



**SIMPOSIO AFI**

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

**Rimini, 10/12 Giugno 2026**

**Soluzioni e logiche di integrazione nella**  
**Digitalizzazione nel mondo operation Life**  
**Sciences: Sostenibilità dei Processi e Rischi di**  
**Compliance**

**Igor Venanzoni - MGA**



# Igor Venanzoni - Bio



Igor Venanzoni  
**Masco Group Automation**  
Sales & KA Manager



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Over 15 years of experience in automation and digitalization solutions for the Life Sciences industry, supporting operational excellence and business growth.

I believe technology is never the final goal, but an enabler of business objectives, helping organizations improve efficiency, drive innovation, and create measurable value.

My focus is connecting people, data, and digital technologies, turning complexity into actionable insights that support better decisions and processes.

Machines



People

*Industrial digitalization has traditionally centered around machines*

***What about the people who make the factory work?***



Manufacturing — in Italy, as well as across Europe — and particularly the pharmaceutical industry, is facing a profound **structural transformation**

#### KNOW-HOW

In Italy, 78% of companies struggle to find workers with the right skills.

#### TURNOVER

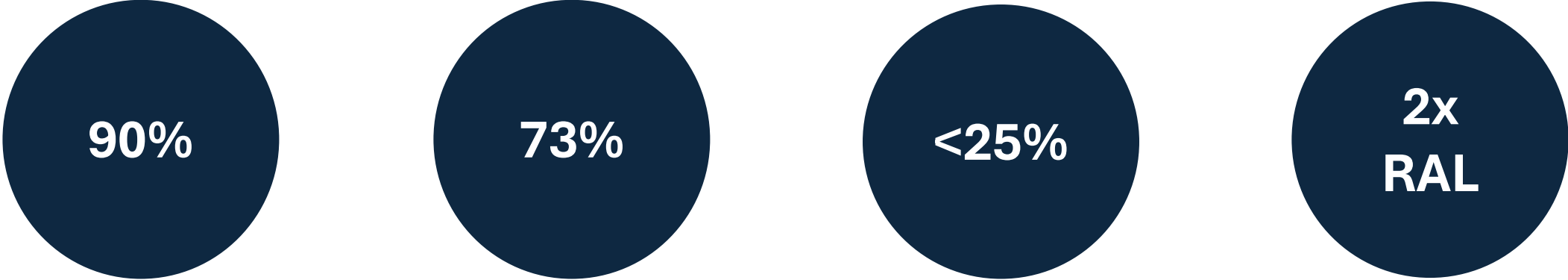
Employee turnover and demographic decline are reducing the availability of experienced operators.

#### COMPLEXITY

As production systems become more complex, advanced technical expertise is becoming harder to find.

#### SOURCES:

- Report «Talent Shortage 2025» - ManpowerGroup
- Report «Industria 2025» - Centro Studi Confindustria



90%

of knowledge resides in  
people's minds.

*(Source: PubMed Central)*

73%

of employees rely on  
uncodified knowledge  
shared by colleagues.

*(Source: Bloomfire)*

<25%

of companies codify and  
retain knowledge.

