



SIMPOSIO AFI

65° SIMPOSIO AFI **L'Industria della Salute** **nel tempo dell'Intelligenza** **Artificiale**

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From Data to Process
Knowledge

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Over 15 years of experience in Industrial Automation and Life Sciences, supporting pharmaceutical and biotech companies in implementing automation and digitalization solutions within GxP-regulated environments.

Connecting business objectives with technology, ensuring compliance, validation readiness, and long-term value creation in regulated environments.

Focused on innovation, efficiency, and measurable results, supporting pharmaceutical and biotech organizations in achieving sustainable growth and performance improvements.

Your plants already generate all the data you need.

The challenge is not collecting them. It is turning them into decisions.



Isolated Data

SCADA, PLC, historian: each system speaks only to itself.



Delayed Reports

Analyses arrive weeks later. The time to act has already passed.



Manual Root Cause Analysis

Cross-system correlations done manually, in Excel, with risk of error.



Regulatory Pressure

- 21 CFR Part 11 / Annex 11
- GAMP5 2nd Ed.: data lifecycle
- FDA ALCOA+ as a standard
- ICH Q10: mandatory CPV



New Operational Expectations

- Real OEE
- Multi-system deviation correlation
- Continuous Process Verification
- CSRD: consumption per batch



Technology Transformation

- IIoT: increasingly informative sensors
- Edge computing without mandatory cloud
- Low-code dashboards, no specialist IT
- Clamp-on: measurements without touching validated systems

The data already exists. It is not correlated, not contextualised, and analyses are still done manually.



No data integrity proof-pipeline

Who modified the file? When? 21 CFR Part 11 requires traceability that Excel cannot guarantee.

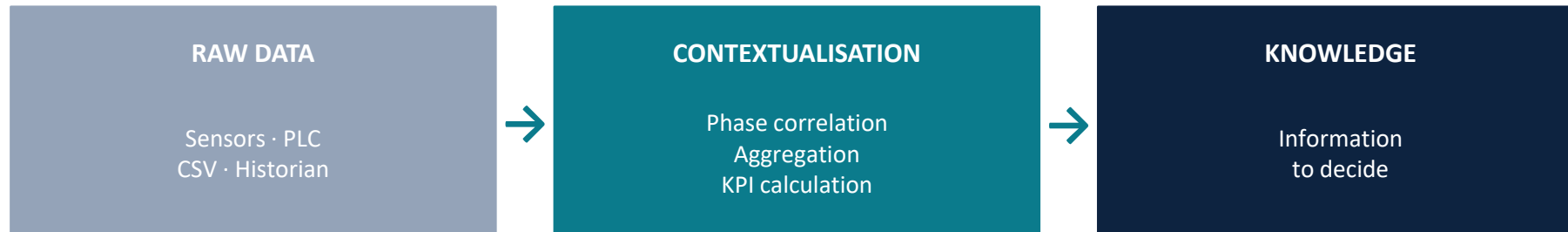
KPIs not in real time

OEE, waste, cost per batch calculated weeks later. Too late to act.

Cross-system correlation impossible

Deviations and energy data in separate silos. Root cause analysis is time-consuming and error-prone.

Collecting data is not enough. Value is created when data is correlated and contextualised.



Consumption → Batch Phase

Not just 'how much' but 'when' and 'during what': every kWh attributed to the specific production phase.

Alarms → Productivity

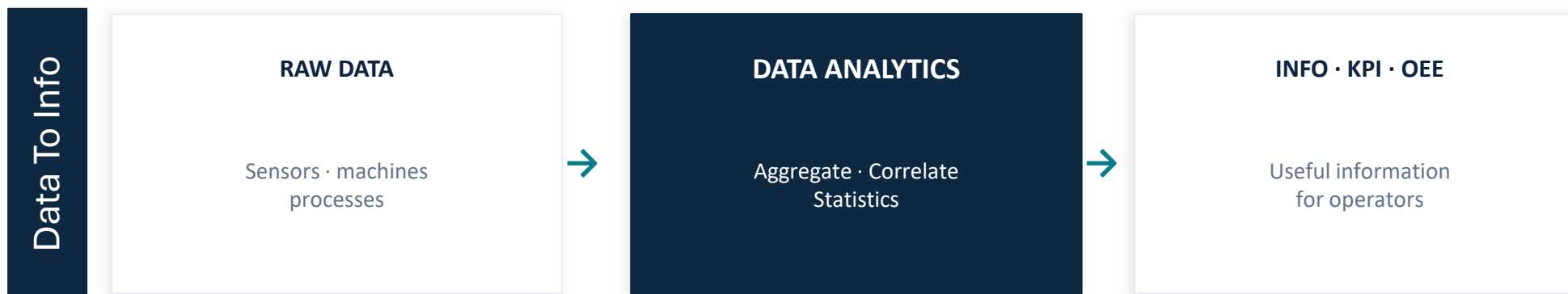
Correlate alarms with productivity: which events actually impacted performance.

