zenon
by COPA-DATA

Data integrity made easy

In zenon, digital entries replace manually updated paper lists. Users can easily implement requirements to meet pharmaceutical industry regulations in their unique GMP production environment using configurable functionalities.

No more FDA warning letters

Hardly any other industry is subject to such strict laws and standards as the pharmaceutical industry. So it is hardly surprising that pharmaceutical companies are among the most frequent recipients of FDA warning letters. Much of this stems from deficits in data integrity. The zenon Software Platform puts an end to these warnings.

COMPLIANCE FROM THE START

Complying with the regulations of FDA 21 CFR Part 11 and EU GMP Annex 11 can be a challenge. zenon solves this and provides users with full compliance in accordance with the given regulations as standard. Audit trail, test reports, alarms, archiving, user administration and authorization, electronic documentation including electronic batch reports (EBR), non-conformance reporting, workflow management, recipe management, data export and much more are available out of the box. Thanks to the Electronic Signature feature, zenon supports a multi-stage approval process, including an index of meanings, comments and signatures. With all these measures, the software platform provides a configurable system that fulfills the requirements of GAMP5 software category 4. This enables companies to implement a compliance regime that is cost-effective, error-free and efficient.

DATA INTEGRITY GUARANTEED

The FDA requires a certified copy of the original recording, which must be retained for the full duration of the record compliance period. With zenon, all data is recorded immediately and archived centrally – in a traceable manner and with a timestamp. Even if a tablet or PC is destroyed, lost or stolen, the data in the system is secure. Changes to the data or deleted entries can be tracked to the original data. Of course, the data is encrypted and protected by individual access rights so that only authorized persons are able to access it. By using the native connection to automation hardware (PLCs), zenon

ensures the reliability of the value displayed simply by configuring the connector. The timestamp is linked automatically to the value recorded, and users can be sure that the data displayed is always correct.

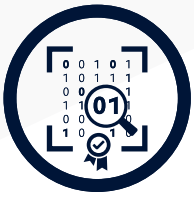
NO MORE MOUNTAINS OF PAPER, NO MORE UNNECESSARY RISKS

Checklists, test reports, etc. are often still filled out on paper by hand, which is time-consuming. Errors, illegibility and intentional or unintended tampering are a risk for data integrity. The zenon Software Platform puts an end to this, because it offers the user the option of making entries via electronic end devices or directly via the HMI. Digital workflows guide the user step-by-step through the process. In some steps, values for critical process parameters (CPP) have to be collected, and these can be overlooked or recorded incorrectly in paper-based data collection processes. With zenon, the sequence and conditions are specified in the configuration. Incorrect entries, expensive storage, tedious paper lists, and loss of data become things of the past. It enables users to ensure data integrity and accurate data archiving. Because reports on the respective batch are available immediately in real time, can be brought to market more quickly.

EFFICIENT VALIDATION

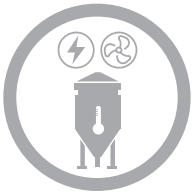
The decision to implement electronic data recording with zenon does not require expensive revalidation of production processes. Because the automated process continues to operate exactly as it did before – with the same data and the same steps. Equipment, processes or procedures do not have to be changed, despite the switch to the new platform. This ensures the requirements of the regulation are met and in-house production is optimized. The improvements are made in a step-by-step manner without having to change the control system. Users can implement further innovations without being hampered by time-consuming and costly revalidation activities.

OUR SOLUTIONS FOR THE PHARMACEUTICAL INDUSTRY:



DATA INTERGRITY COMPLIANCE

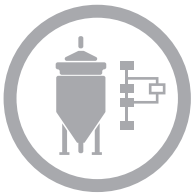
HMI SOLUTIONS



CENTRALIZED TECHNICAL SERVICES

CONTINUOUS MANUFACTURING

DIGITALIZATION AIL



ISA 88 PROCESS AUTOMATION

LINE EXECUTION SYSTEM

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