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Role of Artificial Intelligence and Automation in Transforming Operational Efficiency of Indian Pharmaceutical Companies

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Abstract: **Artificial Intelligence (AI) and automation are becoming more popular with the Indian pharmaceutical industry as a part of the Pharma 4.0 paradigm to improve operational efficiency as more regulatory and market pressures increase. Nevertheless, there is little empirical data on the way these technologies translate to quantifiable efficiency results. The study will focus on direct, mediating, moderating, and interaction effects of AI adoption and automation adoption on the operational efficiency of Indian pharmaceutical companies. Primary data were gathered among 350 workers (production, quality, R and D, supply chain and technology functions) and processed through Structural Equation Modelling (SEM). The results indicate that AI adoption as well as automation adoption have a significant effect on enhancing operational efficiency. Digital preparedness partially mediates the AI adoption and efficiency relation and employee technological competence mediates the automation and efficiency relation. Significantly, the research reveals a new AI-Automation Paradox whereby the interplay between AI and automation has a negative impact on the efficiency of the operations, which implies diminishing returns as a result of the complexity of the technology and organizational absorption capacity. The framework of Integrated Digital Operations Capability (IDOC) has been proven and promotes the Pharma 4.0 literature due to its capability alignment, rather than single technology usage. The research provides practical information to managers and policymakers on how to create sequenced, capability-based digital transformation strategies to achieve sustainable efficiency benefits.**

Keywords: **Artificial Intelligence; Automation; Operational Efficiency; Pharma 4.0; Digital Readiness; Employee Technological Competence; Indian Pharmaceutical Industry.**

1. INTRODUCTION

The pharmaceutical industry is very important to both the global medicines ecosystem and India's economic growth (Wirtz et al., 2017). India is a key supplier of generic drugs, and its domestic market is increasing swiftly since the government is spending more on health care, there are new policies, and the need for health care is rising (Sienkiewicz-Małyjurek and Szymczak, 2024). Investments in research and development: The industry has grown in size and complexity. Experts think it will remain rising until 2030 because people want to make more valuable things and have more space (Ramamoorthy, 2024; Gera and Singh, 2025). But Chain of Supply also implies that supply chain resilience, safety, higher standards for consistent quality, and stricter worldwide regulatory scrutiny are all happening at the same time (Sahoo, 2025; Evangelista et al., 2023). Pharmaceutical manufacturing efficiency is not just a way to save money; it is efficiency in operations. This is because operational efficiency gains lead to lower unit production yield, faster time-to-market, less waste, and stronger compliance (Lee et al., 2015; Palanisamy et al., 2025). The quantity of inspections and the quality of the products are both getting better in Indian markets. This is making production more efficient, which is important for getting into the market, creating a strong name, and being able to increase output to meet demand (Frank et al., 2019; Gupta and Kayande, 2023).

(Akhtar and Asim, 2024) assert that the Internet of Things (IoT), cloud computing, big data analytics, cyber-physical systems, and sophisticated automation are useful in revolutionising the old pharmaceutical processes. An example of such a paradigm shift is the Industry 4.0 approach. (Arden et al., 2021; Kimta and Dogra, 2024) state that Industry 4.0 enables data driven decision-making in supply-chain, production, and quality operations, real-time visibility of the processes, and predictive and prescriptive control of equipment in incremental lean projects. The ability of Industry 4.0 to combine both digital traceability ability, automated records, and ongoing monitoring to quality-by-design will be highly helpful to pharmaceutical regulated manufacturing companies. (Tilley, 2017; Sandle, 2023; Kumar et al., 2020) believe that these factors can be used to improve throughput and significantly decrease compliance risk. AI-cyber predictive analytics could make equipment more effective and reduce unplanned manufacturing downtime by predicting equipment failures and planning proactive maintenance (Preethi et al, 2024; Harrer et al., 2024; Saini et al., 2025). Computer-vision systems and ML classifiers enabling automated inspection with higher sensitivity and throughput than manual methods, facilitating near-real-time detection of defects and deviations in quality control (Markarian, 2016; Shinde et al., 2021; Boddu et al., 2022). Human errors are reduced by robotics in repetitive tasks, enable hygienic processing in sensitive operations, and increase throughput consistency (Reinhardt et al., 2020; Chava, 2022). The effective supply-chain integrity, regulatory traceability and critical for export-oriented manufacturers are strengthen by the automated end-to-end packaging and serialization systems (Bhattamisra et al., 2023; Ahmed et al., 2024). Automation can convert predictive insights into corrective actions in dynamic adjustment of process parameters, creating closed-loop control that elevates both quality and efficiency by the adoption of AI and automation in Indian pharmaceutical firms (Elbadawi et al.2021; Sugandha et al., 2023). The empirical research suggest dynamic focus on primary-data-driven insights measuring the adoption rate of AI and automation, and also the realized operational outcomes (cycle time, yield, downtime, quality metrics), mediating factors (digital readiness, organizational culture, regulatory alignment), and contextual constraints unique to the Indian manufacturing industries (Jaitawat et al., 2025; Nandita, 2024; Kodumuru et al., 2025) . This study empirically investigates how AI and automation initiatives are translating into measurable operational efficiency gains across Indian pharmaceutical companies, by grounding analysis in primary data collected from production, quality, and technology managers, the research aims to produce actionable insights for practitioners and evidence-based contributions to the literature on Pharma 4.0 transformations.

