Intuitive operation of systems

Franz Ziel develops ergonomic cleanroom technology with zenon

Medication saves lives. However, it is a long, hard road from making the active ingredients to the production of life-saving medication. Drugs labeled as sterile must be germ-free. Franz Ziel develops cleanroom technology systems for the pharmaceutical sector. In order to meet the high demands of the sector, Franz Ziel uses the zenon software platform from COPA-DATA.

Sterile medications can only fulfill their life-saving function if they are germ-free. From production through filling to injection, the top priority is preventing contamination. The pioneering company Franz Ziel GmbH has been ensuring clean processes for more than 35 years. Franz Ziel makes high-quality cleanroom technology systems for customers in the pharmaceutical sector. In addition to standard applications, the company provides advice for the planning and implementation of bespoke solutions. The main objective throughout its work is to ensure compliance with the strict guidelines for good manufacturing practices (GMP).

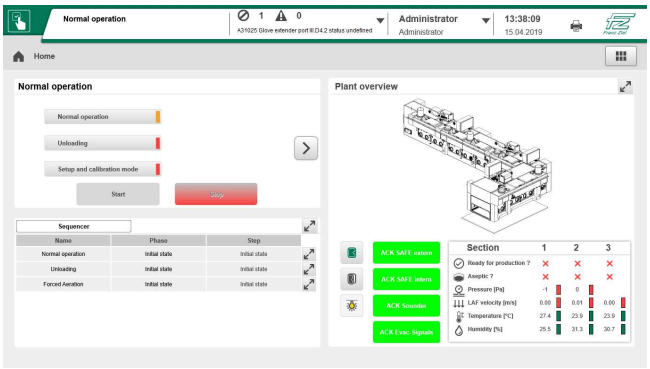
To monitor the required parameters, Franz Ziel uses zenon for its plant, deployed as an HMI/SCADA application.

WIDE RANGE OF REQUIREMENTS FOR A COMPLEX SYSTEM

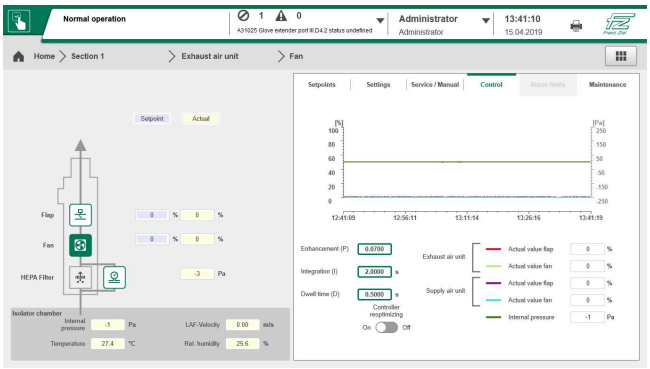
Customer requirements have increased in recent years. For companies in the pharmaceutical sector, controlling the processes and process parameters in production and filling poses an ever-increasing challenge. International regulations on the handling of electronic data and software applications (FDA 21 CFR Part 11, GMP EU Annex 11) have become increasingly important as digitalization gains momentum. The complexity of the previous application required customers to purchase support as an extra service. The complex and costly licensing system also restricted flexibility and, ultimately, led to the decision that a new solution had to be found. In 2016, the machine manufacturer decided to collaborate with COPA-DATA and implement the zenon software platform.

NEW DIRECTIONS

First and foremost, Franz Ziel deliberately opted for an open system that could be integrated within a heterogeneous hardware landscape. The new solution is designed to make it easy to meet all FDA and GMP requirements. Above all, it had to aid in the complete documentation of the entire production



zenon displays the most important plant data clearly in the dashboard, and detail can be accessed directly without going deeper into the project.



Individual areas are displayed clearly. Adjustments can be made easily, if necessary.

