

BEYOND COMMERCIAL ERP: A MIXED-METHODS ANALYSIS OF CHALLENGES AND EFFICIENCY GAINS FROM AN INTERNALLY DEVELOPED KANBAN SYSTEM IN PHARMACEUTICAL PRODUCTION

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Abstract: *This study examines the implementation and impact of an internally developed ERP-based Kanban system in a pharmaceutical company as a cost-effective alternative to commercial ERP. Utilizing a mixed-methods case study, the research first applied Interpretive Structural Modeling (ISM) to structure key implementation challenges, followed by a quantitative comparative analysis of operational efficiency. Findings reveal a six-level hierarchy of challenges, identifying "Lack of Top Management Vision and Leadership" as the fundamental driver. Equally important is the finding that "High initial investment cost" exhibited minimal driving power. The system achieved transformative efficiency gains, reducing data input time by 98.4% and data analysis time by 73.9%. The study provides an original, empirically validated model of implementation barriers and demonstrates that internal development is a viable, high-return strategy for SMEs in regulated industries, enabling enhanced compliance and data-driven decision-making.*

Keywords : *Kanban System, Custom ERP, Pharmaceutical Industry, Operational Efficiency, Interpretive Structural Modeling (ISM), Digital Transformation, Lean Manufacturing, Industry 4.0,*

INTRODUCTION

The global pharmaceutical industry operates within an exceptionally challenging environment characterized by intensifying competition, mounting cost pressures, and increasingly stringent regulatory requirements (Bidhya et al., 2023). In this context, the mandate for strict adherence to Good Manufacturing Practices (GMP) creates an absolute dependency on accurate, timely, and comprehensive documentation throughout the production lifecycle (WHO, 2020). Simultaneously, companies face unprecedented pressure to enhance operational efficiency and reduce time-to-market while maintaining the highest quality standards (Erlangga et al., 2020). This dual challenge has compelled pharmaceutical manufacturers to seek innovative approaches to streamline operations while ensuring compliance.

In response to these pressures, companies are increasingly turning to data-driven decision-making (DDM) as a strategic imperative. The effectiveness of this paradigm, however, is wholly contingent upon the speed, accuracy, and accessibility of underlying

data systems (Oliver et al., 2020). Enterprise Resource Planning (ERP) systems have emerged as a foundational technological response, offering the potential to integrate disparate business functions into a cohesive digital framework that can provide real-time visibility and control over manufacturing operations (Tuli & Kaluvakuri, 2022).

Despite their potential benefits, conventional commercial off-the-shelf (COTS) ERP solutions such as SAP or Oracle present significant implementation barriers, particularly for small and medium-sized enterprises (SMEs). These barriers include prohibitive licensing costs, complex and lengthy implementation cycles, and frequent misalignment with unique, legacy operational workflows that have evolved to meet specific regulatory requirements (Poba-Nzaou & Raymond, 2013). This mismatch between standardized commercial solutions and specialized operational needs has prompted growing interest in internally developed, custom ERP systems that promise greater flexibility, cost-effectiveness, and organizational fit (Gessa et al., 2023).

This research examines one such initiative at “PT. Novell Pharmaceutical Laboratories (NPL)” – a pseudonym for a pharmaceutical manufacturer in Indonesia that developed an ERP system internally and integrated a digital Kanban module to manage production workflows. While this bespoke approach offers considerable advantages in terms of customizability and alignment with specific operational requirements, it introduces a distinct set of implementation challenges related to resource allocation, technical integration, change management, and organizational adaptation that remain underexplored in the academic literature.

The existing academic literature has addressed several relevant domains in isolation. Previous research has investigated Kanban implementation methodologies (Trebuna et al., 2023), measured ERP efficiency gains (Kalwar et al., 2022), and analyzed digitalization challenges using structural modeling approaches (Bakhtari et al., 2021). However, a significant theoretical and empirical gap exists in understanding the complex interdependencies between implementation challenges and the tangible performance outcomes of internally developed ERP-Kanban hybrids within the stringent context of pharmaceutical production.

This gap is particularly noteworthy given the critical importance of documentation efficiency in regulated environments and the potential of custom-developed systems to address the unique needs of SMEs (Bidhya et al., 2023). Previous studies have typically examined either implementation challenges or performance outcomes, but rarely both in an

integrated framework that accounts for the hierarchical relationships between different types of barriers and their collective impact on operational efficiency.

This study aims to address this gap through two specific research questions:

1. What is the hierarchical structure and nature of interdependencies among the challenges faced in implementing an internally developed ERP-based Kanban system in a pharmaceutical manufacturing environment?
2. What is the quantitative impact of this system on the efficiency of critical Good Manufacturing Practice (GMP) documentation processes, particularly in terms of time savings and waste reduction?

Through addressing these questions, this research seeks to provide both theoretical insights into the implementation dynamics of custom digital systems in regulated environments and practical guidance for organizations contemplating similar digital transformation initiatives.

