IT-OT convergence in Life Science industries

A configurable landscape, GAMP s/w cat. 4

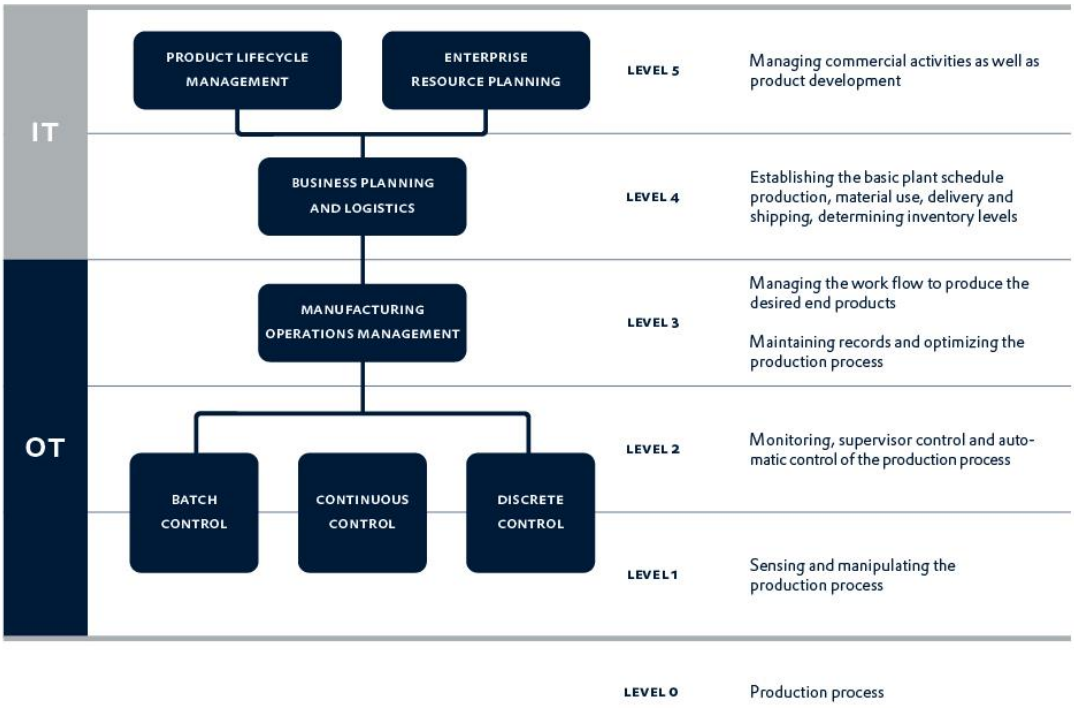
zenon
do it your way

Content

1. IT & OT, business vs. operations.

It is one thing to have machines in your organization that yield data as they work. But it is quite another to find ways to extract the intelligence from those machines, then use it throughout your existing infrastructure to make better decisions, improve processes, and reduce operating cost, thus intrinsically linking the business domain with operations management. Navigating IT and OT integration is critical for manufacturing performance, where the convergence is mostly lead by business managers, and the complexity is in in the hands of engineers. This document provides the landscape that will allow the barriers of convergence to fall away.

Effectively 'IT' (Information Technology) is owned by the organization, and it holds the business orientation. 'OT' (Operational Technology) is orientated around the specific groups of production processes. The different paths OT and IT have taken over the last decades are the result of organization partitions within companies and their different technological needs. Today the technology in use has advanced to adequately embrace both domains, the gap now is only historic, perhaps with a different view of the goals. The major IT/OT convergence issue is the adaptation of information to provide a common structure for information flow.



Breakdown of IT & OT structures and responsibilities.

Positives of integration

IT and OT independently influence a company's performance and ultimately its profit. Providing the mechanisms for smooth bi-directional communication has the effect of bringing production operations closer to the business world, and opening business visibility to the shop floor.

Cost reduction: Adaptation of common technology, standards, maintenance, and system administration, are easier with a single minded approach to its management.

