



Bausch + Ströbel uses the HMI/SCADA solution from COPA-DATA throughout the company

Consistent and safe – zenon in the Pharmaceutical Industry

The HMI/SCADA software zenon is an integrated and safe platform for consistent process and information management. The established special machine builder Bausch + Ströbel is now using the solution from COPA-DATA throughout the company for machine operation, logging of operational data and control and monitoring of entire production facilities in the pharmaceutical industry.

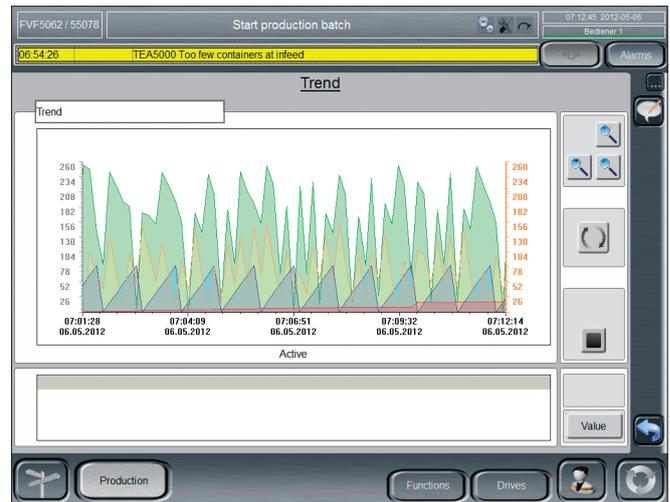
The company Bausch + Ströbel from Ilshofen, Germany manufactures around 300 machines per year – 95 percent of which are for the pharmaceutical industry. Founded in 1967, with four employees, the special machine builder now generates annual revenues of 120 million euros and has around 1,000 employees. More than 90% of the company's goods are exported. There are customers on every continent and the company also has sites and representative offices on every continent.

THE CHALLENGE OF VARIOUS MACHINERY

Bausch + Ströbel offers both customer-specific individual machines as well as multifunctional production lines for industrial processing. The range of machines is orientated towards manufacturers of pharmaceutical products in the primary packaging and secondary packaging fields. This includes products such as ampoules, disposable syringes, carpules and vials. Bausch + Ströbel has produced a total of more than 10,000 individual



zenon makes it possible to create Audit Trails, which are required in the pharmaceutical industry.



Employees can track the production data over a defined period of time in the trend display.

machines for use worldwide. This includes over 130 ampule lines, over 340 vial or bottle lines, over 100 injection lines (mold cavity), over 50 injection lines (bulk) and over 40 carpule lines. Its main working procedures are cleaning, dosing and filling fluid and powdered products, sealing, labeling, checking and transporting and storing the above-mentioned containers. The production facilities of Bausch + Ströbel play a key role in the processing of high-quality, sterile pharmaceutical products. Furthermore, the company also offers labeling machines. The special machine builder also provides services such as qualification and validation, customer training and service and support for all machines.

COMPLEX MACHINES, COMPLEX REQUIREMENTS

Up to now, Bausch + Ströbel used two different software systems for the control process and for the management level, which controlled the machines and used process data from the machines and equipment. The company also developed its own functions and add-ons for the SCADA system. "Two separate systems and additional in-house developments require a large amount of work to ensure the implementation and validation of software - as well as for the maintenance and upkeep of the machines and equipment. Our objective was to stop developing and configure projects instead," explains Michael Pratz, who is in charge of automation, equipment qualification and documentation and the technical IT at Bausch + Ströbel. Bausch + Ströbel

was looking for a system which could consistently operate from machine level through to management level (SCADA) and which also offered good performance for the price. "The decision criteria for an HMI/SCADA solution included comprehensive user administration and the ability to use Microsoft Windows as an operating system platform to allow integration into Active Directory. Furthermore, it was important to us to be able to work with existing tools and modern, intuitive user interfaces," adds Michael Pratz. Another requirement was creating a solution for the end user that can visualize the entire working process. In the process, the work can be designed more efficiently and the likelihood of making errors is reduced. "Our new solution should make it possible to guide the machine operator intuitively and enable them to work on different machines - without a long time to learn the process. This is a necessity nowadays. At the same time, we wanted to increase process safety," says the Bausch + Ströbel Manager.

ZENON – RECORD, VISUALIZE AND LOG

The special machine builder Bausch + Ströbel now offers its customers all the important functions for packaging and production processes in the pharmaceutical industry on the basis of zenon. The new HMI/SCADA application based on zenon aids lot-based recording, visualization and logging of all data that is generated during production and processing. Users receive information on the current machine performance, counter statuses and weight values as a bar chart or in table form with net

“ Our new zenon based application is a complete paradigm shift. The solution works consistently in a process-orientated and task-orientated manner and is extremely user friendly. ”

MICHAEL PRATZ, HEAD OF DEPARTMENT DOT/EL2 AT BAUSCH + STRÖBEL

and tare weight values including the date and time of weighing etc. In the trend display, employees can follow the development of production data over a longer period of time, recognize possible problems in the production process at an early stage and instigate measures to counter them. Object-related production data such as weight values are recorded with high performance during each machine cycle.