LITERATURE REVIEW AND THEORETICAL FRAMEWORK

Lean Manufacturing and Kanban Systems

Lean Manufacturing is a systematic approach to identifying and eliminating waste (non-value-added activities) through continuous improvement while maximizing value for the end customer (Garcia-Garcia et al., 2022). Originating from the Toyota Production System, Lean principles have been widely adopted across various manufacturing sectors, including the highly regulated pharmaceutical industry, where efficiency, traceability, and quality are critical.

Kanban is a foundational Lean tool designed to establish a pull-based production system that synchronizes material and information flow with actual consumption. Traditionally implemented using physical cards as visual signals, Kanban enables just-in-time production, reduces work-in-progress inventory, minimizes bottlenecks, and increases workflow transparency (Senapathi & Drury-Grogan, 2021). In modern manufacturing environments, these systems have evolved into electronic Kanban (E-Kanban) solutions that leverage digital technologies to automate signal transmission, enhance real-time visibility, and enable more responsive production control (Trebuna et al., 2023).

Kanban implementation is commonly supported by analytical tools such as Value Stream Mapping (VSM), which helps organizations visualize material and information

flows, identify process inefficiencies, and design optimal future-state workflows (Poswa et al., 2022). In pharmaceutical operations—where standardized documentation and regulatory compliance are central—Kanban’s visual management capabilities offer particular value by improving process clarity while supporting adherence to GMP requirements (Erlangga et al., 2020).

Industry 4.0 and ERP Systems

Industry 4.0 represents the digital transformation of manufacturing through the integration of cyber-physical systems, the Internet of Things (IoT), cloud computing, and advanced analytics (Imran et al., 2021). These technologies enable the development of “smart factories” characterized by extensive digitization, real-time data exchange, and enhanced automation that fundamentally reshape production processes (Gessa et al., 2023).

Enterprise Resource Planning (ERP) systems serve as the backbone of Industry 4.0 initiatives by providing integrated digital platforms that connect previously siloed business functions such as production planning, inventory management, quality assurance, and supply chain coordination (Kalwar et al., 2022; Rahman et al., 2024). ERP systems create a unified source of data truth, promote process standardization, and support data-driven decision-making—capabilities that are essential in complex and highly regulated manufacturing environments (Tuli & Kaluvakuri, 2022).

While large multinational companies often deploy commercial ERP packages (e.g., SAP, Oracle), small and medium-sized enterprises frequently encounter challenges in adopting such systems due to their high cost, implementation complexity, and limited flexibility (Rahman et al., 2024). These constraints have prompted increasing interest in internally developed, custom ERP systems that can accommodate unique process requirements while reducing dependency on costly commercial solutions (Zheng & Khalid, 2022).

Implementation Challenges in Digital Transformation

Implementing integrated digital systems such as ERP-Kanban hybrids constitute a significant organizational change effort that typically involves multiple interrelated challenges. Bakhtari et al. (2021) identify twelve key obstacles to Industry 4.0 adoption, including technological incompatibility, lack of standardization, insufficient skills, organizational resistance, and uncertain return on investment. Understanding the structural

relationships among these challenges is essential for designing effective implementation strategies.

Interpretive Structural Modeling (ISM) offers a robust methodology for analyzing such complex relationships (Sreenivasan et al., 2023). ISM transforms dispersed or implicit mental models into clear hierarchical structures that reveal direct and indirect relationships among variables. When combined with Matrice d'Impacts Croisés Multiplication Appliquée à un Classement (MICMAC) analysis, ISM further classifies variables according to their driving and dependence power, enabling researchers to identify leverage points that can accelerate successful system implementation (Alawamleh et al., 2023).

Performance Measurement in Digital Systems

Evaluating the effectiveness of digital transformation requires performance measurement frameworks that capture both quantitative efficiency gains and qualitative improvements in organizational capability. Time-based metrics are frequently used to assess ERP performance, with studies such as Kalwar et al. (2022) demonstrating significant reductions in process cycle times following ERP adoption. In pharmaceutical manufacturing—where documentation activities constitute a substantial portion of operational workload—reductions in data recording and processing time directly improve productivity and support faster, more accurate decision-making.

Integrating Lean principles with digital technologies yields strong synergies in waste reduction. Digital systems can automate the detection and elimination of non-value-added activities targeted by Lean methodologies (Buer et al., 2021). This combination supports both the continuous improvement philosophy of Lean and the real-time responsiveness of Industry 4.0 systems, forming a robust foundation for operational excellence.

METHODS

Research Design and Approach

This study employed a mixed-methods research design combining qualitative and quantitative approaches within a single-case study framework. This design was selected to provide both an in-depth understanding of implementation challenges and a rigorous measurement of performance outcomes. The case study approach was performed due to the

contemporary nature of the phenomenon and the need for contextualized insights into implementation dynamics (Imran et al., 2021).

The research site was PT. Novell Pharmaceutical Laboratories (abbreviated to NPL), an Indonesian pharmaceutical manufacturer that internally developed and implemented an ERP system with an integrated digital Kanban module for managing production workflows. The company is an example of a business entity operating in a regulated environment, facing the need to balance compliance with operational efficiency. Prior to implementation, documentation processes were fully manual—relying on paper-based logbooks and spreadsheets—which resulted in delays, redundant data entry, and limited real-time visibility into production activities.