Actual Usage → Theoretical Capacity

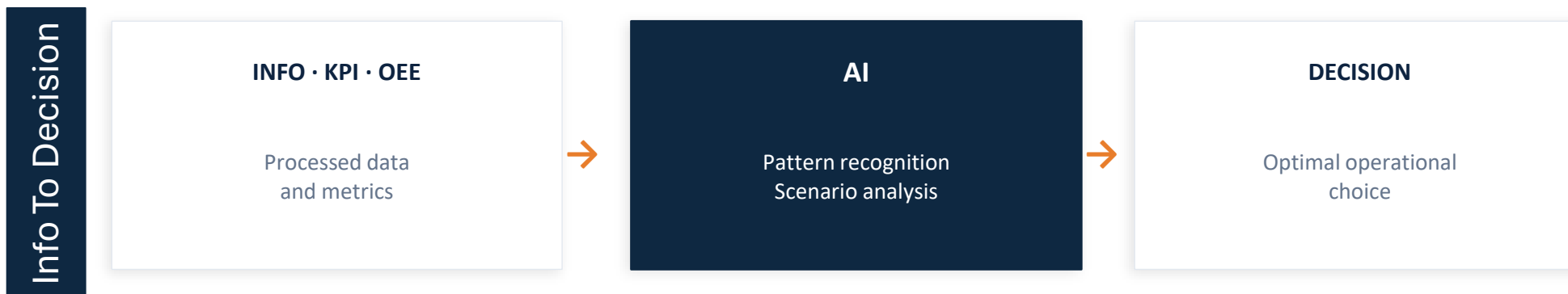
Compare actual usage with nominal capacity: available margins and bottlenecks become visible.

Data Read → KPIs Calculated

Real OEE calculated from integrated data: Availability, Performance and Quality from actual measurements.



We have raw data in abundance. Turning it into information is not straightforward: data analytics makes it possible.



Even when we have information, we must choose between scenarios. AI is here to support these decisions under conditions of uncertainty.

Correct. And that is exactly the starting point.

PRODUCTION SYSTEM — VALIDATED

- PLC / HMI / SCADA — control system
- Recipes, sequences, GxP parameters
- IQ/OQ/PQ documentation
- No modifications. No change control.

Unchanged. Untouched.

*read-
only*
→

ANALYTICS LAYER — NON-GMP

- Data acquisition (edge / VM)
- KPI processing and correlations
- Real-time web dashboard
- Clamp-on sensors: additional non-invasive measurements

No additional validation. No GMP impact.

No plant downtime · No revalidation · Deployment 1–3 weeks · Cloud or on-premises



SIMPOSIO ***EFT***

The Platform

Live Demo



Calculated OEE

Availability, Performance and Quality from integrated data — not theoretical estimates. The figure your QMR requires.



Real-Time Quick Stats

Active production, alarm count, CO₂ emissions: all visible in a single view, updated live.



Production Cost per Batch

Production cost calculated in real time for each individual batch. Not at month end.



Fault Analytics — Alarm Clustering

Treemap: same size = same frequency. Immediate intervention priorities, evidence-based maintenance planning.



Batch Correlation

Every variable correlated with the production phase. Root cause analysis on a timeline. Recurring patterns identified automatically.



Multi-Asset Consumption View

Flow, energy, costs and CO₂ on hourly/daily/monthly scale. Real-time instrument diagnostics.