CREATE A CONSISTENT BASIS FOR DATA

An important point for Bausch + Ströbel – and a significant requirement in the pharmaceutical industry – is the integrity of data, which also decisively influences the product quality. With zenon, Bausch + Ströbel can consistently write all data from processes such as temperatures, presses and weight values to a database, read them again, and evaluate or analyze them, as well as being able to archive them. The use of an SQL database and the OPC UA connection also makes it possible to forward the production results to superordinate systems such as MES solutions.

AUDIT TRAILS IN ZENON – SAFE FROM MANIPULATION, RELIABLE, COMPLETE

zenon supports machine builders and production companies optimally in meeting the requirements of the pharmaceutical industry and complying with legally-binding international regulations such as FDA 21 CFR PART 11 or GMP and – in conjunction with the integrated user administration – creating the Audit Trails required in the pharmaceutical industry. In doing so, zenon checks which users are carrying out which actions and documents this. It is therefore possible to trace all user interventions and relevant results, such as any process events, value changes or limit values being exceeded, at all times.

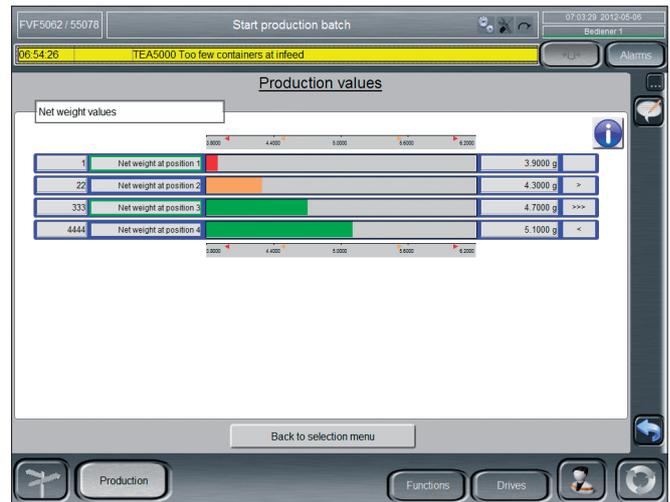
A CONSISTENT FLOW OF INFORMATION IN THE PROCESS OF A BATCH THROUGHFLOW

With the start of a new lot and the lot number being assigned, the start information and production data such as weight values or messages are stored in an SQL database. The application records all of the data generated in this production and packaging process in an Audit Trail. This ensures compliance with FDA 21 CFR Part 11. The employees in charge can view the Audit Trails of the current lot. After a lot has been completed, the lot protocols or trend evaluations are ready to be analyzed, documented or archived. They contain information on the operating status of the machines, any system access by employees, changes to parameters, operational messages, and trends such as temperature, statistics, counter logs etc. Bausch + Ströbel also makes it possible to log production and downtime during a lot, to display the key figures graphically and – as an option at the end of a lot – to print them out.

INCREASED EFFICIENCY THANKS TO RECIPE MANAGEMENT

With the zenon Recipe Group Manager, it is possible to keep individual packaging and manufacturing parameters, target values and commands in a list, which are executed in Runtime with a single function call. Bausch + Ströbel uses this central recipe or format management to edit all format parameters for the individual machines or the whole line; to delete, approve, save and administer. In addition, the customers of Bausch + Ströbel can integrate CIP/SIP format management. Because recipes allow considerable changes to the equipment, zenon protects this with well-developed safety mechanisms and access rights. All changes can also be logged.

In addition to the scalability and consistency, data integrity is a significant factor when deciding to use zenon.



ADDITIONAL MODULES FOR TAILOR-MADE SOLUTIONS

Bausch + Ströbel now offers a variety of modules and functional components so that customers can tailor their own solution which fully meets their requirements for the filling and packaging of pharmaceutical products. These include, for example, a module for object logging and for the saving and requesting of time-driven process data. With the module for time control, users can connect a machine or piece of equipment to an NTP time server and synchronize times. The backup module ensures that data is secure and can be recovered.

ACTING INTERNATIONALLY

Due to the global nature of the pharmaceutical industry and because exports make up more than 90% of its sales, a truly internationally software solution is a fundamental requirement for Bausch + Ströbel. With the language switching in zenon, users can switch language or alphabets as desired whilst the program is running and convert units of measurement - without laborious adaptation being necessary. At the same time, it is ensured that the selected language is used consistently throughout. The Audit Trail is thus also stored in the desired language.

FLEXIBILITY AND PROFESSIONALISM IN COOPERATION

The customer-orientated product development, the clear and well-thought-out release policy and the open communication in terms of the planned development stages for future software versions is valued highly by the automation specialists at Bausch + Ströbel. In addition to the technical solution, Michael Pratz from Bausch + Ströbel stresses the professional cooperation with COPA-DATA in particular: "COPA-DATA has shown

great commitment and shown that the company can quickly implement our requirements and needs, react immediately to queries and support us competently on site – and wishes to go forward together with us." Bausch + Ströbel has currently supplied five machines to customers with the new zenon based application. Sandoz is one of the first users.

ZENON – THE ADVANTAGES FOR THE PHARMACEUTICAL INDUSTRY

- ▶ Consistent basis of data and complete documentation of all processes
- ▶ Traceability thanks to the Audit Trail
- ▶ Compliance with legal requirements such as FDA and GMP guidelines
- ▶ Security thanks to integrated user administration
- ▶ Connection to Active Directory
- ▶ A basis for comprehensive quality management
- ▶ Direct driver for a total of more than 300 controllers, including those from Siemens, Allen-Bradley and Jetter