Analyzing Implementation Challenges with ISM

The study adopted the 12 implementation challenges proposed by Bakhtari et al. (2021), which are widely validated within Industry 4.0 research. This framework aligns conceptually with the integrated ERP-Kanban system, as both represent digital transformation initiatives aimed at achieving connected and intelligent manufacturing. The challenges include:

1. high initial investment cost;
2. lack of training and education;
3. lack of a skilled workforce;
4. data security and digital trust;
5. lack of digital regulations;
6. lack of standardization;
7. technological incompatibility and integration issues;
8. organizational hurdles;
9. uncertainty of return on investment;
10. employment disruption;
11. outdated business models; and
12. lack of vision and leadership.

The listed challenges are then translated to Indonesian and are briefed to respondents to ensure the same understanding of each point before filling in the

questionnaire. The 12 challenges are assembled into 66 pairwise combination each corresponding to the standard ISM directional symbols which are: V (i influences j), A (j influences i), X (mutual influence), and O (no significant relationship) for the questionnaire.

Data were collected using a Structural Self-Interaction Matrix (SSIM) questionnaire administered to a panel of six internal experts. The panel consisted of a Production Manager, two senior supervisors, and three production operators, ensuring representation from both strategic and operational levels. This multi-level composition enabled the study to capture comprehensive insights into the system's implementation challenges.

Participants were selected through purposive sampling based on three criteria:

- A. direct involvement in using or developing the ERP-Kanban system;
- B. relevant knowledge of operational efficiency and documentation processes; and
- C. willingness to be involved in the research.

Individual SSIM responses were consolidated into an aggregate SSIM using modal values, with discrepancies resolved through follow-up discussions to achieve consensus. The aggregate SSIM was converted into an initial reachability matrix using standard ISM rules: V = (1,0), A = (0,1), X = (1,1), and O = (0,0).

The initial matrix was then enhanced with transitive links to produce the final reachability matrix, which reflects both direct and indirect relationships among challenges. Level partitioning was performed iteratively by comparing reachability and intersection sets, beginning with top-level challenges (those with no influence on others) and proceeding downward until all variables were assigned hierarchical levels.

All ISM procedures were conducted using SmartISM (Ahmad & Qahmash, 2021), which automates matrix conversion and level partitioning to ensure computational accuracy. The resulting hierarchical model was subsequently validated with the expert panel directly from the company to confirm alignment with their understanding of real-world implementation dynamics.

Measuring Operational Efficiency

Data were obtained through controlled simulations comparing the time required to complete key documentation tasks using both the legacy manual processes and the new ERP-Kanban system. Two critical documentation activities were evaluated: (1) data

input—recording production parameters such as product identity, process times, and operator details; and (2) data analysis—calculating man-hours for performance monitoring.

For data input, ten operators performed identical recording tasks using both the manual method (paper logbooks followed by spreadsheet entry) and the ERP-Kanban system. For data analysis, three production supervisors completed equivalent tasks using the manual spreadsheet method and the ERP reporting module. All simulations were conducted under controlled conditions, and task durations were captured using precision stopwatches to ensure accuracy. Time data were analyzed using comparative statistical techniques. For each participant and task, the time required in the manual method was compared with the time required in the ERP-Kanban system. Efficiency gain was calculated using:

$$\text{Efficiency Gain (\%)} = [(\text{Manual Time} - \text{ERP Time}) / \text{Manual Time}] \times 100$$

Ethical Considerations

Ethical approval was obtained from organizational management. All participants were informed of the study's purpose and procedures and provided written consent. Confidentiality was ensured through the use of pseudonyms for the organization and individual participants, and all data were anonymized during analysis and reporting to protect privacy

RESULTS

Hierarchical Structure of Implementation Challenges

The analysis began by consolidating the expert responses from the Structural Self-Interaction Matrix (SSIM) questionnaire. Through modal selection and consensus-building discussions, a final aggregated SSIM matrix was established. This matrix, presented in Table 4.1, represents the collective expert judgment on the pairwise directional relationships between all challenges, using the symbols V, A, X, and O.

Table 4.1. SSIM Matrix

Variables	1	2	3	4	5	6	7	8	9	10	11	12
1		O	O	O	O	O	O	O	V	O	O	O

2				O	O	O	O	O	O	O	V	O	A
3					O	O	O	O	O	O	V	O	A
4						O	O	A	O	O	O	O	O
5							O	O	O	O	O	O	O
6								V	O	V	O	A	O
7									O	V	V	O	O
8										O	O	A	A
9											A	O	O
10												O	O
11													A
12													

Source: Processed by author

The final SSIM matrix was then transformed into a binary format following ISM conversion rules. This produced the Initial Reachability Matrix (Table 4.2), which documents the direct influences between challenges. Subsequently, transitivity was incorporated—meaning if Challenge A influences B, and B influences C, then A is considered to indirectly influence C. This step generated the Final Reachability Matrix (Table 4.3), which captures the complete set of direct and indirect relationships, forming the foundation for the structural model.

