The American Journal of Engineering and Technology
ISSN 2689-0984 Volume 08 - 2026

Bridging Low-Code/No-Code and MES in Pharmaceutical and Medical Device Manufacturing

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Digital Manufacturing / Industrial Information Systems / Pharmaceutical Engineering

Received: 27 Apr 2026 | Received Revised Version: 25 May 2026 | Accepted: 14 June 2026 | Published: 30 June 2026

Volume 08 Issue 06 2026 | Crossref DOI: 10.37547/tajet/Volume08Issue06-20

Abstract

Pharmaceutical and medical device manufacturers operate in a highly regulated environment where operational efficiency, data integrity, and regulatory compliance must coexist. Manufacturing Execution Systems (MES) have traditionally served as the backbone of digital manufacturing, enforcing standardized workflows, batch traceability, electronic records, and compliance with regulations such as FDA 21 CFR Part 11, EU Annex 11, and Good Manufacturing Practice (GMP). While MES solutions provide robust governance and audit readiness, they are often associated with long implementation cycles, high costs, and limited flexibility in addressing shop-floor requirements that change quickly.

Low-Code/No-Code (LCNC) platforms have emerged as a complementary enabler of agile application development. Platforms such as Tulip and Mendix allow engineers, quality teams, and business users to design and deploy applications rapidly using visual modeling tools. These platforms support digital work instructions, operator performance monitoring, downtime tracking, and AI-driven defect detection, but face challenges related to scalability, validation, and compliance when deployed independently in regulated settings.

This paper proposes a hybrid framework that strategically integrates LCNC platforms with MES, positioning MES as the system of record for validated, GxP-critical processes and LCNC as a flexible innovation layer for rapid digitization. The framework draws on a qualitative, conceptual research methodology grounded in industry practice, architectural analysis, and regulatory frameworks, and is illustrated through comparative analysis and a proposed reference architecture. Organizations adopting this approach can reduce application backlogs, accelerate digital transformation, and maintain regulatory confidence, with the framework remaining extensible to other regulated manufacturing sectors.

Keywords: Low-Code/No-Code, Manufacturing Execution System, Digital Manufacturing, GxP Compliance, Pharmaceutical Manufacturing, Medical Devices

Cite This Article: Sikligar, D. (2026). Bridging Low-Code/No-Code and MES in Pharmaceutical and Medical Device Manufacturing. The American Journal of Engineering and Technology, 8(06), 219–224. https://doi.org/10.37547/tajet/Volume08Issue06-20

1. Introduction

The pharmaceutical and medical device industries are

undergoing significant digital transformation, driven by global competition, complex supply chains, workforce shortages, and stringent regulatory requirements. Manufacturers face constant pressure to improve operational efficiency, reduce costs, and accelerate time-to-market while safeguarding product quality and patient safety. Digital manufacturing systems are central to enabling standardized, traceable, and compliant operations in this environment.

Manufacturing Execution Systems have long been the cornerstone of regulated manufacturing. MES solutions provide real-time visibility into production operations, enforce process controls, and ensure compliance through electronic batch records, audit trails, and electronic signatures. They integrate with Enterprise Resource Planning (ERP), Laboratory Information Management Systems (LIMS), and shop-floor automation to form a unified, validated manufacturing ecosystem. Despite these strengths, MES implementations are often complex, resource-intensive, and slow to adapt to frequent business or process change.

In recent years, LCNC platforms have gained significant traction across industries, democratizing application development by enabling non-traditional developers to build software using visual interfaces and pre-built components. In manufacturing specifically, LCNC platforms increasingly address localized shop-floor challenges such as manual data collection, operator guidance, real-time dashboards, and continuous improvement initiatives. Their shorter development cycles and lower costs make them attractive alternatives to traditional IT development models.

However, LCNC adoption in regulated industries introduces new questions around governance, validation, and data integrity. Organizations therefore face a strategic choice: rely solely on MES for all digital needs, or adopt a hybrid approach that balances agility with compliance. This paper argues that the future of digital manufacturing lies in the intelligent integration of MES and LCNC platforms rather than in choosing one over the other.

