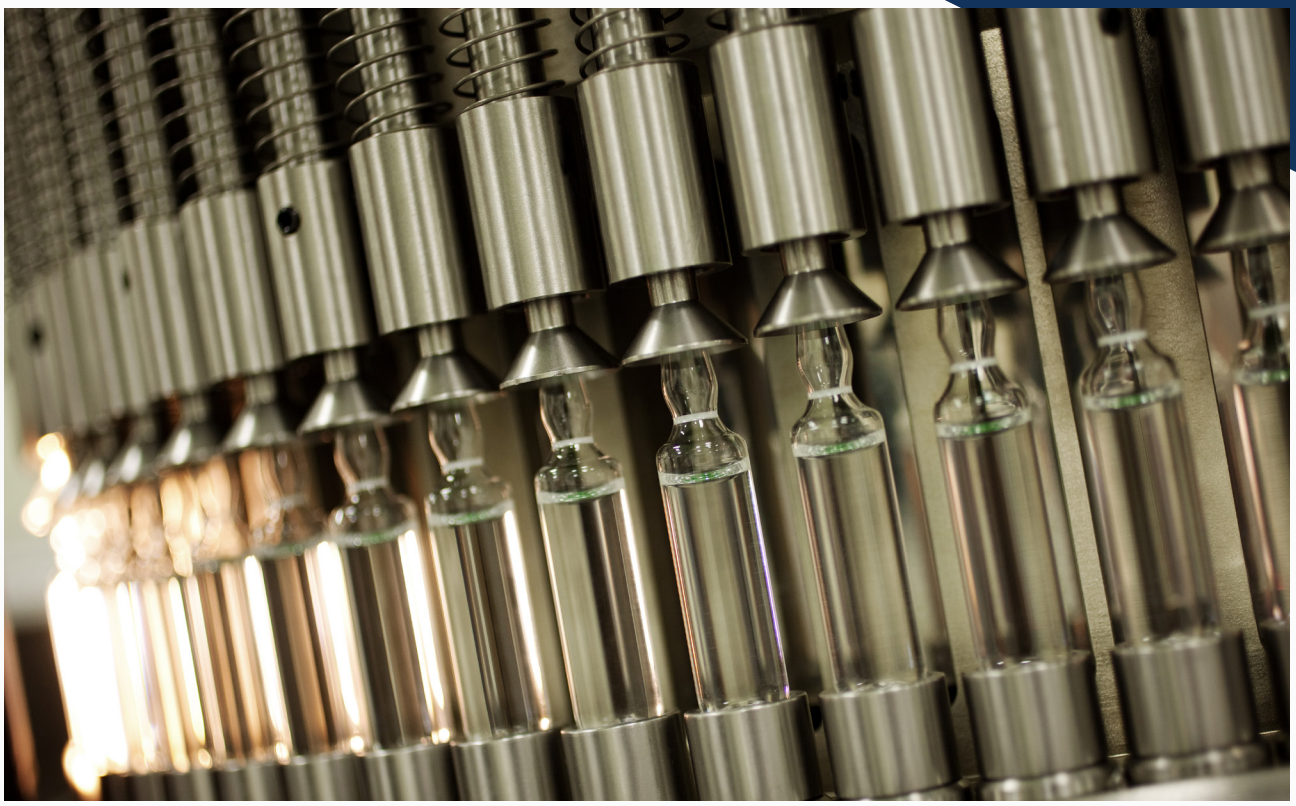
zenon
by COPA-DATA

Automation integration layer for pharmaceutical manufacturing

As middleware for the vertical integration of data between production systems and MES, ERP and other IT platforms, zenon provides a scalable software platform for all data processes in the pharmaceutical industry.



Connect production systems to state-of-the-art IT infrastructure
zenon offers a scalable software platform that solves virtually every challenge, including data integration, an archive server, exception handling, audit trail, recipe management and reporting. With its hardware-independent implementation and seamless integration, zenon gives users control over the entire process and supports users when it comes to optimizing production systems.

ERP AND PRODUCTION – IT AND OT GROWING TOGETHER

In existing (brownfield) systems, there is often no uniform management of all system areas or resources, such as water or compressed air. By contrast, zenon users can connect a wide variety of device types and production areas on a single digital software platform. As a result, companies benefit from a clear overview with centralized process data. The data is available immediately in digital form and can be used for a wide variety of purposes (maintenance, quality management, etc.). zenon uses native interfaces for integration with ERP systems. This allows the smooth flow of data between ERP and batch execution; manual intermediate steps are no longer necessary. A homogeneous environment is created for the production of compliant products.

REAL-TIME ALARMS

In fact, there are still production systems that do not provide central notification in the event of GMP non-conformances (e.g. limit values exceeded). zenon monitors actual values (e.g. the sterilization temperature) and generates a specific alarm. For full traceability, the non-conformance is recorded and the group of persons defined in advance is informed immediately. The same applies, of course, to any non-conformance in GMP-critical parameters for the connected devices. These features significantly reduce the number of rejects. An easily created exception report further facilitates the batch review process. With zenon, users can easily and conveniently monitor and log all changes to the GMP-critical set values. With individually created alarms triggered when unauthorized changes are made, it's easy for having oversight

of important issues. It also adds greater data integrity when managing legacy and existing machines.

COMPLIANCE GUARANTEED

The audit trail and user administration are included in zenon right from the start. The software platform complies with international regulations such as FDA 21 Part 11 and EU Annex 11. As stipulated by category 4 of the ISPE GAMP5 guideline, the implementation takes place entirely without programming. Only parameters are set. This configurability not only allows compliance, but also makes it as simple and efficient as possible. This saves time and money during implementation, maintenance and expansion. Further, the probability of errors during project configuration is minimized.

NO MORE MOUNTAINS OF PAPER

Thanks to the complete integration of zenon in operational processes, production data is recorded and evaluated at the same time. The reports required for the release of the batch are available immediately after the process has ended. The "Paper on Glass" application includes technologies for the electronic acquisition of data previously collected manually and on paper. As a result, safety lists or checklists can be processed using a PC, on mobile devices, or directly at the machine. It prevents the analytical errors that can arise through purely manual processes.

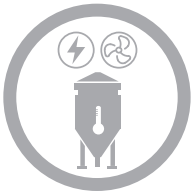
EASILY SERVICE AND VALIDATE SYSTEMS

Validation and maintenance of existing systems is a huge challenge when dealing with bespoke development or individual systems. zenon is GAMP 5 Category 4 software and provides configurable solutions and tools to perform validations out of the box. These tools include documentation, versioning, and change history. This results in less time spent on validation, lower costs, and a clearer overview of the project structure. In addition, companies are less reliant on suppliers.

OUR SOLUTIONS FOR THE PHARMACEUTICAL INDUSTRY:

DATA INTERGRITY COMPLIANCE

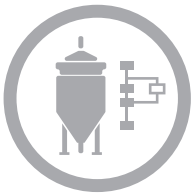
HMI SOLUTIONS



CENTRALIZED TECHNICAL SERVICES

CONTINUOUS MANUFACTURING

DIGITALIZATION AIL



ISA 88 PROCESS AUTOMATION

LINE EXECUTION SYSTEM

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