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Designing a Causal Model of Value-Based Competitiveness in Pharmaceutical Companies Based on Production System Efficiency

ABSTRACT

In the pharmaceutical industry, competitiveness is no longer defined solely in terms of price and market share; rather, sustainable value creation for customers, quality improvement, supply responsiveness, and operational productivity are regarded as strategic competitive advantages. Nevertheless, many pharmaceutical companies face ambiguity regarding how production system efficiency contributes to the development of value-based competitiveness. Therefore, designing a causal model can clarify the relationships between the dimensions of production system efficiency and the components of value-based competitiveness and provide a basis for managerial decision-making and the enhancement of companies' competitive performance. Accordingly, the purpose of this study was to design a causal model of value-based competitiveness in pharmaceutical companies based on production system efficiency. An exploratory mixed-methods research design was employed. In the qualitative phase, thematic analysis was used to identify the components shaping value-based competitiveness based on production system efficiency. Interviews were used as the data collection instrument in this phase. Sampling continued until theoretical saturation was reached, and 14 experts participated in the interviews. In the quantitative phase, confirmatory factor analysis and Interpretive Structural Modeling (ISM) were employed to design the causal model of value-based competitiveness in pharmaceutical companies based on production system efficiency. Quantitative data were collected using two questionnaires, which were distributed among the members of the statistical sample after their validity and reliability had been examined and confirmed. The statistical population in the quantitative phase consisted of managers and experts at different organizational levels of pharmaceutical companies across the country, from whom a sample of 260 participants was selected. The qualitative findings revealed eight main themes and 36 subthemes. In the quantitative phase, the results of Interpretive Structural Modeling indicated that the causal model of value-based competitiveness in pharmaceutical companies based on production system efficiency comprised six hierarchical levels. In this model, human capital and productivity culture demonstrated the greatest driving influence, whereas sustainability and stakeholder value creation exhibited the greatest dependence.

Keywords: value-based competitiveness, production system efficiency, pharmaceutical companies

Introduction

Competitiveness has long been recognized as a multidimensional construct that reflects an organization's capacity to sustain superior performance under conditions of market rivalry, technological change, resource constraints, and shifting customer expectations. In contemporary management, competitiveness is no longer interpreted solely through traditional indicators such as market share, price advantage, or sales growth; rather, it increasingly encompasses the organization's ability to generate superior value through quality, innovation, responsiveness, efficiency, and sustainable stakeholder outcomes. This shift is particularly important in industries in which customers, regulators, investors, and wider society

simultaneously influence organizational legitimacy and long-term survival. Accordingly, recent approaches distinguish between product competitiveness, enterprise competitiveness, and value-based competitiveness, emphasizing that competitive superiority emerges from the interaction of product attributes, organizational capabilities, and the value perceived by customers and other stakeholders [1-4]. From this perspective, competitiveness becomes a dynamic managerial outcome rather than a static market position.

The value-based view of competitiveness places value creation at the center of competitive strategy. Under this view, firms achieve stronger competitive positions when they can convert their resources and capabilities into meaningful economic, functional, relational, and strategic value for customers and stakeholders. Value-oriented management therefore requires firms to move beyond cost minimization and short-term profitability and instead coordinate strategic decisions around sustained value generation. Such an approach connects competitiveness with customer orientation, resource allocation, investment attractiveness, innovation, and stakeholder expectations [5, 6]. In business-to-business contexts, value-based selling further demonstrates that competitive advantage depends not only on providing technically superior products but also on demonstrating and realizing measurable customer value throughout the relationship lifecycle [7, 8]. Consequently, value-based competitiveness may be understood as an enterprise's capacity to deliver and sustain superior stakeholder value through an integrated configuration of operational, technological, human, and strategic capabilities.

The increasing emphasis on value also changes the way enterprise competitiveness should be evaluated. Traditional competitiveness assessments often focus on financial performance, production costs, market position, or product characteristics, whereas more contemporary approaches recognize that enterprise competitiveness is shaped by a broader constellation of interdependent factors. Balanced assessment systems, for example, incorporate financial and nonfinancial dimensions to provide a more comprehensive picture of competitive capability [9]. Likewise, empirical research indicates that enterprise competitiveness is influenced by interacting determinants such as organizational resources, managerial capabilities, innovation, market conditions, and internal operating systems [10]. The competitiveness of an enterprise therefore cannot be reduced to a single dimension; instead, it is the result of coordinated capabilities that allow the organization to create value more effectively than its competitors. This complexity also explains why competitiveness must be managed strategically, particularly in unstable and uncertain economic environments where organizations face pressure to adapt their business models, operations, and resource structures [11, 12].

For manufacturing enterprises, production systems occupy a central position in this competitive architecture because production is the mechanism through which strategic resources are transformed into marketable outputs and stakeholder value. Production system efficiency concerns the extent to which an organization can achieve desired levels of output, quality, reliability, flexibility, and responsiveness while minimizing unnecessary resource consumption, delays, defects, and process losses. Efficient production systems create competitive value by lowering costs, improving delivery performance, increasing utilization of productive assets, and enabling organizations to respond more effectively to fluctuations in demand. Research on enterprise efficiency and competitiveness has consistently shown that these two concepts are strongly interconnected because efficient resource conversion can support stronger market performance, while competitive pressures can stimulate further improvements in efficiency [13, 14]. Similarly, the relationship between business strategy, operational efficiency, and manufacturing performance suggests that operational efficiency functions as a critical mechanism through which strategic choices are translated into measurable competitive outcomes [15].

Within production management, operational excellence represents one of the most important manifestations of production system efficiency. Operational excellence is associated with reducing cycle time, eliminating non-value-adding activities, improving equipment productivity, balancing production capacity, removing bottlenecks, and institutionalizing continuous improvement. Lean manufacturing has been particularly influential in demonstrating how systematic waste reduction and process discipline can improve both quality and efficiency [16]. The integration of lean principles with value-oriented facility design further illustrates that operational improvement becomes more strategically important when efficiency initiatives are explicitly connected to value creation rather than treated as isolated cost-reduction measures [17]. More recent developments extend these principles through Lean Six Sigma 4.0, which combines traditional process improvement techniques with digital technologies and Industry 4.0 capabilities in order to support higher levels of operational excellence [18]. Thus, operational excellence is not merely an internal efficiency objective; it is an important component of a firm's capacity to compete on value.

