



Romaco invests in quality

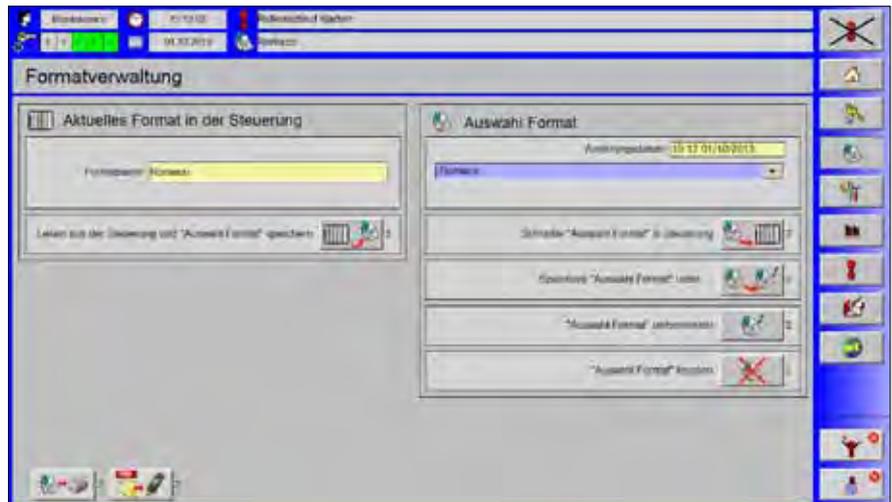
zenon – Intelligent visualization as the key to success

Flexibility, profitability and high quality – these are the requirements that mechanical and plant engineering must fulfill in the pharmaceutical industry today. The established manufacturer Romaco successfully meets these challenges – not only with state-of-the-art machinery, but also with the innovative HMI/SCADA software zenon for machine operation.

The pharmaceutical industry has experienced fundamental change in recent years and is now influenced more than ever by new challenges and tough competition. Higher productivity and machine performance, quick and reproducible format change, minimal maintenance efforts, maximum quality and compliance are the demands that companies in the pharmaceutical industry face today.

ROMACO – INNOVATIVE PACKAGING AND PROCESS SOLUTIONS

The Romaco Group is a company that adapts quickly and flexibly to changes in the industry and utilizes new opportunities and possibilities on the market. The company offers innovative packaging and process technologies for the pharmaceutical, cosmetic, food and chemical industries. The engineering specialist develops, produces and sells machinery and equipment for vari-



Romaco implements an HMI solution with zenon which is not only cost-efficient but also future-proof and offers maximum protection of investment.

ous industrial applications: primary and secondary packaging systems, machines for sterile liquid and powder filling, as well as process plants for semi-solid and solid forms. Romaco Pharmatechnik GmbH – with headquarters in Karlsruhe – manufactures thermoforming machines, heat sealing machines, as well as counting machines for filling pills and capsules. In addition to the headquarters in Karlsruhe, Romaco also has three further locations in Europe. Around 450 employees look after customers in over 180 countries. A total of 50,000 of the provider's machines are in use worldwide.

DECIDING ON FUNCTIONALITY AND FLEXIBILITY

In order to continue fulfilling high-quality company standards, market requirements and compliance guidelines, Romaco decided to introduce a new visualization solution for thermoforming and heat sealing machines, as well as for cartoning systems and filling lines. The goal was to establish the most uniform operation possible and to organize monitoring of the packaging location technologies in order to make their own work more efficient and to be able to offer the customer a more consistent look & feel for all machines and lines. Furthermore, the Romaco Group wanted to introduce consistent and uniform recipe management, as well as standardized audit trails for all further machines. "For quality management and product control it is also important to provide superordinate systems, such as an SAP application, with all relevant data from the production or packaging process – for example, not only the generated quantities,

and time information, but also errors in the process," explains Jürgen Kratzmeier, Engineering Manager at Romaco Pharmatechnik GmbH. In consultation with the Italian subsidiary, the machine and equipment builder decided to implement the HMI/SCADA software, zenon. The innovative HMI/SCADA solution, zenon, distinguishes itself through its flexibility, an intuitive user interface, platform and hardware independence, as well as compatibility to guidelines such as FDA 21 CFR Part 11 or GAMP5. "zenon is a solution that offers a very comprehensive scope of service, and at the same time it is easy to operate," explains Jürgen Kratzmeier, "The software offers possibilities that go well beyond simple machine operation. We profit from the Historian, the detailed statistical analysis capabilities, the array of graphical possibilities, the networking and the range of connectivity to other systems and controllers."

OPERATE MACHINES MORE EFFICIENTLY WITH ZENON

The zenon-based solution for operation, monitoring, and control of the Romaco technologies is unified and standardized for all machinery. The user interface consists of several components: in addition to the status bar with status and error messages, user identification, data and time can be found on the right in a navigation bar, where operators can call up various functions and find information. This includes, amongst other things, "format administration", "configuration and information", "error statistics" and "recent messages". Employees can select, create and edit formats for production in the menu format administration.