Variables	1	2	3	4	5	6	7	8	9	10	11	12	Driving Power
1	1	0	0	0	0	0	0	0	1	0	0	0	2
2	0	1	0	0	0	0	0	0	0	1	0	0	2
3	0	0	1	0	0	0	0	0	0	1	0	0	2
4	0	0	0	1	0	0	0	0	0	0	0	0	1
5	0	0	0	0	1	0	0	0	0	0	0	0	1
6	0	0	0	0	0	1	1	0	1	0	0	0	3
7	0	0	0	1	0	0	1	0	1	1	0	0	4

8	0	0	0	0	0	0	0	1	0	0	0	0	1
9	0	0	0	0	0	0	0	0	1	0	0	0	1
10	0	0	0	0	0	0	0	0	1	1	0	0	2
11	0	0	0	0	0	1	0	1	0	0	1	0	3
12	0	1	1	0	0	0	0	1	0	0	1	1	5
Dependence Power	1	2	2	2	1	2	2	3	5	4	2	1	

Table 4.2. Initial Rechability Matrix

Source: Processed by author

Table 4.3. Final Rechability Matrix

Variables	1	2	3	4	5	6	7	8	9	10	11	12	Driving Power
1	1	0	0	0	0	0	0	0	1	0	0	0	2
2	0	1	0	0	0	0	0	0	1*	1	0	0	3
3	0	0	1	0	0	0	0	0	1*	1	0	0	3
4	0	0	0	1	0	0	0	0	0	0	0	0	1
5	0	0	0	0	1	0	0	0	0	0	0	0	1
6	0	0	0	1*	0	1	1	0	1	1*	0	0	5
7	0	0	0	1	0	0	1	0	1	1	0	0	4
8	0	0	0	0	0	0	0	1	0	0	0	0	1
9	0	0	0	0	0	0	0	0	1	0	0	0	1
10	0	0	0	0	0	0	0	0	1	1	0	0	2
11	0	0	0	1*	0	1	1*	1	1*	1*	1	0	7
12	0	1	1	1*	0	1*	1*	1	1*	1*	1	1	10
Dependence Power	1	2	2	5	1	3	4	3	9	7	2	1	

Source: Processed by author

After the reachability matrix is constructed, the next step in the Interpretive Structural Modeling (ISM) method is to calculate the Reachability Set ($R(i)$), Antecedent Set ($A(i)$), and Intersection Set ($R(i) \cap A(i)$) for each challenge element. The reachability

set is the set of elements that can be reached or influenced by a given element, including the element itself. For example, if element A influences elements B and C, then the reachability set for A is {A, B, C}. Conversely, the antecedent set is the set of elements that influence the element in question, also including itself. Thus, if A and B influence C, then the antecedent set for C is {A, B, C}. Meanwhile, the intersection set is the overlap between the reachability set and the antecedent set. The results of these calculations are used to identify the level of each challenge, allowing them to be depicted in a hierarchical system structure.

Table 4.4. Level Partitioning (First Iteration)

Elements(Mi)	Reachability Set R(Mi)	Antecedent Set A(Ni)	Intersection Set $R(Mi) \cap A(Ni)$	Level
1	1, 9,	1,	1,	
2	2, 9, 10,	2, 12,	2,	
3	3, 9, 10,	3, 12,	3,	
4	4,	4, 6, 7, 11, 12,	4,	1
5	5,	5,	5,	1
6	4, 6, 7, 9, 10,	6, 11, 12,	6,	
7	4, 7, 9, 10,	6, 7, 11, 12,	7,	
8	8,	8, 11, 12,	8,	1
9	9,	1, 2, 3, 6, 7, 9, 10, 11, 12,	9,	1
10	9, 10,	2, 3, 6, 7, 10, 11, 12,	10,	
11	4, 6, 7, 8, 9, 10, 11,	11, 12,	11,	
12	2, 3, 4, 6, 7, 8, 9, 10, 11, 12,	12,	12,	

Source: Processed by author

The process of establishing hierarchical levels, known as Level Partitioning in the ISM method, is carried out gradually through layered iterations that group the challenge elements based on their Reachability Set, Antecedent Set, and the intersection of the two.

This step aims to identify the hierarchical order of challenges, from the most dependent to the most fundamental (root causes).

The Level Partitioning process follows these steps:

1. Identify elements that satisfy the condition $R(i) = R(i) \cap A(i)$ and designate them as elements at the highest level (Level I).
2. Remove the elements whose level has been identified from all Reachability Sets and Antecedent Sets.
3. Repeat the process from steps 1 and 2 until all elements have been assigned a level.

Table 4.5 Level Partitioning (Final Iteration)

Elements(Mi)	Reachability Set R(Mi)	Antecedent Set A(Ni)	Intersection Set $R(Mi) \cap A(Ni)$	Level
1	1,	1,	1,	2
2	2,	2, 12,	2,	3
3	3,	3, 12,	3,	3
4	4,	4, 6, 7, 11, 12,	4,	1
5	5,	5,	5,	1
6	6,	6, 11, 12,	6,	4
7	7,	6, 7, 11, 12,	7,	3
8	8,	8, 11, 12,	8,	1
9	9,	1, 2, 3, 6, 7, 9, 10, 11, 12,	9,	1
10	10,	2, 3, 6, 7, 10, 11, 12,	10,	2
11	11,	11, 12,	11,	5
12	12,	12,	12,	6

Source: Processed by author

Following the completion of the iterative level partitioning procedure, the definitive hierarchical ordering of the implementation challenges is established and presented in the summary below.