This work is a fast maturing landscape of Pharma 4.0, which presents useful academic, practical, and policy level contributions. Proving empirically a holistic structural model that incorporates AI adoption, automation, mediating organisational capabilities, and operational efficiency outcomes to close a critical research gap in the existing literature, which frequently uses conceptual frameworks instead of a data-oriented one (Semchenkova, 2024; Mane and Singh, 2025; Sabapathy, 2025). The article enhances the conceptualization of digital transformation, operations management, and socio-technical systems in regulated industries by basing the analysis on primary data of Indian pharmaceutical industries, (Suriyaamporn et al., 2025; Roy and Srivastava, 2024). In practice, the article focusing on the focus of capability building, and the provision of a clear roadmap of the sequencing of automation and AI implementation according to the workforce readiness, compliance and improvement of processes provides valuable insights into pharma manufacturing industries by defining the high-impact digital technologies, (Pazhayattil and Konyu-Fogel, 2023; Wetsiri and Paireekreng, 2024). On the policy level, the research will facilitate the national policy, which aims to transform the country into a competitive pharmaceutical manufacturing destination by 2030, including the so-called Make in India and Production-Linked Incentive (PLI) programs (Joshi et al., 2024; Abramova et al., 2025; Allam, 2025) in India. The study influences policy-making concerning digital infrastructure, harmonisation of regulations, and development of national skills by revealing the enablers and inhibitors of the operational change through AI. It is on this context that the research questions below have been addressed in this research; (1) To what extent have pharma companies in India embraced Artificial Intelligence and automation technologies in core operational functions? (2) What is the direct impact of the Artificial Intelligence adoption on the operational efficiency outcomes of the Indian pharmaceutical companies? (3) What are the immediate impacts of automation adoption and what role automation plays in the reduction of process inefficiencies and operation errors in Indian pharmaceutical manufacturing settings? (4) Does the use of digital readiness mediate between Artificial Intelligence adoption and operational efficiency in Indian pharma companies, therefore, acquires measurable performance through firms, which make AI capabilities translation possible? (5) Does the automation adoption have a relationship with operational efficiency of pharmaceutical companies in India, which is mediated by employee technological competency? (6) Does AI adoption interact with automation adoption to produce synergies that increase operational efficiency of the India pharma companies?

2. LITERATURE REVIEW

The penetration of Artificial Intelligence (AI) and automation into the everyday practice of the Indian pharmaceutical industry is the new beginning of the transformation in the way the companies manage the production systems, design them, and control them (Henstock, 2019). The attention of industry 4.0 in the world is required to speed up the technological adoption of cyber-physical systems, advanced analytics, robotics, and algorithmic decision-making in various regulated manufacturing industries (Lawrence and Kopcha, 2017; Arden et al., 2021; Sabapathy, 2025). Nevertheless, there are certain peculiarities that include strict regulatory provisions, the product sensitivity, and limitations of process validation, which require the digital transformation process to be critical and challenging to the pharmaceutical manufacturers (Markarian, 2016; Henstock, 2019). Although the empirical knowledge of the AI and automation integration in the emerging economies especially India is still scarce, the multinational corporations have done much in terms of integrating technology in the main manufacturing and quality-management tasks, (Saha et al., 2023; Alanazi et al., 2024; Mundhra et al., 2024; Patel, 2024; Bachhav et al., 2025).

2.1 Industry 4.0 and Pharma 4.0

The Indian and global literature review is based on synthesising the studies of AI and automation adoption, the development of pharma operational efficiency as a performance construct, the mediation by organisational capabilities, regulatory dynamics and barriers to digital transformation in the wider context of Pharma 4.0. Industry 4.0 as the fourth industrial revolution that is marked by the integration of digital technologies in the manufacturing and operational processes including IoT, AI, big data analytics, autonomous systems, and cyber-physical devices (Baur and Wee, 2015; Matthias et al., 2016) introduces smart operations that allow exchanging data in real-time and creating linear models of production to improve the efficiency of operations (Ahmed et al., 2024). Pharma 4.0 underline that the strategic alignment is a paradigm that should be deployed during technological implementation and should enable the pharmaceutical industry to restructure, make smarter manufacturing decisions, quality control, and data-driven decision-making (Stentoft and Rajkumar, 2020; Manzano and Langer, 2018; Lee and Brorson, 2017; Kodumuru et al., 2025). Pharma 4.0 allows enhanced analytics and automation to enhance the efficiency of operations and regulatory adherence, which contests the productivity and quality of pharma operations (Inuwa et al., 2022; Phiri et al., 2025; Phuyal et al., 2020). Industry 4.0 conceptualizes the studies underlying it (Zhong et al., 2017; Barari et al., 2021; Lu et al., 2016) as an ecosystem where the data flow is free across the operational touchpoints, allowing predictive, prescriptive, and autonomous control (Yao et al., 2017; Marques et al., 2017; Xie et al., 2020; Alkhodair and Alkhudhayr, 2025). In pharmaceuticals, AI assists with sustained process checking, computerized batch notes, on-the-spot release testing, and enhanced automation help Pharma 4.0 in the high-risk setting by insignificant error and high-quality assignments with uniformity (Kaur, 2025; Qiu et al., 2025; Vijayapriya et al., 2025). Nevertheless, Pharma 4.0 models indicate that there are certain challenges that are unique to the technology adoption process, and the uncertainty of the validation of the algorithms and data control is a significant concern. The empirical research is characterized by an uneven preparedness, the transformative overhaul of pharmaceutical manufacturing and operation in the emerging economies is done by industry 4.0 and Pharma 4.0 (Islam et al., 2025; Gomaa, 2025; Saleem et al., 2025).