2.Materials and Methods

This study adopts a qualitative, conceptual research methodology based on industry practice, architectural analysis, and regulatory frameworks rather than empirical experimentation or simulation. This approach is appropriate for applied engineering and systems research, where the

contribution lies in synthesizing a practice-grounded reference framework rather than in testing a quantifiable hypothesis. The methodology comprises four stages:

- Review of current MES capabilities and limitations in regulated manufacturing.
- Analysis of LCNC platform features, development models, and representative manufacturing use cases.
- Examination of regulatory expectations related to computerized system validation, data integrity, and GxP compliance.
- Synthesis of a hybrid architectural framework integrating MES and LCNC platforms, supported by a comparative evaluation across governance, validation, cost, and deployment dimensions.

The proposed framework aligns with established validation methodologies such as GAMP 5 and applies risk-based system classification consistent with current regulatory guidance. Published standards, regulatory guidance, and peer-reviewed literature on computerized system validation and Pharma 4.0 were used to ground the framework in current industry and academic understanding.

3. Results

The analysis indicates that MES and LCNC platforms address fundamentally different but complementary needs within regulated manufacturing environments. The following findings are conceptual and architectural in nature, drawn from comparative analysis of platform capabilities and regulatory requirements rather than from empirical testing.

3.1 MES Capabilities

MES solutions excel in managing GxP-critical processes, including:

- Electronic Batch Records (EBR)
- Genealogy and traceability
- Electronic signatures and audit trails
- Enforced process workflows
- Integration with ERP, LIMS, and

automation systems

These capabilities ensure compliance and data integrity but require significant effort to customize or extend.

3.2 LCNC Capabilities

LCNC platforms provide rapid value in areas such as:

- Digital work instructions and SOP execution
- Operator training and certification tracking
- Machine downtime and OEE monitoring
- Non-GxP data collection and visualization
- AI-enabled image analytics and predictive insights

Applications built on LCNC platforms can typically be developed and deployed within weeks, enabling a faster response to operational needs than traditional MES customization cycles allow.

3.3 Comparative Analysis

Table 1 summarizes the comparative characteristics of MES and LCNC platforms across the dimensions most relevant to regulated manufacturing decision-making.

Table 1. Comparative Analysis of MES and LCNC Platforms in Regulated Manufacturing

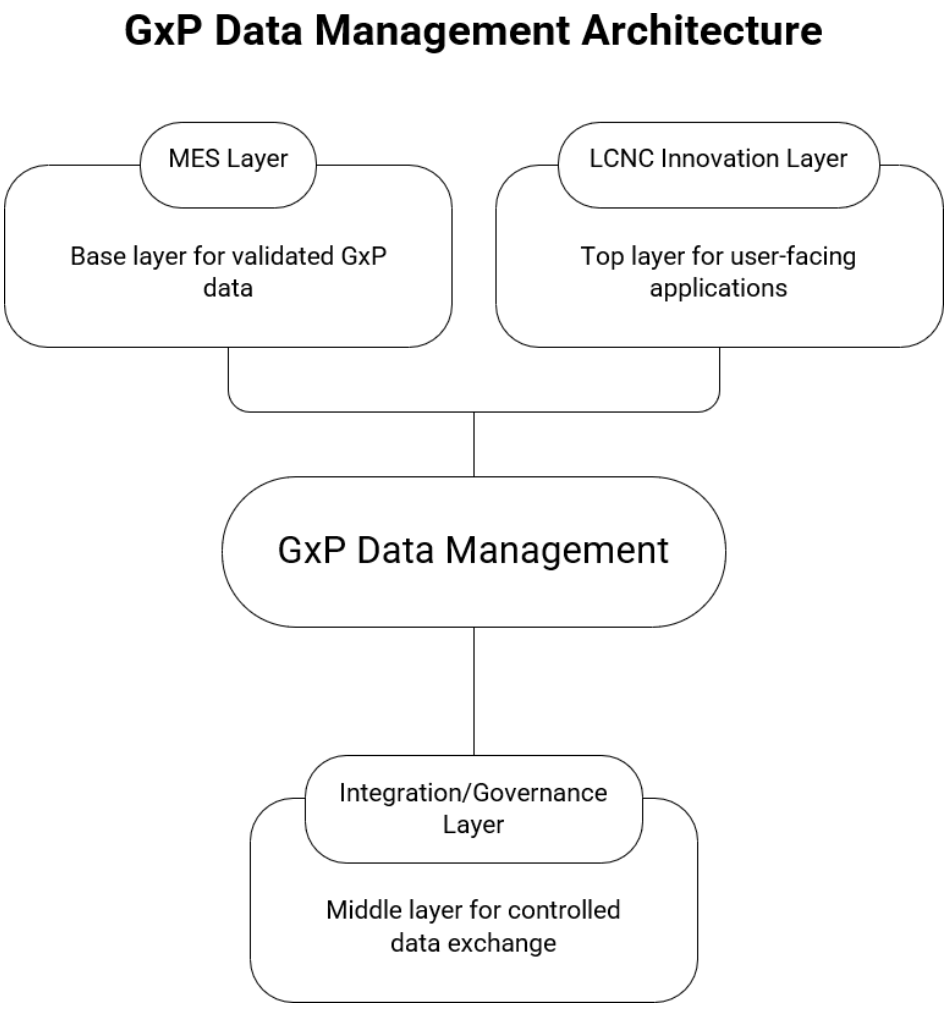
Dimension	MES	LCNC Platforms	Cost	Time-to-Deploy	GxP Suitability
Flexibility	Low — change control intensive	High — rapid iteration	High upfront	Months	High (validated)
Validation Effort	Extensive (full CSV lifecycle)	Minimal to moderate (risk-based)	Embedded in cost	Built into lifecycle	Native
Cost Profile	High capital + maintenance	Low to moderate, subscription-based	Low upfront	Days to weeks	Conditional
Time-to-Deploy	6–18 months typical	Days to a few weeks	—	—	—
Governance Model	Centralized IT/QA ownership	Distributed, business-user driven	—	—	Requires defined policy