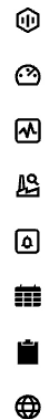


MGA

Asset: Reverse Osmosis

Administrator

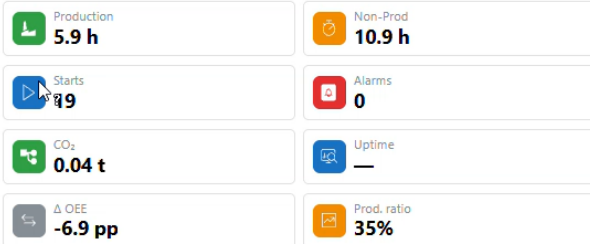
Logout



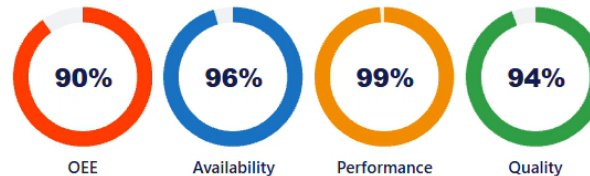
Express Analytics - Today

5 - RO 1^ Production - 2^ Initial Discharge - EDI Out of Service

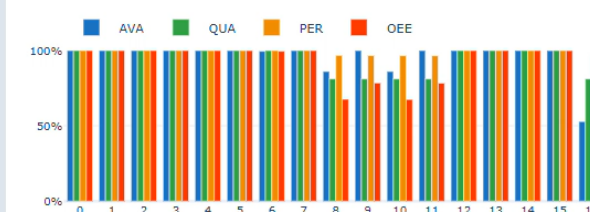
Quick Stats



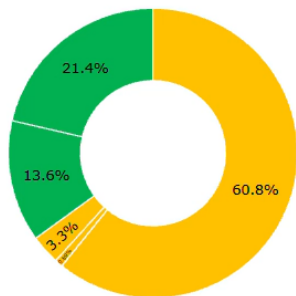
KPI Today



KPI Trend (hourly)



Phase Distribution Today



02:25	7 - RO 1^ Flushing - 2^ Flushing - EDI Flushing	45 min
02:10	6 - RO 1^ Production - 2^ Production - EDI...	14 min
01:25	7 - RO 1^ Flushing - 2^ Flushing - EDI Flushing	45 min
01:10	6 - RO 1^ Production - 2^ Production - EDI...	14 min
00:25	7 - RO 1^ Flushing - 2^ Flushing - EDI Flushing	44 min
00:10	6 - RO 1^ Production - 2^ Production - EDI...	15 min
00:01	7 - RO 1^ Flushing - 2^ Flushing - EDI Flushing	9 min
23:25	7 - RO 1^ Flushing - 2^ Flushing - EDI Flushing	35 min

Top Alarms Today

No alarms today. 🎉

Totalizers Today

Cooling/Steam Costi - Gen Costi - Prod Energia - Gen Energia - Prod Flussi - Gen Flussi - Prod

TCV50-5A Vapore Consumo Totale

0.0 kg

TCV50-5A Vapore Consumo Produzione

0.0 kg

TCV50-5B Acqua Refrig. Volume Totale

0.0 m3

TCV50-5B Acqua Refrig. Volume Produzione

0.0 m3



Case Study

Objective: Real KPIs + decision support for sizing

Client: Pierrel



System: Stilmas



Partner: MGA



The decision challenge

We needed to understand whether the existing infrastructure could truly support the planned expansion.

Distributor flow measurement

Clamp-on on the main PW distributor — non-invasive, no revalidation.

