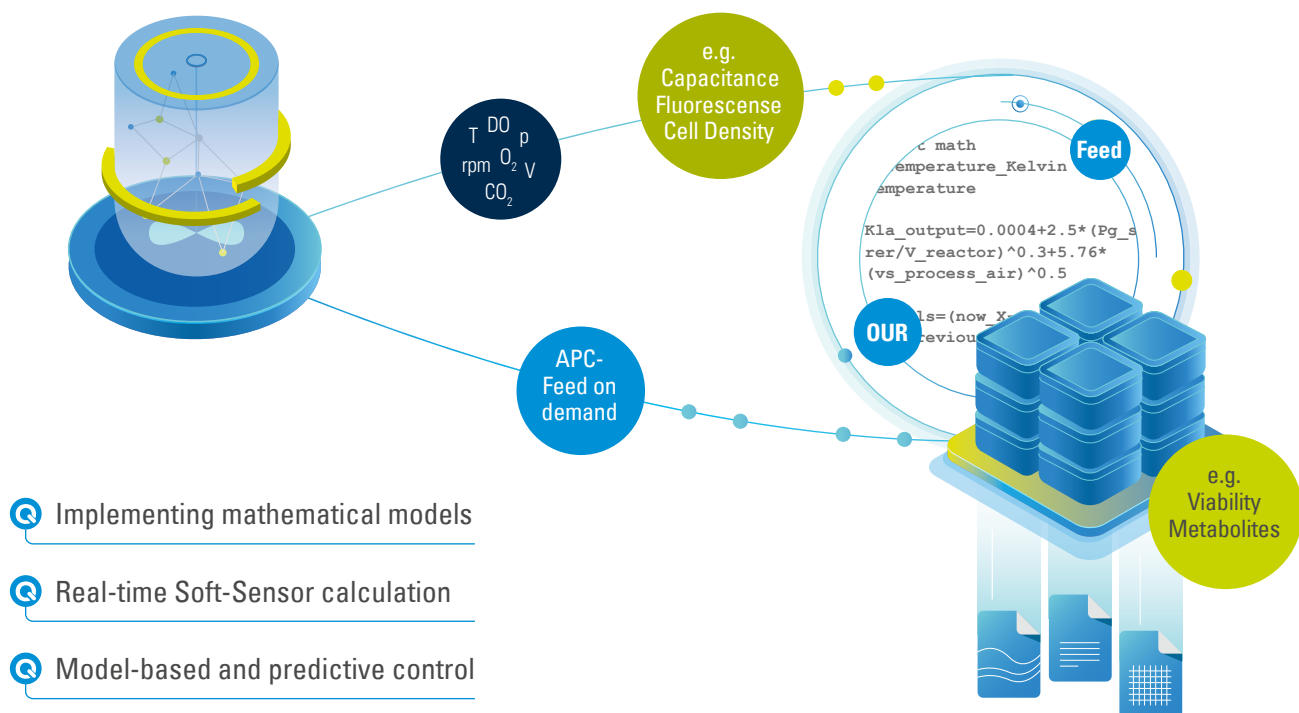
INTEGRATION OF ADVANCED PROCESS CONTROL

One of the main features of Qubicon® is the possibility it offers to implement user-defined computations and control strategies in processes already while planning them. This means that mathematical models are immediately calculated from the time the process starts. Not only can they be applied for monitoring purposes, but they can also be used as model-based or model-predictive control strategies. The option of applying setpoints or alerts during a process in selected phases is also enabled.

One such an example for a state-of-the-art control strategy in bioprocessing, "feed on demand", can easily be realized using Qubicon®'s **Plan** module as follows: Standard online sensors such as temperature, pH or dissolved oxygen and even data from advanced analysers such as

Raman, near-infrared or 2D-fluorescence spectroscopy, are recorded in real time. These data are used as input variables to compute biomass progression on a continuous basis, which then serves as an input variable to calculate the required amount of feed media. The result is then applied to control a feeding pump throughout the entire process or only in process phases of choice.

In conclusion, the higher-level software Qubicon® is capable of full data integration, processing and management. It enables mathematical models to be applied to historical data as well as running processes in an uncomplicated way, meaning that the software can be used in real time for state-of-the-art control strategies and, ultimately, for implementing the Quality by Control concept to processes.