Quality represents another essential bridge between production system efficiency and competitiveness, particularly in industries characterized by high regulatory requirements and substantial consequences of quality failure. Production quality affects customer satisfaction, brand reputation, operating cost, rework, waste, and regulatory risk. In pharmaceutical manufacturing, this relationship becomes especially critical because quality must be designed, controlled, documented, and maintained in accordance with Good Manufacturing Practice requirements. GMP systems provide a formal framework for ensuring that products are consistently manufactured and controlled according to predetermined quality standards, making compliance an integral component of operational capability rather than a peripheral regulatory obligation [19]. Quality assurance also contributes to product integrity and can accelerate pharmaceutical research, development, and commercialization by reducing uncertainty, improving compliance, and strengthening confidence in production systems [20]. Therefore, quality and regulatory compliance are simultaneously protective and competitive capabilities in pharmaceutical companies.

The digitalization of quality and production systems has further expanded the strategic meaning of efficiency. Industry 4.0 technologies enable firms to integrate data, automate processes, improve traceability, monitor operations in real time, and support predictive decision-making. The digitalization of quality-control processes can improve the timeliness, consistency, and visibility of quality information, while also reducing dependence on fragmented and manually intensive control systems [21]. At the same time, Industry 4.0 changes the competencies required of quality and operations professionals because digital manufacturing environments increasingly demand data literacy, systems thinking, technological adaptability, and cross-functional problem solving [22]. Digital transformation therefore does not simply automate existing routines; it alters the organizational capabilities through which production efficiency and competitiveness are created.

More broadly, the Industry 4.0 revolution has intensified the strategic importance of smart manufacturing. Smart production systems combine digital connectivity, data analytics, automation, intelligent monitoring, and predictive maintenance to improve decision speed and process reliability. These technologies can create significant competitive advantages when they are effectively integrated with organizational processes and human capabilities. However, technological adoption alone does not guarantee superior performance, because the value of Industry 4.0 depends on the firm's ability to redesign work, develop human capital, integrate data, and align technology with production objectives [23]. This consideration is particularly relevant to pharmaceutical companies, where process automation and data integration must

coexist with stringent validation, documentation, and compliance requirements. Consequently, digital transformation should be understood as an enabling layer that interacts with quality systems, manufacturing innovation, workforce capability, logistics, and operational excellence.

Innovation in manufacturing processes constitutes another important pathway through which production system efficiency contributes to value-based competitiveness. Process innovation allows firms to improve throughput, flexibility, precision, resource productivity, and responsiveness while also supporting the development of new production capabilities. Advanced process technologies can increase both efficiency and sustainability when they are implemented through systematic optimization and effective process control [24]. In pharmaceutical manufacturing, process innovation may include advanced manufacturing technologies, continuous production, improved process integration, automation, technology transfer, and simplified operating procedures. These innovations can reduce variability and waste while strengthening the organization's ability to meet changing product, market, and regulatory requirements. Innovation therefore creates value not only by generating new products but also by transforming the way products are manufactured and delivered.

Production efficiency is also inseparable from supply-chain and logistics performance. Pharmaceutical manufacturers depend on reliable access to raw materials, active ingredients, packaging materials, transportation systems, warehousing capacity, and distribution networks. A disruption in any of these areas can affect production continuity, product availability, cost, and customer value. Integrated production logistics and supply-chain management are therefore essential to maintaining competitiveness. Reliable suppliers, effective inventory management, demand-production coordination, and material-flow traceability can reduce uncertainty and improve responsiveness. From a broader sustainability perspective, competitive manufacturing increasingly requires organizations to integrate production and supply-chain decisions with responsible resource use and environmental considerations [25]. Value-based planning approaches also demonstrate that competitiveness depends on balancing economic efficiency, uncertainty, and long-term system value rather than focusing exclusively on immediate cost advantages [26].

Resource management and economic productivity represent another major component of production system efficiency. Manufacturing firms must continually optimize the use of materials, labor, equipment, energy, water, and financial resources in order to reduce unit costs while maintaining quality and reliability. Resource efficiency becomes especially significant in pharmaceutical production because manufacturing processes can be capital-intensive, highly regulated, and technically sensitive. Waste, rework, excessive material consumption, equipment downtime, and energy inefficiency can reduce profitability and weaken the value delivered to customers and stakeholders. Therefore, economic productivity should not be interpreted as cost reduction alone; it involves generating greater productive and stakeholder value from a given resource base. This interpretation is consistent with research emphasizing that enterprise competitiveness depends on effective resource utilization and coordinated efficiency management [13, 14].

Human capital is equally central to the performance of production systems because technologies, standards, and process designs ultimately depend on employees' ability to operate, interpret, improve, and coordinate them. Competitiveness can be strengthened when organizations enhance the strategic role of human resources, particularly through competency development, continuous learning, participation, and alignment between workforce capabilities and organizational objectives [27]. In advanced manufacturing environments, specialized knowledge, digital competencies, quality awareness, operational leadership, and cross-functional collaboration are becoming increasingly important. The broader Industry 4.0

literature also highlights the interdependence between technological transformation and human-capital development, suggesting that digital transformation can only create sustained value when firms simultaneously invest in people and organizational learning [23]. Knowledge-management infrastructure further supports this process by enabling organizations to capture, disseminate, and apply organizational knowledge in ways that enhance problem solving and innovation [28].

Human capital is also closely related to organizational culture. A productivity-oriented culture encourages continuous improvement, disciplined execution, learning from errors, employee involvement, and the systematic pursuit of operational value. In such a culture, efficiency is not restricted to formal performance indicators but becomes embedded in managerial and employee behavior. This cultural dimension is particularly important in pharmaceutical firms, where production performance requires simultaneous attention to technical efficiency, documentation, compliance, safety, and quality. Competitiveness research in other organizational contexts likewise suggests that human and axiological dimensions influence the capacity of individuals and institutions to remain competitive under changing conditions [29, 30]. Accordingly, human capital and productivity culture may function as foundational drivers from which other production capabilities emerge.

Sustainability has also become increasingly integrated into the concept of competitiveness. Organizations are now expected to generate value while reducing environmental impacts, preserving resources, demonstrating social responsibility, and meeting the expectations of multiple stakeholder groups. Sustainable manufacturing extends competitive analysis beyond productivity and market performance by incorporating ecological and social outcomes into production strategy [25]. Similarly, evidence linking environmental, social, and governance performance with innovation and corporate value indicates that sustainability-oriented practices can contribute to value creation when they are supported by appropriate innovation capabilities [31]. In the pharmaceutical industry, this perspective is especially relevant because the social value of production is directly connected to sustained access to medicines, product safety, responsible resource consumption, and reliable supply. Therefore, stakeholder value creation should be regarded as an ultimate competitive outcome rather than as an external corporate responsibility activity.