Risk: A common platform means that security and reliability are jointly addressed. Increased control over distributed operations, resulting with better regulatory compliance and tracking.

Enhanced performance: Generate more relevant KPIs, attain higher efficiency and reliable performance. The pursuit of common objectives will improve automation and visibility, leading to more responsive systems and improved organizational performance. Opening up unrecognized potential through the increased interoperability, and collaborative decision making.

Flexibility: Transparency of operations, cost, cost structure, supply chain, and business orders. With harmonization of production and business strategy across sites and departments, the organization will be more flexible, allowing global manufacturing to move between locations. A more effective workforce is anticipated through improved information.

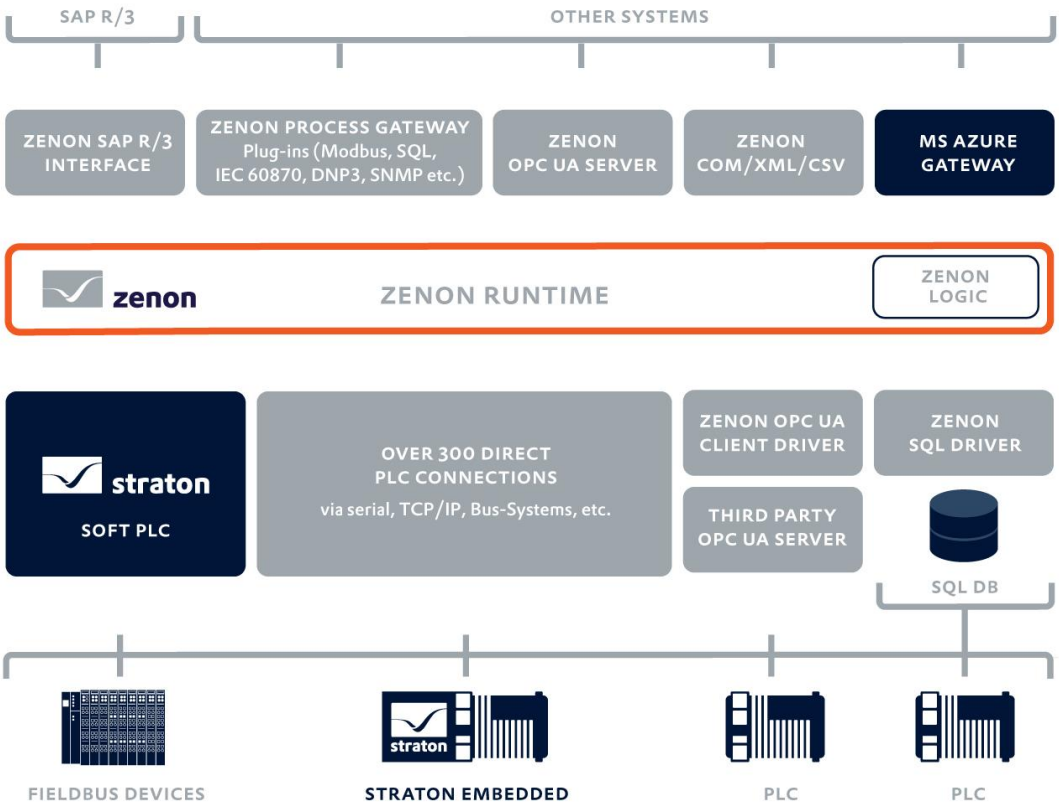
Strategic / Organizational: Better strategic decisions based on more timely and accurate information. Avoid duplication, with reduction of overlapping functions and internal procedures. A common understanding of the business supply chain into the manufacturing process.

zenon is well placed in both communication strength and functional capabilities. The configurability of zenon removes the need of the designer to understand the connection mechanisms, it connects equally to ERP systems such as SAP as it does to a PLC, or a temperature probe or SQL database. Therefore linking IT and OT through configurable and well know interfaces. The addition of functional modules for example the RGM, Batch Control, and Report Viewer, translate each domain's requests into actionable processes, returning results intelligently in recognized formats.