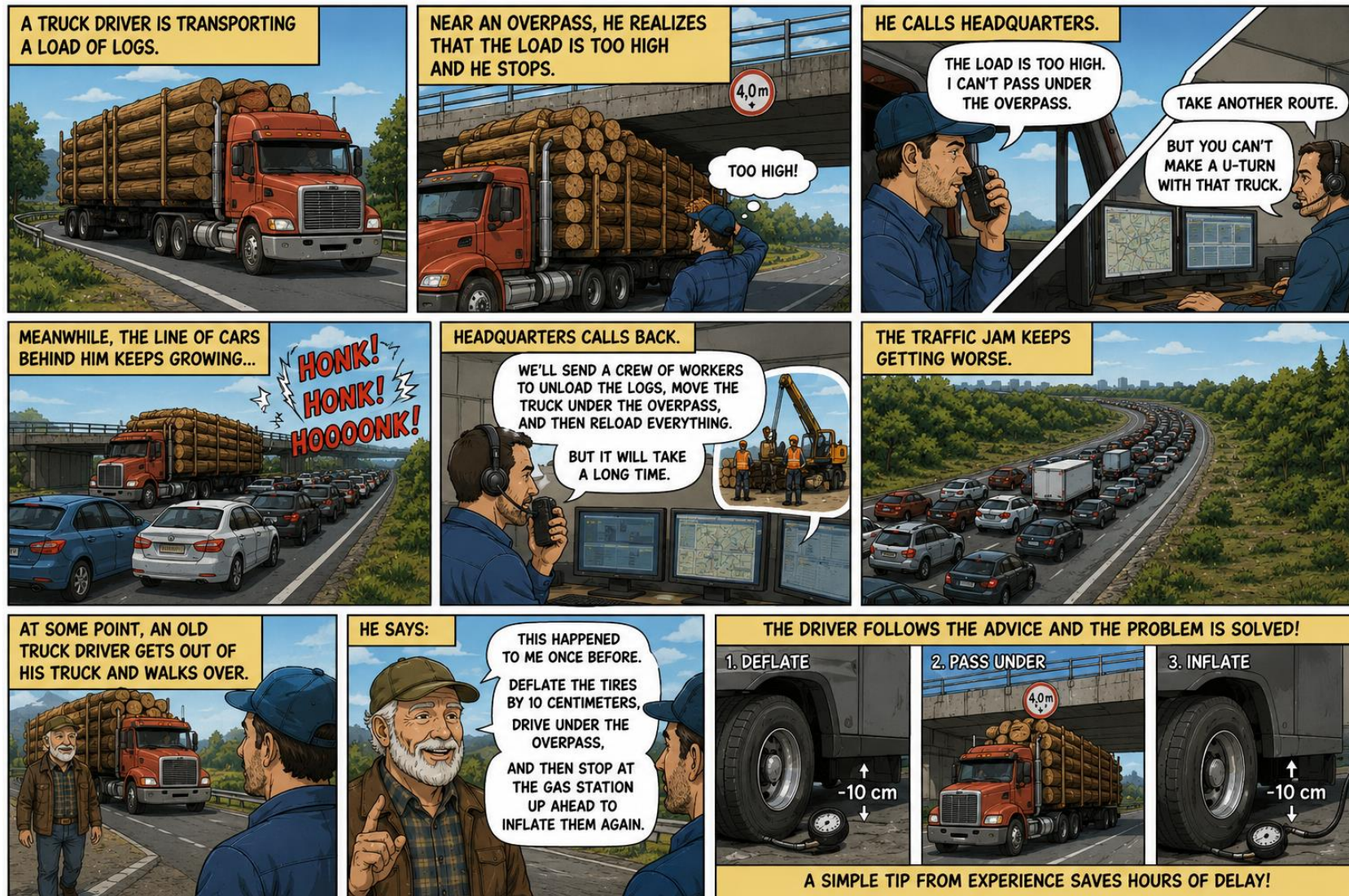
*(Source: Bloomfire)*

2x  
RAL

to rebuild the knowledge  
lost when an employee  
leave the company.

*(Source: Gallup)*

“A **Knowledge Management System (KMS)** is a platform designed to capture, organize and share the ***knowledge and expertise*** of an organization, enabling people to improve ***efficiency and operational performance***.”