A further issue concerns the causal ordering of these factors. Although previous studies have individually examined competitiveness, operational efficiency, digital transformation, quality, human capital, innovation, and sustainability, these variables are often treated as separate determinants or parallel dimensions rather than as components of an integrated causal system. Yet management theory increasingly recognizes that organizational outcomes emerge through interdependent relationships among capabilities. Epistemological analyses of competitiveness and innovation, for example, highlight the importance of clarifying the conceptual relationships between competitive performance and innovation-related constructs [32]. Similarly, strategic competitiveness research suggests that no single managerial factor can adequately explain competitive performance because the effects of strategy, resources, operations, and market forces interact with one another [10, 11]. A causal modeling approach is therefore valuable because it can distinguish between foundational drivers, intermediate capabilities, and higher-level outcomes.

This need is particularly pronounced in pharmaceutical companies. Pharmaceutical manufacturing operates at the intersection of market competition, public health responsibility, advanced technology, regulatory compliance, and supply-chain vulnerability. A pharmaceutical firm may achieve low production costs but still fail competitively if quality is inconsistent, delivery is unreliable, innovation is weak, or regulatory compliance is inadequate. Conversely, superior quality or advanced technology may not create sustainable value if production resources are inefficiently managed or organizational

capabilities are poorly integrated. Product competitiveness is thus connected to enterprise competitiveness, while enterprise competitiveness is in turn influenced by the efficiency and strategic coherence of the production system [1]. At the same time, contemporary value approaches emphasize that the ultimate test of competitive capability lies in the value generated for customers and other stakeholders [2, 8].

Accordingly, there is a need to move from fragmented analysis toward an integrated model that explains how production-system capabilities interact to produce value-based competitiveness. Existing literature provides substantial evidence regarding operational excellence, lean systems, digital quality control, advanced process technologies, human-resource capabilities, strategic competitiveness, sustainability, and value-oriented management, but it provides less clarity regarding the hierarchical and causal relationships among these elements within pharmaceutical manufacturing. Such a model can help managers identify which capabilities should be treated as antecedent drivers, which should function as intermediate operational mechanisms, and which should be regarded as final competitive outcomes. This is particularly important for managerial prioritization because organizations rarely possess sufficient resources to improve all capabilities simultaneously. Understanding causal structure can therefore support more rational investment decisions, more coherent improvement programs, and more effective allocation of managerial attention [15, 17, 18].

From a strategic perspective, a causal model can also reconcile the efficiency and value dimensions of competitiveness. Efficiency-oriented management tends to emphasize cost, productivity, capacity utilization, and waste reduction, whereas value-oriented management emphasizes stakeholder benefits, customer outcomes, differentiation, and long-term value realization. These orientations are not necessarily contradictory. Rather, sustainable competitive advantage may emerge when efficient production systems are deliberately configured to create superior value instead of merely reducing internal cost. Contemporary value-oriented and customer-oriented approaches reinforce this interpretation by showing that the strategic significance of organizational capabilities depends on the extent to which they contribute to stakeholder value [5, 6]. Likewise, competitiveness assessment increasingly requires simultaneous consideration of quality, price, and value rather than reliance on any single criterion [4]. Therefore, integrating production efficiency with value-based competitiveness offers a more comprehensive framework for understanding competitive performance in pharmaceutical companies.

In light of the theoretical and practical gap identified above, the aim of the present study was to design a causal model of value-based competitiveness in pharmaceutical companies based on production system efficiency.

Methodology

From the perspective of purpose, this study was developmental-applied, and in terms of research methodology, it employed an exploratory mixed-methods design.

In the qualitative phase, thematic analysis was employed to identify the study variables and the indicators of the causal model of value-based competitiveness in pharmaceutical companies based on production system efficiency. The primary instrument for data collection in this phase was the interview.

Experts familiar with the subject matter were recruited to conduct the thematic analysis. Considering the case-specific context of the study, the experts were required to meet the following criteria:

1. Managers of pharmaceutical companies with more than 20 years of managerial experience and familiarity with competitiveness, production management, and production system efficiency.

2. University faculty members with teaching experience and a publication record in the areas of competitiveness, production management, and production system efficiency.

In the qualitative phase, sampling was conducted based on theoretical saturation. Accordingly, the number of experts was determined by the point at which theoretical saturation was achieved. To select these individuals, pharmaceutical companies in Iran were repeatedly approached, and information about potential participants was obtained from various sources to prepare an initial list of experts in the field. Given that sampling in thematic analysis was theoretical and that sample size was determined based on theoretical saturation, saturation was achieved with the 11th expert. However, three additional interviews were conducted to ensure sufficient saturation. Of the 14 experts participating in the study, 11 were managers and three were university faculty members.

The quantitative phase consisted of two stages. In the first stage, confirmatory factor analysis was used to validate the findings obtained from the qualitative phase in order to ensure, on the basis of empirical data, the validity of the models derived from the qualitative phase for the main themes. The statistical population in this phase consisted of all managers and experts at different organizational levels of pharmaceutical companies across the country. For this purpose, a preliminary review of pharmaceutical companies was conducted. The results indicated that 768 managers and experts were employed in these companies. Therefore, the statistical population of the quantitative phase comprised 768 managers and experts working in pharmaceutical companies. The sample size was determined using the Krejcie and Morgan table. According to this table, an appropriate sample size for a population of 768 individuals was 260 participants. Proportionate random sampling was employed in this phase. In the second stage of the quantitative phase, the experts who had participated in the qualitative phase were used to determine the relationships among the main components.

A researcher-developed questionnaire based on the identified subthemes was used to collect data in this phase. In the specific items of the questionnaire, respondents were asked to indicate their level of agreement using a five-point Likert scale ranging from strongly disagree to strongly agree.

To examine the validity of the questionnaire, face validity was assessed, and construct validity was also examined and confirmed using confirmatory factor analysis. The reliability of the questionnaire was evaluated using Cronbach's alpha coefficient separately for each main theme. The results are presented in Table 1. Based on the Cronbach's alpha coefficients obtained for the main themes, the reliability of the questionnaire was confirmed.

Table 1

Cronbach's Alpha Coefficients for the Main Themes

Main Theme	Cronbach's Alpha
Operational Excellence in Production	0.978
Production Quality and Regulatory Compliance	0.983
Innovation in Manufacturing Processes	0.973
Digital Transformation and Smart Manufacturing	0.990
Production Logistics and Integrated Supply Chain	0.984
Resource Management and Economic Productivity	0.980
Human Capital and Productivity Culture	0.984
Sustainability and Stakeholder Value Creation	0.975

For quantitative data analysis, confirmatory factor analysis was employed in the first stage. In the second stage, Interpretive Structural Modeling (ISM) was used to design the causal model of value-based competitiveness in pharmaceutical companies based on production system efficiency. Data for this stage were collected using a pairwise-comparison

questionnaire based on the ISM method. Because ISM is based on expert judgments, the questionnaire was administered to the same 14 experts who had participated in the qualitative phase. Through pairwise comparisons, the experts determined the influence of each variable (main theme) on the other variables included in the model.

