



zenon in Pharmaceutical

Optimization and Efficient Validation
for the Life-Science Industry

“ *In a global market of international regulations, zenon provides opportunities that bring new ideas into production. Robust, configurable solutions, saving valuable time on validation.* ”



Translate your vision into profit!

Automation in the Pharmaceutical industry faces more requirements than other manufacturing sectors, with greater challenges and deeper demands on: safety, quality and regulatory 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, out-of-the-box GMP

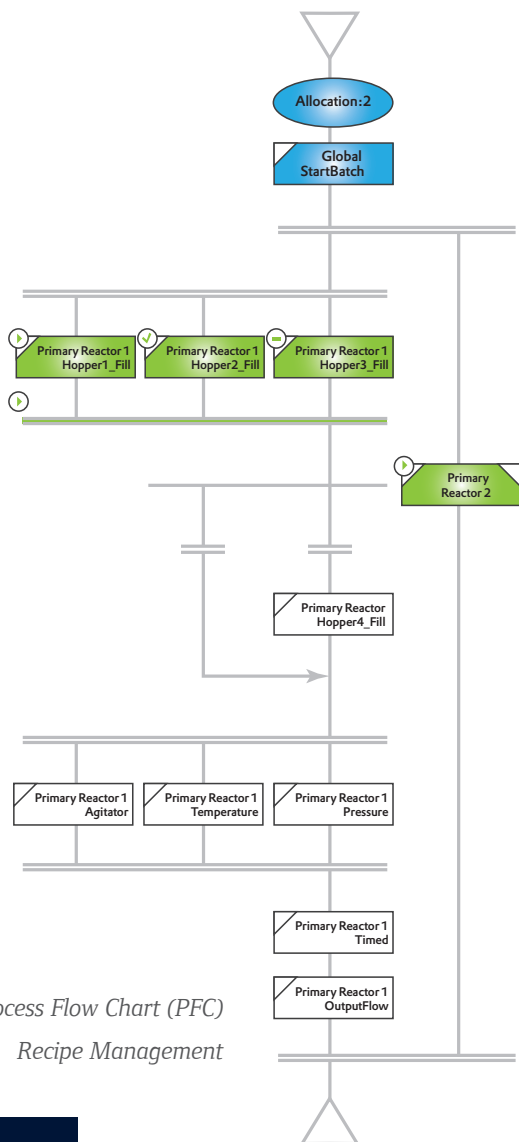
REDUCE RISK AND INCREASE QUALITY

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

SENSOR TO ERP

- ▶ Incorporate global Cloud solutions
- ▶ Extensive native communication library
- ▶ Bring multiple and different systems together
- ▶ Integrate automation into business

Process control & GMP reporting systems.



Process Flow Chart (PFC)
Recipe Management

The zenon Batch Control module is a flexible ISA-88 compliant batch engine. Production automation benefits from the separation between 'Equipment control' and 'Process control'. Our communication platform and zenon functionality seamlessly integrates legacy brownfield, new greenfield technology and manual operations, providing process control and production reporting systems.

ISA-88 COMPLIANT BATCH CONTROL

- ▶ Easy to use, engineering and process parameterization
- ▶ Concurrent batch operations
- ▶ Scalable to machine, line, or site control

START TO FINISH IN ONE PRODUCT

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

“Quality is our Recipe!”



The fully integrated zenon Product Family creates an enriched solution to meet automation and production needs. Configurable functionality brings together the direct needs of the Part 11 regulations, production operations, and engineering development.

For example, zenon delivers production reports, quality reports, analysis, historian, user administration, audit-trail and alarm management in one system.

PAPER ON GLASS

Paper on Glass puts automation into the hands of the operator. Replacing paper batch records with a zenon-powered tablet starts the automation earlier and gives you the benefit of batch-to-batch consistency, point of entry verification, automated collation of data, instant analysis and GMP report creation. This boosts “right first time” by eliminating missing entries and incorrect entries. Providing significant cost avoidance as there is no need to produce and store large volumes of paper post-batch.

Seamlessly integrate manual operations with automated equipment, to have a homogenous and automated audit-trail. All this without making any changes to equipment, and executing the same production processes. Maximum benefit with minimal validation effort and risk.



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 a 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 through reducing risk, novelty, and complexity.



“ *A 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.

An integral large function library brings robust and flexible control. Out-of-the-box GMP automation is only possible through configurable software, where all functionality is contained in one product that actively engages the regulations. Such an environment brings the required security to large distributed and integrated systems, while equally empowering stand-alone systems the same level of 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 functions.. 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.