Source: Author's synthesis, based on platform capability analysis and regulatory guidance reviewed in Section 2.

3.4 Hybrid Framework Outcomes

The hybrid framework positions MES as the validated system of record while LCNC platforms act as an innovation and user-experience layer. Figure 1 presents the proposed reference architecture.

Figure 1. Hybrid MES–LCNC Reference Architecture (conceptual)



The diagram should depict three layers: (1) the **MES layer** at the base, acting as the validated system of record for GxP-critical data — EBR, genealogy, e-signatures, and audit trail; (2) an **integration/governance layer** in the middle, representing the API, middleware, or data-bus boundary where risk-based validation policy determines what data may cross between systems; and (3) the **LCNC innovation layer** at the top, representing user-facing applications such as digital work instructions, OEE dashboards, and AI-enabled analytics. Arrows should run bidirectionally between the MES and LCNC layers through the governance layer, indicating that validated data flows down to LCNC applications for visualization and operator use, while operational data collected in LCNC applications flows up to MES once it meets defined data-integrity and validation criteria.

Data flows bidirectionally between the layers, with MES ensuring compliance and LCNC enabling rapid experimentation and continuous improvement. This approach reduces development backlogs, shortens deployment timelines, and lowers total cost of ownership relative to MES-only or LCNC-only strategies.

4. Discussion

The results highlight that neither MES nor LCNC platforms alone can fully address the digital transformation needs of regulated manufacturing. MES provides stability and compliance but lacks agility, while LCNC offers speed and flexibility but requires strong governance. The hybrid approach mitigates these limitations by clearly defining system boundaries and responsibilities between the two.

Key success factors include robust governance models, clear validation strategies, and standardized integration patterns. Organizations must establish policies defining which processes are GxP-critical and require MES control, as distinct from those suitable for LCNC

deployment. Validation of LCNC applications should follow a risk-based approach consistent with GAMP 5 principles, ensuring regulatory compliance without stifling innovation.

Emerging trends such as AI-driven analytics, connected worker platforms, and Industry 4.0 architectures strengthen the case for hybrid ecosystems. As regulatory bodies increasingly recognize digital innovation within quality systems, organizations that adopt balanced, well-governed architectures will be better positioned for sustainable growth.

It is worth acknowledging the limitations of this study. As a conceptual and qualitative contribution, the proposed framework has not yet been validated through a quantitative case study, simulation, or controlled deployment, and several supporting claims draw on industry market reports rather than peer-reviewed literature. These limitations are characteristic of early-stage architectural research and are addressed further in Section 6.

5. Conclusion

Pharmaceutical and medical device manufacturers face the dual challenge of maintaining strict regulatory compliance while rapidly adapting to changing business and operational demands.