2. Communication

zenon is an independent and flexible automation system. It can connect natively to different industrial systems, IT systems, devices, and networks. Native communication drivers connect directly to these systems, enabling many different system to be connected together in the most efficient and robust manner. As no modification or addition to the 3rd party system is needed, in a read only situation the validation of this system is unaffected.

Bringing these two worlds together needs a deep understanding of each of the systems involved. The native communication driver is exactly this, each driver holds the unique protocol and interactions of the system. Such connectivity can include previously isolated machines into the process flow, bridge different technology and disparate processes, seamlessly include the wider scope of building management, energy management, and environmental monitoring systems.



zenon connects natively, bringing multiple systems together.

Native communication has the benefit of being independent of hardware manufacturer, providing easy integration of new and legacy systems. Configurable interfaces have significant positive effects on quality by reducing complexity and risk, resulting in a major reduction of validation effort and engineering design time.

3. GAMP software category 4, Parameterization

zenon is a configurable product using parameterization instead of programming, correctly administered solutions are classified as 'GAMP software category 4'. This has a major impact on Risk, Novelty and Complexity, and under the GAMP 5 guidelines zenon provides a very efficient validation environment.

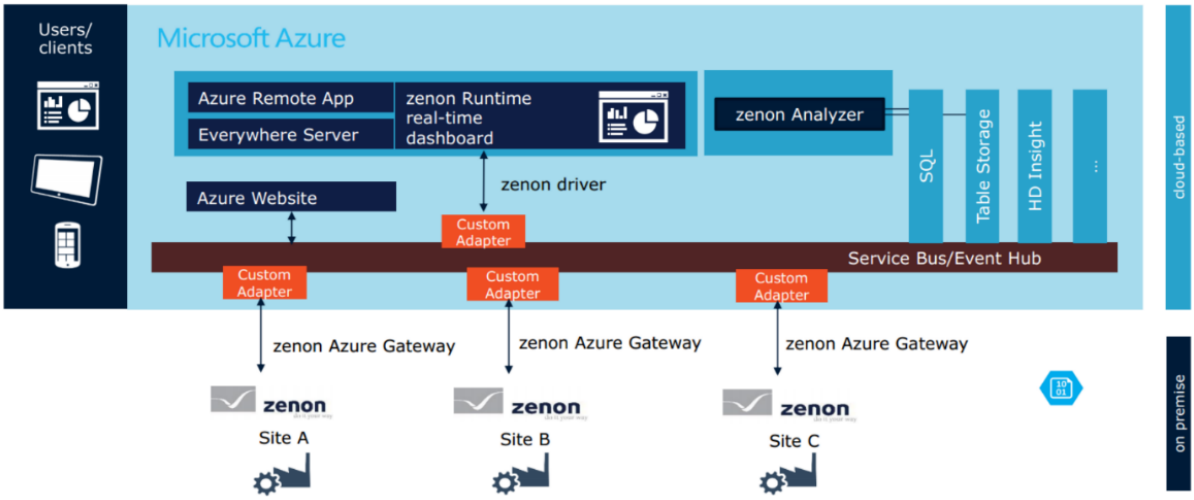
Using a configurable system to bridge the different domains of IT & OT therefore has significant benefits. zenon takes proven technology, and connects the two worlds in their native language. Facilitating the passage and processing of information, accurately and with the full context of the process. With the real possibility that these interactions continue to evolve over time, further benefits are envisaged at each modification.

4. Integral functionality

zenon has a wide range of integral functionality offering the full scope of application utilizing its internal function library. Holding such functionality internally to all installations of zenon, means that entire GMP projects can be implemented in one product. The GMP and regulatory requirements for Audit-trail, Alarm management, User authorization, Historian, Reporting, and Analysis, are all catered for in each zenon installation. This offers the advantage that full production processes can be realized in standalone applications, or as fully integrated systems taking advantage of the communication capabilities.