Level 6 (Root Driver): Lack of vision and leadership from top management (Challenge 12) emerged as the dominant root driver. This challenge influenced nearly every other element in the system while remaining largely uninfluenced by them, underscoring the centrality of leadership commitment.

Level 5 (Strategic Driver): Expiring old business models (Challenge 11) occupied the second-lowest foundational level, reflecting how strategic misalignment and outdated business assumptions propagate upward to procedural and technical challenges.

Level 4 (Procedural Driver): Lack of standardization (Challenge 6) served as a key procedural barrier affecting system integration, documentation consistency, and workflow harmonization.

Level 3 (Technical & Human Resource Linkages): These challenges functioned as conduits through which deficiencies in leadership, strategy, and standardization translated into operational difficulties.

This level contained three strong linkage challenges:

1. Technological incompatibility (Challenge 7)
2. Lack of skilled workforce (Challenge 3)
3. Lack of training and education (Challenge 2)

Level 2 (Operational Outcomes): These challenges represented operational concerns that arise as consequences of deeper systemic issues.

1. Employment disruption (Challenge 10)
2. High initial investment cost (Challenge 1)

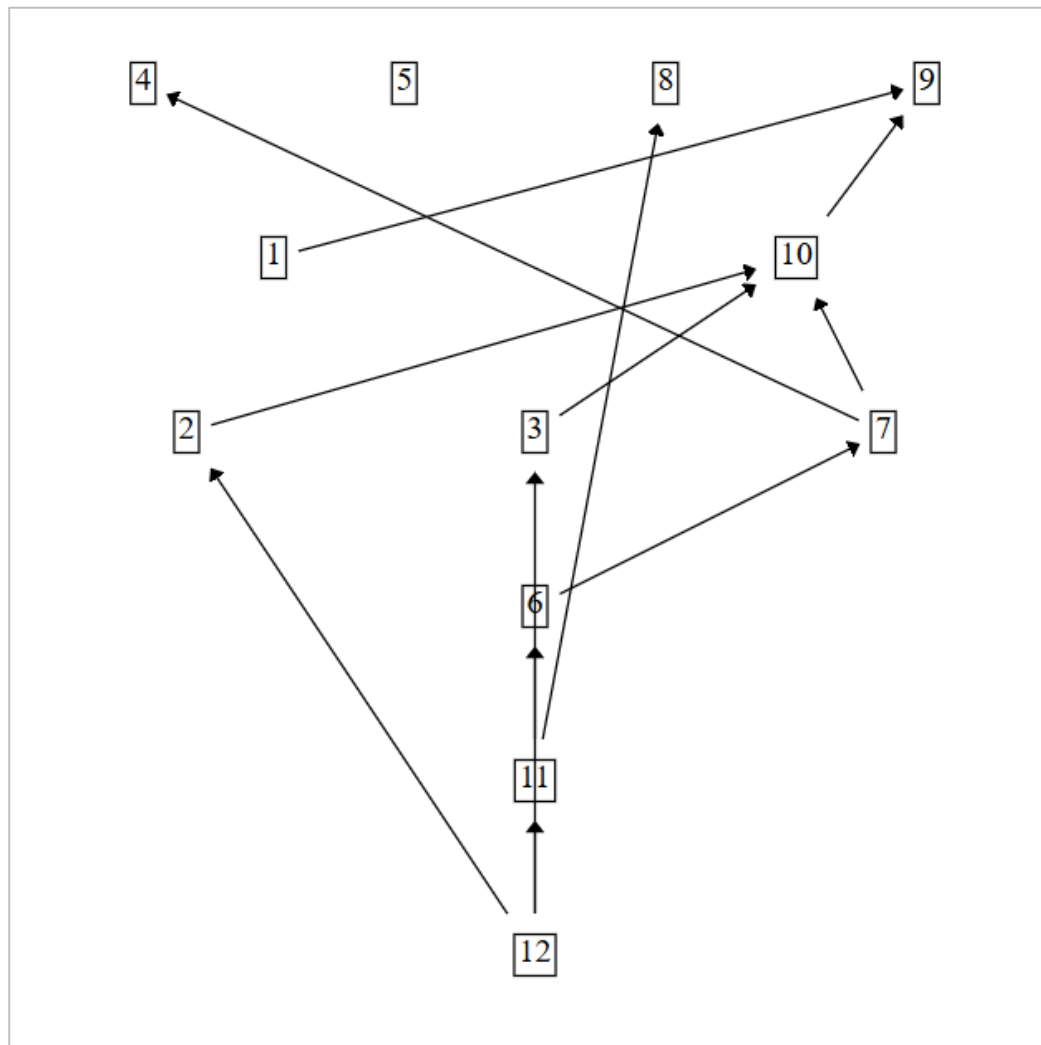
Level 1 (Dependent Challenges): These dependent challenges were strongly influenced by other elements but exerted minimal influence themselves.