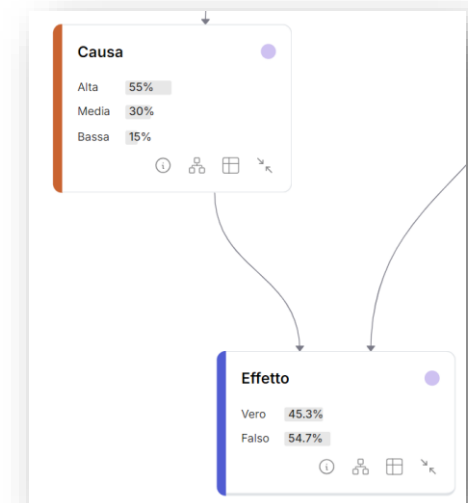
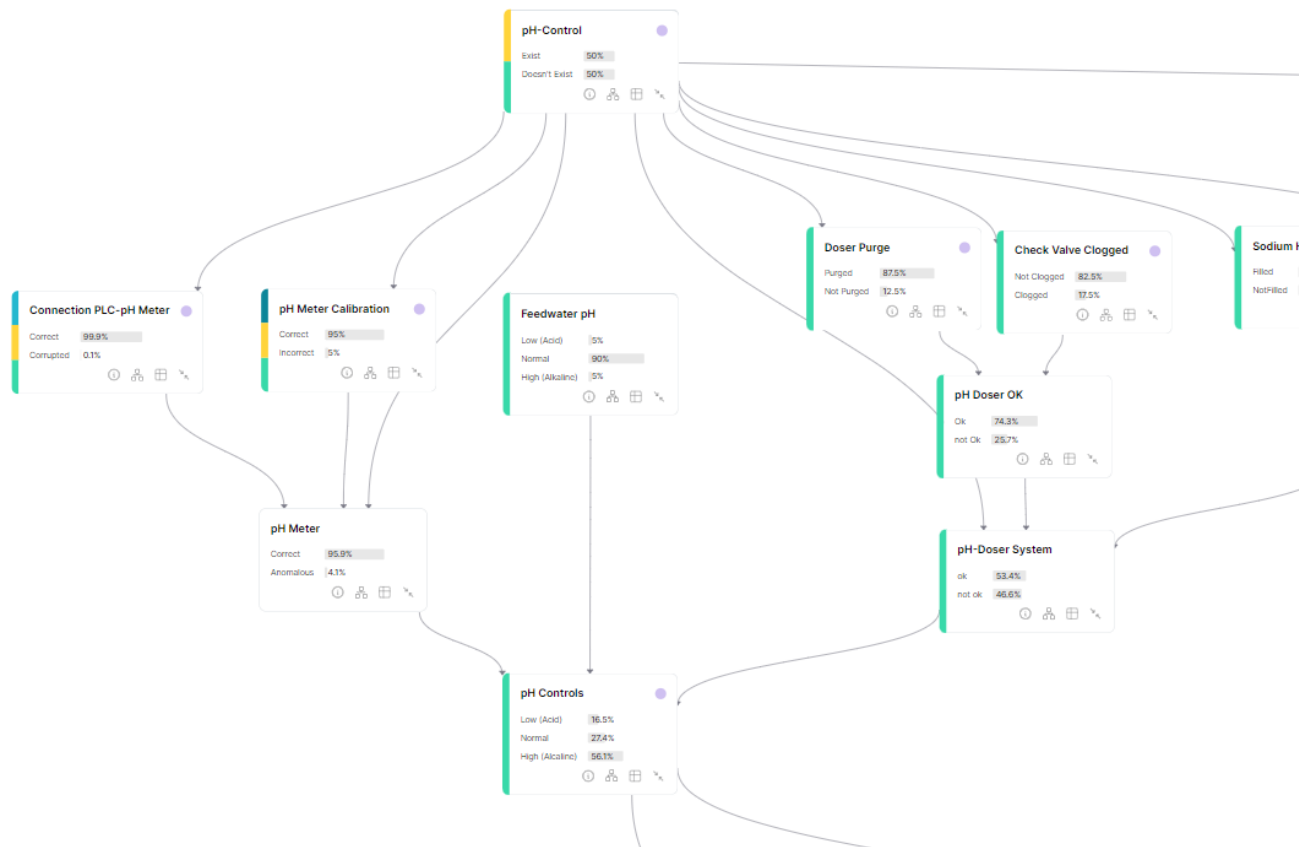
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# Steps to Implement a KMS



