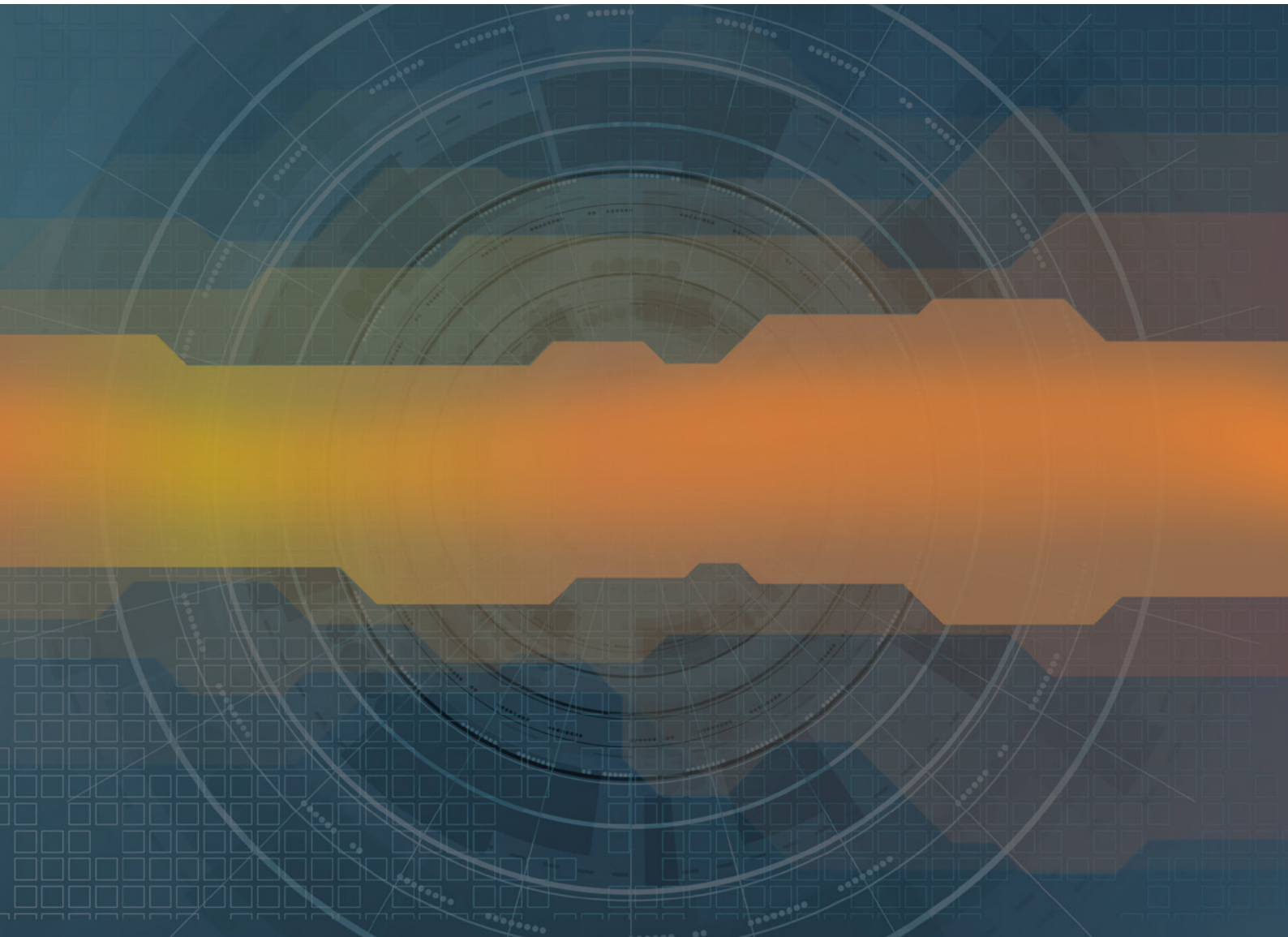
METRONIK

Case Study

# How STADA Built a Paperless Pharma 4.0 Packaging Facility with MePIS LS MES



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# Executive Summary

**STADA, a broad-based global pharmaceuticals manufacturer, decided to use the construction of a new greenfield supply-chain hub in Turda, Romania, as a strategic opportunity rather than a purely operational expansion. The ambition was clear: to establish a fully paperless, Pharma 4.0–ready production environment from day one.**

Instead of gradually digitalizing paper-based processes, the company chose to leap directly to a Smart Paperless Plant. This had to be achieved within a tight timeline, without modifying the global ERP system, and with full regulatory compliance from the very first batch. To meet these demands, the manufacturer selected **MePIS LS MES** as the digital backbone of production.

