



zenon

by COPA-DATA

INDUSTRY SOLUTIONS



zenon
Pharma Edition

THE SOLUTION TO THE CHALLENGES
IN THE LIFE SCIENCES SECTOR

COPA-DATA: a partner you can trust in GMP-regulated environments.

For more than 30 years, COPA-DATA has been providing the pharmaceutical industry with digital end-to-end solutions. Its zenon Software Platform offers customers an integrated platform for HMI, SCADA and more. Supported by more than 300 native drivers and communication protocols, such as OPC UA, and interfaces to third-party IT systems, including MES/ERP, zenon is a state-of-the-art communication, visualization and process control solution designed to improve efficiency in project engineering and operational processes, as well as optimizing verifiable documentation.



The intelligent solution to the challenges of pharmaceutical production

The pharmaceutical industry and its software must continuously ensure compliance with regional and international laws. Every step in the manufacturing process has to be traceable and documented carefully. Failure to comply with regulations can lead to unsafe products with health risks, heavy fines or delays in approval. In particularly severe cases, there is also risk of criminal prosecution.

The zenon Software Platform from COPA-DATA has been specially engineered to help companies in the pharmaceutical industry meet these challenges. Through its innovative technology, zenon enables companies to optimize all of their key processes.

zenon provides a fully integrated solution for automation and production requirements. The platform incorporates the strict regulatory requirements of EU GMP Annex 11 and FDA 21 CFR PART 11 directly in production processes and project engineering. Basic components such as Audit Trail, Alarm Administration, Recipe Management, Production and Quality Reporting and Analysis are available out of the box.

Thanks to its compatibility with older zenon versions, the software platform provides a future-proof solution with low maintenance costs. The equipment can typically



zenon from COPA-DATA improves process visualization and control with powerful, state-of-the-art and customizable HMIs. As a user, you can maintain an overview and entire sites can work productively, efficiently and safely at all times

Where versatility meets reliability

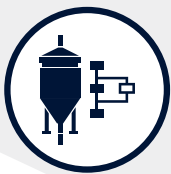


Data integrity compliance

The versatile zenon platform complies as standard with all of the requirements of FDA 21 CFR Part 11 and Annex 11 of the EU GMP guidelines. To ensure data integrity, the software solution offers a fully configurable Audit Trail with eSignature support. This ensures that changes and records can be tracked seamlessly, both in terms of time and personnel. Alarm administration, archive, user administration, security and extensive reporting options provide additional process security. Recipe management, discrepancy detection, electronic batch reports and the zenon Historian archive server combine to make pharmaceutical production facilities fit for future challenges.

The ISPE-GAMP-5 guidelines for a category 4 “Configured Product” software reduce the time and expense required for system validation and qualification. With out-of-the-box and configurable functionality, users fulfill the ALCOA+ principles. Parameterized automation solutions improve quality and reduce risks and complexity.

The zenon Software Platform can help customers successfully take the step to paperless data recording. As a user, you enter data via mobile devices or directly on the machine’s HMI. The electronic data record system guides you through each process step and only continues with the next step when the entries are complete and within the defined tolerances. As a result, conventional paper checklists are no longer necessary.



ISA-88 process automation

zenon Batch Control (batch production) is ISA-88 compliant and features impressively fast, hardware-independent implementation, seamless integration and comprehensive user-friendliness. Thanks to the high level of connectivity, batch control solutions can be implemented easily and cost-effectively. The modular NAMUR module type package (MTP) concept allows a range of process devices to be integrated flexibly. zenon also supports users in generating MTP templates, instancing process equipment assemblies (PEAs) and, subsequently, orchestrating a range

of devices in a process orchestration layer (POL). zenon enables control over the entire process and supports you in optimizing your production systems. Process managers can easily add and update recipes without programming knowledge via a graphical user interface. As part of the zenon Software Platform, the Batch Control module interacts with modules such as Historian and Reporting and demonstrates its strengths through state-of-the-art HMI capabilities (HTML5). Numerous analysis and reporting tools are available in zenon to enable you to get even more out of your existing system. Batch Control with zenon provides flexibility, scalability and reports in real time.