From Recipe or Batch instruction and throughout the production operation, the process is monitored and recorded from several angles provided by zenon's audit-trail, alarm list, and historian; providing live analysis, concluding with production, regulatory and quality reports. The divide at which you define the collation of GMP relevant data is under the user's discretion. The process and archived data can then be exported on command, automatically on event, or on a time basis. Providing the possibility to have a standalone system generating all GMP data, or as a fully integrated system.

5. Microsoft Azure connection



The Azure cloud technology integration into zenon is highly scalable in scope and functionality, effectively extending the zenon structure. For example, historian data can be moved to the cloud enabling efficient data management, storage and analysis; live processes can be communicated opening the possibility of global visibility; with the zenon Analyzer being available as a cloud solution.

- Azure Process gateway / Azure driver
- Archive evacuation
- Azure ReportApp
- Analyzer in the cloud

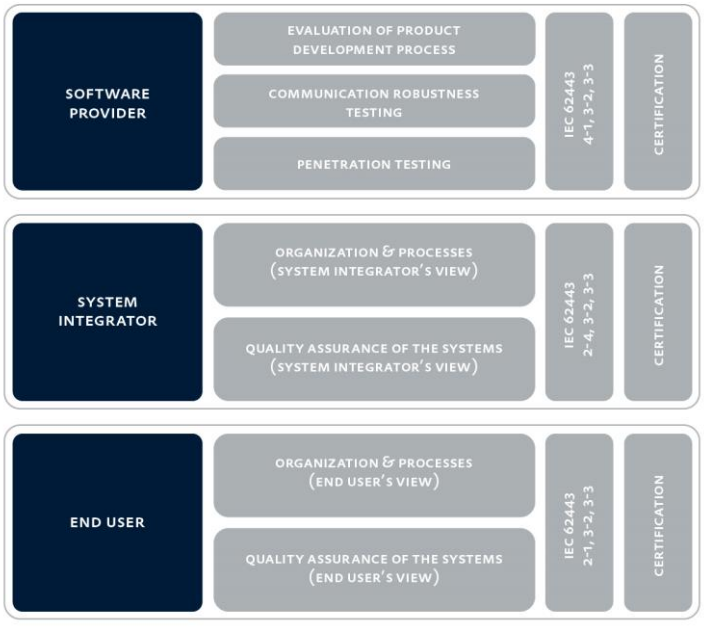
Security is a prime questions as cloud solutions by nature involve taking data offsite. The security measures for user administration and encryption between zenon systems is extended to cloud solutions. Additionally the Azure process gateway uses a Microsoft encrypted transport, upholding the high level of security and data integrity.

6. Industrial network security

At COPA-DATA, security has always been as important as reliability. Security is not something that can just be be bolted on as an afterthought, it needs to be designed as a key element of any functionality from the initial concept. The IEC 62443 ' Industrial communication networks - Network and system security' standard directly addresses IT security for Industrial Control Systems and their networks. Adherence to this standard is one of our requirements in zenon development, and form the core of our 'Security by design' philosophy.

The zenon runtime application is well protected with for example the user authorization limiting who has access to sensitive information. The zenon system has other mechanism in place to restrict unauthorized manipulation. All installation files are digitally signed and have certificates from VeriSign, this ensures the correct core installation is authentic. All runtime files are binary and therefore are very difficult to modify. When the zenon runtime detects a modified or corrupted binary file, the actual file will not be utilized by the system, and in the case of the password file of the user authorization, access to the system is closed. zenon continues to successfully undergo penetration and hacking tests carried out via various independent institutions.

Under the IEC 62443 standard, effective implementation of security strategies need to address both technical and organizational aspects of how people access and use the system. The diagram below displays how responsibility and actions are separated between the 'industrial software provider', the design of the system by the 'system integrator', and the utilization of the system by the 'end user or company'. Risk assessment of the solution and possible scenarios is a basic requirement to move towards the best implementation, including the use of tools such as 'whitelisting' which only allow authorized executables to be used on a specific PC. Within the perspective of zenon, COPA-DATA can offer guidance which choices support the best industrial network environment.



