

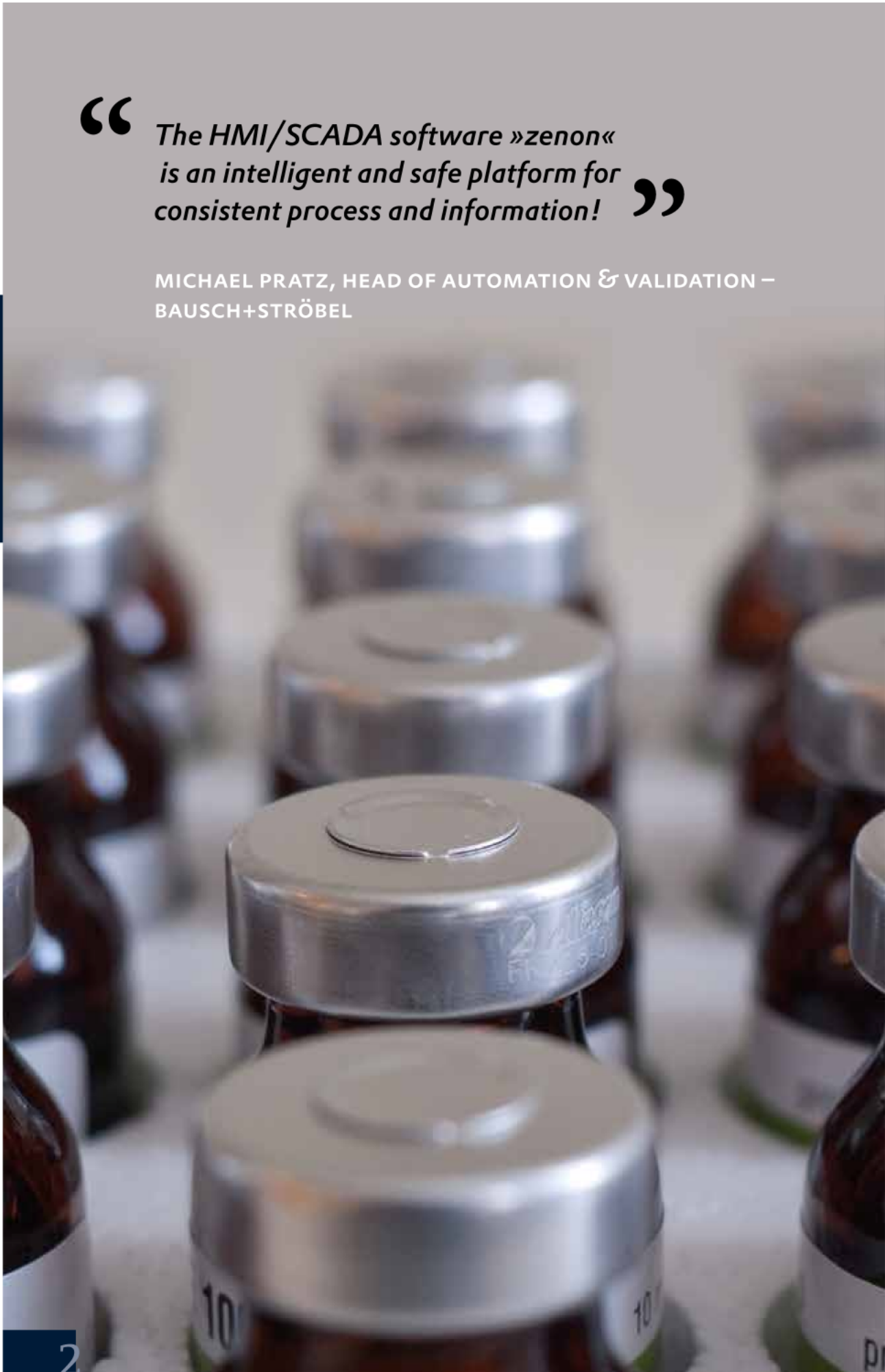


# zenon in Pharmaceutical

Optimization and Efficient Validation  
for the Life-Science Industry.

“ *The HMI/SCADA software »zenon«  
is an intelligent and safe platform for  
consistent process and information!* ”

MICHAEL PRATZ, HEAD OF AUTOMATION & VALIDATION –  
BAUSCH+STRÖBEL



# Translate your vision into profit!

Automation in the Pharmaceutical industry calls for more requirements than other manufacturing sectors, with greater challenges and deeper demands on: Safety, Quality, and Regulation compliance.