Continuous manufacturing

In contrast to batch production, continuous manufacturing is primarily aimed at improving a system’s flexibility and agility (e.g. different batch sizes). Real Time Release Testing (RTRT) enables users to shorten the batch release time. Process analytical technology (PAT) and new process control strategies lead to a sustainable improvement in quality – regardless whether for large or small quantities. Thanks to this communication ability and openness, you can easily and consistently integrate PAT, Multivariate Data Analysis (MVDA) and automation systems with the zenon Software Platform, and benefit from integrated services such as Historian, Recipe Management and Reporting. With individually configurable views for trends and non-conformance in critical process parameters (CPPs) or sophisticated in-process monitoring systems and interpretable data models, issues can be identified before they can cause greater damage. Thanks to preconfigured and adaptable functions and services in accordance with GAMP5 category 4 software, zenon can significantly reduce the time and expense of validation.



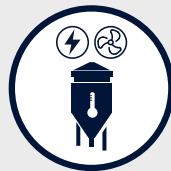
HMI for pharmaceutical manufacturing

To meet the complex requirements of a GMP-regulated environment, zenon visualizes operational processes in a data-security-compliant and ergonomic manner. A state-of-the-art HMI improves usability for operators and minimizes the likelihood of operating errors. Thanks to vertical integration, all machines remain connected. A large number of hardware protocols ensures maximum independence when choosing machines and systems. Electronic batch reports are available immediately and shorten release time in batch production. zenon detects GMP non-conformances during operation and automatically notifies the right people. This makes every production environment a networked system, ready for DPMM Level 3, Connected Plant*.



Control pharmaceutical production lines

zenon visualizes line execution systems ergonomically and in compliance with data protection regulations. The software platform ensures that all equipment and processes are integrated horizontally and vertically in the company, and it provides a modular solution at line level in a service-oriented architecture. By networking machines over the entire production line, data silos are eliminated and the monitoring of the production process is simplified significantly with zenon. For example, it is far less complex to implement a central Audit Trail for an entire line. The software platform stores data in accordance with applicable laws and customer requirements. Production line control with zenon provides for a „Connected Plant“ (DPMM level 3*) and supports further upgrades to a „Predictive Plant“ (DPMM Level 4*).



Automation Integration Layer

The zenon Automation Integration Layer (AIL) for pharmaceutical manufacturing is the proven solution for connecting existing, heterogeneous production systems to state-of-the-art IT infrastructure. Software gateways such as OPC UA servers or special connections to the MES or ERP level enable simple data exchange with higher-level systems. zenon is a scalable software platform that provides support for features and services from data integration to Plant Historian, Exception Handling, Audit Trail, Recipe Management, Reporting and Workflow Management. With web technology or predefined PDF reports, the recorded data can be distributed easily throughout the company. zenon delivers all of this as GAMP-5 Cat. 4 software, with out-of-the-box functionalities and compliance with regulations for data integrity.



Centralized technical services

With zenon as an efficient environmental monitoring system (EMS) or building management system (BMS), GMP-related parameters such as temperature, pressure and humidity can be easily monitored and controlled. For example, clean room monitoring with a particle counter, pressure sensor, etc. can be checked, logged and recorded in accordance with cGMP regulations. In this way, non-conformances are detected as they occur. Power supply, lighting and security systems are centralized. Users manage all areas in an understandable, fully regulated, and easy-to-use system, and clearly this makes it easier to meet requirements.

*Digital plant maturity model from BioPhorum

High level security included

A secure, state-of-the-art software platform that continually provides enhancements yet still leaves room for flexibility: this philosophy makes zenon one of the most durable systems on the market today. As a software platform whose product development cycle complies with the IEC 62443 industrial safety standard,, zenon systematically addresses security risks with every development phase – from planning through implementation to the product's end of life. Through the combination of highly developed security settings, zenon protects projects comprehensively against data loss or unauthorized access. zenon defines access rights based on user roles and ensures that only authorized users can perform critical operations. In addition to user administration, zenon also

supports user authentication via Active Directory. Login credentials and access rights can be linked conveniently to Windows user authentication. Easily configurable authorization levels ensure that only users who are authorized to do so can carry out operating activities.

All communication is strongly encrypted, if the connected machines support it. In this way, zenon not only provides security for communication in the company but also for access via mobile communication devices.



zenon provides the technologies required to protect your production operations against threats such as cyberattacks or data loss.