IEC 62443 Responsibilities

7. SAP Interface

The zenon SAP Interface facilitates a simple configurable connection to a SAP system. This brings an efficient bidirectional link between business ERP, supply chain, and process operations. Deep understanding of SAP is not needed, simply connect to the SAP system, select the required SAP module(s), the module interface variables are then available in zenon. Real time data and events are communicated over the defined variables, using this two way interface the business layer is updated and informed on the process operations, and the production environment is in synch with the business requests.

The RGM and Batch Control modules prove as a good example to possible further integration. The desired recipe is selected and initiated through SAP, zenon receives these requests and transfers the recipe to the control system(s), the production process is then instructed to execute. For a better control of procedures and data integration, zenon can call directly the SAP system through a Remote Function Call (RFC), remotely executing SAP modules from within the zenon runtime. During production, zenon reports back the progress, status, and events. Incorporating the Report Viewer and/or Historian export, the full production information can then be handed over as a complete end to end management.

8. ERP, MES, SQL, OSI-Pi, Werum, OPC-DA, OPC-UA

zenon has many capabilities to use standard interfaces, OPC has become a de-facto standard to communicate with production execution systems. Using either OPC-DA or OPC-UA, 3rd party clients can access the complete information contained within a zenon run time system, in this manner older legacy systems and proprietary protocols can be included in a wider infrastructure. The OPC server publishes requested information which each client can interface, this is a bidirectional interface facilitating two way communication. As OPC is a widely used protocol with a long history, many systems in the MES and ERP layer have adopted this efficient method of integration as an off-the-shelf connection for infrastructure and production execution systems such as Werum and OSIsoft-Pi.

SQL provides an efficient mechanism to transfer information using a standard platform. Although not a communication protocol, this is an actual database which zenon connects and transfers information. SQL is widely used in a business framework, to store and track many sources of data, e.g. financial, supply chain, inventory, or production orders. With a strong reporting element, interfacing to SQL is a corner stone in the zenon communication library.

9. HTML 5 Projects

The internet browser is an everyday tool that most people are familiar with, and feel comfortable using. HTML5 is a dynamic visualization which is platform independent, mobile, and uncomplicated to use. Browser visualization provides a key component bringing data to people not familiar with automation or the process control environment.

From the project perspective, providing HTML5 content is an easy task which is more or less fully automated. The dashboard and process overview screens are developed using the standard zenon editor, select the desired screens to be HTML5, and then published them using the zenon web server. The Web Server extends the same security principles as with a closed zenon system, using user authentication and encrypted communication technology.

10. Report Viewer

Human readable data is extremely important in the regulatory environment, to provide regulatory production or batch reports, for quality management of production recipes, and for analysis of production equipment. The Report Viewer uses common formats such as 'pdf' to present and store data, reports can be exported, or printed directly as a hard copy. Reports can be automatically executed, or manually requested on demand.

The Report Viewer can gain information from a variety of sources and present data in different formats, which facilitates a wider use. For example using the same data as for production reports, dashboards with KPIs such as OEE are easily calculated and presented, energy usage and a breakdown of machine operating times are easily collated.

11. Recipe Group Manager (RGM)

In production execution, the Recipe Group Manager (RGM) forms the translation from a supply chain request in the business layer, into a specific dimension for the operational equipment, where each recipe relates directly to a specific type of production order.

In zenon, each recipe holds a set of parameter values which are loaded into a specific set of variables on the connected PLC's and devices. For each recipe the RGM implements quality management with Version and State information, therefore tracking and controlling the

evolution of each recipe. Communication of the recipe is monitored providing feedback on the downloading progress, which recipe was loaded, together with the version and status.

zenon holds the operational specific information, which is referenced through a unique name. The Business layer would provide this information and a start signal through the prescribed communication gateway, and in return receive recipe and production status information. Thus an integrated structure is utilized.