## **THE DOOR TO OPPORTUNITY IS OPEN!**

The zenon Product Family embraces these challenges 'Head-On'

### **INTERNATIONAL REGULATIONS**

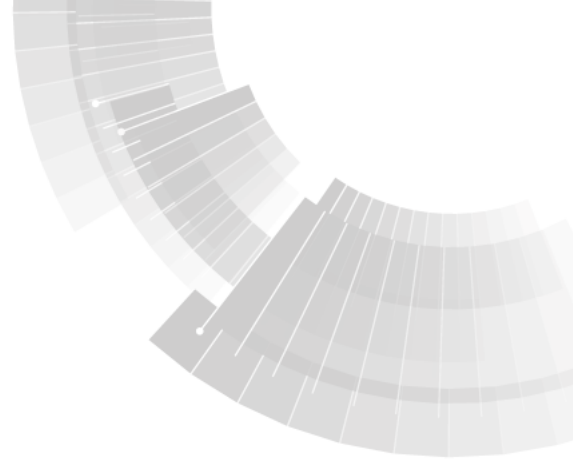
- ▶ FDA 21 CFR Part 11 Compliance
- ▶ Parameterization instead of programming
- ▶ GAMP 5 Software Category 4
- ▶ Validation efficiency

### **REDUCE RISK AND INCREASE QUALITY**

- ▶ Reduce Complexity
- ▶ Reduce Novelty
- ▶ Increase Reliability

### **SENSOR TO ERP**

- ▶ Strong Communication platform
- ▶ Bring Multiple Systems together
- ▶ Native communication drivers
- ▶ Integrate to Business Systems



# Ergonomics drives Performance.

## SYSTEM INTEGRATION

Communication drivers allow integration to many different systems without the need for any changes or additions to the 3<sup>rd</sup> party system.

Vertical integration to higher level systems bridge control structures into senior operations and business IT, e.g. through native SAP interface.

## QUALITY MANAGEMENT

Full compliance to international regulations such as the FDA 21 CFR Part 11 with electronic Records & Signatures.

Full documentation of Batch recipes and RGM recipes.

Full production documentation, recording events, critical process values, RBE, and regulatory compliance.

## DESIGN ENGINEERING

Parameterization brings flexible integral functionality to life in a regulated GMP environment, making Validation as efficient as possible.

- ▶ Reduce design and development time.
- ▶ Increase quality.
- ▶ Reduce novelty, complexity and risk.

Project history, project comparison and automated documentation, highlight the changes, risk and quality implications with project evolution and development.



## BUSINESS MANAGEMENT

Linking business and production with live, real-time and accurate results, benefits decision making with empirical data. Closed loop application of initiatives which enhance Quality, Performance and Energy consumption.

## OPERATORS

Create individual and ergonomic production control environments. Through transparency the operator can view machine status and alarms across the production line or facility, without the need to visit each machine.

Multi-Touch intuitive interfaces provide intelligent user interaction and optimized presentation of processes. The use of Multi-Touch applications will increase usability and operating safety.

View projects in multiple languages and regional units.

## PRODUCTION MANAGEMENT

Cross-System reporting visualizes your enterprise, enabling you to see the optimization opportunities.

Lift machines into processes, with process wide analysis, audit-trail, and alarm management. See where you can really make a difference.

Analyze, compare and report across all systems. Focus the data to individual needs, and get information in real-time.

Implement ISO 50001 compliance to reduce energy consumption.

zenon Everywhere Smartphone App keeps you informed with focused information.



# Regulation Compliance.

**PUSH INNOVATION INTO THE PROCESS,  
SIMPLE CONFIGURATION BRINGS IT INTO COMPLIANCE.**

zenon solutions operating in regulated areas have the essential functionality to comply with international regulations such as the FDA 21 CFR Part 11. Compliance is firmly fixed in zenon’s philosophy, but zenon goes further.

Product and patient safety are core qualities we protect through integrated functionality. Audit-trail, Alarm management, Archive, User Administration, Security, and strong reporting possibilities provide reassurance of the process.

Configurable systems significantly reduce the validation effort associated with automation in GMP environments, strictly adhering to international regulations with a suite of technology focusing on efficient validation.

Integral functionality, and native communication to systems and devices, makes any project an FDA compliant project.

System validation and qualification is reduced by applying the ISPE GAMP5 guidelines software category 4 ‘Configured Product’.