Findings and Results

In this phase, thematic analysis was employed to extract the indicators of the causal model of value-based competitiveness in pharmaceutical companies based on production system efficiency. Following the stages of thematic analysis, the dataset obtained from the interviews was first reviewed, after which initial coding was performed. In total, 291 initial codes were extracted from the interviews. Coding was conducted on the basis of key points identified in the interview data.

The initial codes extracted from the key points of the interviews were either directly considered as subthemes or grouped into subthemes according to their conceptual similarity. In the third stage, selective coding was conducted to determine how the different codes identified in the previous stage could form broader themes. At this stage, preliminary themes were developed, resulting in a total of 41 initial themes. In other words, from the 291 initial codes, 41 preliminary subthemes were obtained during selective coding after duplicate and irrelevant codes had been removed. In the fourth stage, the preliminary themes identified in Stage 3 were reviewed and refined, resulting in 36 final subthemes. Finally, in the fifth stage, the main themes were identified by determining the underlying conceptual domain represented by the subthemes. Table 2 presents the main themes and subthemes identified in the study.

Table 2

Main Themes and Subthemes of the Causal Model of Value-Based Competitiveness in Pharmaceutical Companies

Main Theme	Subtheme	Code	Frequency
Operational Excellence in Production (OX)	Reduction in production cycle time	OX1	11
	Increased equipment productivity	OX2	10
	Capacity optimization and production-line balancing	OX3	8
	Reduction of bottlenecks and waste	OX4	9
Production Quality and Regulatory Compliance (QRC)	Implementation of Good Manufacturing Practice (GMP)	QRC1	7
	Quality by Design	QRC2	9
	Validation	QRC3	6
	Data integrity	QRC4	6
	Quality risk management	QRC5	5
Innovation in Manufacturing Processes (PI)	Advanced manufacturing technologies	PI1	8
	Process flexibility	PI2	9
	Operational simplification	PI3	7
	Technology transfer	PI4	10
Digital Transformation and Smart Manufacturing (DT)	Real-time monitoring	DT1	4
	Intelligent automation	DT2	6
	Predictive maintenance	DT3	3
	Data integration	DT4	5
	Big data analytics	DT5	2
Production Logistics and Integrated Supply Chain (ISC)	Timely supply	ISC1	9
	Inventory management	ISC2	10
	Supplier reliability	ISC3	8
	Production and demand planning	ISC4	6
	Material flow traceability	ISC5	3
Resource Management and Economic Productivity (RM)	Reduction in total production cost	RM1	11
	Energy and water efficiency	RM2	2
	Reduction in waste and rework	RM3	7
	Optimization of material consumption	RM4	3
Human Capital and Productivity Culture (HCC)	Specialized skills	HCC1	2
	Continuous training	HCC2	9

	Continuous improvement culture	HCC3	5
	Cross-functional collaboration	HCC4	2
	Operational leadership	HCC5	1
Sustainability and Stakeholder Value Creation (SVC)	Sustainable access to medicines	SVC1	1
	Reduction of environmental impacts	SVC2	4
	Social responsibility	SVC3	3
	Balance between value and efficiency	SVC4	6

The research literature was used in naming the main themes based on the conceptual nature of their corresponding subthemes. Accordingly, eight main themes—Operational Excellence in Production; Production Quality and Regulatory Compliance; Innovation in Manufacturing Processes; Digital Transformation and Smart Manufacturing; Production Logistics and Integrated Supply Chain; Resource Management and Economic Productivity; Human Capital and Productivity Culture; and Sustainability and Stakeholder Value Creation—were identified as the principal dimensions of the causal model of value-based competitiveness in pharmaceutical companies based on production system efficiency.

After the main themes had been labeled on the basis of their respective subthemes and the themes had been categorized, confirmatory factor analysis was employed to determine whether the models derived from the empirical data were appropriate. The results of the confirmatory factor analyses for the models corresponding to the identified themes are presented in Table 3.

Table 3

Results of Confirmatory Factor Analysis for the Main Themes of the Causal Model of Value-Based Competitiveness

Main Theme	Subtheme	Factor Loading	*t* Value
Operational Excellence in Production (OX)	Reduction in production cycle time	0.95	20.75
	Increased equipment productivity	0.97	21.43
	Capacity optimization and production-line balancing	0.95	20.61
	Reduction of bottlenecks and waste	0.96	20.80
Production Quality and Regulatory Compliance (QRC)	Implementation of GMP	0.96	21.70
	Quality by Design	0.98	22.01
	Validation	0.94	20.31
	Data integrity	0.95	20.50
	Quality risk management	0.91	19.07
Innovation in Manufacturing Processes (PI)	Advanced manufacturing technologies	0.99	22.06
	Process flexibility	0.92	19.54
	Operational simplification	0.91	19.17
	Technology transfer	0.98	21.84
Digital Transformation and Smart Manufacturing (DT)	Real-time monitoring	0.98	21.96
	Intelligent automation	0.98	21.93
	Predictive maintenance	0.97	21.60
	Data integration	0.96	21.05
	Big data analytics	0.98	21.81
Production Logistics and Integrated Supply Chain (ISC)	Timely supply	0.96	21.12
	Inventory management	0.98	21.64
	Supplier reliability	0.94	20.38
	Production and demand planning	0.97	21.31
	Material flow traceability	0.95	20.66
Resource Management and Economic Productivity (RM)	Reduction in total production cost	0.97	21.24
	Energy and water efficiency	0.95	20.72
	Reduction in waste and rework	0.95	20.57
	Optimization of material consumption	0.98	21.91
Human Capital and Productivity Culture (HCC)	Specialized skills	0.95	20.80
	Continuous training	0.97	21.62
	Continuous improvement culture	0.95	20.76
	Cross-functional collaboration	0.96	20.97
	Operational leadership	0.96	21.07

Sustainability and Stakeholder Value Creation (SVC)	Sustainable access to medicines	0.97	21.29
	Reduction of environmental impacts	0.95	20.60
	Social responsibility	0.95	20.53
	Balance between value and efficiency	0.94	20.16

Each factor loading represents the relationship between a main component and the indicators associated with that component. From an empirical perspective, factor loadings greater than 0.50 are generally considered acceptable and satisfactory. The factor-loading results presented in Table 3 indicate that all factor loadings were greater than 0.50, demonstrating an appropriate relationship between each main component and its corresponding indicators. Statistically, at a 95% confidence level, the *t* value associated with each positive factor loading should exceed 1.96. The results presented in Table 3 also indicate that the *t* values for all factor loadings were greater than 1.96, demonstrating the statistical significance of all factor loadings within the target population. In addition to examining factor loadings and their significance, confirmatory models should also be evaluated according to model-fit criteria to ensure that each confirmatory model provides an acceptable fit to the empirical data. The results concerning the goodness of fit of the confirmatory models according to various criteria are presented in Table 4.