12. Batch Control

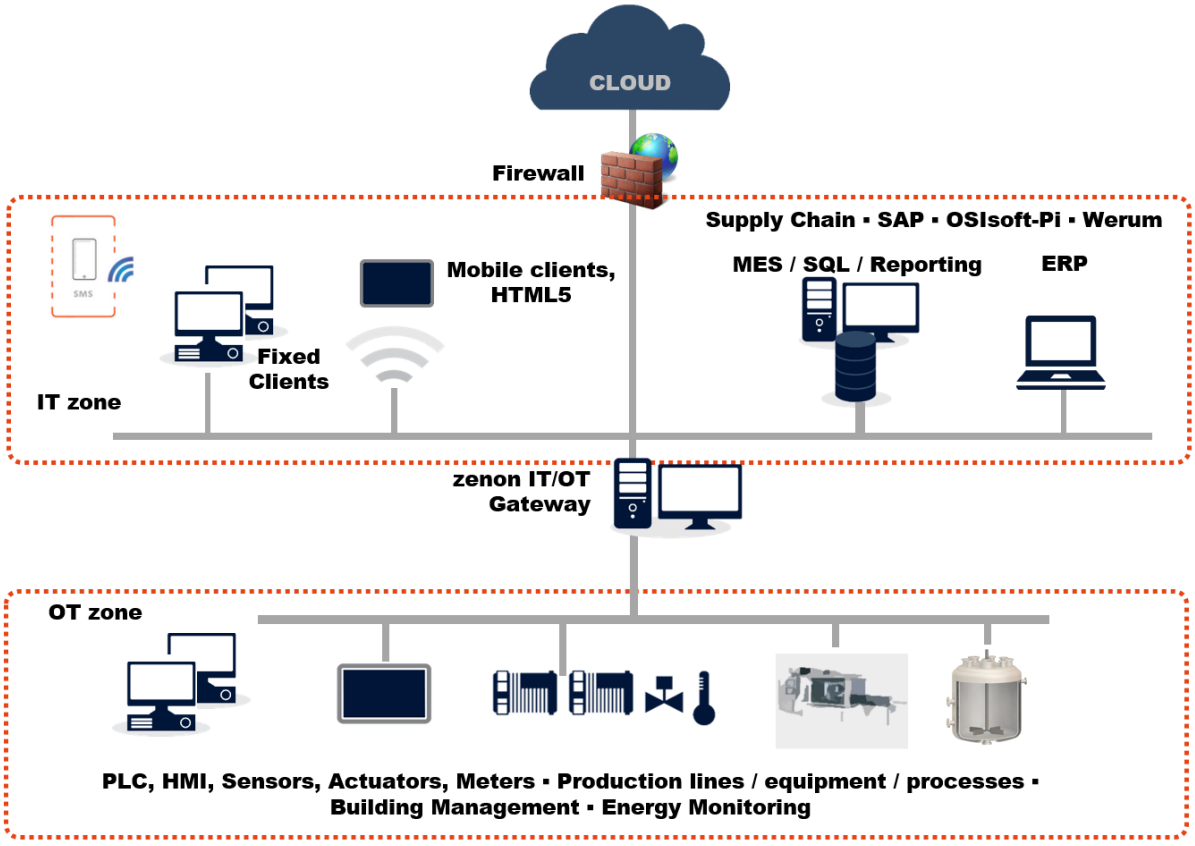
The ISA 88 compliant Batch Control module is a process control environment, where zenon controls the process parameters and performs the process control in synchronization with the connected PLC's and devices. The control process is far greater than the RGM environment, however in this layer the functionality has the same effect, to translate the business supply chain request, into production operations.

Each production process is defined in a Master Recipe, which holds the process flow, controlling parameters, and synchronization information. The Master Recipe (MR) is under quality management control, where each MR must be released for production before being executed. Each production batch can only be executed using a Control Recipe (CR). A CR is unique, and can only be executed once. The CR is created from a released MR, and has a unique name within the context of the MR. Is it common that the supply chain has a unique identifier for each production entity, to facilitate traceability and establish a direct link to the Control Recipe, a 'JobID' can be applied to each CR, accommodating the supply chain reference and traceability.