Parameterized automation solutions increase quality, and reduce risk, novelty, and complexity.



“ *Configurable library of high end functionality, making validation as efficient as possible.* ”

## Out of the box GMP.

### STOP DEVELOPING, AND START CONFIGURING EFFICIENT VALIDATION SOLUTIONS.

A large function library brings complex, robust and flexible control. Out-Of-The-Box GMP automation is possible through configurable software, where all functionality is contained in one product that actively engages the regulations. Such an environment in one product family brings the required security to large distributed and integrated systems, whilst empowering standalone systems the same security with all required GMP features.

Parameterization means system validation is as efficient as possible. It enables efficient Engineering and development through a suite of advanced control.

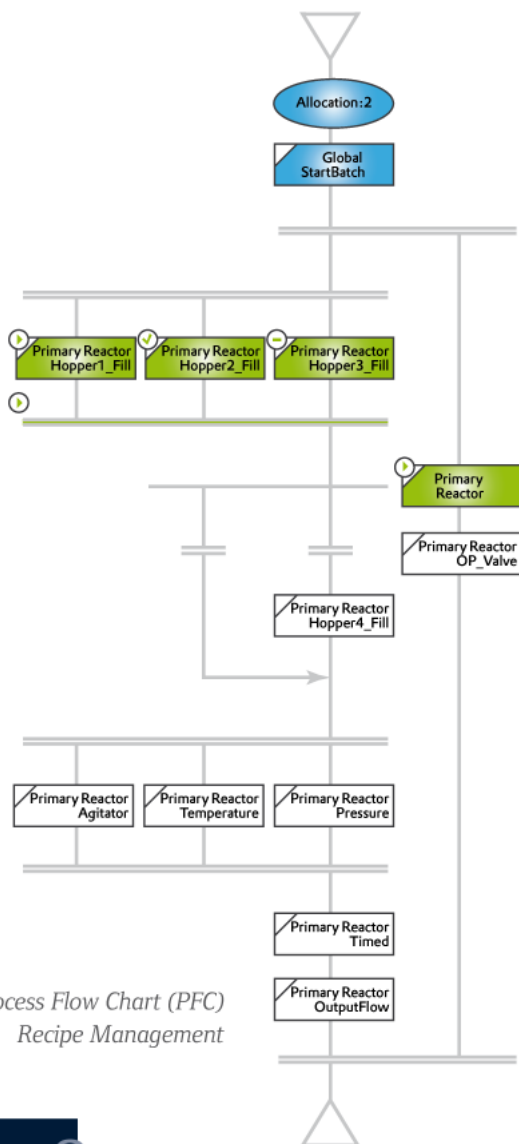
Native communication drivers, achieve connection to other systems and networks through configurable interfaces, which do not require design on the 3rd party system. Choose the technology you need, simply connect and configure.

Who did What, When, Where, Why and How is embraced in a culture of security: Audit-trail, Alarm Management, User Administration, secure Communications, Archives, and strong Reporting capabilities. You know exactly what is happening on your production systems.

Intelligent redundancy aims for systems to have high reliability and availability, which guarantee consistent and robust performance.



# From Equipment Control to Reporting.



Process Flow Chart (PFC)  
Recipe Management

zenon Batch Control is a flexible ISA 88 compliant engine. Production automation solutions benefit from the separation between 'Equipment control' and 'Recipe process control'. Our communication platform links the Batch Control equally to legacy brownfield sites, and new greenfield facilities.

## ISA 88 COMPLIANT

- ▶ Easy to use, engineering & process parameterization
- ▶ Concurrent Batch operations
- ▶ Two representation of recipes, PFC and Matrix

