



FRANZ ZIEL

THE CUSTOMER

The ground-breaking company Franz Ziel GmbH has been building high-quality cleanroom technology systems for customers from the pharmaceutical industry for more than 35 years. In addition to standard applications, the company also 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).

THE CHALLENGE

For companies in the pharmaceutical sector, controlling the processes in production and filling poses an ever-increasing challenge. International regulations on the handling of electronic data and software solutions (FDA 21 CFR Part 11, GMP EU Annex 11) are becoming increasingly important as digitalization gains momentum. All data must be recorded and archived completely. With Franz Ziel's previous software solution, it was becoming difficult to comply with FDA and GMP regulations. In addition, the complexity of the legacy application posed a major challenge.

THE SOLUTION

Franz Ziel decided in 2016 to implement the zenon software platform from COPA-DATA. Working closely together, the two companies

developed an individual HMI based on zenon, which has been optimized specially to meet the requirements of Franz Ziel machines and customers. With the support of CaderaDesign, Franz Ziel's team developed a uniform, CI-compliant design for all user interfaces. Operation is intuitive, and can be carried out by personnel with minimal training.

THE TECHNOLOGY

zenon is deployed as a platform-independent HMI/SCADA application. It can be easily connected to existing systems and integrated in heterogeneous plants. The creation of standardized PLC blocks allows older systems to be integrated. zenon supports all the different PLC hardware providers selected by Franz Ziel, and can be customized flexibly.

THE BENEFITS

Strict compliance with certain parameter sets is particularly important in the pharmaceutical sector. With zenon Recipegroup Manager, it is very easy to edit and save any number of parameter sets. The tool also conforms to FDA 21 CFR Part 11, GMP EU Annex 11. At the push of a button, set values can be configured at the process level. For Franz Ziel's customers, these parameters include the required internal pressure in the isolators and in the closed RABS, the temperature, the humidity and the speed

of the laminar airflow. If the limits of the parameters are not observed exactly, the system triggers an alarm, and the user interface displays the next steps that need to be taken on the user interface. In addition, all the acquired data is recorded seamlessly. Reports can be generated from the raw data, which can then be adapted to individual requirements.

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