Using communicated variables between zenon and the business layer, CR can be created, started, and controlled. With feedback to the business layer, for example with batch status and event information. Additionally MR's can be exported and imported into the zenon runtime, providing the business supply chain with full control over the execution, storage, and quality management for each production process.

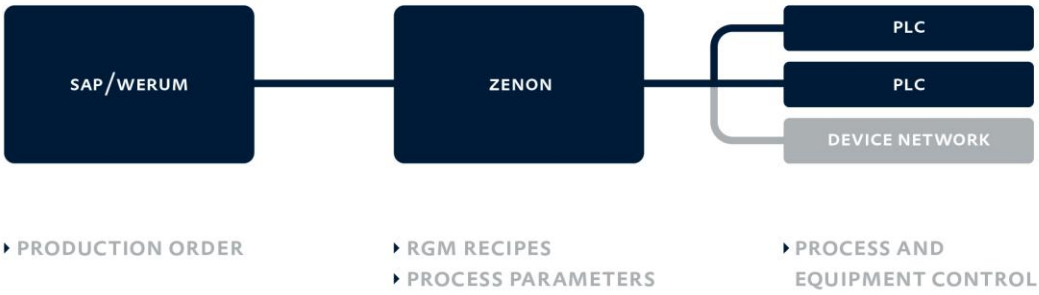
13. Workflows

Network topology and infrastructures are unique to any company, site or department. Scalable technology allows you to place the ideal structure for each automation zone. For example the Historian and Batch Control could be placed locally at the machine or production line level, and/or involving a more traditional approach having servers at the top of the control structure servicing all the processes. Redundant systems build in greater security, with multi-server systems improving flexibility. The diagram below displays a possible structure highlighting each of the described elements, with zenon most any topology could be implemented with the same functionality.



Example production infrastructure topology

Supply chain production order – RGM managed recipes

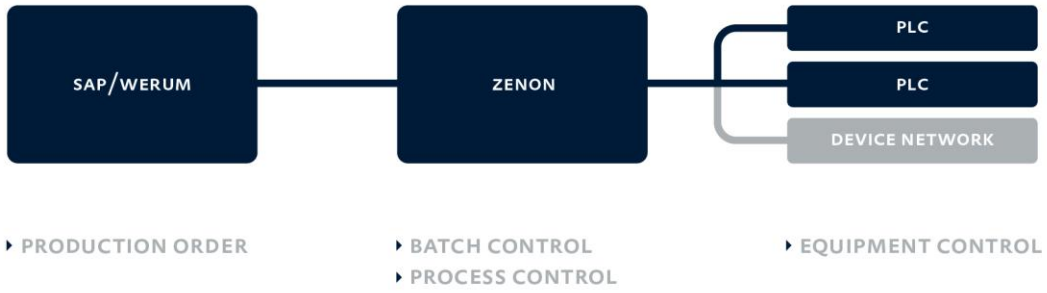


zenon provides the translation from a supply chain production order in the business IT, to orientate and execute specific production processes on the OT system. zenon receives the production order through the defined ERP or MES connection, maps these to a Recipe, communicates the correct parameters to the correct production machines, then issues a start command. Production status and key values are communicated back up from the equipment to the ERP or MES.

ERP/MES	→ Recipe group name, recipe name, start signal.
	← Recipe status, production KPIs.
zenon	Loads the requested recipe, writes control parameters to the connected process equipment, starts production.

This example shows the command to execute the production process. An example is given later in this section demonstrating how zenon monitors the production, archives data, and reports on this process.