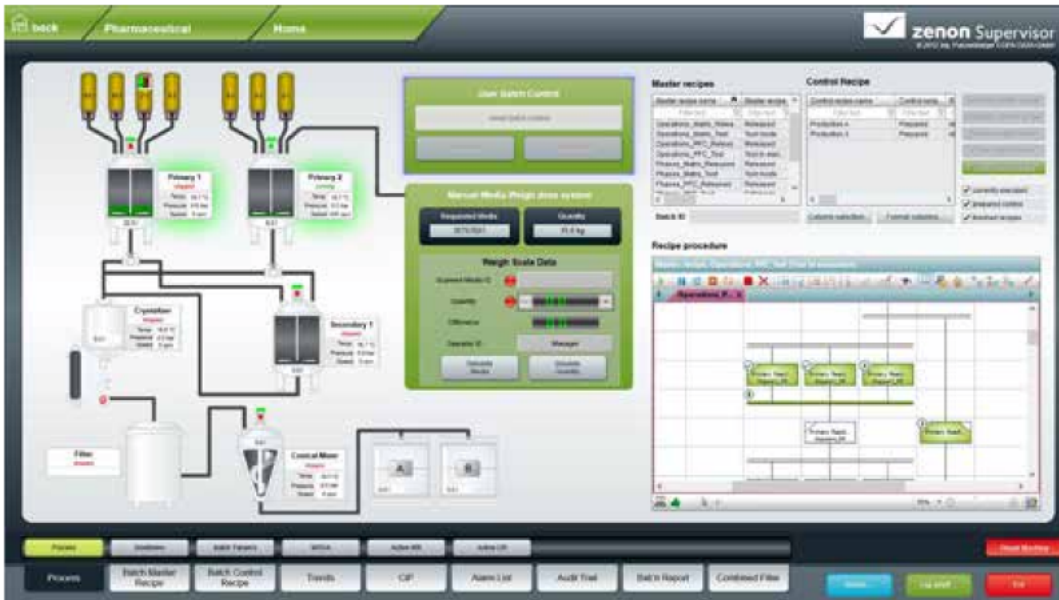
## START TO FINISH IN ONE PRODUCT

- ▶ Cost effective production automation
- ▶ Integrated zenon Product Family
- ▶ Reporting & Analysis
- ▶ Consistent Control





“Quality is our Recipe!”

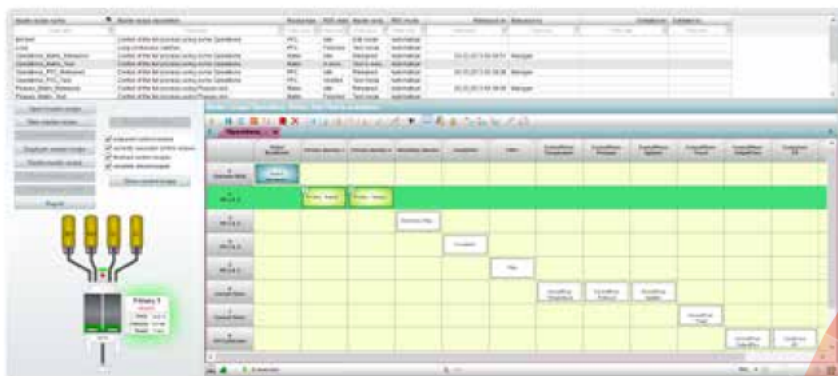


Ergonomic and ISA-88 compliant Batch Control

Full integration into the zenon Product Family creates an enriched solution for automation and production needs. Configurable functionality brings together the direct needs of the Part 11 regulations, Production operations, and Engineering.

For example, it includes Production reports, Quality reports, Analysis, Archiving, User Administration, Audit-trail, Alarm management in one system.

Separating the process from the equipment gives full flexibility, supporting continuous evolution and improvement, to drive optimization as a culture. The recipe changes and the equipment control remain flexible.



Sequential Recipe Management

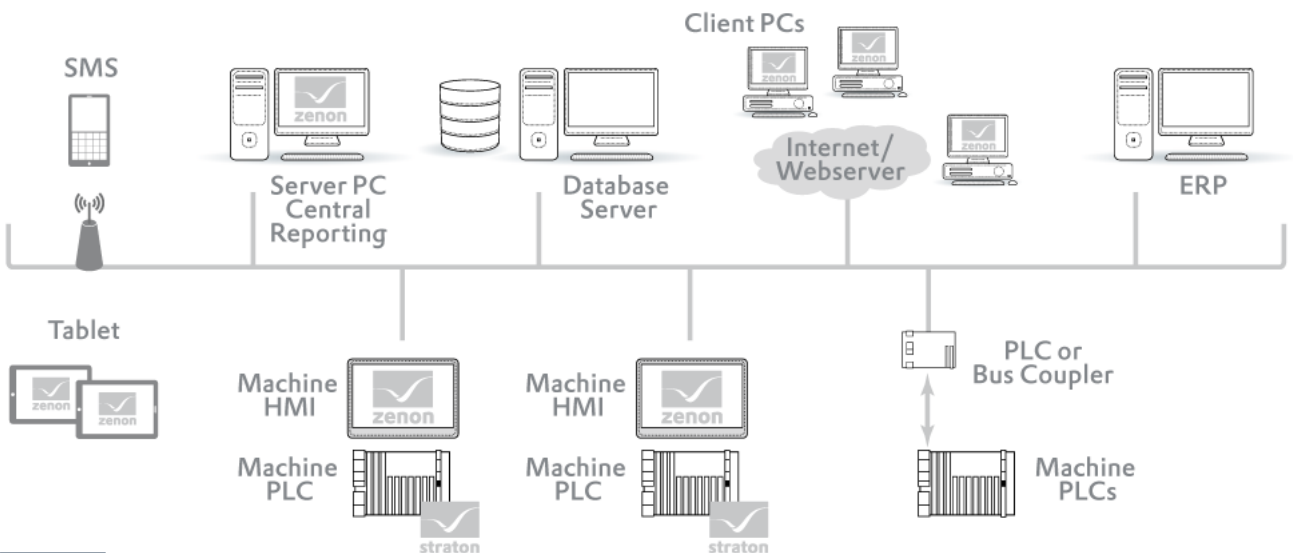
# Integrated site-wide automation.