1. Data security and digital trust (Challenge 4)
2. Lack of digital regulations (Challenge 5)
3. Organizational hurdles (Challenge 8)

4. Uncertainty of return on investment (Challenge 9)

To synthesize these hierarchical relationships into a comprehensive structural framework, the Final ISM Model is constructed, as shown in Figure 4.6. This directed graph translates the level assignments and contextual relationships from the reachability matrix into a visual map of influence among the challenges.

Figure 4.6. Final ISM Model



Source: Processed by author

Operational Efficiency Gains

Under the manual system, data input required two sequential activities: operator logbook writing and administrative spreadsheet entry. The average time required for

manual logbook entry by operators is 479 seconds while the average time required for manual spreadsheet entry by admin is 216 seconds. The result for total average duration of manual system amounts to 695 seconds per cycle.

For data analysis by supervisors, the complete workflow from opening the Excel file to calculating results required an average of 84.9 seconds per analysis cycle. The process was dominated by the data preparation phase (Sorting/Filtering), which consumed an average of 48.0 seconds, or approximately 56% of the total manual effort. The subsequent calculation step took an average of 34.8 seconds. Notably, there was significant variability between individuals, particularly in the sorting/filtering stage (ranging from 43.33 to 56.11 seconds), suggesting a dependence on user proficiency and the specific complexity of the dataset being handled.

Table 4.7. Time Required for Manual Logbook Entry by Operators

Subject	Work duration (hh:mm:ss)	Average = 00:07:59 = 479 seconds
Operator 1	00:09:07	
Operator 1	00:08:55	
Operator 1	00:07:23	
Operator 2	00:06:26	
Operator 2	00:09:38	
Operator 2	00:09:36	
Operator 3	00:05:35	
Operator 3	00:08:56	
Operator 3	00:06:18	

Source: Primary data collected by author

Table 4.8. Time Required for Manual Spreadsheet Entry by Admin

Subject	Work duration (hh:mm:ss)	Average = 00:03:36 = 216 seconds
Admin 1	00:03:49	

Admin 2	00:03:09	
Admin 3	00:03:50	

Source: Primary data collected by author

The time required of data entry via Kanban ERP by operators are summarized in Table 4.9. The complete process required an average of 11.42 seconds per steps. The workflow consisted of six distinct steps. The initial system access phase—comprising opening the application, logging in, and navigating to the Kanban menu—took an average of 5.47 seconds in total. The core transactional task of entering the product batch number and selecting the machine was the most time-intensive single step, averaging 5.01 seconds. Performance was consistent across simulation by ten operators, with total times ranging narrowly from 11.15 to 12.03 seconds.

Tabel 4.9. Time Required for Data Entry via Kanban ERP by Operators

Steps Taken for Data Entry	Work duration (Seconds)										Average
	OP1	OP2	OP3	OP4	OP5	OP6	OP7	OP8	OP9	OP10	
Opening the application	1,45	1,32	1,63	1,47	1,48	1,54	1,42	1,31	1,52	1,54	1,47
Login	2,18	2,15	1,89	1,92	2,11	1,87	1,84	2,16	1,87	2,17	2,02
Selecting Kanban Menu	2,09	2,04	1,87	2,05	1,88	1,83	2,07	1,90	2,19	1,84	1,98
Entering Product Batch Number & Selecting Machine Used	5,04	5,08	4,87	4,86	5,01	5,18	4,98	5,07	5,11	4,88	5,01
Clicking Start	0,36	0,31	0,42	0,42	0,54	0,69	0,35	0,43	0,68	0,32	0,45
Clicking End	0,36	0,69	0,51	0,45	0,32	0,62	0,50	0,51	0,66	0,43	0,50
Total time taken (Seconds)	11,49	11,59	11,20	11,15	11,34	11,73	11,16	11,38	12,03	11,17	11,42

Source: Primary data collected by author

The manual data analysis workflow required a substantial and variable amount of time, as detailed in Table 4.10. The complete process averaged 84.9 seconds per analysis.

The workflow was dominated by the data preparation phase (Sorting/Filtering), which alone consumed an average of 48.0 seconds, accounting for approximately 57% of the total manual effort. The subsequent data calculation step took an average of 34.8 seconds. Significant variability was observed between the three supervisors, with total completion times ranging from 77.08 to 97.67 seconds. This variation was most pronounced in the sorting/filtering stage, where times differed by nearly 13 seconds, indicating that the manual method's efficiency is highly dependent on individual user proficiency and the specific complexity of the dataset.