Table 4

Goodness-of-Fit Indices for the Confirmatory Models

Confirmatory Model (Main Theme)	*p* Value	CMIN	GFI	CFI	RMSEA	RMR
Operational Excellence in Production	0.11707	2.145	0.99	1.00	0.066	0.0046
Production Quality and Regulatory Compliance	0.76552	0.514	1.00	1.00	0.000	0.0025
Innovation in Manufacturing Processes	0.94808	0.055	1.00	1.00	0.000	0.00074
Digital Transformation and Smart Manufacturing	0.95279	0.222	1.00	1.00	0.000	0.0012
Production Logistics and Integrated Supply Chain	0.47553	0.906	0.99	1.00	0.000	0.0040
Resource Management and Economic Productivity	0.86169	0.150	1.00	1.00	0.000	0.0013
Human Capital and Productivity Culture	0.96935	0.182	1.00	1.00	0.000	0.0018
Sustainability and Stakeholder Value Creation	0.26472	1.330	0.99	1.00	0.036	0.0013

Various criteria can be used to evaluate the goodness of fit of confirmatory models. Among the most commonly used indices are the chi-square significance level (*p* value), relative chi-square (CMIN), Goodness-of-Fit Index (GFI), Comparative Fit Index (CFI), Root Mean Square Error of Approximation (RMSEA), and Root Mean Square Residual (RMR). The criteria for acceptable model fit include a chi-square significance level greater than 0.05, a relative chi-square value below 2, an RMSEA value below 0.09, an RMR value below 0.05, and GFI and CFI values greater than 0.90. The results presented in Table 4 indicate that the values obtained for all main components generally demonstrated acceptable confirmatory model fit according to the various fit criteria. Accordingly, the goodness of fit of all confirmatory models was supported by the empirical data, indicating that all main components of value-based competitiveness in pharmaceutical companies based on production system efficiency could be incorporated into the development of the causal model for the study population.

Following confirmation of the main themes, Interpretive Structural Modeling was used to design the causal model of value-based competitiveness in pharmaceutical companies based on production system efficiency. Accordingly, pairwise-comparison questionnaires concerning the main themes were administered to the same experts who had participated in the qualitative phase. In the initial step, an initial reachability matrix was constructed based on the majority opinion of the experts. The initial reachability matrix represented the direct relationships among the main components (main themes) of value-based competitiveness in pharmaceutical companies based on production system efficiency. The initial reachability matrix is presented in Table 5.

Table 5

Initial Reachability Matrix for Value-Based Competitiveness in Pharmaceutical Companies

Components	Code	OX	QRC	PI	DT	ISC	RM	HCC	SVC
Operational Excellence in Production	OX	0	0	0	0	0	0	0	1
Production Quality and Regulatory Compliance	QRC	1	0	1	0	0	0	0	0
Innovation in Manufacturing Processes	PI	1	0	0	0	0	0	0	0
Digital Transformation and Smart Manufacturing	DT	0	1	1	0	0	0	0	0
Production Logistics and Integrated Supply Chain	ISC	0	0	1	0	0	1	0	0
Resource Management and Economic Productivity	RM	1	0	0	0	0	0	0	1
Human Capital and Productivity Culture	HCC	0	1	0	1	1	0	0	0
Sustainability and Stakeholder Value Creation	SVC	0	0	0	0	0	0	0	0

In the next step, the final reachability matrix was calculated. For this purpose, the initial reachability matrix was first combined with an identity matrix of the same dimensions, after which indirect relationships were determined. The resulting final reachability matrix is presented in Table 6.

Table 6

Final Reachability Matrix for Value-Based Competitiveness in Pharmaceutical Companies

Code	OX	QRC	PI	DT	ISC	RM	HCC	SVC
OX	1	0	0	0	0	0	0	1
QRC	1	1	1	0	0	0	0	1*
PI	1	0	1	0	0	0	0	1*
DT	1*	1	1	1	0	0	0	1*
ISC	1*	0	1	0	1	1	0	1*
RM	1	0	0	0	0	1	0	1
HCC	1*	1	1*	1	1	1*	1	1*
SVC	0	0	0	0	0	0	0	1

The final reachability matrix represents both direct and indirect relationships. The values marked with an asterisk indicate indirect relationships in the final reachability matrix.

In the next step, the final reachability matrix was partitioned into different hierarchical levels. At this stage, the variables were first classified according to their reachability sets and antecedent sets, and the intersection of these two sets was then used to determine the output associated with each level. A summary of the results of the hierarchical level partitioning is presented in Table 7.

Table 7

Final Results of Hierarchical Level Partitioning of the Components of the Causal Model of Value-Based Competitiveness in Pharmaceutical Companies