2.2 AI in Pharmaceutical Manufacturing

The uses of AI in pharmaceutical manufacturing are very diverse and encompass vast scope of functional domains including predictive maintenance, quality control, supply chain optimisation and advanced process control system (Naim et al., 2025). One of the most common answers to the question of AI benefits in manufacturing is Predictive Maintenance and Equipment Management (Thattukolla, 2025). With sensor data and machine-learning models, AI systems are able to forecast possible equipment failures prior to them taking place and implement planned interventions to minimize downtime (Mitta, 2024). Research (Tummala and Gorrepati, 2024) also reveals that predictive maintenance can enhance overall equipment effectiveness (OEE) by 15-30 percent in process industries. Production rescheduling, compliance issues, and significant financial losses are the consequences in pharmaceutical plants where unexpected downtime may cause huge losses (Baviskar et al., 2023). The quality control is also a labour-intensive and error-prone process in most Indian pharmaceutical companies (Saha et al., 2023). The development of AI-based computer vision systems has been implemented to identify defects in tablets, anomalies during packaging, and label errors with high precision levels surpassing the usual manual inspection (Rajesh and Elumalai, 2025). Also, machine-learning models assist statistical process control to detect abnormal process variations and behaviour earlier than traditional control charts. The papers show the increase in lowered batch variability, more precise inspection, and shortened detection time, noting that AI enhances operational efficiency of pharma operations, but at the same time, it contributes to the strict compliance with the high regulatory requirements (Saini et al., 2025; Jaitawat et al., 2025). The pharma manufacturing AI and ML models used in maintenance and quality assurance help in controlling the advanced processes by learning complex and non-linear relationships between process parameters and product quality outcomes making it optimised in real-time. Reinforcement learning and related applications have shown significant benefits in terms of improving yield and energy savings and consistent control of processes in continuous manufacturing (Wetsiri and Paireekreng, 2024). The factors of improvement fit right in the indicators of operational efficiency such as higher production throughput, shorter cycle-time, and minimisation of waste (Sugandha et al., 2023). Pharma manufacturing demand forecasting can be characterized as constant problems since the market is volatile, regulating factors are uncertain, and supply chains are vulnerable (Arden et al., 2021). Demand forecasting models that use AI make much more precise predictions as they are able to capture the complicated demand patterns and more effectively address the traditional time-series approach influencing factors (Sandle, 2023; Frank et al., 2019). According to the empirical evidence, the accuracy of forecasting has allowed inventory optimisation, stockouts reduction, and stabilisation of production planning as main drivers of operational effectiveness in pharma manufacturing (Kaur, 2025; Islam et al., 2025).

2.3. Pharmaceutical Operations Automation

One of the pillars of Pharma 4.0 is automation, which includes industrial robotics, automated material handling system, automated packaging and robotic process automation of documentation and compliance-related processes (Saini et al., 2025). Robotic implementation enhances precision of operations, nets out human error, and minimises contamination risk especially in aseptic and hazardous production settings (Ramamoorthy, 2024; Sabapathy, 2025). The increasing worldwide integration of the use of collaborative robots (cobots) in the tablet compression, granulation, and sterile filling processes have seen increased implementation across the world, where research has demonstrated cycle-time savings of 20 to 40 percent and significant major improvements in consistency and repeatability (Thulasiraman, 2022), Indian pharmaceutical sectors have started using cobots, but implementation is limited to bigger companies because of the high investment requirements. Automated packaging systems are exceptionally fast and accurate in their bottling, blistering, labelling and serialization (Pethappachetty et al., 2025). Export markets that demand a high level of machine coordination, track and trace and automated data capture are required to be serialized (Ullangula, 2025). Research points to better packaging throughput, less rework and increased traceability as the benefits of extensive packaging automation (Allam, 2025; Chava 2022). The manufacturing of pharmaceuticals comes with a lot of documentation to be used in its validation, deviations, CAPA (Corrective and Preventive Actions) and batch records. RPA automation saves administration workload by automating repetitive documentation duties (Naim et al., 2025). The studies suggest that RPA is able to reduce documentation processing by 40-60 percent and, therefore, allow companies to comply with the regulatory timelines and minimize human mistakes in the compliance processes (Mathavan, 2025; Boddu et al., 2022).

2.4 Operational Efficiency

Operational efficiency is multidimensional that involves maximum utilisation of resources to attain maximum output using the least possible waste, cost, variability and trade cost, quality, speed and reliability (Sahoo, 2025; Palanisamy et al., 2025). The operational efficiency in pharmaceuticals has to be assessed within the margins of regulation and therefore compliance is not merely an operational aspect, but also an essential result of efficiency (Roy and Srivastava, 2024). Digital readiness is a term that describes how an organisation is ready to embrace and use digital technologies such as digital infrastructure, data management systems, interoperable software, cyber-security standards, and leadership commitment (Wetsiri and Paireekreng, 2024). Companies that are more digital-ready realize additional gains on AI and automation investments, whereas fragmented digital systems prevent companies from expanding beyond pilot-tests (Bachhav et al., 2025), employee preparedness and skills are once again mentioned as central factors of digital change. The fact that workers have to familiarize themselves with automated systems, analyze the obtained data, and cooperate with robots and AI-based equipment (Pazhayattil and Konyu-Fogel, 2023) demonstrates that the technological proficiency of the workforce positively mediates efficiency in AI-enabled settings (Yegeswaran et al., 2025). To execute digital transformation, the culture needs to be willing to experiment and foster cross-functional collaboration and the development of a digital mindset (Ramalingam, 2025) imply that resistance to change, job displacement anxieties, and lack of a strategic vision are significant retarding factors.

2.5 AI, Automation, and Operational Efficiency

Research has shown that AI and automation in production always lead to better efficiency results, especially in industries like logistics, electronics, and cars (Kaur, 2025; Saini et al., 2025; Allam, 2025). AI cuts down on mistakes, makes equipment work better, and raises production yield (Saha et al., 2023; Abramova et al., 2025). According to (Mane and

Singh, 2025; Joshi et al., 2024), automation improves throughput, worker productivity, and the dependability of processes. In the validated frameworks that connect digital adoption to operational success, digital readiness, innovation capacity, and workforce skills are often found to have mediating effects (Semchenkova, 2024). Artificial intelligence and robotic process automation can change the pharmaceutical industry for the better by making it more efficient, high-quality, compliant, and productive (Rajesh and Elumalai, 2025). There are not many models that have been quantitatively tested that include AI adoption, automation intensity, organisational capacities that act as intermediaries, and operational efficiency outcomes (Sienkiewicz-Małyjurek and Szymczak, 2024; Sahoo, 2025). While recognised in the literature (Preethi et al, 2024; Saini et al., 2025; Yegeswaran et al., 2025), empirical investigations into mediating factors such as digital readiness and workforce technological competence within Indian pharmaceutical companies are limited. The present study employs primary data to quantify the extent of AI and automation adoption, analyse their influence on operational efficiency, evaluate mediating factors, and develop a validated empirical model tailored for the Indian pharmaceutical industry. This review confirms the necessity of the study.