Table 4.10. Time Required for Manual Data Analysis via Spreadsheets by Supervisors

Steps Taken for Data Analysis	Work Duration (Seconds)			
	SPV1	SPV2	SPV3	Average
Opening Spreadsheet File	1.44	2.44	2.34	2.1
Manually sorting and/or filtering to get the necessary data	56.11	43.33	44.52	48.0
Calculating from selected data	40.12	34.11	30.22	34.8
Total	97.67	79.88	77.08	84.9

Source: Primary data collected by author

The results for the digital data analysis workflow are presented in Table 4.11. Using the internally developed Kanban ERP system, the complete analytical process was completed in an average of 22.18 seconds. The procedure involved six sequential steps. The most time-consuming phases were selecting the data time range (average of 5.92 seconds) and waiting for the system to process the query (average of 6.62 seconds), which together constituted over half of the total time. Completion times across the three supervisors (SPV1-SPV3) showed moderate consistency, ranging from 20.33 to 23.29 seconds. This digital process demonstrates a significant reduction in time and variability compared to the manual method, shifting the primary time burden from manual data manipulation to automated system processing.

Table 4.11. Time Required for Data Analysis via Kanban ERP by Supervisors

Steps Taken for Data Analysis	Work Duration (Seconds)			
	SPV1	SPV2	SPV3	Average
Opening ERP application	1.67	1.54	1.54	1.58
Login	2.46	2.44	2.34	2.41

Selecting Kanban Menu	3.11	2.77	2.82	2.90
Selecting The Equipment to analyze	2.44	2.67	3.11	2.74
Choosing data range	4.88	5.43	7.44	5.92
Waiting for the application to process	5.77	8.44	5.66	6.62
Total Time (Seconds)	20.33	23.29	22.91	22.18

Source: Primary data collected by author

DISCUSSIONS

Analysis of Implementation Challenges

The results of this study provide important insights into both the implementation challenges and operational benefits of custom-developed ERP-Kanban systems in regulated manufacturing settings. The ISM analysis reveals a deeply interconnected hierarchy of implementation barriers that challenges common assumptions about digital transformation obstacles. Meanwhile, the efficiency analysis demonstrates the substantial operational value that can be unlocked when digital solutions are closely aligned with existing processes and regulatory requirements.

Several important directional relationships emerged from the ISM model:

1. Leadership (Challenge 12) directly influenced the availability of training (2), workforce capability (3), organizational support (8), and strategic orientation (11), showing that leadership weaknesses cascade broadly across the system.
2. Standardization (6) directly influenced technological incompatibility (7), indicating that procedural inconsistency is a key antecedent to technical integration issues.
3. Technological incompatibility (7) influenced data security concerns (4), ROI uncertainty (9), and employment disruption (10), highlighting those technical limitations manifest as both financial and human-resource challenges.
4. High initial investment cost (1) had limited systemic influence, affecting only ROI uncertainty (9), implying that cost concerns were outcomes rather than core drivers.

The identification of “*Lack of vision and leadership from top management*” as the foundational driver in the hierarchical structure is particularly noteworthy. This finding disputes the common belief that digital transformation struggles are primarily caused by

technological or financial barriers. Instead, it emphasizes that leadership commitment and strategic clarity are the most critical prerequisites for successful system implementation. The ISM results demonstrate how leadership deficiencies cascade upward, influencing training availability, workforce preparedness, change readiness, and even strategic decision-making such as business model evolution.

Equally important is the finding that “*High initial investment cost*” exhibited minimal driving power. This implies that in highly regulated sectors such as pharmaceuticals—where documentation efficiency, auditability, and data integrity are mission-critical—financial constraints tend to be secondary considerations. Instead, they may function as surface-level explanations that obscure deeper cultural or organizational barriers. This offers a valuable lesson for practitioners: strengthening leadership readiness may be more impactful than focusing on cost-reduction strategies during early planning phases.

Analysis of Efficiency Gains

The comparative analysis of manual and digital workflows reveals dramatic efficiency improvements, as summarized in Table 5.1. The implementation of the ERP-Kanban system resulted in substantial time savings and efficiency gains across two core tasks

Table 5.1. Comparison of Manual Data Entry and Analysis between Manual Workflow and Via Kanban ERP

Workflow	Work Duration (seconds)		Time Saving	Efficiency Gain
	Manual	Kanban ERP		
Data Entry	695.3	11.4	683.9	98.4%
Data Analysis	84.9	22.2	62.7	73.9%

Source: Primary data collected by author

For data input, the manual process required 695.3 seconds, while the digital system reduced this to just 11.4 seconds. This represents a time saving of 683.9 seconds and an efficiency gain of 98.4%, effectively near-total automation of the task. In data analysis, the manual method took 84.9 seconds compared to 22.2 seconds with the digital system, yielding a saving of 62.7 seconds and a significant efficiency gain of 73.9%. The results demonstrate that the system delivers transformative operational performance, with the most profound impact on the repetitive data entry process.

The substantial efficiency gains realized through the Kanban ERP system confirm the theoretical alignment between Lean manufacturing principles and digital technologies. The 98.4% reduction in data input time represents a near-total elimination of waste associated with manual documentation processes. This outcome directly aligns with Lean's focus on eradicating non-value-added activities and reinforces the argument that digital tools can significantly amplify the waste-elimination potential of traditional Lean practices (Lanza-León et al., 2021; Rahman et al., 2024). Similarly, the 73.9% reduction in data analysis time strengthens the argument that digital transformation enhances visibility, responsiveness, and proactive decision-making—core components of the Lean continuous improvement mindset (Maware & Parsley, 2022).