Modules that make the difference



eSignature

In a GMP-regulated environment, eSignatures can play an important role when developing applications that comply with data integrity regulations. It ensures that changes to critical parameters or initiated process steps can be tracked seamlessly, both in terms of time and personnel. A one, two or three-stage release process can be configured in the project engineering environment; for example, to change setpoints or recipe values and GMP parameters. All steps carried out are logged precisely in the Audit Trail. In addition, eSignatures make work easier for operating personnel, who no longer need pen and paper.



Recipegroup Manager

zenon provides individually parameterizable recipe group management that does not require any programming. A variety of functions are available for user-defined management of any number of recipes in Service Engine during operation. This includes opening, writing, reading, overwriting, copying, duplicating or exporting and importing recipes. This makes it easier to manage complex collections of recipes. Recipes can be grouped logically and formatted templates can be custom designed. Workflows for recipe approval can also be implemented easily via user administration. The Audit Trail monitors full recipe development and all related activities.



Process Recorder

The zenon Process Recorder archives actual process workflows and offers users the option of analyzing errors and malfunctions retrospectively – jumping back in time, so to speak. It functions as an add-on to popular zenon tools such as Extended Trend, Alarm Message List or Chronological Event List (CEL), providing even more accurate troubleshooting.



Historian: integrated archive server

zenon provides seamless recording and highly accurate archiving of data in real time. This makes it easy to retrieve real-time data and, at the same time, access historical data related to processes, events and alarms. Readings can be saved to archives either in cycles, based on events, or when values change. Users can also store and export data in a range of formats, including to SQL, to a centralized location on-premises, in the cloud, or locally on the machine. zenon provides you with a versatile solution designed to be adaptable to your needs.



Comprehensive reporting

With zenon, users benefit at every level of the production system from comprehensive reporting functions, such as statistical process control. Quality, and performance reports are easy to prepare and are available in different languages during operations. This allows users to clearly compare current and historical data. All of the key figures are either cloud-based or stored on central SQL servers, and are available at any time. Production data saved in the cloud can be retrieved at any time and used in real-time KPIs, historical comparison reports and more.



Smart Objects

The Smart Objects in zenon make it possible to cluster related elements and significantly accelerate project engineering. A unit consists, for example, of variables, drivers, symbols, faceplates (e.g. pop-ups), reaction matrices and scripts. These can be copied and customized at the push of a button. Centralized maintenance and easy instantiation further reduce engineering time. Versioning of the Smart Objects supports validation.

Technical Highlights



Built-in Soft Logic

The integrated IEC 61131-3 programming environment provides users with a homogeneous bases that incorporates sophisticated elements for control, mathematics, algorithms and communication in the SCADA environment. This ensures SCADA control and data acquisition is firmly integrated in process and device control activities.



