



zenon
by COPA-DATA



Electronic Data Recording with zenon

In zenon data is collected electronically. The user is guided through the process. Data entries on mobile devices replace manually managed paper lists.

Put an end to paper lists in pharmaceutical production

zenon supports electronic data recording in the pharmaceutical industry. Entries on mobile devices replace manually managed paper lists. Digital workflows guide the user through the process, making erroneous entries, data loss or cumbersome paper list storage a thing of the past.

Unlike manually managed checklists, which are still commonly used - such as for quality control, as an accompanying document for production or for operating instructions - electronic recording saves time and is less prone to error. The application "Electronic Data Recording" in zenon solves these problems. Operating staff create entries on tablets or PCs and electronically record the readings. As a result, analyses are immediately available, and an alarm is automatically triggered when limit values are exceeded.

SAY GOODBYE TO MOUNTAINS OF PAPER

"Electronic Data Recording" applications in zenon include technologies for electronically recording data that has previously been manually recorded on paper. As a result, security lists or checklists are processed with a PC, directly at the machine panel or via mobile devices. Hence, paper-based lists and reports are a thing of the past, thereby eliminating the cumbersome and space-consuming archiving of paper lists. It optimizes data recording for all types of testing processes.

ACCURATE AND UNDERSTANDABLE

The "Electronic Data Recording" offers the user step-by-step assistance throughout the production process. For every step, the user needs to provide the critical quality attributes (CQA) that can be overlooked or erroneously recorded during paper-based data recording. The next step is only executed when the figures are entered and are within the tolerance ranges. The order and conditions are thereby specified in the

project engineering. All information is given a timestamp and is available in real time. The application immediately detects incorrect, missing or incomplete entries.

QUICK RESULTS

With zenon, information is available as early as during the production process for the currently produced batch, and reports with quality documentation are provided immediately thereafter. As a result, products from the batch can be approved and marketed significantly faster, reducing costs and producing greatly improved data quality, transparency and accuracy.

KEEP TRACK OF EVERYTHING

A higher-quality database is needed for detailed and valid reports. In addition to reports about the respective batch process, zenon creates further production analyses, based on electronically recorded data, such as trends, Gantt charts, alarm and event lists. Key indicators such as overall equipment effectiveness (OEE) and failure probability (MTBF, MTTF) are continuously available.

zenon works with a uniform time format throughout the entire system, and all timestamps are synchronized. Even if manual processes are still required, they are automatically synchronized.

DIRECTLY DETECT ERRORS

In addition to data entry, sensor data can also be read automatically via zenon. If data is automatically recorded, then there is no chance of incorrect figures being recorded.



If a figure exceeds a limit, then quality management automatically receives an alert.

Analyzing deviations in the process is difficult and time-consuming with paper-based documentation. If a figure is specified in zenon that is not understandable or exceeds limits, the user can comment the reason and correct the figure. The original and the corrected figure are recorded with a timestamp so that the process is understandable and the deviation can be quickly analyzed and corrected.

SECURE ARCHIVING

With zenon, all data is immediately recorded and securely archived – with a timestamp and in a traceable manner. The data is securely and centrally stored in the system, even if a tablet or PC breaks, is lost, or stolen. Changes to data or deleted entries can be traced back to the original data. Naturally, the data will be encrypted and protected by individual access rights so that only authorized persons may access it.

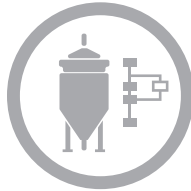
MORE THAN AN AUDIT TRAIL

zenon can interactively display training documents, instructions, documentation, etc. on a tablet or PC. As such, relevant work instructions, training documents or documentation can be issued in pre-defined workflows and provide the best-possible assistance to the user. Even valuable staff knowledge about the process can be shared as an electronic chronological event list with zenon, which benefits the entire team.

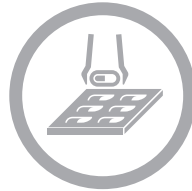
SIMPLE IMPLEMENTATION AND EFFICIENT VALIDATION

No costly revalidation of the production process is required if a company opts for electronic data recording. The reason being is that the automated process continues to be carried out just as before – the same data, the same steps, the same reports with the same information. Equipment, processes or operations do not need to be altered in spite of the conversion.

OUR SOLUTIONS FOR THE PHARMACEUTICAL INDUSTRY:



**BATCH
CONTROL**



PACKAGING



**QUALITY
ASSURANCE**



**EFFICIENT
VALIDATION**



**BUILDING AND
AUXILIARY
MANAGEMENT**



**ELECTRONIC
DATA RECORDING**

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