Another key insight is the transformation of supervisory roles. Digitalization shifted supervisors away from repetitive data processing toward higher-order analytical work. This demonstrates how digital systems can complement rather than replace human capabilities, empowering staff to focus on interpretation, decision-making, and improvement initiatives (Tuli & Kaluvakuri, 2022). Such alignment between human expertise and digital capability reflects a mature integration between Lean philosophy and Industry 4.0 tools, positioning the organization for sustainable long-term performance.

Theoretical Implications

This study contributes several important insights to the academic literature on digital transformation in regulated manufacturing contexts. First, by applying ISM, this analysis moves beyond listing independent factors to illustrate the structural interrelationships among implementation challenges. The resulting hierarchical model reveals how foundational organizational factors shape technical and environmental outcomes, providing a more dynamic and nuanced understanding of digital adoption. The ISM model provides a hierarchical map of these relationships, revealing how foundational organizational factors shape technical and environmental outcomes. This offers a more nuanced understanding of digital adoption dynamics compared to traditional factor-based models.

Second, the research provides empirical evidence supporting the viability—and in some cases superiority—of custom digital systems over commercial ERP solutions. In highly specialized environments such as pharmaceuticals, the ability to tailor workflows, documentation flows, and user interfaces appears to deliver greater operational fit and

substantially higher efficiency gains than what is commonly achievable with standardized commercial platform. Third, the study enhances the literature on Lean–digital integration. It demonstrates that digital systems do not replace Lean methods but instead function as powerful enablers that amplify Lean’s core objectives. As Industry 4.0 technologies continue to evolve, this empirical evidence strengthens the argument for integrated Lean–digital transformation strategies rather than standalone technological upgrades.

Practical Implications

The findings offer several important practical implications for decision-makers responsible for digital transformation in regulated manufacturing environments. First, leadership commitment is non-negotiable, as strong executive understanding of operational and regulatory contexts is foundational to ensuring technical and financial investments yield sustainable results. Consequently, for firms in strict regulatory environments, custom system development presents a strategic and viable alternative to commercial solutions, given the significant efficiency gains and superior process alignment demonstrated. To navigate implementation, the ISM model provides a structured roadmapping tool, enabling managers to prioritize resources by first addressing root-cause drivers like leadership and standardization. Finally, the clear benchmarks of reduced processing time offer powerful quantitative evidence to strengthen the business case, helping to justify investments and secure stakeholder buy-in for digital transformation initiatives.

CONCLUSION

Main Contributions

This research contributes to both theory and practice in the domain of digital transformation within regulated manufacturing environments. Theoretically, the study develops and validates a hierarchical model of implementation challenges for internally developed digital systems. The identification of top-management leadership as the fundamental driver—surpassing traditional emphases on technical capacity or financial resources—offers a reconceptualization of digital transformation barriers in highly specialized, compliance-driven contexts.

Practically, this research provides empirical evidence that internally developed ERP-Kanban systems can serve as high-value alternatives to commercial ERP solutions for small and medium-sized enterprises operating under strict regulatory frameworks. The

observed improvements—particularly the 98.4% reduction in data input time and 73.9% reduction in data analysis time—demonstrate not only the cost-effectiveness of bespoke systems but also the strong operational synergy between Lean principles and digital technologies. These findings highlight how custom digital tools can eliminate waste, enhance responsiveness, and elevate human decision-making capabilities.

Limitations and Future Research

Several limitations of this study open opportunities for further investigation. First, the single-case design, while valuable for in-depth contextual insights, restricts the generalizability of the proposed implementation challenge hierarchy. Broader quantitative validation across multiple firms and sectors is needed to confirm whether the hierarchical structure holds in diverse regulatory or organizational environments. As mentioned in previous statements, study on hierarchical structure of implementation challenge is done based on a set of challenges listed on previous studies by Bakhtari et al. (2021). More in depth research by re-evaluating the challenges based on each organization context could also be performed instead of using a pre-determined lists of challenges.

Second, this research assessed performance outcomes primarily through documentation efficiency. Digital transformation, however, often influences multiple dimensions of organizational performance—such as quality, compliance robustness, process flexibility, and innovation capability. Future research should incorporate these additional dimensions to build a more comprehensive understanding of the benefits of custom digital solutions. Further studies by connecting to the commonly used Technological-Organizational-Environmental (TOE) framework is one such recommendation.

Finally, the focus on the pharmaceutical sector limits the ability to distinguish between industry-specific and cross-industry challenges. Comparative studies across other regulated environments—such as medical devices, aerospace, or food processing—would strengthen understanding of which barriers are universal and which arise uniquely due to sectoral regulatory pressures.

Despite these limitations, this study provides a strong foundation for both scholarship and practice. By integrating a theoretically grounded challenge hierarchy with empirical evidence of substantial efficiency gains, it offers actionable guidance for

organizations seeking to pursue custom digital transformation while maintaining regulatory compliance and strengthening competitive advantage.

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