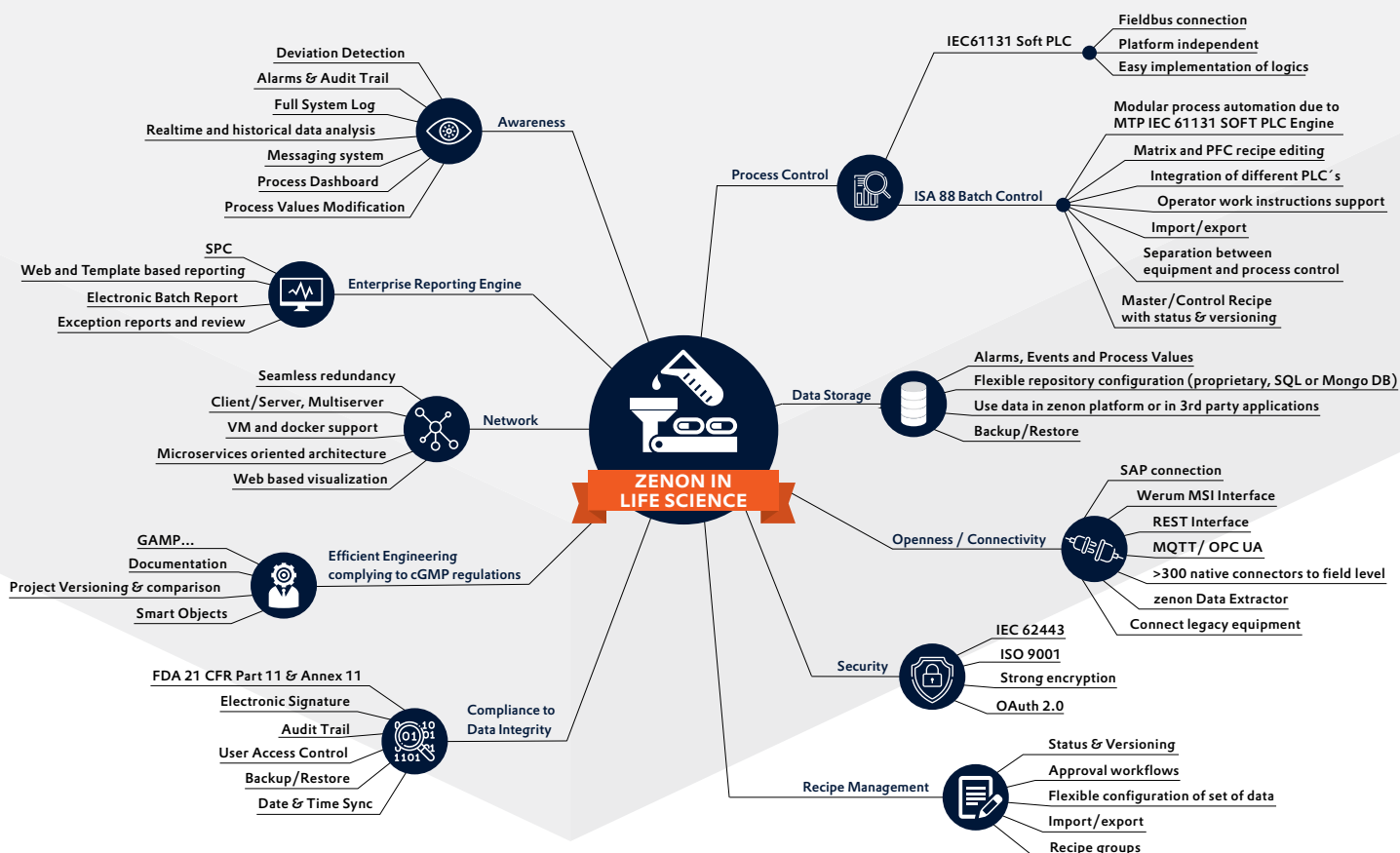
Connectivity

zenon offers hardware independence at field level. With over 300 native drivers and communication protocols, you can connect the majority of machines and sensors available on the market. In addition, data from the production level can be easily transferred to higher-level IT systems and processed there.



Network

When it comes to complex and stable infrastructures that can be parameterized with a click of the mouse, zenon is outstanding. Users benefit from a decentralized system with client-server encryption and patented circular redundancy. This ensures maximum protection and system stability you can count on.



As standard, zenon comes with all the components, modules and templates to optimize operating processes and comply with regulations to ensure product safety and quality.



Alarms and chronological events list

Quickly detecting errors and their causes, and responding consistently is a prerequisite for ensuring high productivity and saving resources. zenon provides all the tools you need, with alarms and documentation of events in the Audit Trail. GMP-related records can be filtered and displayed easily. The software platform provides impressive, ready-made features, simple parameterization, and full compatibility with regulations such as FDA CFR 21 Part 11.



A tailored user experience

zenon enables users to flexibly customize languages, units of measurement and colors. In this way, each project can be adapted in detail to meet the different user requirements during operation. All personal settings are active immediately upon login. Thanks to ergonomic automation, information can be concentrated and employees can be better deployed. With intuitive, user-friendly interfaces, zenon offers cross-location automation and bundled information for each individual function.