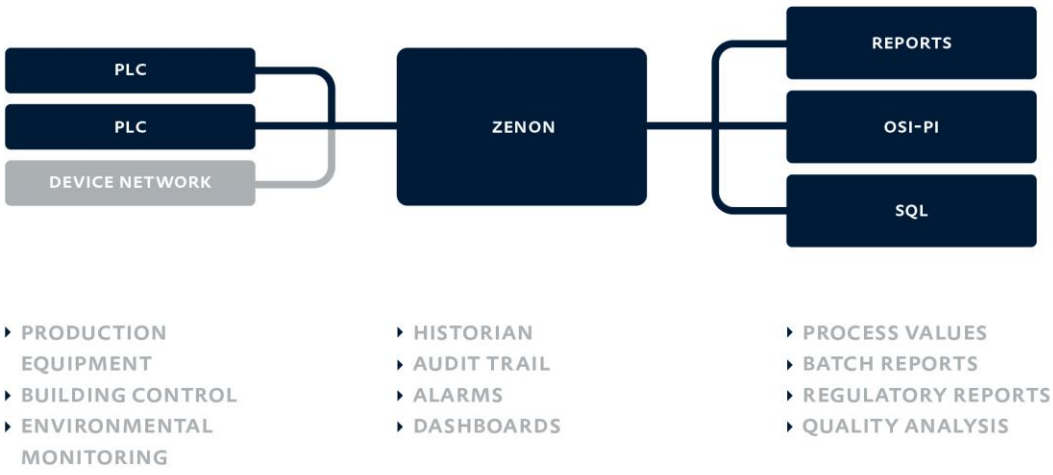
Supply chain production order – Batch Control



zenon provides the translation from a supply chain production order in the business IT, to control each required process on the OT system. zenon receives the production order through the defined ERP or MES connection, maps these to a Master Recipe, creates a Control Recipe, and when requested starts the production execution. Production status and key values are communicated back up from the equipment to the ERP or MES.

ERP/MES	→ Master Recipe name, Control Recipe name, start signal. ← Recipe status, production KPIs.
zenon	Create a Control Recipe from the Master Recipe, on start request controls the process equipment.

Production reporting



zenon uses its communication library to connect to all production equipment and devices, variables are defined in an alarm structure, and in a historian structure. Using either the Report Viewer or zenon Analyzer, reports can be generated automatically or manually, and stored on a secure server.

Using the same data several different reports can focus the information to fulfil different tasks. For regulatory compliance a complete batch report may be needed, with very detailed and accurate audit-trail and alarms, including process values on critical quality attributes. This is quite a long report. Condensing this information is possible, for example a RBE (Report By Exception) report, only includes data when critical processes have been violated or are in a warning situation, thus reducing the amount of information and making batch analysis easier. Reports focused on process analysis for quality and engineering, production efficiency through OEE KPIs, and energy management are all easily within the capabilities of this system. QMS is very much supported as the Report Viewer can provide hard copies of RGM and Batch Control recipes. Therefore several different reports can be generated simultaneously from the same source of data.

External storage of data, SQL, OSI-Pi

Using the same structure as the reporting function above. Structured data can be easily exported using several mechanisms. Historian archives, audit-trail, and alarms can be exported to SQL. Additionally specific SQL tables can be populated and synchronized with live zenon data.

OPC facilitates live streaming of data, and with OPC-UA historical and events can be communicated.

Possible implementation would include a trigger variable i.e. batch start, including the production order request ID from the ERP/MES supply chain. Collating the process data in zenon, and on batch completion the historian, audit-trail, and alarm information is securely passed to the requested system

Dashboards, HTML5

zenon uses its communication library to connect to all production equipment and devices. This information is then focused to the specific needs of each department or group, through the specific screens and user authorization, the information is freely available to the authorized persons. The screens can be located on a zenon client system, or equally using the web interfaces in a browser, providing PC workstation, mobile tablet and smart phone easy access. Possible examples are to have KPIs calculated in zenon. HTML5 then facilitates using a mobile device or telephone to view key production metrics, or have large screens in public areas displaying production counts, OEE, or energy consumption information.

14. Conclusion

Ineffective connectivity between IT and OT creates a gap that will reduce the potential to implement productivity gains and improve processes. Digital information is rewriting the rules of industry, and we have all the ingredients to provide a common structure of seamless communication, which understands enough of each process to translate between business supply chain and production operations.

The understanding of the two domains is achieved in the zenon function and communication library. Robust solutions, where proven technology is enabled through configuration, facilitates efficient design and validation in regulated environments.

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