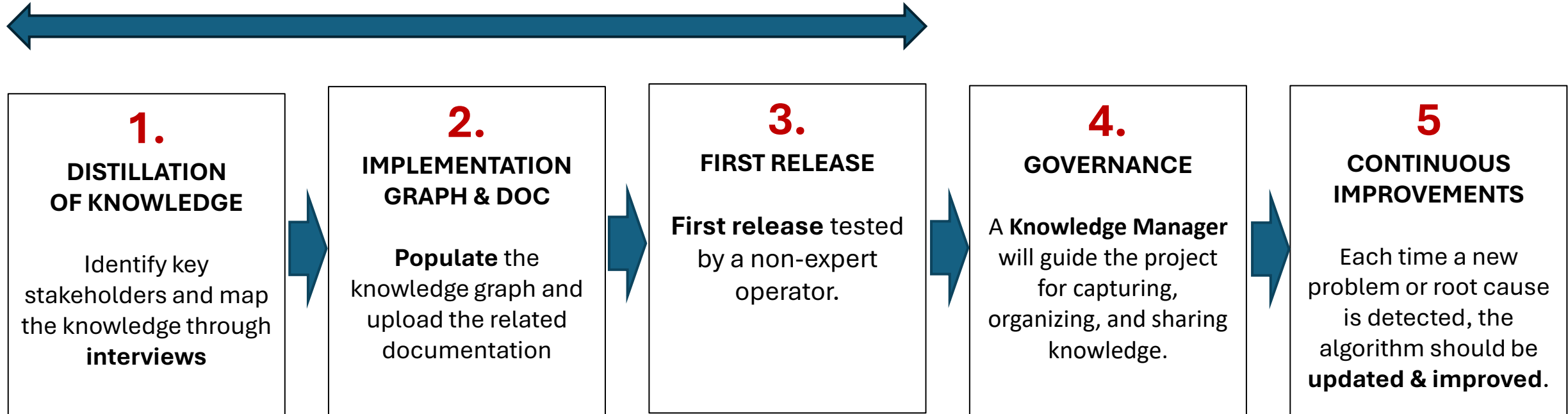
**Humans reason through cause and effect.** When we observe something, we instinctively connect it to possible causes and investigate further to identify the right one. Causal algorithms do exactly that.

The causal graph (**Bayesian graph**) is composed by events or conditions (**nodes**), which have different connections (**cause-effect relationships**) with probabilities for every possible status.



**PoC** for one production line in **2–3 months**.

Afterward, **scale-up and scope extension** across the entire factory.



A **Knowledge Manager** is the person responsible for collecting, organizing, maintaining, and continuously improving company knowledge to ensure it can be easily shared, reused, and transformed into operational value. Commitment:

- 1–2 days per week until first release
- progressively decreases to 2 hours per week at steady state

## Regulatory Context

- **FDA Warning Letter (April 2026)**

The FDA highlighted concerns regarding the use of AI agents in cGMP activities without adequate human oversight, quality review, and validated controls, reinforcing the need for accountability and governance in regulated processes.

- **EU GMP Annex 22 (Draft Guidance on AI)**

Current EU guidance indicates that Generative AI and Large Language Models are not considered suitable for critical GMP applications, while static and deterministic AI models may be adopted under a validated lifecycle approach.

## Key Takeaway

*Current regulatory expectations do not support Generative AI for critical GMP use cases. Validated **deterministic AI models represent a compliant and sustainable approach for AI adoption in regulated pharmaceutical environments.***

MGA is an active contributor to the “ISPE GAMP® Artificial Intelligence Working Group”, with roles as educator and practitioner in the application of AI to regulated Life Sciences environments.



-  **The AI is not generative** — the system behaves like a second-level support operator, providing guided and contextual answers.
-  **Operators can access the document knowledge base through natural language queries (semantic search)** — the system retrieves the most relevant documents and related sections based on the user's request, without using generative AI.
-  **Outcomes are deterministic and predictable** — the system is based on deterministic logic, ensuring repeatable, traceable, and auditable results aligned with GMP expectations.
-  **The system does not intervene on machines in any way** — it only suggests the most probable root cause of a fault.