**The result is a scalable, compliant, and high-performance supply-chain facility that now serves as a replicable digital standard for future sites.**

# The Business Challenge

**Building a greenfield facility created both an opportunity and a significant management challenge. The plant had to reach full operational capacity quickly in order to meet global supply requirements, while at the same time complying with strict regulatory expectations.**

A critical constraint was the requirement to keep the global ERP system completely standard, without any custom developments that could hinder future upgrades. At the same time, the shop floor demanded a high degree of flexibility, real-time machine integration, and digital execution of production processes. Complicating matters further, this project represented the organization's first-ever MES implementation, with a clear expectation that the solution would later be rolled out across more than a dozen global sites.

Traditional paper-based manufacturing was not a viable option. STADA needed a solution that could deliver speed, compliance, and long-term scalability without adding operational complexity.

# Project Objectives

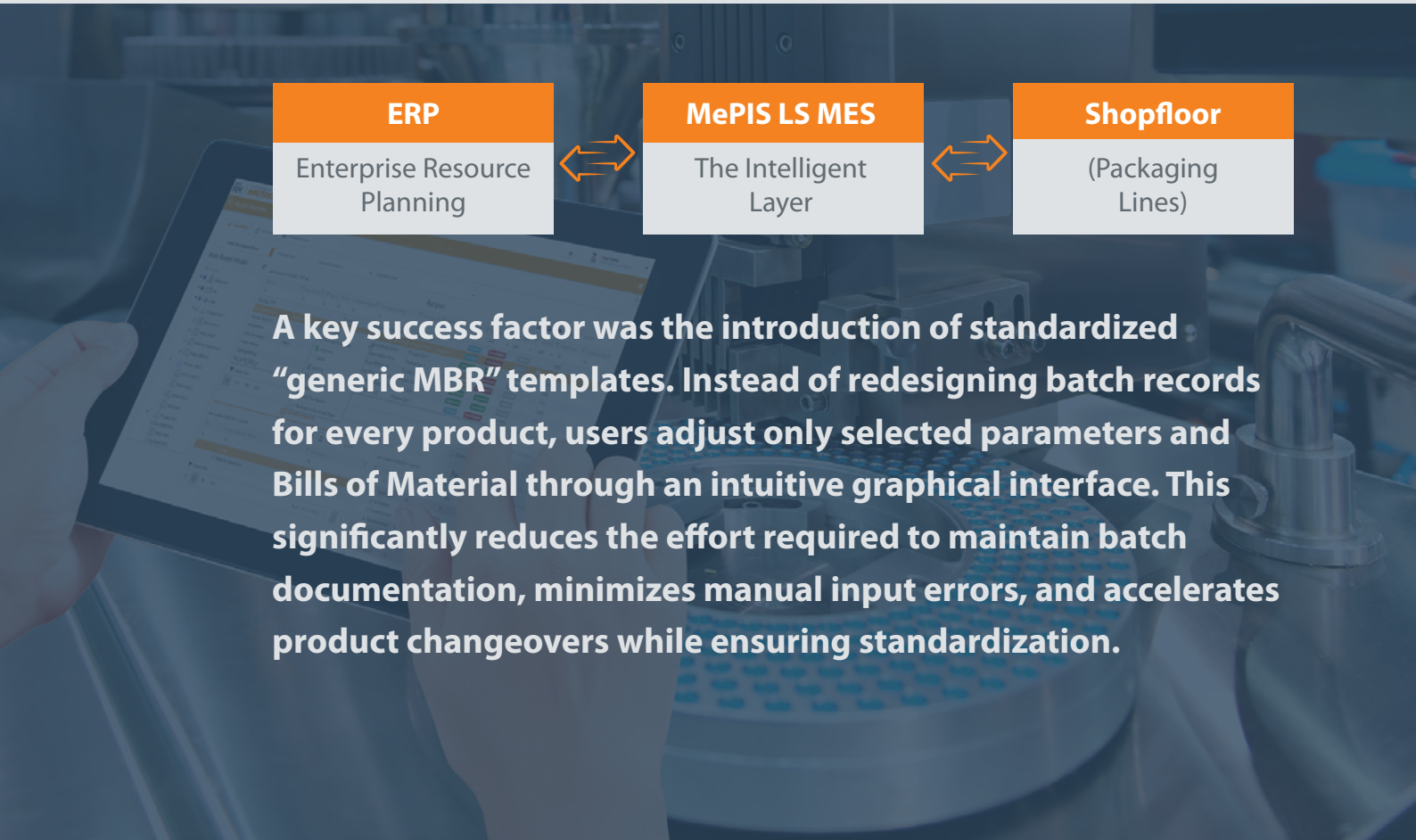
**From the outset, the project objectives were defined in clear business terms. The organization aimed to eliminate paper entirely from production execution, replacing manual documentation with electronic batch records and structured digital workflows. Manual data entry needed to be reduced as much as possible in order to minimize human error and operational risk.**