Actual consumption measurement

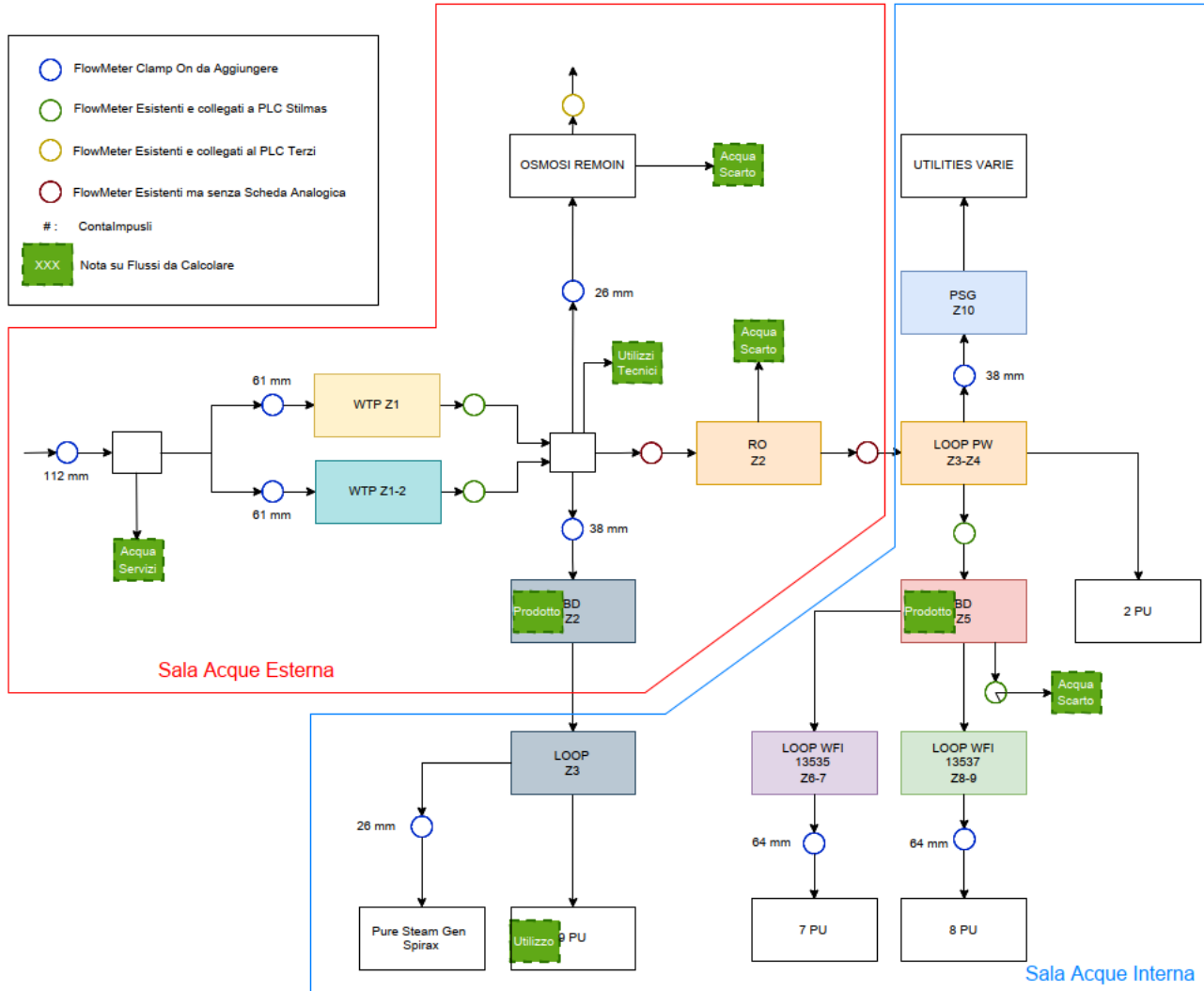
Data from the Stilmas PLC already connected. No additional hardware.

Loop behavior analysis

Consumption + diverting (recirculation). Both flows must be considered.

Water balance verification

Production $\neq$ consumption alone. Using only consumption, the balance did not add up.



The questions to be answered

The new water room requires the addition of two new PW points of use. Is the existing system capable of supporting them?

What is the residual capacity of the RO Z2 generator?

The nominal flow rate data does not reflect the actual behavior of the loop: a loop behavior analysis was needed.

Do we need a new generator dedicated to the new room?

Two options are being considered: connection to the existing generator (RO Z2) or a new dedicated RO.

How can I measure real-world consumption without modifying the validated system?

Solution: Clamp-on sensors (blue circles in the diagram) — no piping modifications, no revalidation.

Distributor output measurement

4150_Z3 TK PW: daily flow rate in m3 measured with clamp-on on the main distributor of the PW loop.

Consumption measurement at points of use

4150_Z5: Actual consumption measured on the user lines. Data available from the already connected Stilmas PLC.

Diverting (recirculation) calculation

Divert = Distributor - Consumption. This portion—not negligible—represents the recirculation flow not used productively.

Checking the water balance

The balance is correct only when considering: Distributor = Consumption + Diverter. The nominal flow rate alone led to an incorrect estimate of the generator load.



Result: The actual behavior of the loop is different from that described by the nominal data.

- RO Z2 has production margins.
- Consumption shows peaks and variability.
- Simultaneous requests are the real constraint.
- Average consumption is not sufficient for sizing.

Conclusion: The measured data show that the RO Z2 generator has production margin under current conditions. However, average consumption is not sufficient for sizing decisions: the critical factor is the simultaneity of PW demand when the new points of use are added.

