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COPA-DATA publishes major release: zenon 10

eSignature improves integrity of GMP data

Strict compliance with regulations and absolute data integrity remain huge challenges in the life science industry. With the major release zenon 10, software specialist COPA-DATA publishes an integrated total solution of its software platform for the implementation of industrial IoT in the pharmaceutical sector.

The events of the last 16 months have placed the focus more heavily on digital solutions and business models. With the major release zenon 10, software specialist COPA-DATA meets these challenges in the life science industry and makes compliance with regulations and data integrity more convenient.

Fusion of OT and IT

The automation and digitalization of the production and energy sectors has been in the DNA of software manufacturer COPA-DATA for more than 30 years. "I see zenon today as synonymous with the fusion of OT and IT. With zenon 10, we have the perfect platform for introducing production systems to IT. In the future, there will be more tools and services that round out the whole package. But zenon 10 already has all the important blocks," says COPA-DATA founder and CEO Thomas Punzenberger.

Many successful machine manufacturers in the pharmaceutical industry rely on the ergonomic usability of the software platform zenon to control their machines.

Using Batch Control in accordance with ISA-88, simple compliance of FDA 21 CFR Part 11, approaches for continuous production, state-of-the-art HMI options for machine manufacturers as well as GAMP5 category 4 compatible software solutions, zenon has offered for years a comprehensive solution range for the pharmaceutical Industry. In all these areas, with zenon 10 additional improvements were achieved once again.

eSignature

With the new functions around the **eSignature** in zenon 10, data integrity in GMP-regulated environments was further improved. The eSignature strictly follows the ALCOA principle. This states that documented data must be stored in a way that is attributable, legible, contemporaneous, original and accurate. "The software platform zenon has been heavily advanced, thanks to constructive feedback from the pharmaceutical Industry and its machine manufacturers in recent years. In particular, our new eSignature will make life easier for companies in the life sciences industry," says Bernhard Korten, Industry Manager Pharmaceutical at COPA-DATA.

**Authorization can take place in up to three steps**. As a result, the change of an operator at a machine must first be verified by another person and then approved from an additional person with a higher user level. Only then is a change accepted by the system. All of these steps are documented properly in an attributable manner in the **Audit Trail with unique signature registration**. In this process, the eSignature can also be integrated in the shorter **two-step mode** flexibly into the different zenon applications – such as for the change of a variable with confirmation by another person. In zenon Engineering Studio, this is easy to configure.

In order to save and manage the raw and original data of a manufacturing process centrally, with zenon 10 **smart data storage** is available. Alarms, events and historical process values are saved in a central database. The integrity of the GMP-relevant data is ensured thanks to the **security mechanisms** of SQL or the internal data storage of the zenon Service Grid. The central storage location (repository) also satisfies IT managers, ensures simple administration and reduces the maintenance effort through backup and restore functions. The database server can run in a virtual environment here and also secure connections to third-party applications are possible.

Video: zenon 10 for the pharmaceutical industry

The highlights of zenon 10 for the pharmaceutical industry can be viewed in detail in this [video](https://go.copadata.com/zenon10-pharmaceutical).
The general new features can be viewed in detail in this [video](https://go.copadata.com/zenon10).

Captions:

Bernhard\_Korten\_PR\_Image\_1500x2400px.jpg
"Our new eSignature will make life easier for companies in the life sciences industry,” Bernhard Korten, Industry Manager Pharmaceutical at COPA-DATA.

Thomas\_Punzenberger\_PR\_Image\_1500x2400px.jpg
“With zenon 10, we have the perfect platform for introducing production systems to IT,” says COPA-DATA founder and CEO Thomas Punzenberger.

zenon10\_Pharma\_Visual\_PR\_Image\_2400x1300px.jpg
The major release of zenon 10 from software specialist COPA-DATA delivers an integrated software platform for implementing industrial IoT in the pharmaceutical sector.

About COPA-DATA
COPA-DATA is an independent software manufacturer that specializes in digitalization for the manufacturing industry and energy sector. Its zenon® software platform enables users worldwide to automate, manage, monitor, integrate and optimize machines, equipment, buildings and power grids. COPA-DATA combines decades of experience in automation with the potential of digital transformation. In this way, the company supports its customers to achieve their objectives more easily, faster and more efficiently.
The family-owned business was founded by Thomas Punzenberger in 1987 in Salzburg, Austria. In 2020, with more than 300 employees worldwide, it generated revenue of EUR 54 million.

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