zenon
by COPA-DATA

Combine production lines with zenon

The zenon Software Platform connects all of the machines in a production line, or even entire locations, and manages them in compliance with the requirements of the international pharmaceutical industry.

From individual active ingredient to packaged drug

The zenon Line Execution System is a secure and future-proof solution for visualizing, managing and monitoring an entire production process in the pharmaceutical industry. With a central audit trail, alarms, user management and recipe management, as well as extensive reporting functions, zenon combines production steps, reduces complexity, and improves overall system efficiency.

A heterogeneous machine park, especially one with an increasing number of products and processes, inevitably lead to significant complexity. New drugs are forcing companies to reduce their batch sizes and increase the number of retoolings. As a line execution system, zenon is a scalable and secure solution for consistently mapping all sections of a pharmaceutical production system and making the entire process easy to manage. The zenon Software Platform can be implemented with or without a higher-level Manufacturing Execution System (MES) and directly increases the degree of digitalization of every production system.

CONNECT PRODUCTION ISLANDS AND ELIMINATE DATA SILOS

zenon is open and independent; it can be easily integrated in an existing IT infrastructure via Active Directory and other identity services. Thanks to a wide range of connection options via its many connectors, companies can integrate systems with a broad variety of PLCs, drives, testing devices, inspection and camera systems out-of-the-box. Both existing and new systems can be connected independent of manufacturer. zenon stores the data from all equipment centrally and provides this data in a clear manner. This means that all GMP-related content remains easily accessible and it also eliminates data silos.

COMPLIANCE INTEGRATED FROM THE START

zenon not only meets the highest requirements in terms of quality and robustness, but also offers as standard full compliance with FDA 21 CFR Part 11. Whether as a stand-alone or integrated system, zenon comes with electronic signatures, audit trail, test protocols, alarms, archiving, access control, electronic documentation including electronic batch reports

(EBR), data exports, workflow management, recipe management and much more. The applications meet the guidelines of Annex 11 of the EU GMP. Additionally, as a configurable system, zenon meets the requirements of GAMP5 software category 4. With zenon, compliance can be implemented cost-effectively, error-free, and easily as an integral part of every project.

CLEAR CONTROL AND PREDICTIVE MAINTENANCE

zenon provides extensive options for visualization. With zenon, users always have an eye on the entire production line and, if necessary, can zoom in or out from production hall to individual sensors in the same image. The information density adapts automatically to the current zoom level and the corresponding level of detail. A production line managed by zenon also displays the state of the current batch, alarms and events in real time. Units and languages can be changed easily during operation. User administration is integrated throughout and restricts access rights according to the role of the user. This prevents unauthorized or accidental tampering. Thanks to the latest HTML5 technology, users can also access dashboards, key data, and process overviews on their mobile device while on the go. In the event of potential complications (e.g. GMP non-conformances), preventive measures can be taken without delay. By implementing predictive maintenance with zenon, users know in advance when maintenance work is due. This prevents unnecessary downtime and any associated production losses.

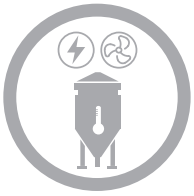
ELIMINATE MOUNTAINS OF PAPER FOR GOOD

zenon supports electronic data acquisition in the pharmaceutical industry. Users can work through safety or checklists digitally and directly on the machine panel or using mobile devices. Instead of writing results and comments on paper, users enter them via a touchpad or workstation app. This data is then displayed and archived immediately with a timestamp and user information in line with data integrity requirements. This optimizes data acquisition for all kinds of inspection processes. Since the results are readily available during batch production and the complete electronic report is available immediately after batch completion, zenon saves users considerable time. Because there is only one report for a whole line, stacks of paper are a thing of the past. And QA staff can release the batch much faster.

OUR SOLUTIONS FOR THE PHARMACEUTICAL INDUSTRY:

DATA INTERGRITY COMPLIANCE

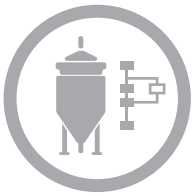
HMI SOLUTIONS



CENTRALIZED TECHNICAL SERVICES

CONTINUOUS MANUFACTURING

DIGITALIZATION AIL



ISA 88 PROCESS AUTOMATION

LINE EXECUTION SYSTEM

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