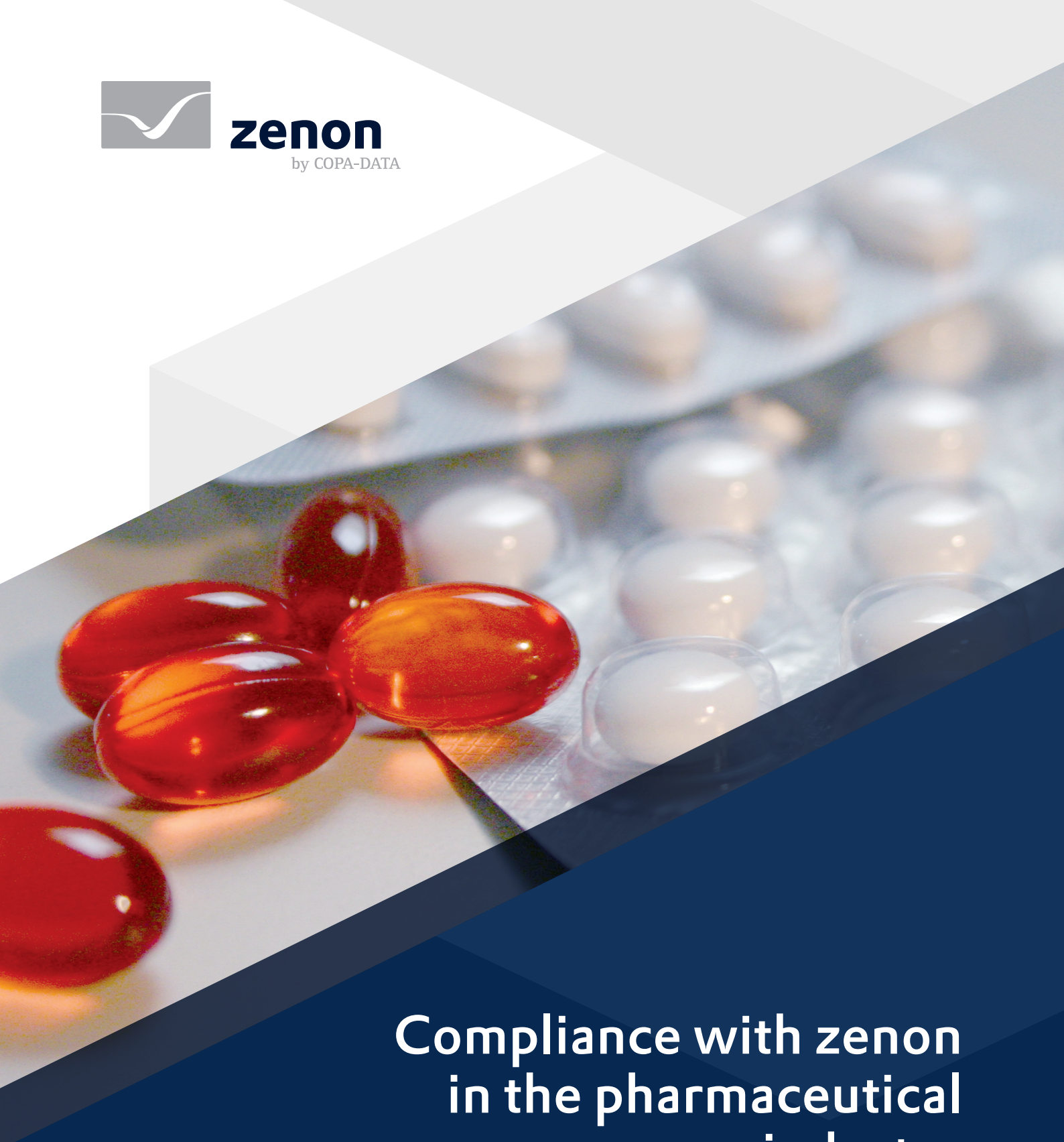
zenon
by COPA-DATA



Compliance with zenon in the pharmaceutical industry

Functions that assist with compliance are available out of the box in zenon. As such, requirements from pharmaceutical industry regulations can be efficiently implemented.

Innovative in spite of regulations

With zenon, not only can you control, monitor, and optimize the production process, but you can also efficiently meet the provisions of numerous regulations for pharmaceutical manufacturers, because compliance is available out-of-the-box in zenon.