**Quale informazione ti serve?**

Consulta un documento o chiedi a  
assistant di cercare un'informazione per te

 Chiedi all'AI 

La tua ricerca

**Convertitore frequenza**

Filtra per tipo di documento:

5 risultati in 1 documento

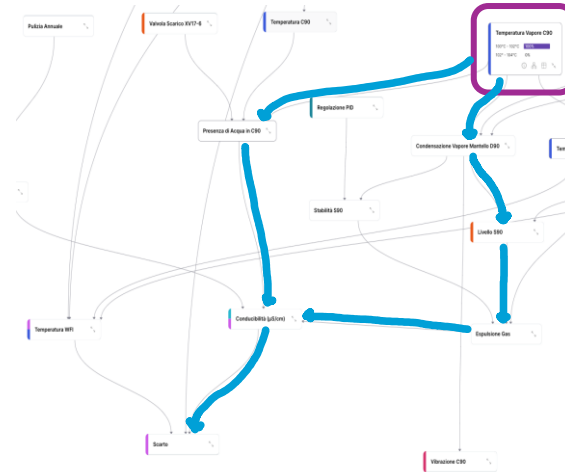
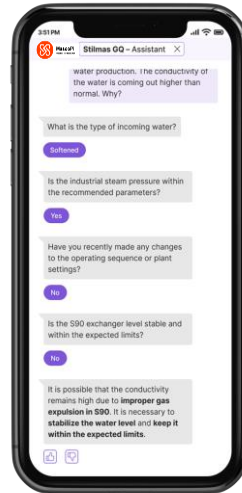
“■ Compatibilità con interruttori differenziali Il convertitore di frequenza è adatto per l'uso con interruttori differenziali di tipo B. Nota: In dotazio...



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# How a KMS works ?



70%  
Case solved



Access

With his smartphone the operator **scans a QR Code sticker** on the machine and connects to KMS interface.

Interrogate  
KMS

The integrated **chatbot** enables operators to interact with the KMS.

Reply to AI questions

**Navigating the cause-effect knowledge graph**, KMS responds with intelligent questions, to find in the shortest time the possible solution.

Solve the issue

KMS computes the **most probable fault** and suggest how to solve it.