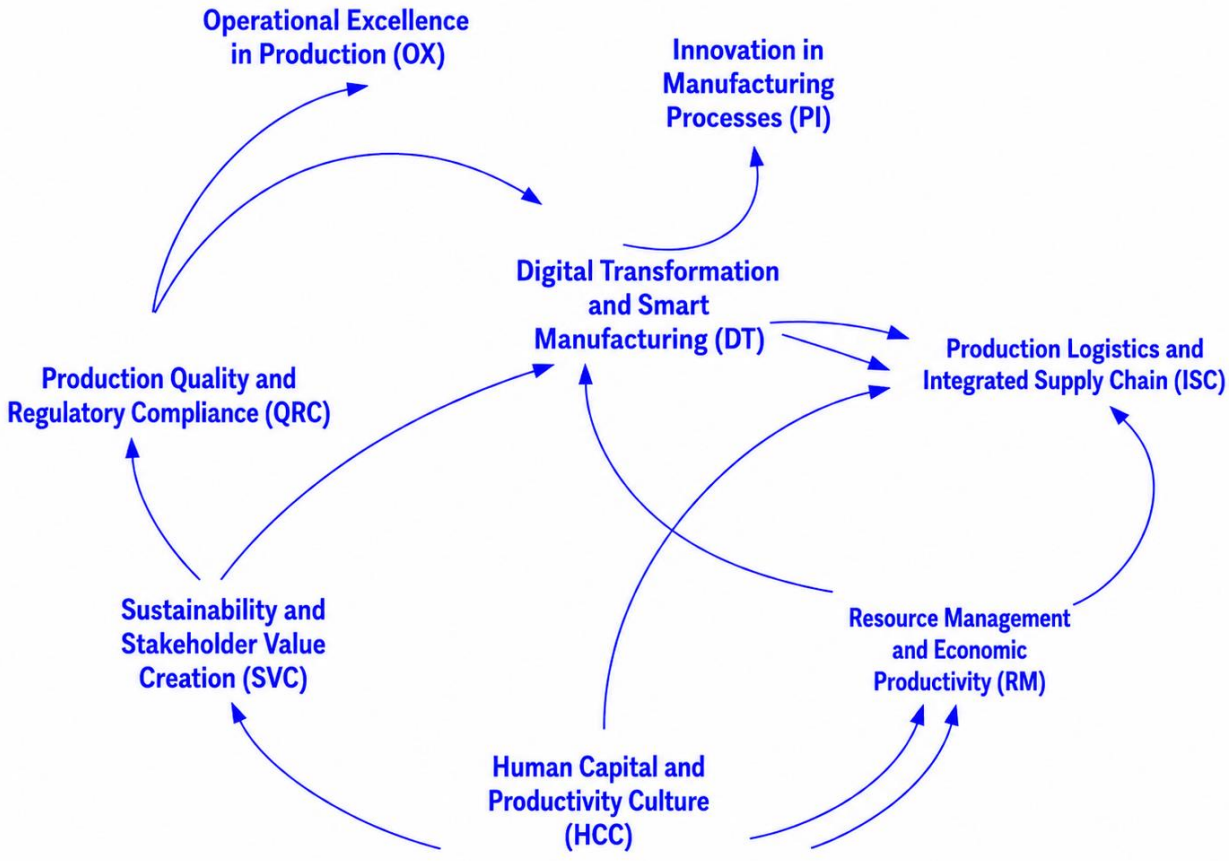
Level	Main Theme	Reachability Set	Antecedent Set	Intersection	Output
First	Sustainability and Stakeholder Value Creation	SVC	OX, QRC, PI, DT, ISC, RM, HCC, SVC	SVC	SVC
Second	Operational Excellence in Production	OX	OX, QRC, PI, DT, ISC, RM, HCC	OX	OX
Third	Innovation in Manufacturing Processes	PI	QRC, PI, DT, ISC, HCC	PI	PI
	Resource Management and Economic Productivity	RM	ISC, RM, HCC	RM	RM
Fourth	Production Quality and Regulatory Compliance	QRC	QRC, DT, HCC	QRC	QRC
	Production Logistics and Integrated Supply Chain	ISC	ISC, HCC	ISC	ISC
Fifth	Digital Transformation and Smart Manufacturing	DT	DT, HCC	DT	DT
Sixth	Human Capital and Productivity Culture	HCC	HCC	HCC	HCC

According to the results presented in Table 7, the output of the first level is the main component of Sustainability and Stakeholder Value Creation in the causal model of value-based competitiveness in pharmaceutical companies based on

production system efficiency. This component is positioned at the highest level of the causal model. The output of the second level is Operational Excellence in Production, which is positioned below Sustainability and Stakeholder Value Creation in the causal model. The third level comprises two components: Innovation in Manufacturing Processes and Resource Management and Economic Productivity. The fourth-level outputs consist of the two main components of Production Quality and Regulatory Compliance and Production Logistics and Integrated Supply Chain, which are positioned below Innovation in Manufacturing Processes and Resource Management and Economic Productivity. The fifth-level output is Digital Transformation and Smart Manufacturing. Finally, the sixth level, representing the lowest level of the causal model of value-based competitiveness in pharmaceutical companies based on production system efficiency, consists of Human Capital and Productivity Culture. As this component occupies the lowest hierarchical level of the model, it represents the most influential main component in the causal model of value-based competitiveness in pharmaceutical companies based on production system efficiency. In the final step, a diagram was constructed according to the hierarchical levels of the variables after indirect relationships had been removed. This diagram represents the causal model of value-based competitiveness in pharmaceutical companies based on production system efficiency and is presented in Figure 1. As illustrated in Figure 1, moving from the bottom toward the top of the diagram corresponds to a decrease in the driving influence of the components and an increase in their dependence on other components.

Figure 1

Causal Model of Value-Based Competitiveness in Pharmaceutical Companies Based on Production System Efficiency



The findings of this section demonstrate that value-based competitiveness in pharmaceutical companies emerges from a hierarchical causal chain that begins with human capital and ultimately culminates in sustainability and stakeholder value creation. In this model, competitiveness is not conceptualized as the direct result of a single factor; rather, it is explained as the ultimate outcome of the interaction among multiple layers of human, technological, logistical, quality-related, and operational factors. The underlying logic of the model indicates that production system efficiency constitutes the intermediate core of this process; however, its development requires a set of antecedent drivers and predictive mechanisms that exert sequential effects on one another.

Discussion and Conclusion

The findings of the present study showed that value-based competitiveness in pharmaceutical companies is shaped through a hierarchical causal system consisting of eight principal components: operational excellence in production, production quality and regulatory compliance, innovation in manufacturing processes, digital transformation and smart manufacturing, production logistics and integrated supply chain, resource management and economic productivity, human capital and productivity culture, and sustainability and stakeholder value creation. Confirmatory factor analysis supported the validity of all eight components, and the factor loadings of all subcomponents exceeded the acceptable threshold. The Interpretive Structural Modeling results further demonstrated that these components are not positioned at the same causal level. Rather, they form a six-level structure in which human capital and productivity culture constitute the most fundamental and influential driver, followed by digital transformation and smart manufacturing, production quality and regulatory compliance together with production logistics and integrated supply chain, innovation in manufacturing processes together with resource management and economic productivity, operational excellence in production, and finally sustainability and stakeholder value creation as the most dependent and outcome-oriented component. This hierarchical configuration indicates that value-based competitiveness is not created directly by a single operational or market factor; instead, it emerges from a chain of mutually reinforcing capabilities whose effects accumulate from foundational human and organizational capacities toward higher-order operational and stakeholder outcomes.

The identification of human capital and productivity culture as the most influential component is theoretically consistent with the view that organizational competitiveness depends fundamentally on the capabilities, competencies, learning orientation, and behavioral patterns of the workforce. Employees are responsible for operating production technologies, complying with quality requirements, interpreting production data, identifying inefficiencies, and implementing process improvements. Therefore, the effectiveness of advanced manufacturing systems depends on the competencies of employees and managers who use those systems. This interpretation is supported by Mascu, who emphasized the strategic role of human resources in enhancing organizational competitiveness, particularly through competency development and stronger integration of human resources with organizational objectives [27]. It is also aligned with the findings of Sima et al., who showed that the transition toward Industry 4.0 is closely associated with changes in human capital requirements and that digital transformation cannot be separated from workforce development [23]. In addition, Kannan and Garad demonstrated that quality professionals operating in Industry 4.0 environments require new combinations of technical, analytical, digital, and organizational competencies [22]. Thus, the placement of human capital and productivity culture at the deepest causal

level suggests that pharmaceutical competitiveness is rooted not only in physical assets or production technologies, but also in the knowledge, learning, leadership, and continuous-improvement orientation of organizational members.