3. RESEARCH METHODOLOGY

The research design adopted in this study is descriptive research design and analytical research design because it intends to investigate the adoption of AI and automation adoption to revolutionize the operational efficiency of the chosen Indian pharmaceutical firms. A structured questionnaire-based research instrument (Rajesh and Elumalai, 2025) was employed to gather the primary data having been developed as a result of thorough review of the available literature and providing a high level of validity through expert review and pilot test. The questionnaire is employing the multi-item Likert scales to understand the role core latent constructs of AI adoption, automation adoption, digital preparedness, employee technological competence and operational efficiency using.

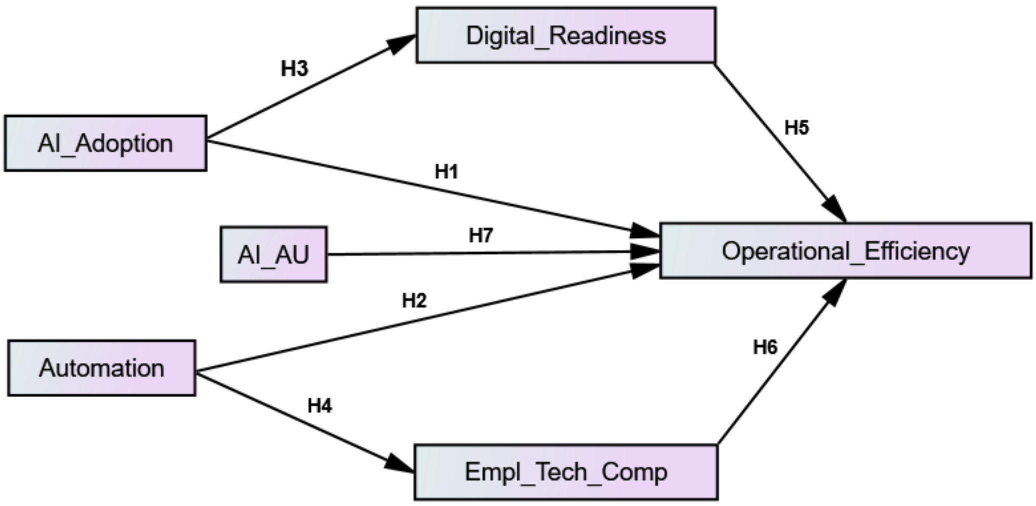

Figure 1; Hypothesized Model

The study's sample population consisted of personnel from chosen Indian pharmaceutical firms, with a sample size of 350 respondents established according to recognized sample adequacy criteria for multivariate and structural equation modeling. The sample responders comprise production managers, research and development professionals, quality assurance workers, information technology specialists, supply chain coordinators, and administrative staff within the Indian pharmaceutical manufacturing ecosystem.

4. RESULTS AND DISCUSSIONS

Table 1 shows the distribution of demo Demographic organizational characteristics, such as age group, gender, work experience, company size, job position, type of company, and amount of automation in the department. The sample comprises 350 participants from several segments of Indian pharmaceutical enterprises, guaranteeing representativeness and variety across functions, including production, QA/QC, R&D, supply chain, IT/TIT/Tech administration. The percent shows how much of the entire sample each group makes up.

Table 1. Demographic Profile of the Respondents (N = 350)

Demographic	Frequency	Percentage	Demographic	Frequency	Percentage
Age Group of the Respondents			Job Role of the Respondents		
Below 25	32	9.1	Production	82	23.4
26-30	103	29.4	QA/QC	63	18.0
31-35	107	30.6	R&D	47	13.4
41-45	76	21.7	Supply Chain	75	21.4
Above 45	32	9.1	IT/Tech	36	10.3
Gender of the Respondents			Admin	47	13.4
Male	212	66.3	Type of the Company		
Female	118	33.7	Formulation	119	34.0
Experience of the Respondents			API	87	24.9
Below 2 Years	41	11.7	Biotech	67	19.1
2-5 Years	92	26.3	Medical Device	49	14.0
6-10 Years	121	34.6	CRO	28	8.0
Above 10 Years	96	27.4	Department Automation Level		
Size of the Company			Low	77	22.0
Low	87	24.9	Medium	176	50.3
Medium	150	42.9	High	97	27.7
High	113	32.3	Source: Primary data; (N=350)		

In terms of age group of the respondents, the majority fall within the productive mid-career stages, with 30.6% belonging to the 31–35 years age group and 29.4% falling between 26–30 years, while smaller proportions are below 25 years (9.1%) and above 45 years (9.1%). Gender classification shows majority at 66.3% are male respondents, compared to 33.7% female respondents. According to work experience, most of the respondents (34.6%) having 6–10 years of experience and possess substantial industry exposure, 27.4% having more than 10 years, followed by 26.3% with 2–5 years' experience, and only 11.7% with less than two years. The job functions Indian pharma operations represent production employees constitute the largest share (23.4%), followed by Supply Chain (21.4%), QA/QC (18.0%) and Admin (13.4%) and R&D roles (13.4%), with IT/Technology staff accounting for 10.3%. The pharmaceutical industry wise distribution represent major segments from formulation companies (34.0%), 24.9% from API manufacturing, 19.1% from biotech firms, 14.0% from medical device manufacturing, and 8.0% from CROs. Majority of pharma companies are medium-sized (42.9%), 32.3% from large size, and 24.9% from small size. The penetration of automation in the departments indicates that digital transformation is moderately progressing in the sector, 50.3% of the respondents reported operating in departments with medium levels of automation, followed by 27.7% working in highly automated environments and 22.0% in low automation settings.