Manufacturing Execution Systems remain essential for ensuring data integrity, traceability, and audit readiness, but their rigidity limits innovation. Low-Code/No-Code platforms introduce agility and accessibility but require careful governance in regulated environments.

This paper has demonstrated that a hybrid MES–LCNC framework offers a practical and scalable solution. By combining the compliance strengths of MES with the flexibility of LCNC platforms, organizations can accelerate digital transformation, reduce costs, and enhance operational performance without compromising regulatory standards. As digital technologies continue to evolve, such hybrid architectures are likely to form the foundation of next-generation regulated manufacturing.

6. Future Research Directions

The framework presented here is conceptual and would benefit from empirical validation in future work. Promising directions include a longitudinal case study tracking a hybrid MES–LCNC deployment across its validation lifecycle, a comparative cost-of-quality analysis between hybrid and MES-only implementations, and the development of a maturity model that organizations could use to assess their readiness for hybrid adoption. Such empirical extensions — particularly case-study or mixed-methods designs situated within information systems and digital transformation research — represent a natural progression of this work and a direction the author intends to pursue through doctoral research.

References

1. Alarcón, F., et al. (2025). Conceptual frameworks for industrial modernization: Toward digital technology adoption in manufacturing. [Industry 4.0 conceptual study].
2. Dieguez, T., & Machado, J. (2025). MES evolution and integration with Industry 4.0: A global review of trends including AI and digital twins.
3. Gaffley, G., & Pelser, T. G. (2025). Strategic models for digital transformation toward smart, AI-integrated manufacturing systems.
4. Gomes, M. M., et al. (2024). Key factors for implementing MES in Industry 4.0 contexts for small and medium-sized enterprises.
5. Joshi, K., Sinha, A., & Dhuri, S. (2025). Transformative trends in Pharma 4.0: Digital technologies in pharmaceutical manufacturing.
6. Kumar Parimi, V. (2025). Impact of low-code/no-code platforms on digital transformation, productivity, and innovation across enterprises.
7. Nurdiyanto, H., & Kindiasari, R. (2024). The critical role of Manufacturing Execution Systems in digital transformation and real-time decision-making.
8. Ozman, S. (2025). A systematic literature review of current developments in low-code/no-code (LCNC) solutions, including governance and scalability considerations.
9. Pokhrel, S., Sapkota, R., & Ghimire, B. (2025). The role of low-code/no-code platforms in enterprise digital transformation.
10. Sahay, A., et al. (2021). Low-code/no-code platforms: Concept, characteristics, and adoption implications.
11. Sanchis, R., et al. (2020). Low-code as an enabler of digital transformation in manufacturing contexts.
12. Tabim, V. M., et al. (2024). MES 4.0 implementation challenges and the role of knowledge sharing during Industry 4.0 transitions.

13. Tetteh, M. G., Jagtap, S., & Salonitis, K. (2023). Pharma 4.0: Revealing drivers of the digital transformation in the pharma sector. In H. Kohl, G. Seliger, & F. Dietrich (Eds.), Manufacturing Driving Circular Economy (Lecture Notes in Mechanical Engineering). Springer. https://doi.org/10.1007/978-3-031-28839-5_59

14. Journal of Young Pharmacists. (2025). Pharma 4.0: Enhancing process robustness in pharmaceutical manufacturing through Industry 4.0 integration. https://doi.org/10.5530/jyp.20250104

15. ScienceDirect / Sustainable Chemistry and Pharmacy. (2023). Impact of GAMP 5, data integrity, and QbD on quality assurance in the pharmaceutical industry: How obvious is it?

16. Saeedi, M. (2025). Digital twins as an advanced Industry 4.0 technology: A review relevant to manufacturing analytics.

17. Lamanna, J. (2025). Structured evaluation criteria for selecting low-code platforms in enterprise digital strategy. [Industry analysis].

18. Verified Market Reports. (2025). Market forecast analysis of low-code/no-code development platform adoption in manufacturing. [Industry/market report].

19. Business Research Insights. (2025). Market growth and drivers for MES adoption in the pharmaceutical sector. [Industry/market report].

20. Research & Markets. (2025). Low-code development platform market size and adoption trends. [Industry/market report].

21. ResearchGate. (2025). Case outcomes from MES deployment showing operational performance improvements. [Supplementary industry case material].