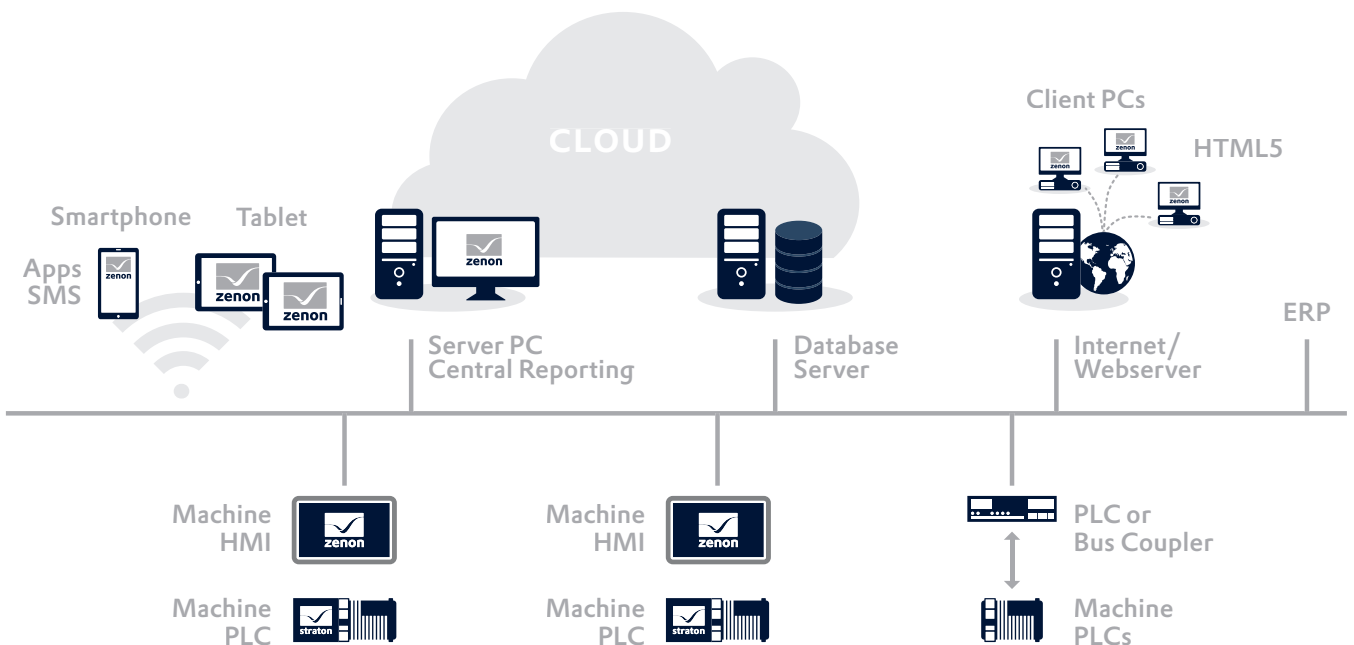
Integrated site-wide automation.

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

Use our Part 11 compliant product family as one collaborative automation system, or individually as standalone performant solutions.

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 connected systems.

Individual machines are lifted into processes. Performance is viewed on real-time KPIs. Optimization has a direct effect: instant feedback means continuous improvement becomes organic.



Innovation technology – upfront & visible.

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

Integrating with 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 link to process
- ▶ Generate KPIs
- ▶ Batch Control, Recipe Management
- ▶ Scheduling

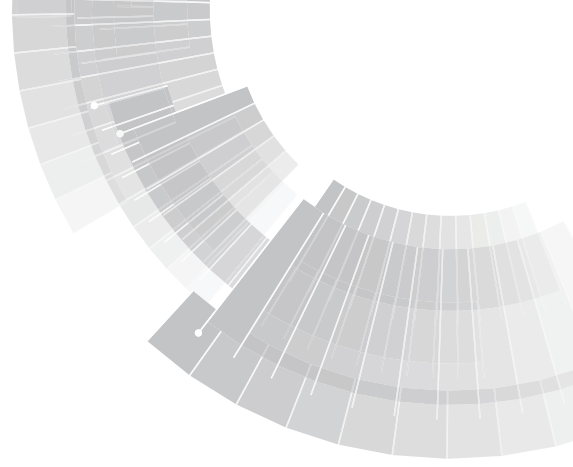
Integrate production and critical process information into the business layer.

- ▶ Abstract the automation layers through intelligent functionality
- ▶ Report on processes in real-time
- ▶ Historian
- ▶ Capture your process activity through production, batch, regulatory compliance, and quality reports
- ▶ Optimization, OEE, Operational excellence
- ▶ Dashboards in HTML5
- ▶ Tablet, smartphone, mobile devices



Microsoft Partner

Gold Application Development
Gold Intelligent Systems
Silver Cloud Platform



Ergonomics drives performance.