In the context of an entire facility, automation has many roles to fulfill, in different environments.

Use our product family as one collaborative automation system. Or individually as standalone Part 11 compliant performant systems.

The key to control on this scale is communication. Real-time access to all data is crucial in holistic production automation. Native communication drivers connect PLC, Devices and Industrial Networks. With this we can apply our integrated functionality to all systems connected.

Individual machines are lifted into processes. Performance is viewed on Real-Time KPI's. Optimization has a direct effect, with instant feedback where continuous improvement is organic.



# Innovation technology – Upfront & Visible.

Getting the data and controlling the process under its command, is only one side of the coin.

Integrating to Manufacturing Execution & Business Systems through efficient interfaces continues the Ergonomic nature of zenon.

- ▶ Native SAP interface
- ▶ Database access and Archives, SQL
- ▶ OPC standard connection to MES

Command & Control with ERP & MES interfaces

- ▶ Direct to process
- ▶ Access KPI's
- ▶ Batch control, RGM control
- ▶ Scheduling

Push production and critical process information into the business layer

- ▶ Abstract the automation layers through intelligent functionality
- ▶ Report on processes in real-time
- ▶ Through user-centric browser access
- ▶ Archive reports automatically
- ▶ Capture your process activity through Production, Batch, Regulation, and Quality reports
- ▶ Optimization, OEE, Operational excellence
- ▶ Integrated in SCADA or as a facility-wide
- ▶ Facility-wide 'zenon Analyzer' dynamic reporting
- ▶ Integrated SCADA reporting



**Microsoft Partner**  
Gold Application Development



# Innovation Technology.

## DYNAMIC PRODUCTION REPORTING

Produce high quality and graphical production, RBE, quality, and performance reports. ISO 50001 compliant Energy Management. Reporting on any level in your production facility.

Identify improvement potential. Bring systems together through site-wide access to data, and bridge production into business.

## USER ADMINISTRATION

From standalone systems using the integral user security functionality. Or integrated into user management systems through Windows Active Directory, your processes are protected, and user identification for critical operations is assured. zenon links directly into your User Management.

## SCADA REPORTING

Production and Quality reporting. Production reports can incorporate Real-time, Archived, Audit-trail, and Alarm information, in highly graphical representations. Batch recipes and RGM recipes document production operation and quality assurance.

## BATCH CONTROL

Efficient production control and agile manufacturing, where concurrent batch recipes are executed on distributed process equipment.

## MULTI-TOUCH

User-centric, and intuitive interfaces to complex processes. Using well-known or user defined gestures; operators can navigate, control, and obtain information. Maximizing on the automation technology and display possibilities.

## COMMUNICATION DRIVERS

Native communication drivers and protocols are the key to integrate systems with great flexibility and performance. Whilst offering restriction free connectivity, you also get the security of data connection directly to the device or system, with no addition or change to that device or system.

## NETWORK

Complex and stable infrastructures parameterized by mouse click. Benefit from a distributed system with, Client-Server encryption, Redundancy, IPv6 enabled. We have the communication to bring systems together, and the intelligence to make it happen.

## RECIPE GROUP MANAGER

Recipes send parameters to connected systems. Grouped recipe management enables intelligent structures to be applied e.g. according to recipe function or equipment location. Change control is facilitated through recipe Versioning. User-defined Recipe states can be attributed enabling quality management (e.g. development, released, obsolete). The audit-trail monitors all recipe evolution and activity. Apply your QMS structure in zenon functionality.