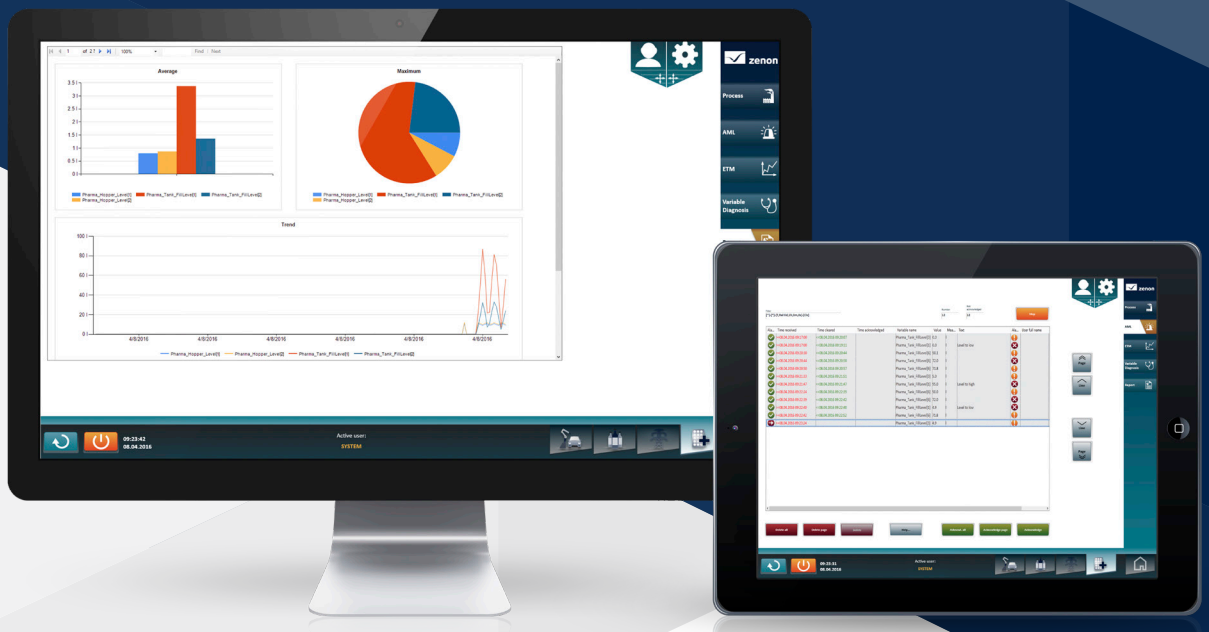
Few industries are subject to such strict laws and standards as the pharmaceutical industry. Standards must be demonstrably met, compliant behavior must be documented, but at the same time, there needs to be an increasingly faster and more flexible response to market requirements while simultaneously increasing efficiency in production.

INTEGRATED COMPLIANCE

zenon offers you full compliance as standard. Solutions with zenon meet international regulations such as FDA 21 CFR Part 11 or Annex 11 of the EU GMP guidelines. It includes a chronological event list, test logs, alarms, archive, user administration and authorization, data export, reports and much more. As a configurable system, it meets the requirements of GAMP 5 Software Category 4, allowing for economical, flawless and effective compliance.

HOW TO STAY INNOVATIVE IN SPITE OF REGULATIONS

With zenon, you can change or improve your processes without revalidation, thereby saving you significant costs. New processes including data recording, historian and reports are established in existing process monitoring with no modification thereof required. zenon offers exactly the



monitoring that is required by pharmaceutical industry guidelines. Hence, you can both meet regulatory requirements and optimize your production. Improvements are made step-by-step without requiring changes to the control system. Implement innovations and simultaneously avoid a time-consuming and costly revalidation.

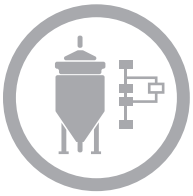
BATCH PRODUCTION WITH ZENON

Do you produce small quantities of different products with your equipment and is each configuration complex and expensive? Batch Control in zenon is perfect for batch production. As soon as the system is validated once, you can change recipes on this basis with no revalidation required. As such, the configuration process for each new product becomes quick and economical. Result: Your production becomes more flexible and profitable.

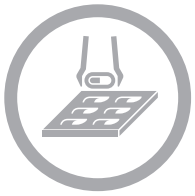
PUT AN END TO MOUNTAINS OF PAPER

Check lists, test logs, etc. are often still inconveniently filled out on paper by hand. This bears risks due to errors, illegibility and intentional or unintentional tampering. zenon puts an end to that since it offers the operator the option to make entries via an electronic terminal such as a tablet. As a result, you ensure data integrity and accurate data archiving. Advantage: The processes need not be changed, nor is revalidation required to implement this solution, because the operator inputs the exact same information but does so directly in the system instead of on paper. It is not necessary to revalidate if a production standstill occurs. And since the reports on the batch in question are immediately available in real time, they can be brought to market faster.

OUR SOLUTIONS FOR THE PHARMACEUTICAL INDUSTRY:



BATCH CONTROL



PACKAGING

QUALITY ASSURANCE

EFFICIENT VALIDATION

BUILDING AND AUXILIARY MANAGEMENT

ELECTRONIC DATA RECORDING

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