DATA MANAGEMENT AND COMMUNICATION INTERFACES

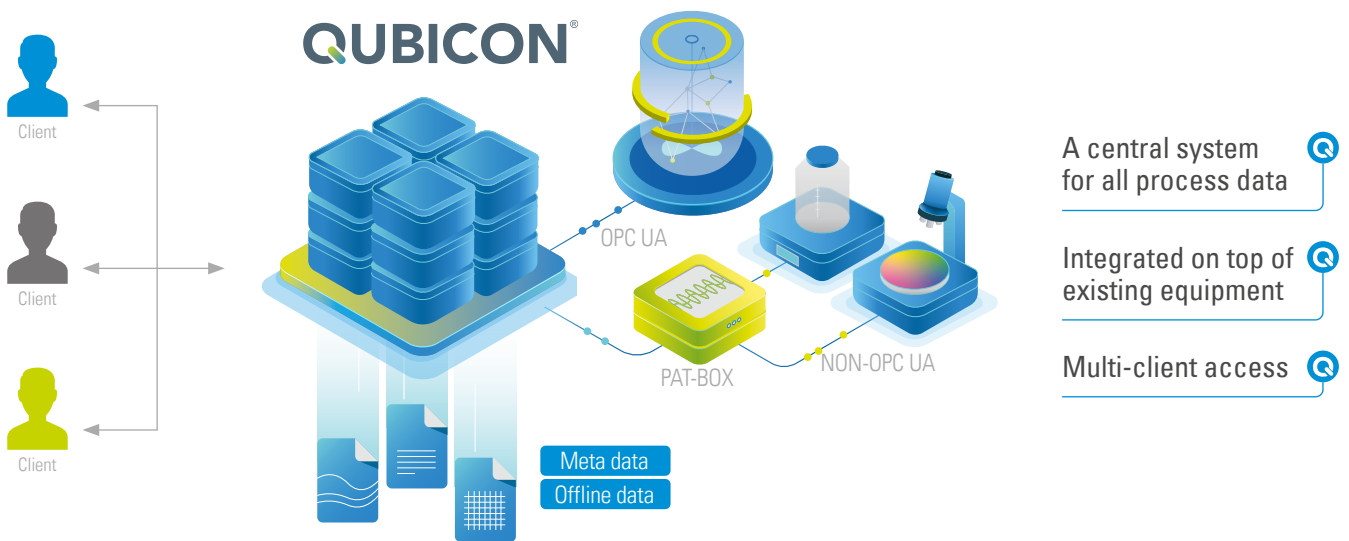
Being placed on top of existing equipment enables the software to connect virtually to any device in a quick and easy way. The industrial standard OPC UA (Open Platform Communications Unified Architecture) is used for data transfers between Qubicon® and the equipment.

The PAT-Box communication bridge can be interconnected between device and the Qubicon® server for non-OPC UA-capable equipment. Even instruments conducting at-line measurements, such as cell counters or substrate analysers, are supported. This is made possible thanks to automatic read-outs from export files and subsequent import of correctly time-aligned measurement results to the corresponding process by means of sample IDs. Automatically assigning data from multiple analysers in this way takes data integration to an entirely new level.

Qubicon® brings all process data together in one centralised system. Data generated offline or complete historical data sets can be added by means of the **Import** module. Online and offline measured values are automatically time-aligned and can be exported as a complete data set for subsequent statistical analysis.

The **Libraries** module serves as the main access to connected devices and their available sensors. It also makes it possible to manage recurring meta-information such as organisms, media, and units.

The client-server architecture of the database also allows several users to work on one project at the same time, enabling processes to be simultaneously planned, monitored and analysed without any interference.






DATA TRANSLATION VIA PAT-BOX

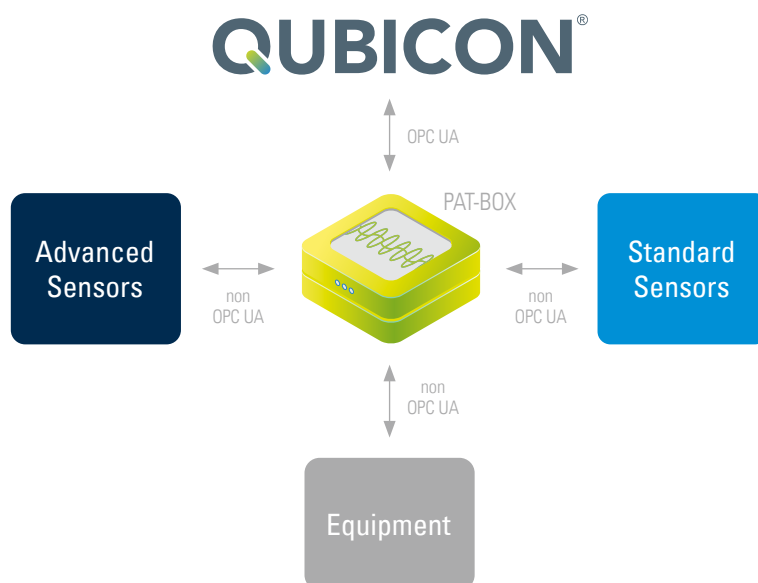
The PAT-Box is another innovation by Bilfinger, especially designed for translating data between different communication protocols. It enables data from several communication interfaces to be converted for OPC UA, which is currently the data exchange standard for industrial applications. The PAT-Box ultimately enables measurement values to be accessed from almost any device delivering data in real time.