Option A | New Water Room — Existing Generator

✓ Low investment

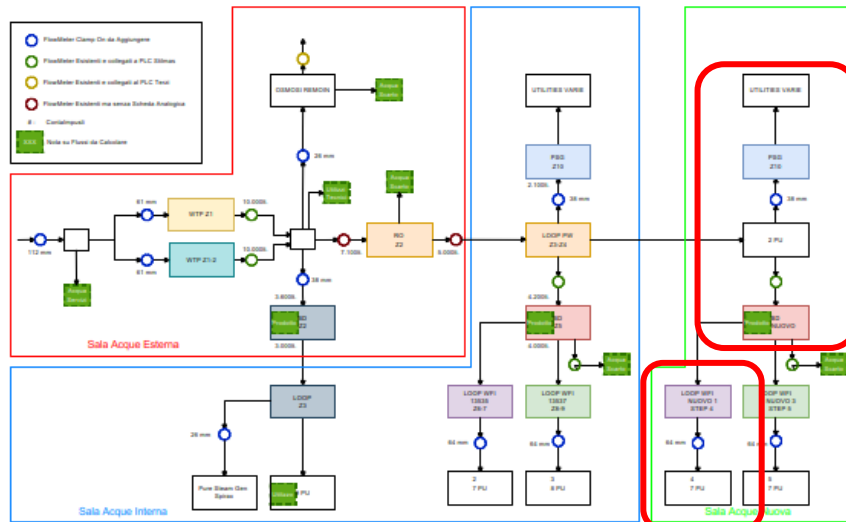
No new water production equipment required.

✓ Rapid implementation

Steps 4 and 5 connected directly to the existing PW Loop Z3-Z4.

✓ Capacity confirmed by data

Actual measured consumption (excluding diverter) leaves operating margin on RO Z2.



Current RO capacity is not the main limitation. The risk is overlapping demand from multiple users.

Option B | New RO dedicated to the new room



► When to evaluate it

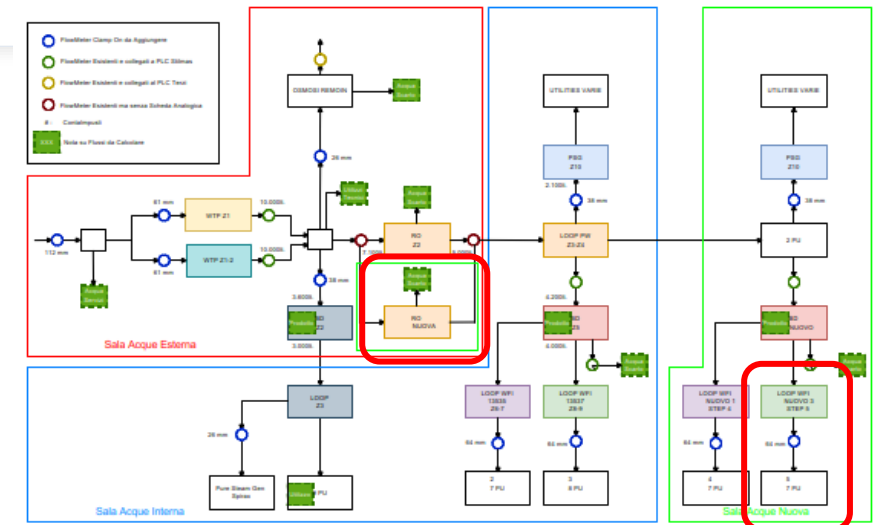
If future production growth increases consumption beyond the RO Z2 capacity or in the case of further expansions (Step 6+).

► Current limitation

Not justified by current consumption data: the RO Z2 still has available capacity.

► Advantage

Complete hydraulic independence of the new room: no interference with existing loops.



"What the sustainability report requires can easily be integrated into an already installed MascoDash. Three clamp-on sensors are all it takes."

The Starting Point

MascoDash already running

OEE, KPIs, alarm analysis — operational for months.

GMP Data Available

Process parameters, machine states, partial consumption data.

The CSRD Gap

Scope 1+2: missing steam, water and energy data per circuit, attributed to the batch.

The Solution: 3 Clamp-On Sensors

S1

Total Steam (Scope 1)

Clamp-on on the main manifold. Steam consumption per batch. Zero piping modifications.

S2

Cooling Water (Scope 1)

Added to the existing circuit. m³ per batch correlated with the production phase.

S3

Electrical Energy (Scope 2)

kWh measured and attributed to each individual batch through correlation with machine states.

Result: Automatic energy-to-lot traceability · CSRD Scope 1+2 reports ready for the sustainability report



The Real Challenge of Multi-Vendor Digitalisation

Data exists in every machine — but they speak different languages. The value is not in visualising them: it is in making them comparable and consistently readable.