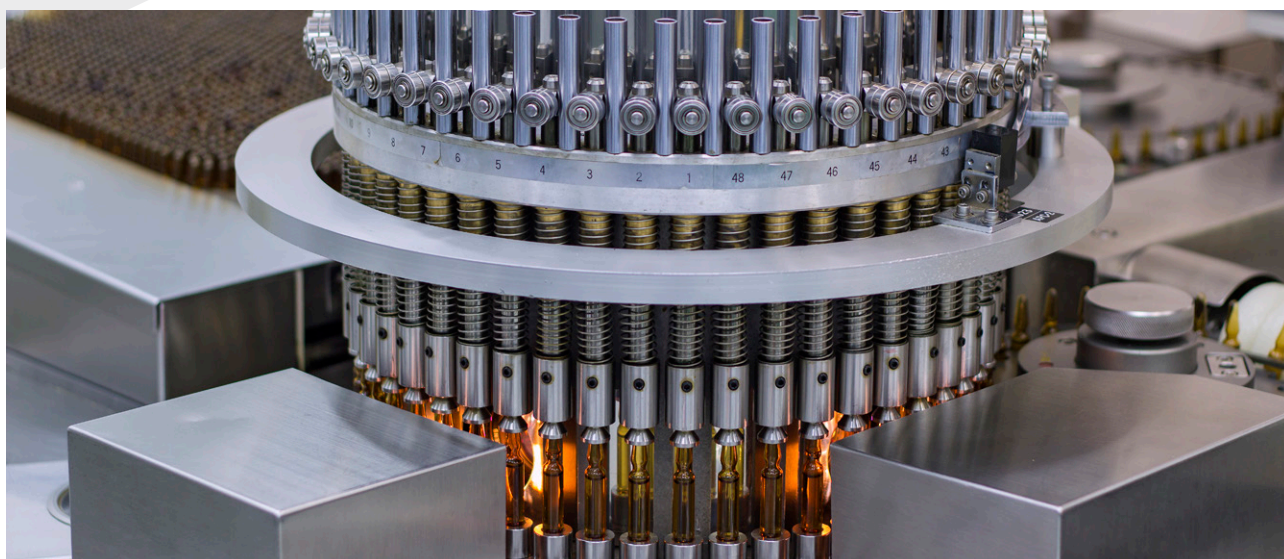
Multi-touch

Using intuitive gestures familiar from mobile devices, operating personnel can navigate, zoom, control, and access information. Two-handed operation supports machine operation in case of safety-related entries. The operator has to activate a release with one hand, in order to be able to carry out the corresponding action with the second hand. In this way, automation technology and display options are exploited in full.



Worldview

With Worldview functionality, you can display your entire production system graphically – from one sensor to the full plant – including the complete power supply. By zooming in and out, you can display the desired level of detail. You can also benefit from this overview in a browser via HTML5.



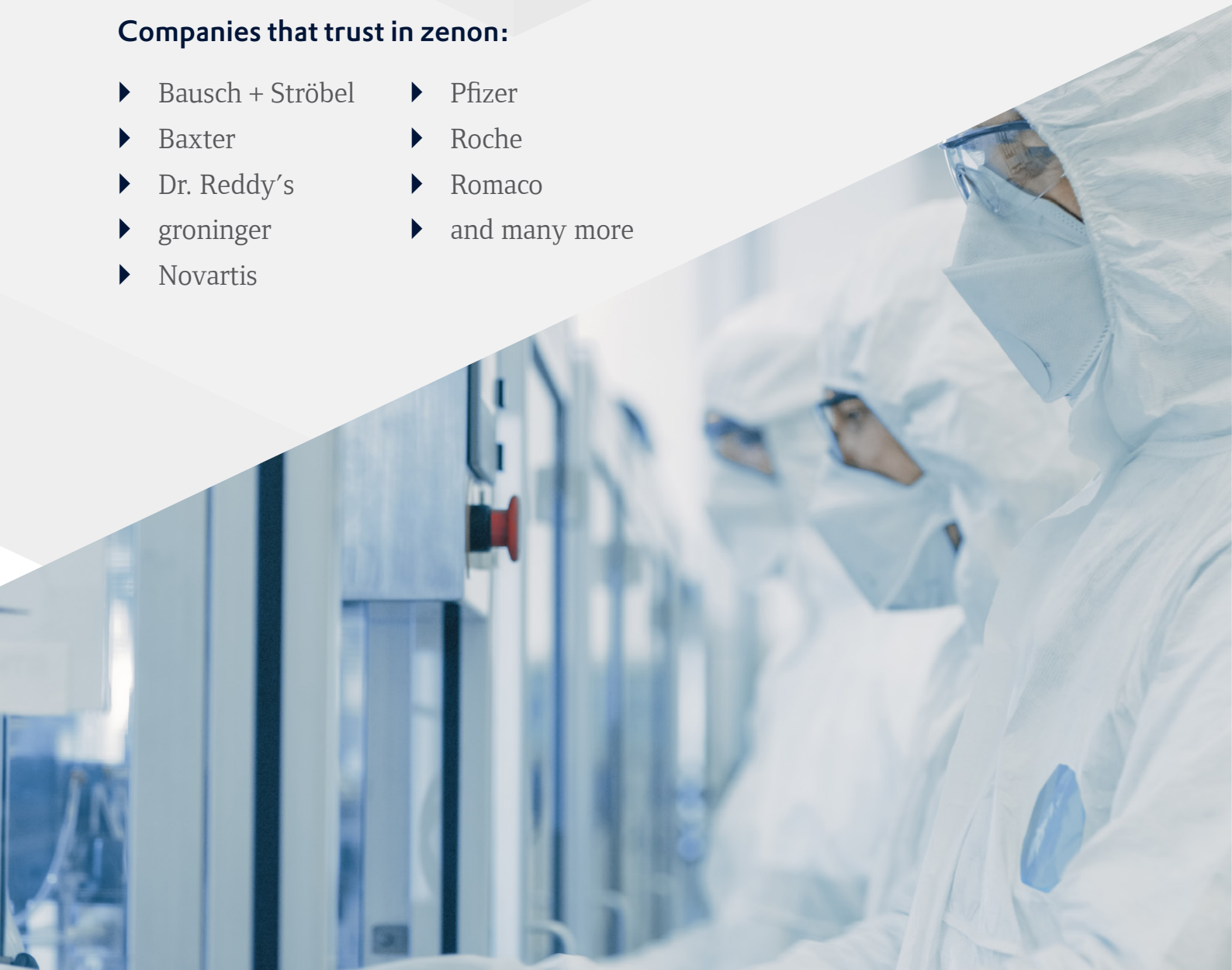
Thanks to the scalability and flexibility of the zenon Software Platform, you can control everything from individual processes to the entire production system.