The importance of productivity culture within this foundational level also deserves particular attention. A productivity-oriented culture can institutionalize continuous improvement, problem solving, cooperation, accountability, and the efficient use of organizational resources. Such cultural characteristics help transform individual competencies into organizational capabilities. In pharmaceutical companies, where production processes are highly regulated and technically sensitive, a productivity culture can encourage employees to view compliance, quality, efficiency, and waste reduction as interconnected objectives rather than separate managerial demands. The importance of knowledge infrastructure in supporting such organizational behavior is consistent with Taghizadeh and Shokri, who showed that knowledge-management infrastructures contribute to the development and dissemination of organizational knowledge [28]. The broader argument that competitiveness includes personal and axiological dimensions also aligns with Shalimova's emphasis on the value-related and personality dimensions of competitiveness [29]. Accordingly, the present findings indicate that sustained competitiveness is difficult to achieve when employees lack the specialized skills, learning opportunities, cross-functional collaboration, and operational leadership needed to maintain and improve production systems.

The second causal level was digital transformation and smart manufacturing. This finding suggests that once appropriate human and cultural foundations exist, digital technologies can serve as a major enabling mechanism for enhancing production efficiency and strengthening value-based competitiveness. Real-time monitoring, intelligent automation, predictive maintenance, data integration, and big data analytics can improve visibility across production processes, reduce response time, support preventive decision-making, and increase the precision of quality and operational control. This result is strongly supported by Dutta et al., who argued that the digitalization of quality-control processes constitutes an important priority in Industry 4.0 adoption because it enables more integrated, timely, and data-driven quality management [21]. Similarly, Rathi et al. highlighted how Industry 4.0 technologies can be integrated with Lean Six Sigma to strengthen operational excellence and improve process performance [18]. The present results therefore confirm that digital transformation is not simply an independent technological intervention; rather, it serves as an infrastructural capability through which other production-related dimensions can be improved.

The positioning of production quality and regulatory compliance and production logistics and integrated supply chain at the fourth level indicates that these two areas are influenced by foundational human and digital capabilities and, in turn, act as important mediating mechanisms in the development of higher-level competitive outcomes. In pharmaceutical manufacturing, quality and regulatory compliance are indispensable because production efficiency cannot create sustainable value if products fail to meet quality and safety requirements. The strong role identified for this component is consistent with Edik's emphasis on the critical function of GMP audits in pharmaceutical and biotechnology industries [19]. It also corresponds with Kabir et al., who noted that quality assurance accelerates pharmaceutical research and development while protecting product integrity and regulatory compliance [20]. The current findings extend these perspectives by showing that quality and compliance are not merely regulatory obligations; they are embedded within a causal system that contributes directly to competitiveness. Effective quality systems reduce deviations, rework, recalls, and compliance risk while simultaneously enhancing customer trust and organizational reliability.

The importance of production logistics and integrated supply-chain management at the same hierarchical level also reflects the specific operational realities of pharmaceutical production. Pharmaceutical firms depend on the timely availability of raw materials, active pharmaceutical ingredients, packaging inputs, storage capacity, and distribution systems. A failure in supplier reliability or inventory planning may disrupt the entire production system and undermine product availability in the market. Therefore, the identified subcomponents of timely supply, inventory management, supplier reliability, production and demand planning, and material-flow traceability have direct implications for competitive performance. This is consistent with Gunasekaran et al., who highlighted the importance of integrated and sustainable manufacturing strategies for twenty-first-century competitiveness [25]. It also aligns with the value-based planning approach reported by Nazaré et al., in which competitiveness depends on the coordinated consideration of cost, reliability, and long-term system value [26]. Hence, supply-chain integration can be interpreted as a mechanism through which production continuity and market responsiveness are translated into stakeholder value.

Innovation in manufacturing processes and resource management and economic productivity were positioned at the third level of the model. This suggests that these components are influenced by digital, human, quality, and logistics capabilities and subsequently contribute to operational excellence. The role of manufacturing process innovation is consistent with Alemede, who emphasized that advanced process technologies, optimization, and control can simultaneously improve efficiency and sustainability [24]. The present findings similarly indicate that advanced manufacturing technologies, process flexibility, simplified operations, and technology transfer can enhance the ability of pharmaceutical companies to respond to changing market demands and improve resource utilization. These results are also compatible with the broader innovation–competitiveness relationship discussed by Stadnyk and Mykhalchuk, who emphasized the conceptual interdependence between innovation-related competitiveness and overall competitive management objectives [32]. Therefore, manufacturing innovation should be considered not merely a technological upgrade but a strategic mechanism for improving value creation and competitive adaptability.

Resource management and economic productivity were also found to play a significant role in the causal chain. Reducing total production cost, improving energy and water efficiency, decreasing waste and rework, and optimizing material consumption are particularly important in pharmaceutical production because inefficient use of inputs can significantly raise manufacturing costs and reduce the value delivered to stakeholders. This finding is consistent with Gouveia et al., who emphasized the role of efficiency in strengthening SME competitiveness [14], and with Golovchenko et al., who linked the management of efficiency to enterprise competitiveness [13]. The finding is also compatible with Kovács, who showed that combining lean and value-oriented approaches can generate substantial efficiency improvements and cost reductions [17]. Accordingly, resource productivity appears to function as a key intermediary between production capabilities and higher-order competitive outcomes.

Operational excellence in production was located at the second-highest level of the causal structure, immediately below sustainability and stakeholder value creation. This finding indicates that operational excellence acts as a proximate mechanism through which lower-level capabilities are translated into visible competitive outcomes. Reduction in production cycle time, improvement in equipment productivity, capacity optimization, production-line balancing, and reduction of bottlenecks and waste directly influence speed, cost, reliability, and responsiveness. This finding is strongly aligned with Ghelani's discussion of lean manufacturing as a means of improving quality and efficiency in production systems [16]. It is

also consistent with Handoyo et al., who demonstrated that operational efficiency is closely related to manufacturing performance and interacts with business strategy under conditions of market uncertainty and competition intensity [15]. Furthermore, Rathi et al. positioned operational excellence as a central outcome of the integration of Lean Six Sigma and Industry 4.0 technologies [18]. The present results therefore suggest that operational excellence functions as an integrative outcome of human, digital, quality, logistics, innovation, and resource-management capabilities.