“ Today, we can offer our customers a cost-effective software solution with zenon which fulfills their wide-ranging requirements and can optimally support customers in mastering daily tasks within the production and packaging areas. ”

**JÜRGEN KRATZMEIER, ENGINEERING MANAGER
AT ROMACO PHARMATECHNIK GMBH**

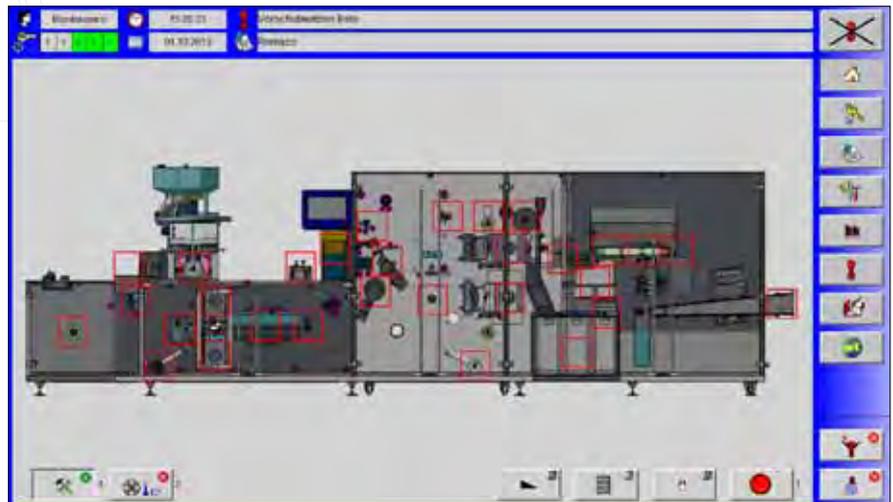
All variable data that is required for the production process is saved in these format sets (or recipes). For example, the user can find diagnosis functions for hardware components under Configuration and Information. Machine data, control inputs and outputs as well as software status can also be displayed here. Error statistics display the production parameters such as the batch run times, set value batch, and the number of correctly made packages, as well as the reject amounts per lot. Under Current Messages users can find current error, warning or instructive messages in a tabular format – classified by message type and therefore according to importance and relevance. Based on an assembly number or electrical control plans, users can easily localize a disturbance or error source. Additionally, it is possible to call up help texts for troubleshooting. All messages are also archived and can be exported to a log file.

In the workspace (main screen in the middle) users are given an overview window of the machinery or equipment. They can comfortably and quickly reach parameter screens via the colored markings of the machine components. It is therefore

possible to view, correct and adapt all variables of the packaging process. These include the process parameters as well as format and packaging parameters. In the case of the Noack thermoforming machine, the user is able to call up format parameters such as feed length, blister dimensions etc. Furthermore, from here the users can comfortably access the settings of the format sections, the mechanical settings based on scales or the settings of the product feed.

FULFILL COMPLIANCE REQUIREMENTS WITH ZENON

As with every machine and equipment builder, Romaco must also observe a variety of legal compliance guidelines. As the company has an export ratio of more than 75%, the international FDA specifications according to 21 CFR Part 11 are all the more important. “One of the highlights of zenon and also the main reason why we chose zenon, is that we have the possibility of fulfilling and documenting legal requirements,” Jürgen Kratzmeier confirms. The 21 CFR Part 11 set of rules stipulated



Using zenon, Romaco can fulfill present and future customer requirements – without compromise – and offer maximum flexibility at the same time.

by defined guidelines from the U.S. Food and Drug Administration (FDA) requires that electronically saved data are subject to the same standards as paper documents. This covers, amongst other things, production protocol, information regarding quality management, as well as the archiving of these documents and data. Romaco achieves compliance to these standards with the help of the Chronological Event List in zenon. The Chronological Event List defines all interventions to the program or the data set. Romaco customers can thereby gain a filtered view – in the Runtime – of all relevant events of a machine or piece of equipment, and document these. This includes, for example, process events, value changes, overrunning limits or user input. These audit trails can be archived and analyzed according to diverse criteria – whilst being continually protected from manipulation.

Furthermore, it must be ensured that only authorized company personnel can access data and intervene in processes. In order to comply with the strict FDA guidelines, zenon also offers a sophisticated user administration for Editor and Runtime.

Each user can thereby be assigned different access rights for a machine. Romaco has set up a five-step user concept for the thermoforming and heat sealing machines, so that companies can assign every user selective access authorization according to each task and their scope of duties – be it the administrator, the service technician, the machine setter, the production manager or operating personnel.

POTENTIAL CREATED FOR THE FUTURE

In the meantime, the Romaco Packaging specialist team has provided more than 60 machines with a zenon-based user interface. “With zenon implemented on our machines we have been able to fulfill the requirements of differentiating ourselves from the competition in a highly competitive pharmaceutical market. The zenon solution has enabled us to create potential for the future,” comments Jürgen Kratzmeier. End customers using these machines include pharmaceutical, cosmetic and healthcare companies, as well as contract packers and manufacturers worldwide.