Many customers already benefit from zenon

Through its subsidiaries and distributors, COPA-DATA provides local sales and support in more than 50 countries. Over 5,000 companies worldwide are already using zenon, making life – at least a little bit – easier for themselves. As a holistic platform, zenon is also able to handle complex tasks. Nevertheless, no two projects are alike, because the focus is always on users and their individual, customized requirements.

Companies that trust in zenon:

- ▶ Bausch + Ströbel
- ▶ Baxter
- ▶ Dr. Reddy's
- ▶ groningen
- ▶ Novartis
- ▶ Pfizer
- ▶ Roche
- ▶ Romaco
- ▶ and many more



zenon

Designed to make your life easier.

zenon is a software platform that makes it easy to engineer and automate operations for manufacturing and infrastructure equipment. Whether working in manufacturing or in the energy industry, zenon can help you achieve and maintain your operational objectives.

COMPREHENSIVE SOFTWARE FOR MANUFACTURING AND ENERGY

zenon ensures that equipment runs reliably, flexibly, and efficiently. Decision-makers, engineers, and operators in manufacturing companies and in energy distribution use the capabilities of this comprehensive software platform to connect all relevant areas – from project creation through to maintenance. The result is a notable increase in overall equipment effectiveness.

EMPOWERING PEOPLE

Using zenon, all users – from production through to management – can create synergies and make a sustainable impact on business in a measurable and positive way.

ENABLING THE DIGITAL TRANSFORMATION

The zenon Software Platform provides one integrated environment that combines data recording, machine operation, and business intelligence. This helps businesses to maintain a competitive edge throughout their digital transformation.



PROPERTIES

▶ Scalability

zenon provides an optimal, seamless scalability from small to company-wide applications.

▶ Robustness

zenon runs robustly and enables the highest system availability and operating reliability.

▶ Security

zenon provides comprehensive security features and can be integrated seamlessly in holistic security concepts.

▶ Performance

Ever increasing networking is resulting in an explosion of data, and zenon helps you meet this challenge with optimal performance.

▶ Flexibility

Software has to support business processes that are changing and becoming more agile, and zenon can help you flexibly scale up and adapt your solution to meet these demands.

▶ Openness

As an open platform, zenon supports easy integration across the value chain.

▶ Validation

For highly regulated industries, zenon enables users to perform validation efficiently with a maximum of flexibility while meeting the regulatory regime.

▶ Ergonomics

zenon provides the best possible ergonomics for people interacting with technology in digital processes.

▶ Lifecycle management

zenon ensures long-term maintainability, adaptability and updateability over the entire lifecycle of your equipment.

▶ Interdisciplinarity

zenon leverages synergies across different disciplines.



zenon
by COPA-DATA

Your smart software solution in the life sciences sector.



COPADATA

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