The highest and most dependent level of the model was sustainability and stakeholder value creation. This finding is especially important because it indicates that the ultimate consequence of production system efficiency is not merely higher productivity or lower cost, but broader and more sustainable value creation. Sustainable access to medicines, reduction of environmental impacts, social responsibility, and balance between value and efficiency represent outcomes that depend on the successful functioning of all lower-level capabilities. This result is consistent with the growing literature linking competitiveness with sustainability and stakeholder-oriented value. Zheng and Feng demonstrated that ESG performance and green innovation are associated with corporate value creation [31], while Gunasekaran et al. emphasized that sustainable manufacturing practices are increasingly integral to manufacturing competitiveness [25]. The findings are also consistent with Dzoba's value-oriented approach to corporate management, in which organizational performance is evaluated in relation to broader value creation rather than narrow short-term economic outcomes [5].

The positioning of stakeholder value creation as the final outcome is also compatible with the broader transition from traditional competitiveness toward value-based competitiveness. Sattorovich distinguished quality, price, and value as different but related criteria for assessing product competitiveness, emphasizing the growing significance of value in competitive assessment [4]. Similarly, Chugh et al. showed that value-based selling and customer success management can jointly strengthen customer competitiveness by focusing on the realization of customer value rather than transactional exchange alone [8]. Keränen et al. likewise emphasized the strategic importance of value-based selling, particularly under challenging economic conditions [7]. These studies support the present finding that competitiveness should ultimately be understood in terms of sustained value creation for multiple stakeholders rather than merely cost or market position.

The results also reinforce the notion that enterprise competitiveness is a systemic and multidimensional phenomenon. Fuior et al. noted that competitiveness can be assessed using multiple methods because it reflects several interacting aspects of organizational performance [3]. Faizova et al. similarly demonstrated the usefulness of multidimensional systems such as the Balanced Scorecard for competitiveness assessment [9]. Wu et al. further showed that enterprise competitiveness is shaped by interacting determinants rather than a single isolated factor [10]. The present study advances this perspective by specifying not only which factors contribute to competitiveness, but also how these factors may be ordered causally. In this regard, the model provides a clearer distinction between deep drivers, intermediate mechanisms, and final competitive outcomes.

The results are also consistent with the strategic view that competitiveness must be managed dynamically under uncertainty. Pogodina et al. emphasized the necessity of strategic management for maintaining industrial-company competitiveness in unstable economic environments [11]. Nailevich similarly highlighted the need for enterprises to adopt multiple mechanisms to improve competitiveness rather than relying on a single competitive factor [12]. In addition, the relationship between enterprise competitiveness and product competitiveness identified by Voronov suggests that organizational capabilities and product-level value should be examined as interconnected rather than independent

phenomena [1]. The present findings align with this argument by showing that value-based competitiveness in pharmaceutical companies emerges from the cumulative operation of organizational and production capabilities that ultimately influence market and stakeholder outcomes.

Overall, the model developed in this study suggests that pharmaceutical companies should not attempt to improve competitiveness by focusing exclusively on downstream indicators such as profitability, market share, or product availability. Instead, competitiveness must be built from the bottom of the causal hierarchy. Human capital and productivity culture establish the organizational foundation; digital transformation provides an enabling infrastructure; quality, regulatory compliance, and supply-chain integration create process reliability; manufacturing innovation and resource productivity improve technical and economic performance; operational excellence integrates these capabilities into superior production performance; and sustainability and stakeholder value creation emerge as the ultimate expression of value-based competitiveness. This interpretation is consistent with the value-added perspective of competitiveness proposed by Ceglowski [2] and with the broader argument that competitiveness is ultimately determined by an organization's ability to convert its resources and capabilities into differentiated and sustainable value.

This study was subject to several limitations. First, the qualitative phase relied on the judgments of a relatively limited number of experts, and although theoretical saturation was achieved, the findings may still reflect the specific professional experiences and managerial perspectives of the participating experts. Second, the quantitative phase was conducted among managers and experts working in pharmaceutical companies, and therefore the model reflects primarily an organizational and managerial perspective rather than the views of other stakeholders such as customers, patients, regulators, suppliers, or healthcare professionals. Third, the cross-sectional nature of the quantitative data limits the ability to examine changes in causal relationships over time. Fourth, Interpretive Structural Modeling is based on expert judgments and identifies hierarchical relationships among variables but does not estimate the magnitude of causal effects in the same way as longitudinal or experimental designs. Finally, the study was conducted within the pharmaceutical industry of one national context, and institutional, technological, regulatory, and supply-chain conditions may limit the direct generalizability of the findings to other countries or industries.

Future studies are recommended to test the proposed model in different national and industrial settings in order to assess its external validity and identify possible contextual differences in the causal hierarchy. Researchers may also examine the model longitudinally to determine whether the relationships among human capital, digital transformation, operational excellence, and stakeholder value change over time. The model could further be tested using structural equation modeling, partial least squares structural equation modeling, or longitudinal path analysis to estimate the strength of direct and indirect relationships among the identified components. Comparative studies between large pharmaceutical companies and small or medium-sized pharmaceutical manufacturers may also clarify whether organizational size moderates the proposed relationships. Future research could additionally incorporate the perspectives of external stakeholders, including regulators, suppliers, healthcare providers, and patients, to develop a more comprehensive assessment of stakeholder value. Further studies may also examine whether environmental turbulence, regulatory intensity, digital maturity, innovation capability, or supply-chain resilience moderate the relationships identified in the present model.

Pharmaceutical-company managers should prioritize the development of human capital and a productivity-oriented culture before making large-scale investments in advanced production technologies. Continuous training, specialized

technical development, cross-functional teamwork, and operational leadership should be integrated into production strategy. Managers should also establish a coherent digital-transformation roadmap that connects real-time monitoring, intelligent automation, predictive maintenance, and integrated data systems with quality-management and production objectives. Quality assurance and regulatory compliance should be treated as strategic competitiveness capabilities rather than merely compliance functions, while supply-chain integration should focus on supplier reliability, inventory optimization, traceability, and coordinated production-demand planning. Manufacturing innovation initiatives should be evaluated in terms of their contribution to flexibility, cost reduction, process simplification, and value creation. At the same time, managers should systematically monitor energy use, material consumption, waste, rework, and production costs to strengthen resource productivity. Most importantly, performance-management systems should connect operational efficiency with broader outcomes such as reliable access to medicines, environmental responsibility, social value, and stakeholder satisfaction so that production-system improvements are consistently directed toward sustainable value-based competitiveness.

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Authors' Contributions

All authors equally contributed to this study.

Declaration of Interest

The authors of this article declared no conflict of interest.

Ethical Considerations

The study protocol adhered to the principles outlined in the Helsinki Declaration, which provides guidelines for ethical research involving human participants. Written consent was obtained from all participants in the study.

Transparency of Data

In accordance with the principles of transparency and open research, we declare that all data and materials used in this study are available upon request.

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