Table 2. Correlation Matrix for AI Adoption, Automation Adoption, Digital Readiness, Employee Technological Competence, and Operational Efficiency.

	AI Adoption	Automation Adoption	Digital Readiness	Employee Tech. Competence	Operational Efficiency
AI Adoption	1				
Automation Adoption	.706**	1			
Digital Readiness	.579**	.586**	1		
Employee Tech. Competence	.114*	.215**	.119*	1	
Operational Efficiency	.658**	.698**	.602**	.356**	1

Table 2 shows a very high level of interrelationship among elements of digital transformation in Indian pharmaceutical firms, a significant positive relationship between AI Adoption and Automation Adoption ($r = .706$, $p < .01$) and, thus, one can infer that the organizations that invest in AI technologies are also supporting their automation systems. AI Adoption demonstrates a moderately high correlation with Digital Readiness ($r = .579$, $p < .01$), indicating that AI-driven initiatives can improve the preparedness of a particular firm to a larger-scale digital transformation, as well as has a high correlation with Operational Efficiency ($r = .658$, $p < .01$), which confirms that increasing the extent of AI integration directly leads to more favorable performance results of a pharma. Automation Adoption highlights the central role of automation as a means of speeding up productivity, minimizing manual errors, and supporting lean operational workflows with strong positive correlation with Operational Efficiency (r = .698, p <.01), positively correlates with Digital Readiness (r =.586, p <.01), initiatives are frequently accompanied by better digital infrastructure and organizational preparedness. The substantial correlation between Digital Readiness and Operational Efficiency (r =.602, p <.01) means the presence of digitally progressive companies with developed technologies and practical performance benefits. AI Adoption (r = .114, p < .05), Automation (r = .215, p < .01), and Digital Readiness (r = .119, p < .05) show a weaker correlation with Employee Technological Competence, and having a meaningful moderate correlation with Operational Efficiency (r = .356, p < .01) reflects a human-technology synergy effect that significantly elevates operational gains.

Table 3. Multiple Regression Results for the Effects of Demographic and Organizational Variables on Operational Efficiency.

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	Model Summary / ANOVA	
	B	Std. Error	Beta				
Operational_Efficiency	2.398	.135		17.790	.000		
AGE	.009	.018	.019	.497	.620	R	.705a
Gender	-.003	.041	-.003	-.065	.948	R2	.498
Job_Role	-.022	.011	-.073	-1.902	.058	Adjusted R2	.487
Experience	.066	.020	.127	3.308	.001		
Company_Type	-.033	.015	-.083	-2.157	.032		
Company_Size	.392	.026	.581	15.041	.000	F	48.409
Dep_Automation_Level	.264	.028	.365	9.500	.000	Sig.	.000b

Table 3 assessing the influence of organizational and demographic factors on operational efficiency reveals a strong explanatory power, with an R = .705 and R^2 = .498, indicating that nearly 50% of the variance in operational efficiency is explained by the combined predictors and the overall model is statistically significant (F = 48.409, p < .001). It turns out that the size of the company has the biggest effect on operational efficiency (β =.581, p < .001) bigger pharmaceutical companies tend to be much more operationally efficient and are better at improving performance because they can better use their resources, use more advanced technologies, and benefit from economies of scale. There is a strong and statistically significant effect on Department Automation Level (β =.365, p < .001) that shows higher levels of automation processes consistently lead to better operational outcomes by acting as operational enablers and directly affecting throughput, accuracy, regulatory compliance, and cycle-time reductions. The experience of respondents positively influences (β =.127, p =. 0 0 1) and reflects more effectively in operational performance as experience in domains where tacit knowledge is more relevant, as well as the experience in learning and familiarity with the processes. There are considerable negative relationships between the Company Type (β = -.083, p =.032), which suggests that regulation complexity, variability in the batches, or lesser digital maturity can encounter more operational difficulties than formulation-focused companies, and operational performance depends on the context of the pharma sub-sector, which most generalized digital transformation models fail to explain. The demographic characteristics of Gender (β = -.003, p =.948) and Age (β =.019, p =.620) do not influence the efficiency results. Job Role (β = -.073, p =.058) also has the potential to affect efficiency though it is less influential than the structural predictors such as company size and automation. The insights outline that a digital infrastructure and human expertise collaboratively define performance outputs and attaining operational excellence in a sustainable manner through the major levers such as strategic scaling, focused automation, and workforce development based on experience.

Table 4. Tests of Between-Subjects Effects for Predictors of Operational Efficiency

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	57.463a	19	3.024	30.288	.000
Intercept	1.323	1	1.323	13.250	.000
Job_Role	.814	5	.163	1.630	.151
Experience	.455	3	.152	1.520	.209
Company_Type	.311	4	.078	.778	.540
Company_Size	.065	2	.033	.327	.721

Dep_Automation_Level	.045	2	.023	.227	.797
AI_Adoption * Automation	5.942	1	5.942	59.511	.000
Digital_Readiness	2.802	1	2.802	28.058	.000
Empl_Tech_Comp	1.978	1	1.978	19.813	.000
Error	32.951	330	.100		
Total	5180.960	350			
Corrected Total	90.414	349			
a. R Squared = .636 (Adjusted R Squared = .615); Dependent Variable: Operational_Efficiency					

The results of the effect analysis of the factors that impact the Operational Efficiency in Indian pharmaceutical companies model in Table 4 is highly important ($F = 30.288$, $p < .001$), which has a significant proportion of variance ($R2 = 0.636$; adjusted $R2 = 0.615$), which attributes to digital transformation variables in influencing the formation of operational results. The most significant interaction term (AI Adoption × Automation; $F = 59.511$, $p < .001$) indicates that the adoption of AI or automation is not a single effect on the operation efficiency, but in fact that it is positively interactional to the extent that AI adoption or automation can only exert its greatest influence on the operation efficiency in digitally automated environments. The innovative input implies that AI and automation are mutually supportive pillars that bring about operational excellence, which justifies the new understanding of the industry that AI without automation is still under-explored, whereas automation without AI is fixed and stiff in its adaptability. There are also strong and statistically significant effects of the technological capability Digital Readiness ($F = 28.058$, $p <.001$), and Employee Technological Competence ($F = 19.813$, $p <.001$) variables. Traditional organizational attributes (Job Role, Experience, Company Type, Company Size, or Department Automation Level) no longer define digitally transforming operational efficiency in the pharma companies but are becoming increasingly defined by the digital maturity variables.