Equally important was the requirement to remain audit-ready from the first production batch, while preserving a standard, unmodified ERP environment. The solution also had to comply with Pharma 4.0 principles and provide a scalable template that could be reused across future greenfield and brownfield sites.

# The Solution: MePIS LS MES as the Digital Backbone

**To reconcile a rigid ERP landscape with the need for shop floor agility, STADA selected MePIS LS MES, a modular Manufacturing Execution System designed specifically for regulated industries.**

MePIS LS MES was implemented as an intelligent digital layer between ERP and the shop floor. It enables digital execution of production processes, real-time machine integration, electronic equipment logbooks, and full material and batch traceability. Master Batch Records are seamlessly transformed into Electronic Batch Records, ensuring consistent and compliant execution across all packaging lines.




**A key success factor was the introduction of standardized "generic MBR" templates. Instead of redesigning batch records for every product, users adjust only selected parameters and Bills of Material through an intuitive graphical interface. This significantly reduces the effort required to maintain batch documentation, minimizes manual input errors, and accelerates product changeovers while ensuring standardization.**

# Implementation Highlights

**During implementation, existing SOPs and IT/OT frameworks from established production sites were adapted to provide a proven operational foundation for the new facility. MePIS LS MES was configured rather than customized, ensuring long-term maintainability and alignment with corporate standards.**

Operators are guided through production using step-by-step digital instructions, with full digitalization allowing them to use tablets for real-time scanning and execution, enforcing process discipline and reducing variability. This approach enabled rapid onboarding of personnel and stable operations immediately after go-live. The pilot go-live in January 2024 confirmed that even complex greenfield MES projects can be delivered efficiently when supported by the right digital architecture.

# Results and Business Impact

**The facility in Turda, Romania, currently utilizes a fully digitalized packaging infrastructure designed for high-volume output. Production execution and data capture take place in real time, providing management with accurate and timely operational insight.**

01

**GROWTH**

Scalable digital blueprint

02

**OPTIMIZE**

Replicated

03

**IMPROVEMENT**

Long-term Pharma 4.0 initiatives

From a quality and compliance perspective, the facility benefits from end-to-end material and batch traceability and fully electronic batch documentation. The effectiveness of the solution was demonstrated when the first production batch successfully passed its first audit.

Strategically, the project delivered far more than a single operational site. STADA now has a scalable digital blueprint that can be replicated across future facilities, reducing rollout time, operational risk, and dependence on manual processes. The solution also provides a strong foundation for long-term Pharma 4.0 initiatives and continuous improvement.