## INTEGRATED HISTORIAN

Precise archiving of data, real-time data acquisition, consistent time-stamped and secure data storage. Store and evacuate data to a variety of formats including SQL.

## OUT-OF-THE-BOX COMPLIANCE

Native communication, integral functionality and parameterization create a framework of efficient validation. zenon brings any project into Part 11 compliance. Electronic Records & Signatures, system and process events are controlled and captured through: secure closed systems, Audit-trail, Alarm management, Archiving, Reporting, User management.

## ZENON LOGIC

Integrated IEC 61131-3 programming environment, give an homogeneous environment incorporating sophisticated control, mathematics, algorithms and communications into the SCADA visual and analysis environment. Tightly integrate the SCADA control and data acquisition with the process and equipment control.

## HIGH GRAPHICAL USABILITY

Through Ergonomic automation you achieve focused knowledge engaging your workforce. With intuitive interfaces aimed at high usability by different people in different roles, our product family embraces site-wide automation. Concentrating the data for specific functions.

# Do it Your Way.

**FLEXIBLE, CUTTING-EDGE AUTOMATION SOLUTIONS BY COPA-DATA.**

zenon has been the system of choice for many companies in various industries. Over 25 years and 80,000 installations prove that zenon is firmly positioned in automation, particularly in the Pharmaceutical, Food & Beverage, Energy & Infrastructure and Automotive industries.

## **GLOBAL PRESENCE – LOCAL SUPPORT**

COPA-DATA is present in over 40 countries around the world with subsidiaries, distributors and partners providing local sales and support services.

## **COMPREHENSIVE AUTOMATION SOLUTIONS**

In collaboration with our capable partners of the COPA-DATA Partner Community, COPA-DATA offers tailor-made automation solutions.

## **REFERENCES**

Pharma:

- ▶ Baxter
- ▶ Lifescan
- ▶ Roche
- ▶ Bausch + Ströbel
- ▶ Bosch Packaging Systems
- ▶ Harro Höfliger
- ▶ ...

Other industries:

- ▶ BMW
- ▶ Audi
- ▶ Swarovski
- ▶ Festo AG
- ▶ Sony DADC
- ▶ ...

# zenon Pharma Edition.

MATCHED TO THE NEEDS OF THE LIFE-SCIENCE INDUSTRIES.



## zenon Analyzer

Dynamic Production Reporting

Platform-independent Dynamic Production Reporting tool, which processes and presents data from the process to the ERP in real time.



## zenon Supervisor

Independent SCADA System

Facilitate full visualization and control of complex processes in a validation efficient regulation framework.



## zenon Operator

Embedded HMI System

Specialized simple and ergonomic machine and equipment control.



## zenon Logic

Integrated PLC System

zenon integrated PLC system with IEC 61131-3 programming environment.

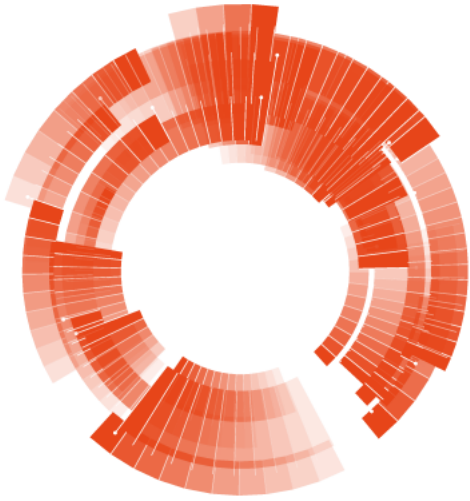
Automation solutions lifting machines into processes, bringing systems together, bridging production into business.

All products work seamlessly together encompassing the entire production environment from Sensor to ERP.

Holistic processes with Ergonomic control, puts the Person at the center of information.

### OUT OF THE BOX GMP

- ▶ Standalone or Integrated systems
- ▶ Part 11 compliant
- ▶ GAMP 5 guidelines adherence
- ▶ Strong Communication and Networking
- ▶ Safe and Reliable Compliant Systems
- ▶ One product family for all



SOLUTIONS FOR THE  
PHARMACEUTICAL INDUSTRY.

“ *Take the ergonomic path  
of high performance and optimize  
your facility with zenon.* ”

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