Table 5. Regression Weights: Maximum Likelihood Estimates

Observed Variables		Latent Construct	Estimate	S.E.	C.R.	P
Digital_Readiness	<---	AI Adoption	.703	.110	7.933	***
Empl_Tech_Comp	<---	Automation	.251	.069	3.780	***
management support (AI5)	<---	AI Adoption	.478	.114	7.648	***
prediction accuracy (AI4)	<---	AI Adoption	.537	.150	7.648	***
process optimization (AI3)	<---	AI Adoption	.602	.147	8.154	***
Decision support (AI2)	<---	AI Adoption	.524	.141	7.536	***
AI tool usage (AI1)	<---	AI Adoption	.547	.144	7.732	***
Technology upgrades (AU5)	<---	Automation	.548	.135	7.687	***
Rework reduction (AU4)	<---	Automation	.511	.125	7.687	***
Speed improvement (AU3)	<---	Automation	.599	.133	8.591	***
Error reduction (AU2)	<---	Automation	.510	.122	7.673	***
Measuring task (AU1)	<---	Automation	.606	.122	8.655	***
Interaction 5	<---	AI * Automation	.644	.088	10.648	***
Interaction 4	<---	AI * Automation	.670	.100	10.648	***
Interaction 3	<---	AI * Automation	.720	.101	11.271	***
Interaction 2	<---	AI * Automation	.661	.098	10.522	***
Interaction 1	<---	AI * Automation	.653	.093	10.424	***
Operational_Efficiency	<---	AI * Automation	-.562	.010	-12.852	***
Operational_Efficiency	<---	Automation	.563	.093	10.010	***
Operational_Efficiency	<---	AI Adoption	.759	.176	7.455	***
Operational_Efficiency	<---	Empl_Tech_Comp	.104	.040	4.101	***
Operational_Efficiency	<---	Digital_Readiness	.110	.083	1.841	.046

The findings of Table 5 give high evidence to the hypothesized relationships between AI Adoption, Automation, Digital Readiness, Employee Technological Competence and Operational Efficiency in pharmaceutical companies. Digital Readiness is a significant predictor of AI Adoption ($\beta =.703$, C.R. = 7.933, $p < .001$), which implies that more significant AI tools, predictive analytics, decision-support systems, and process-optimization technology use has a significant beneficial effect on the digital maturity of an organization. The adoption of automation also has a positive impact on

Employee Technological Competence (β =.251, C.R. = 3.780, p <.001), which means that exposure to automated systems forces employees to sharpen their digital skills, rather than be flexible and adaptable as an enabling capacity of the process, but as a force of automation. A good direct relationship exists between AI Adoption and Operational Efficiency (β =.759, C.R. = 7.455, p < .001), AI-led intelligence significantly increases the performance results by enhancing the level of prediction, management, and streamlined workflows. Automation (β =.563, C.R. = 10.010, p <.001) shows a high efficiency increase as a support of process consistency, speed, and elimination of errors. Digital Readiness (β = .110, C.R. = 1.841, p = .046) and Employee Technological Competence (β = .104, C.R. = 4.101, p < .001) have positive contributions that both organizational preparedness and human capabilities convert technological inputs into measurable operational improvements in pharma industry. However, AI × Automation have strong negative interaction effect on Operational Efficiency (β = –.562, C.R. = –12.852, p < .001), the novel significant finding is of, AI and automation individually enhance efficiency, their simultaneous intensification may trigger workflow misalignment, cognitive overload, and system complexity. The advanced digital technologies AI–Automation Paradox creates diminishing or even adverse returns, challenging the prevailing assumption that always operate synergistically, the understanding of digital transformation in the pharmaceutical industry by highlighting that human, organizational, and technological factors interact in complex, nonlinear ways to shape operational performance in Indian pharma company. Table 6 shows the measurement validity assessment, Composite Reliability (CR) of all constructs satisfy the recommended threshold of 0.70, except Employee Technological Competence (ETC = 0.62) which is acceptable moderate internal consistency. All the constructs are achieve satisfactory convergent validity, Employee Technological Competence (√AVE = 0.25) demonstrates limited shared variance among its variables, which could indicate heterogeneity in skill-related attributes among employees in the Indian pharmaceutical industry.

Table 6. Test of Composite Reliability, Convergent Validity and Discriminant Validity

Construct	AIA	AUA	AI_AU	DR	ETC	OE	CR	√AVE
AIA	0.60						0.78	0.60
AUA	0.706	0.62					0.80	0.62
AI_AU	0.759	0.563	0.75				0.89	0.75
DR	0.703	0.251	0.644	0.70			0.70	0.70
ETC	0.251	0.215	0.653	0.206	0.25		0.62	0.25
OE	0.759	0.563	–0.562	0.110	0.104	0.57	0.74	0.57

Discriminant validity (Table 6) is highlighting the novel observation that AI Adoption, Automation Adoption, and Operational Efficiency are the emergence of a digitally convergent operational environment in Indian pharmaceutical industry. The adoption of Artificial Intelligence and Automation are resulting in strong shared variance both technologically and behaviorally, digital readiness and employee competence are collectively partial lack of discriminant validity but an indicator of evolving digital maturity patterns in high-compliance sectors and form a unified capability cluster driving performance.