SYSTEM INTEGRATION

Communication drivers allow integration to many different systems without the need for any changes or additions to the 3rd 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

Compliance to international regulations such as the FDA 21 CFR Part 11 with electronic records and signatures.

Full documentation and versioning of Batch recipes and RGM (Recipe Group Manager) 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 accurate data. Closed-loop application of initiatives which enhance quality, performance and energy efficiency.

OPERATORS

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

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

PRODUCTION MANAGEMENT

Cross-system dashboards and reporting visualizes your enterprise, enabling you to see optimization potential.

Lift machines into processes, with process-wide analysis, audit-trail, and alarm management.

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 on the move.

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 authorization 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 production 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 integrating systems with great flexibility and performance. While offering restriction-free connectivity, you also get the security of a 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 and redundancy. We have the communication to bring systems together, and the intelligence to make it happen.

RECIPE GROUP MANAGER

Recipes send parameters to connected systems, and grouped recipe management enables intelligent structures to be applied. Change control and quality management is facilitated through recipe versioning and recipe states, where user-defined attributes can be applied. The audit-trail monitors all recipe evolution and activity.



INTEGRATED HISTORIAN

Precise archiving of data with real-time data acquisition, consistent time-stamped and secure data storage. Store and evacuate data in a variety of formats e.g. 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 and user management.

ZENON LOGIC

Integrated IEC 61131-3 programming environment provides a homogeneous environment that incorporates sophisticated control, mathematics, algorithms and communications into the SCADA environment. Tightly integrate the SCADA control and data acquisition with the process and equipment control.

HIGH GRAPHICAL USABILITY

Through ergonomic automation, you can focus information to better engage your workforce. With intuitive interfaces aimed at high usability by different people in different roles, our product family embraces site-wide automation, and focuses information for each specific function.

CLOUD

Our partnership with Microsoft provides a consistent uniform integration to the Azure cloud, thus creating a cost-effective and highly scalable infrastructure for analyses and safe transfer of data across a distributed company structure.

zenon transfers the data to the Azure cloud by means of secure encryption to ensure data protection and consistency. The data is physically saved in Microsoft datacenters around the world, the exact location you can choose together with the respective service.

Secure transfer and data storage, high availability, high visibility, and easy integration.

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. 30 years of experience and 100,000 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 50 countries around the world with subsidiaries, distributors and partners providing local sales and support services.

COMPREHENSIVE AUTOMATION SOLUTIONS

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

REFERENCES

- ▶ Roche
- ▶ Baxter
- ▶ Abbotts
- ▶ Groninger
- ▶ Bausch + Ströbel
- ▶ Romaco
- ▶ Harro Höfliger
- ▶ ACG
- ▶ Bosch Packaging Systems
- ▶ Müller Cleaning
- ▶ Brevetti

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 ergonomic machine and equipment control.



zenon Logic

Integrated PLC System

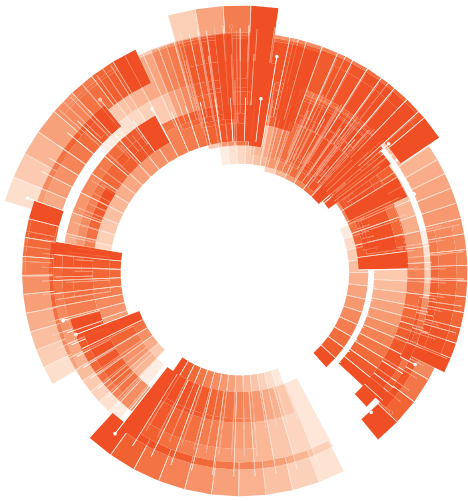
zenon integrated PLC system with IEC 61131-3 programming environment.

Automation solutions that lift machines into processes, bring systems together and bridge 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 INDUSTRIES.

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

COPA-DATA Headquarters

Ing. Punzenberger COPA-DATA GmbH
Karolingerstr. 7B, 5020 Salzburg
Austria

t +43 (0) 662 43 10 02-0
f +43 (0) 662 43 10 02-33

info@copadata.com
www.copadata.com

Find your regional contact at:
www.copadata.com/contact



do it your way

© Copyright 2016, Ing. Punzenberger COPA-DATA GmbH. All rights reserved. This document may not be reproduced or photocopied in any form (electronically or mechanically) without a prior permission in writing from Ing. Punzenberger COPA-DATA GmbH. The technical data contained herein have been provided solely for informational purposes and are not legally binding. Subject to change, technical or otherwise. Registered trademarks zenon® and zenon Analyzer® are both trademarks registered by Ing. Punzenberger COPA-DATA GmbH. All other brands or product names are trademarks or registered trademarks of the respective owner and have not been specifically earmarked. We thank our partners for their friendly support and the pictures (www.istockphoto.com) they provided.

Publication number: CD-ZEF-16-01-20