What this means is that using the PAT-Box makes it possible to integrate devices (irrespective of the manufacturer) into Qubicon® that are not compatible with OPC UA and, as a result, facilitate the bidirectional exchange

of data. The PAT-Box also facilitates the use of devices and analysers in a very flexible way in combination with any other item of equipment. A broad variety of standard sensors (e.g. scales), advanced sensors (e.g. Raman spectrophotometer) or actors (e.g. pumps) can be connected to the software, while the bidirectional connection enables versatile and flexible new control loops to be realised.

As many as five independent devices can be connected via one PAT-Box, while of course several PAT-Boxes can be simultaneously linked to Qubicon® if desired.

-  Combining equipment in a flexible way
-  Translating various interfaces to OPC UA
-  Realising versatile control loops



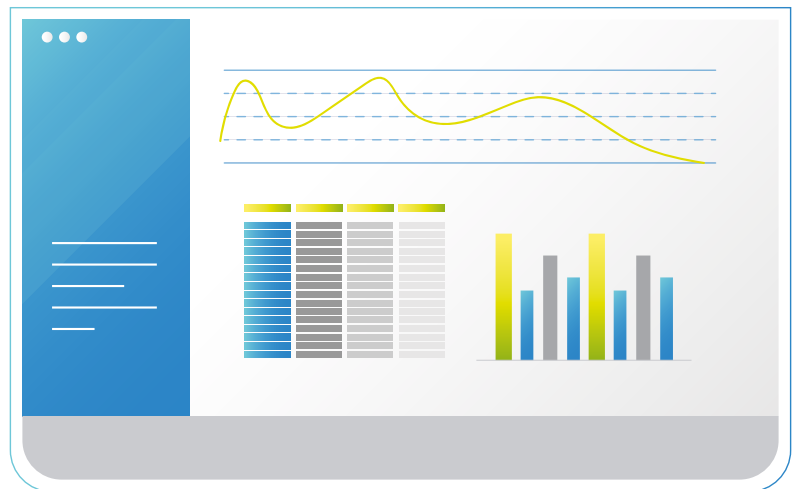
AUXILIARY FUNCTIONALITIES AND SUMMARY

Qubicon® supports the creation of process reports that show important data and events as well as meta-information such as the media, recipes or control strategies used. Moreover, process data sets that have been properly time-aligned can be exported for statistical analyses.

A user can access the software by means of an identification and authentication procedure. The system administrator defines the user access rights. All actions within Qubicon® are logged in a way that can be easily audited, whereby all user actions are stored and can be reviewed, filtered and reported. This includes for example log data, recipe changes, alerts and version histories. Moreover, the web-based software runs on a server infrastructure and can be accessed simultaneously by multiple clients.

In conclusion, Qubicon® takes manufacturing processes to the next level, having been developed especially for advanced process monitoring and control. It enables the enhanced monitoring of processes by comparing live data to reference runs and calculating key performance indicators (KPIs) in real time. Furthermore, Qubicon® goes a step beyond monitoring and enables the user to be in complete control of the manufacturing process. The software also functions as an indispensable data management tool, automatically unifying the entire process data in a single centralised system. Integrating the entire production chain becomes a viable option by being able to combine multiple process equipment items in a flexible manner.

- Q Profound process design and planning
- Q Exporting time-aligned data sets
- Q User management and audit trail



SCOPE OF SUPPLY

- › Setting up Qubicon® on-site
- › User training course on-site
- › Consulting on interfaces to peripheral devices
- › PAT-Box hardware for signal translation
- › On-site equipment integration directly via OPC or the PAT-Box
- › First/Second/Third-level support
- › Regular software updates and upgrades
- › Support for data integration, mathematical model development and implementation
- › Optional: Optimal server hardware incl. Linux operating system and Qubicon® software
- › Optional: Qubicon® installation on existing Linux server
- › Optional: Network Attached Storage (NAS) system for data backup
- › Optional: SMS alerting gateway
- › Optional: Interface to existing user management systems
- › Additional on-site technical and software support

Recommended Qubicon® System Requirements

Server processor	Intel Xeon
Server memory	Min. 32 GB
Server hard drive	SSD
Server operating system	Linux (min. Ubuntu 16.04 or equiv.)
Client screen resolution	1920×1080

Technologies

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