Unified View: Comparable KPIs Across Different OEMs

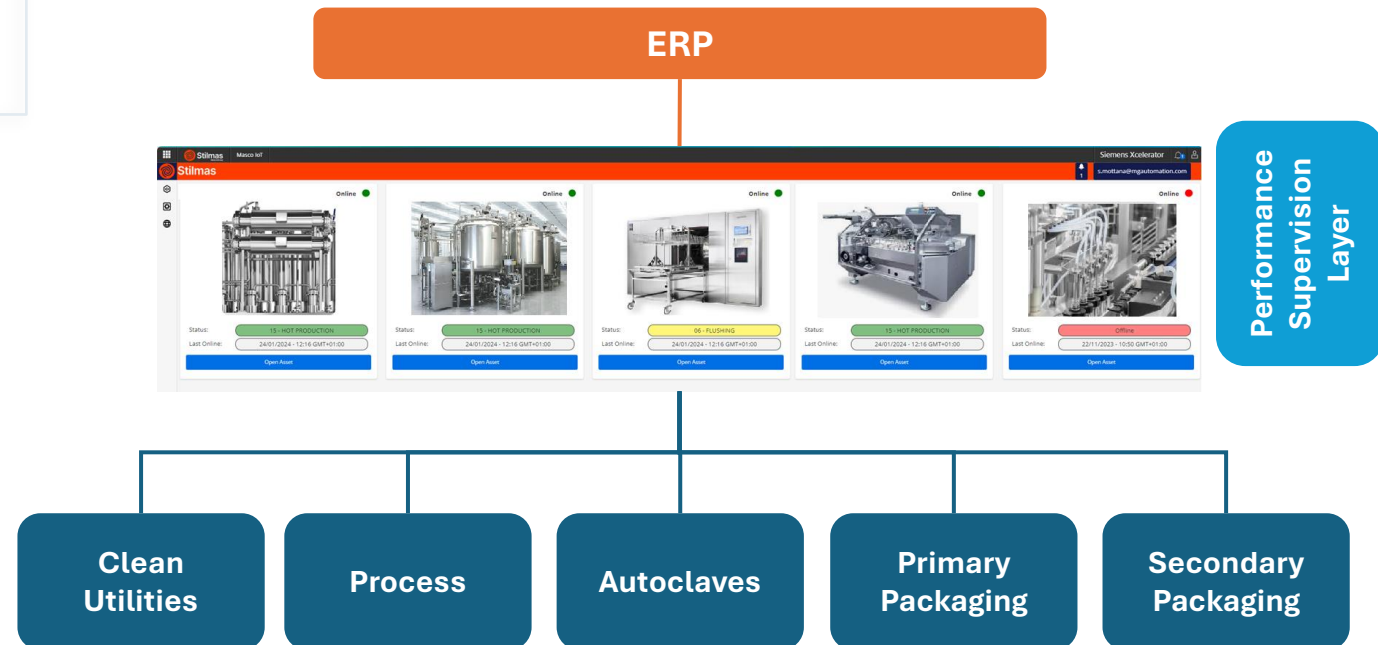
Alarms, OEE and consumption in a single dashboard — regardless of the OEM.

No Modifications to Existing Systems

Read-only. Validated systems unchanged: zero change control, zero revalidations.

Industry 4.0 compliant

All investments across the various machines qualified for tax incentives.



The point is not to have a better-looking dashboard. It is understanding what it enables — operationally and with a view to the future.

Identify Inefficiencies

Waste and bottlenecks that remain invisible with GMP data alone.

Improve Performance

Objective, comparable indicators: the foundation for documented continuous improvement.

Monitor Consumption per Batch

Consumption per machine, per phase, per batch: granularity that becomes a lever for optimisation.

Support Maintenance and Troubleshooting

Alarm clustering + phase correlation: targeted interventions, planned on the basis of historical evidence.

Have Objective Indicators to Decide

Real OEE, calculated reject rate, costs per batch: real numbers, not estimates.

Sustainability and CSRD — Looking Ahead

Carbon footprint per product, energy-to-lot traceability, automatic CSRD-ready reports.

1

Plants already hold most of the data they need.

There is no need to start from scratch. The starting point is making the most of what already exists — sensors, PLCs, SCADA, historians.

2

Value is created when data is correlated and contextualised.

An isolated data point is just a number. Contextualised data — by phase, by batch, by machine — is process knowledge.

3

A dashboard can become an operational and decision-making tool.

Not just visualisation: active support for sizing, maintenance, energy optimisation, quality and CSRD.



Grazie per l'attenzione