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>
> **THOMAS GROßE HÜLSEWIESCHE, FRANZ ZIEL GMBH ELECTRICAL ENGINEER**

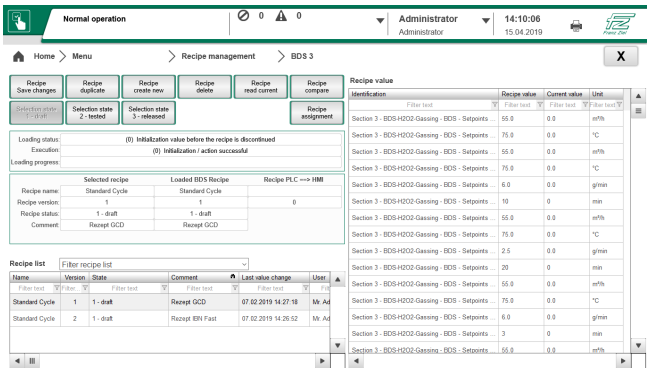
plant. By using SCADA functionality, the documentation will be immutable, since all data is captured digitally and can therefore not be tampered with. The new system also needed to be easy and intuitive for plant operators to operate.

zenon software from COPA-DATA can be used as a platform-independent HMI/SCADA application. Franz Ziel and COPA-DATA have developed an individual HMI based on zenon, which has been optimized specially to meet the requirements of machines and customers. In addition, zenon can be easily connected to existing systems and integrated in heterogeneous infrastructure. As a result, the solution supports the different PLC hardware providers selected by Franz Ziel, and ensures flexible customization.

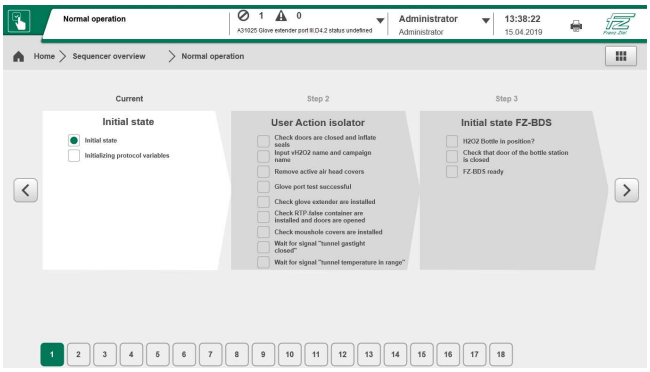
With the support of CaderaDesign, Franz Ziel's team developed a uniform, CI-compliant design for all user interfaces. "We receive very positive feedback on our design from all our customers," says Thomas Große Hülsewiesche, electrical designer at Franz Ziel. "Operation is intuitive, and can be carried out by personnel with less training."

Strict compliance with certain parameter sets is particularly important in the pharmaceutical sector. With zenon Recipe Group Manager, it is very easy to edit and save any number of parameter sets. It also conforms to FDA 21 CFR Part 11, GMP EU Annex 11. At the push of a button, parameter sets can be predefined as set values at the process level. In the application cases of Franz Ziel's customers, these parameters include the required internal pressure in the isolators or in the closed RABS, the temperature, the humidity and the speed of the laminar airflow. Laminar airflow or low-turbulence displacement flow is a specific airflow in the room that removes any contaminants or particles from the process room from top to bottom. If the limits of the parameters are not observed exactly, the system triggers an alarm, and the machine operators are shown the next steps that need to be taken on the user interface.

All acquired data is recorded seamlessly throughout the entire production plant. Various reports can be generated from the raw data, which can be adapted to suit individual requirements.



The zenon Recipe Group Manager ensures strict compliance with predefined parameter sets. Nonconformances can be detected at a glance.



In case of a nonconformance, zenon triggers an alarm, then displays the required next steps on the user interface.

EVEN GREATER POTENTIAL

"Even though we already use zenon very effectively for our customers, we have not yet exhausted its full potential," says Thomas Große Hülsewiesche. There are currently plans to use the software in other areas, as well. For example, the maintenance and repair of the machines can be planned in advance with zenon, and thus made more efficient. Predictive maintenance makes it possible to service systems exactly when maintenance is due, rather than by predefined cycles. This delivers cost reduction savings and prevents production stoppages.

HIGHLIGHTS:

The pharmaceutical sector presents machine manufacturers with very particular challenges. With zenon, Franz Ziel overcomes these challenges.

- The zenon Recipe Group Manager facilitates the editing and saving of any number of parameter sets. zenon and Recipe Group Manager areis FDA 21 CFR Part 11, GMP EU Annex 11 compliant.
- Seamless data records across the entire production plant.
- Platform independent HMI/SCADA application that can be connected to existing systems and integrated with heterogeneous plants.
- Intuitive operation and CI-compliant user interface.