Table 7. Model Fit Indices

Fit Index Category	Observed Value(s)	Acceptable Threshold	Interpretation
RMR	0.016	< 0.05	Shows excellent fit.
GFI	0.963	≥ 0.90	Indicates good overall model fit.
AGFI	0.813	≥ 0.80	Indicates acceptable fit.
NFI	0.954	≥ 0.90	Good incremental fit.
IFI	0.958	≥ 0.90	Good model improvement over null model.
TLI	0.859	≥ 0.90	Slightly below ideal; suggests moderate fit.
CFI	0.958	≥ 0.90	Indicates very good comparative fit.
RMSEA	0.076	< 0.08	Acceptable

Table 7, shows an inherently interdependent structure of the digital transformation constructs in pharmaceutical operations; AI adoption, automation adoption, digital readiness, and employee competence exhibit fits well within a unified structural equation modelling framework. The high fit indices have consistently been high, making it possible to suggest that digital capability formation in Indian pharma industry can be an integrated capability architecture and not a set of heterogeneous technological constructs. Operational efficiency is described as an empirical evidence that does not describe it as a product of individual technologies, but one a result of synergistic digital ecosystems.

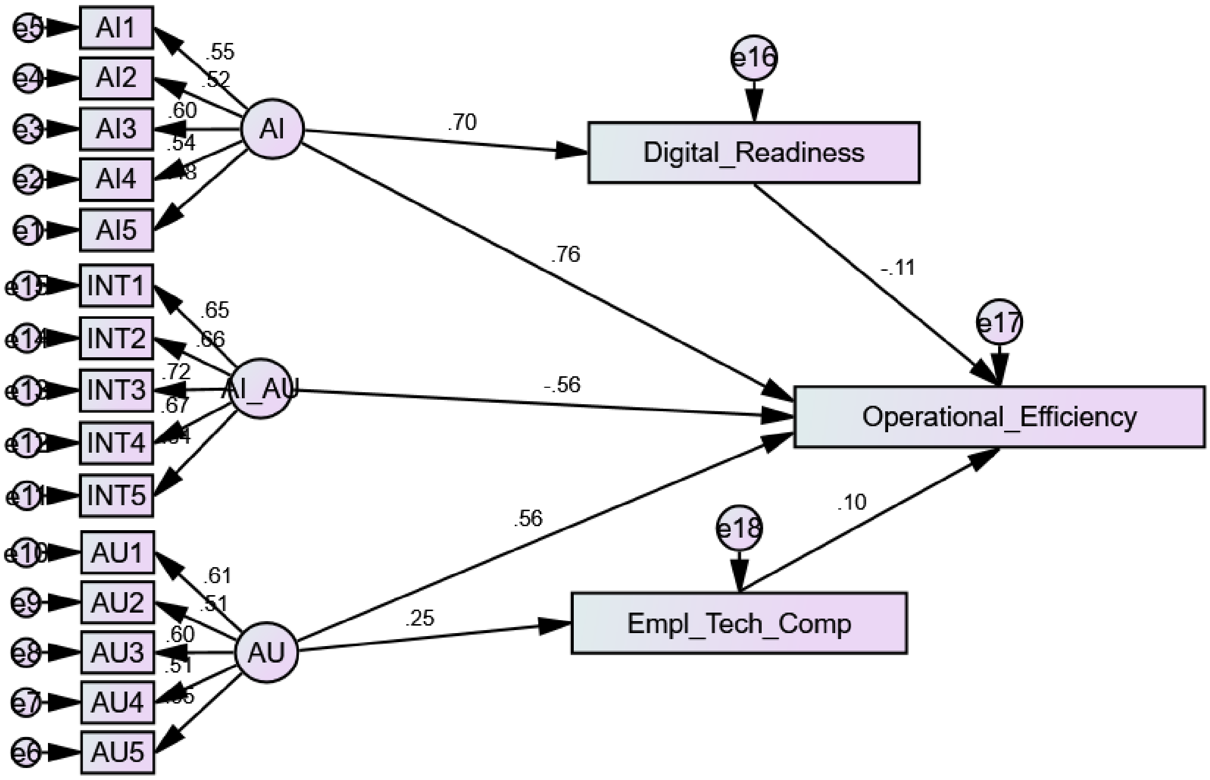

Figure 2. Standardized Factor Loadings (AI-Artificial Intelligence Adoption, AU-Automation Adoption, Interaction of AI * AU, Digital Readiness, Employee Technological Competence, and Operational Efficiency)

5. RESEARCH IMPLICATIONS

The adoption of Artificial Intelligence and automation in operational efficiency has a number of research implications that are far-reaching, and contribute to enriching theoretical knowledge and provide a subtle insight on the digital transformation debate of the Indian pharmaceutical companies. The empirical validation of the Integrated Digital Operations Capability (IDOC) framework essentially changes the conceptualization of digital transformation as a linear, incremental adoption paradigm to an interdependent ecosystem paradigm where AI adoption, automation, digital readiness, and staff technological competence are interdependent capabilities instead of individual interventions. The result of this contradicts the established fact in the literature that technological capabilities are not synergistic, but instead indicates that in highly regulated markets like the pharmaceuticals industry, the operational system formed by the convergent behaviors of digital technologies, organizational preparedness and human capital produces performance gains at a rate of complementary instead of additive. The finding of the AI-Automation Paradox, the interrelation between AI and automation proves to have a strong negative coefficient with the degree of operational efficiency, which provides a critical theoretical refinement of current digital transformation models and proposes the possibility that uncontrollable complexity that will occur with simultaneous implementation of advanced technologies can surpass the capacity of organizations to absorb it, and an incremental, capability-maturity-consistent approach to technology implementation should be adopted instead of active concurrent implementation. Moreover, the observation that the operational efficiency is chiefly conditioned by the variables of technological maturity, i.e. the adoption of AI, automation, digital readiness and employee competence instead of conventional organizational demographics, i.e. the size, type or hierarchy of a company, can be viewed as a paradigmatic shift of efficiency models based on structure to capability models, which suggests that the competitive advantage in the pharmaceutical industry will be gradually transferred to organizations that focus on developing and integrating digital capabilities instead of streamlining their structure. The low but significant contribution of employee technological competence to mediate the technology-efficiency correlation brings about the Human-Technology Synergy Effect, which proves that even slight increases in staff digital literacy and analytical ability bring out the disproportionate improvement in operational performance, which proves the human-capital-based approach to the discourse of Industry 4.0 and counters the determinist views of digital transformation that are pure technological determinism. This research also provides new empirical support of the mediating roles of the digital readiness and the employee technological competence in transforming technological inputs into the performance outputs, which is an important gap in literature because it shows not only that these mediating variables are important, but also the extent to which they mediate the technology-performance relationship in the Indian pharmaceutical environment. The industry-specific information about the existence of differential barriers to adoption between small and medium enterprises and multinational corporations, along with reported difficulties in regulatory certification of the algorithmic systems, contributes to the context-specific understanding of digital transformation, implying that the generalized Pharma 4.0 systems in use need to be significant localized to take into consideration the regulatory complexity, resource heterogeneity, and institutional capacity differences across emerging and developed markets.