in partnership with



**MGA**, in partnership with **AISENT**, has verticalized the **METI** platform for the Life Sciences industry.

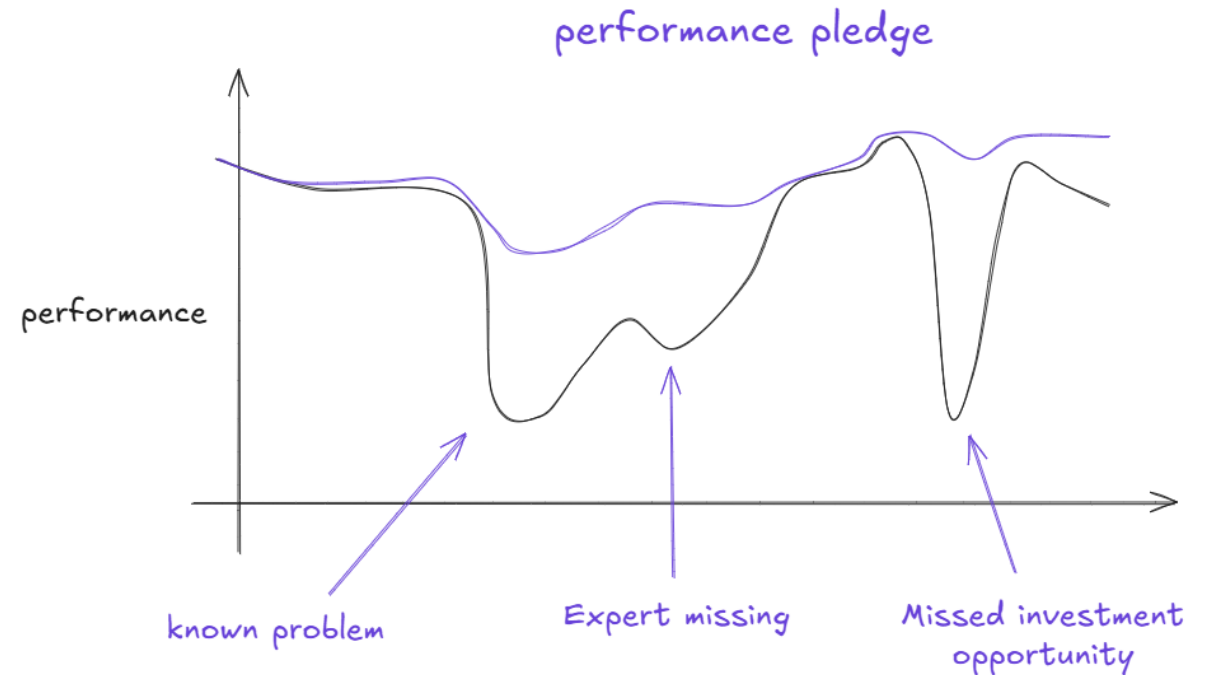




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# Impact

*“The resolution of known issues no longer relies on individual operators but becomes shared company knowledge.”*



| KPIs / Size                                | Small<br>(<10 MLN) | Medium<br>(10-50 MLN) | Large<br>(> 50 MLN) |
|--------------------------------------------|--------------------|-----------------------|---------------------|
| Gross salary                               | 60.000,00 €        | 60.000,00 €           | 60.000,00 €         |
| Recruitment cost (15% gross salary)        | 9.000,00 €         | 9.000,00 €            | 9.000,00 €          |
| New hire per year                          | 0,5                | 1,5                   | 4                   |
| Improved Time-to-Competency (solar month)* | 2                  | 2,5                   | 3                   |
| Less experts needed                        | 0,2                | 3                     | 8                   |
| External support**                         | 5.000,00 €         | 20.000,00 €           | 100.000,00 €        |
| Vacancy cost***                            | 10.000,00 €        | 50.000,00 €           | 150.000,00 €        |
| Discount rate                              | 12%                | 12%                   | 12%                 |
| Useful knowledge life (Years)****          | 5                  | 5                     | 5                   |
| Discount factor                            | 4,037              | 4,037                 | 4,037               |
| Asset value (year)                         | 41.500,00 €        | 276.000,00 €          | 781.000,00 €        |
| Actualized Value (5 years)                 | 167.535,50 €       | 1.114.212,00 €        | 3.152.897,00 €      |

\*Faster time-to-competency for new hires

\*\*Reduction in using external specialists

\*\*\*Cost of an unfilled expert role (overtime, delays, etc.)

\*\*\*\*Assumed period of time in which knowledge is still valid

Operational savings represent the diminished Mean Time To Repair / Restart, regaining production time and OEE, without considering the possible quality discards.

| KPIs / Size                                                | Small<br>(<10 MLN) | Medium<br>(10-50 MLN) | Large<br>(> 50 MLN) |
|------------------------------------------------------------|--------------------|-----------------------|---------------------|
| Number of accidents (year)                                 | 100                | 150                   | 200                 |
| MTTR [H]                                                   | 1                  | 1,5                   | 2                   |
| KMS improvement                                            | 25%                | 30%                   | 35%                 |
| Hourly conversion rate [€]                                 | 1.000,00 €         | 5.000,00 €            | 20.000,00 €         |
| <b>Total operational savings x year<br/>N*H*Impr,*Conv</b> | 25.000,00 €        | 337.500,00 €          | 2.800.000,00 €      |





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# Key Takeaways

**Human factor is becoming increasingly critical**

The world of work is changing, and most operational knowledge still resides in the minds of experienced operators.

**A Knowledge Management System (KMS) transforms knowledge into a tangible company asset**

capturing, structuring, and making expertise accessible across the organization.

**The ROI is driven by both workforce efficiency and production savings**

reducing dependency on key individuals while improving operational continuity and productivity.



**Grazie per l'attenzione**