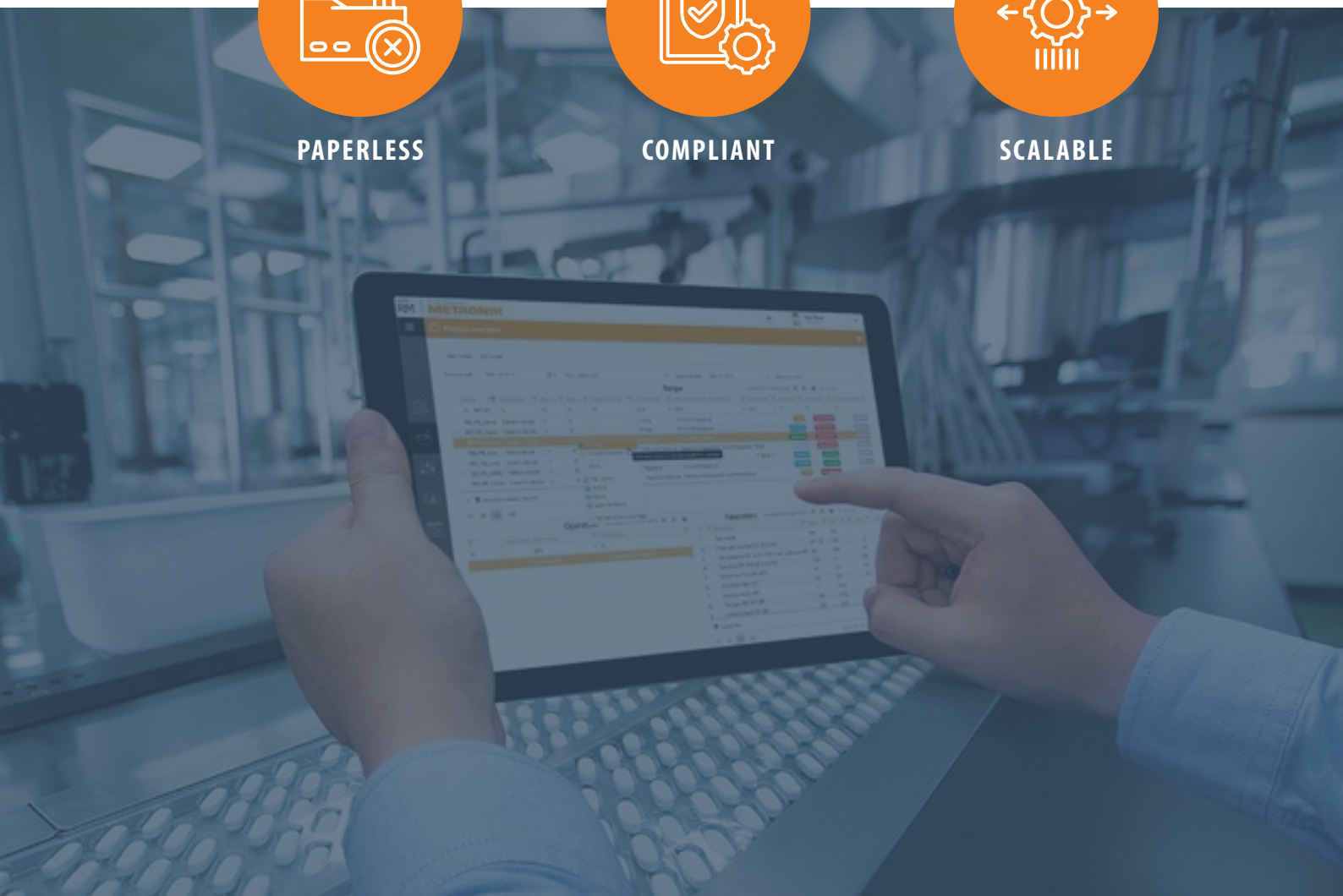
# Why This Matters for Pharma Management

**This project demonstrates that a paperless, compliant, and scalable production environment is achievable without compromising ERP standards or speed to market. By treating digitalization as a business strategy rather than an IT retrofit, pharmaceutical executives can unlock operational resilience, regulatory confidence, and sustainable competitiveness.**

PAPERLESS

COMPLIANT

SCALABLE



# Conclusion

**With MePIS LS MES, STADA did more than commission a new supply-chain hub. It established a future-proof digital production standard that supports operational excellence, audit readiness, and global scalability from day one.**

## Interested in building a paperless production environment from day one?

Discover how MePIS LS MES supports Pharma 4.0 strategies for both greenfield and brownfield projects.

# Get in touch with us

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