6. CONCLUSION

The research about the operational efficiency of Indian pharmaceutical companies in the framework of the AI and adoption of automation yields a range of far-reaching implications of the research which contribute to the further theoretical development and provide more subtle insights into the discourse of digital transformation. The empirical confirmation of the Integrated Digital Operations Capability (IDOC) paradigm essentially alters the conceptualization of the digital transformation as the linear, incremental model of its adoption, towards a more interconnected ecosystem model, in which AI adoption, automation, digital preparedness, and technological competence of employees serve as reinforcing capabilities instead of the isolated interventions. This result contradicts the existing literature assumption that all technological capabilities act separately, revealing that in highly regulated markets including the pharmaceuticals the interactive effect of digital technologies, organizational readiness, and human capital to form a convergent system of operations, with performance gains being complementary, not additive. The finding of the AI-Automation Paradox where the interaction between AI and automation significantly has a negative coefficient with the efficiency of operations introduces a crucial theoretical refining to the current models of the digital transformation and indicates that uncontrolled complexity that can be created by simultaneous introduction of new advanced technologies may surpass the absorption capacity of an organization, and the introduction of new technologies should be carried out in a sequence of ability-maturity-structured way, as opposed to ambitious joint implementation. Moreover, the observation that the main determinants of operational efficiency are the technological maturity variables (AI adoption, automation, digital readiness, employee competence) and not the conventional demographics of the organization (e.g., size, type, hierarchical structure) is an indication of a paradigmatic shift in the structure-based to the capability-based efficiency models and the idea that further competitive advantage in the pharmaceutical industry belongs to such organizations that focus more on developing and integrating digital capabilities and less on structural optimization. The minor but significant contribution of employee technological competence to mediate the technology-efficiency relationship brings about the Human-Technology Synergy Effect, which shows that even a small improvement in the digital literacy of the workforce and its analytical ability returns a disproportionately large increase in the level of operational performance, which proves a human-capital-centered approach to the discussion of Industry 4.0 and refutes the purely technology-deterministic vision of digital transformation. The study also provides the new empirical evidence of how the mediating factors of digital readiness and employee technological competence transform technological input into performance output, which is a major gap in the literature as it not only proves that the mediating factors are of relevance but also the specific manner in which the mediating factors influence the technology-performance relationship in the Indian pharmaceutical sector. The sector-related information about the presence of differences in the barriers to adoption between small and medium enterprises, on the one hand, and multinational corporations, on the other hand, and the recorded limitations in the regulatory validation of the algorithmic systems, supplement the information about the context-based digital transformation by indicating that generalized Pharma 4.0 models have to be largely localized to incorporate the regulatory complexity, resource heterogeneity, and institutional capacity differences in the emerging and developed markets.

7. LIMITATIONS OF THE STUDY

This study offering robust empirical insights into the artificial intelligence and automation adoption in enhancing operational efficiency of Indian pharma companies, subject to certain limitations that should be acknowledged when interpreting the findings. First, a cross-sectional research design adopts in this study, relying on primary data collection for examining structural relationships using SEM, it limits the ability to infer causality or capture the dynamic evolution of AI and automation capabilities. Efficiency gains may materialize with time lags that a cross sectional design cannot fully capture and digital transformation initiatives in regulated industries such as pharmaceuticals often unfold in phases. Second, using questionnaire method the key constructs are measured, including AI adoption, automation adoption, digital readiness, and employee technological competence, is based on self-reported perceptions of sample respondents were drawn from relevant functional domains (production, QA/QC, IT, supply chain, and R&D), perceptual data may be influenced by role-based interpretations, optimism bias, or limited visibility across enterprise-wide systems. Consequently, perceived efficiency improvements may not always correspond perfectly with objective operational metrics such as actual cycle time reduction, defect rates, or equipment utilization. Third, this study incorporates interaction effects (AI × Automation) and mediating mechanisms, does not explicitly differentiate between types or maturity levels of AI and automation technologies like rule-based automation versus adaptive AI, pilot deployments versus scaled implementations. The model captures the strength of relationships but may understate heterogeneity in outcomes arising from differing implementation depth or technological sophistication. Fourth, the diverse responses is confined to distinct regulatory, infrastructural, and labor-market context of Indian pharmaceutical companies; validation practices, workforce skill availability, and regulatory stringency may differ substantially from those in advanced economies, potentially limiting the generalizability of findings to other national contexts or highly digitized pharmaceutical ecosystems. Technological factors and internal organizational are primarily focuses in this study, the external factors may play a significant role in realizing benefits of AI and automation. The external ecosystem influences like regulatory agility, vendor capability, supply-chain digitization, cyber-security incidents and beyond firm

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