zenon
by COPA-DATA

Navigate pharmaceutical production with zenon

The zenon Software Platform provides users with the transparency required to meet the complex requirements of a GMP-regulated environment by visualizing operating processes in a data-compliant and ergonomic manner.

Ergonomically manage equipment and ensure production complies with regulatory requirements

zenon provides a state-of-the-art, regulation-compliant HMI to visualize pharmaceutical production processes. The Software Platform can be easily integrated with existing infrastru cture and meets international standards for future projects.

VISUALIZE NEW AND LEGACY MACHINES WITH ZENON

Since equipment in a pharmaceutical environment is seldom purchased from a single manufacturer, zenon offers extensive connectivity to enable end-to-end production control. With more than 300 native connection protocols, connection to existing hardware is easy out of the box. From flexible vertical data integration to a range of gateway modules, e.g. OPC UA, both equipment manufacturers and end customers benefit. Machine-related project configuration work can be carried out automatically with wizards, thus minimizing time spent on commissioning. Online or historical data, audit trail logs, recipe data, and alarms can also be shared easily with other systems, e.g. an existing manufacturing execution system (MES). Real-time and historical data can be processed directly. This enables a continuous flow of information between operational and process control levels.

DATA COMPLIANCE OUT OF THE BOX

To comply with GMP regulations, the configuration and validation of projects in the pharmaceutical industry can often take considerable time. As GAMP-5 Category 4 software, zenon enables, as standard, full compliance with GMP guidelines in accordance with Annex 11 and FDA 21 CFR Part 11. Elements such as electronic signature, audit trail, test reports, alarms, archiving, access control, electronic documentation including electronic batch reports (EBR) data exports, work-

flow management, and recipe management are an integral part of the software platform. Engineering with zenon also provides versioning, change history and documentation to support the validation process. Detailed diagnostic options assist further; for example, to quickly identify problems in communication.

SECURITY ACROSS THE BOARD

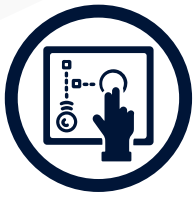
zenon supports secure end-to-end production operations and addresses security risks directly as they develop through a certified security-by-design system that complies with IEC 62443. Many security gaps can be closed right away when starting the project creation process: secure password protection, protection against unauthorized access, and encrypted data transmission are integrated functional components in zenon. It is therefore easy to configure these concepts across the board. The seamless redundancy in zenon ensures maximum data consistency, so that there are no gaps, even when switching to a standby server. In zenon, the software integrator configures archiving functions quickly and easily, using an integrated archive server. The same principle applies here: users set parameters instead of performing time-consuming programming. Comprehensive rights management also comes as standard. Plus, simple backup/restore options for GMP-related data simplifies IT and OT convergence.

END-TO-END ERGONOMICS

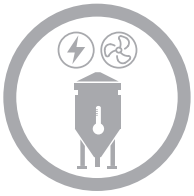
zenon supports its users with a state-of-the-art and user-friendly HMI. The QA department can rely on configurable modules, which minimize the effort for project configuration and validation. The application is maintained from a central library. In addition, intuitive operating concepts reduce training lead times. Even less-experienced operators can run projects thanks to zenon's optimized usability. Languages, units of measurement, and colors can be customized easily. Tailored to each individual user, the ideal application interface is created in each case. When it comes to design, companies have free rein; design adjustments can be implemented quickly and flexibly with zenon, without interrupting operations. Data is recorded completely electronically, which saves time and avoids reliance on error-prone manual checklists. In fact, all areas of a zenon project can be maintained with minimal effort and without any system downtime.

OUR SOLUTIONS FOR THE PHARMACEUTICAL INDUSTRY:

DATA INTERGRITY COMPLIANCE



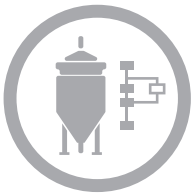
HMI SOLUTIONS



CENTRALIZED TECHNICAL SERVICES

CONTINUOUS MANUFACTURING

DIGITALIZATION AIL



ISA 88 PROCESS AUTOMATION

LINE EXECUTION SYSTEM

GET IN TOUCH:

pharmaceutical@copadata.com
www.copadata.com/contact

linkedin.com/company/copa-data-headquarters
facebook.com/COPADATAHeadquarters
twitter.com/copadata
xing.com/companies/copa-data
youtube.com/copadatavideos

Publication number: CD-SL-Quality-Assurance-18-08-DE

COPADATA