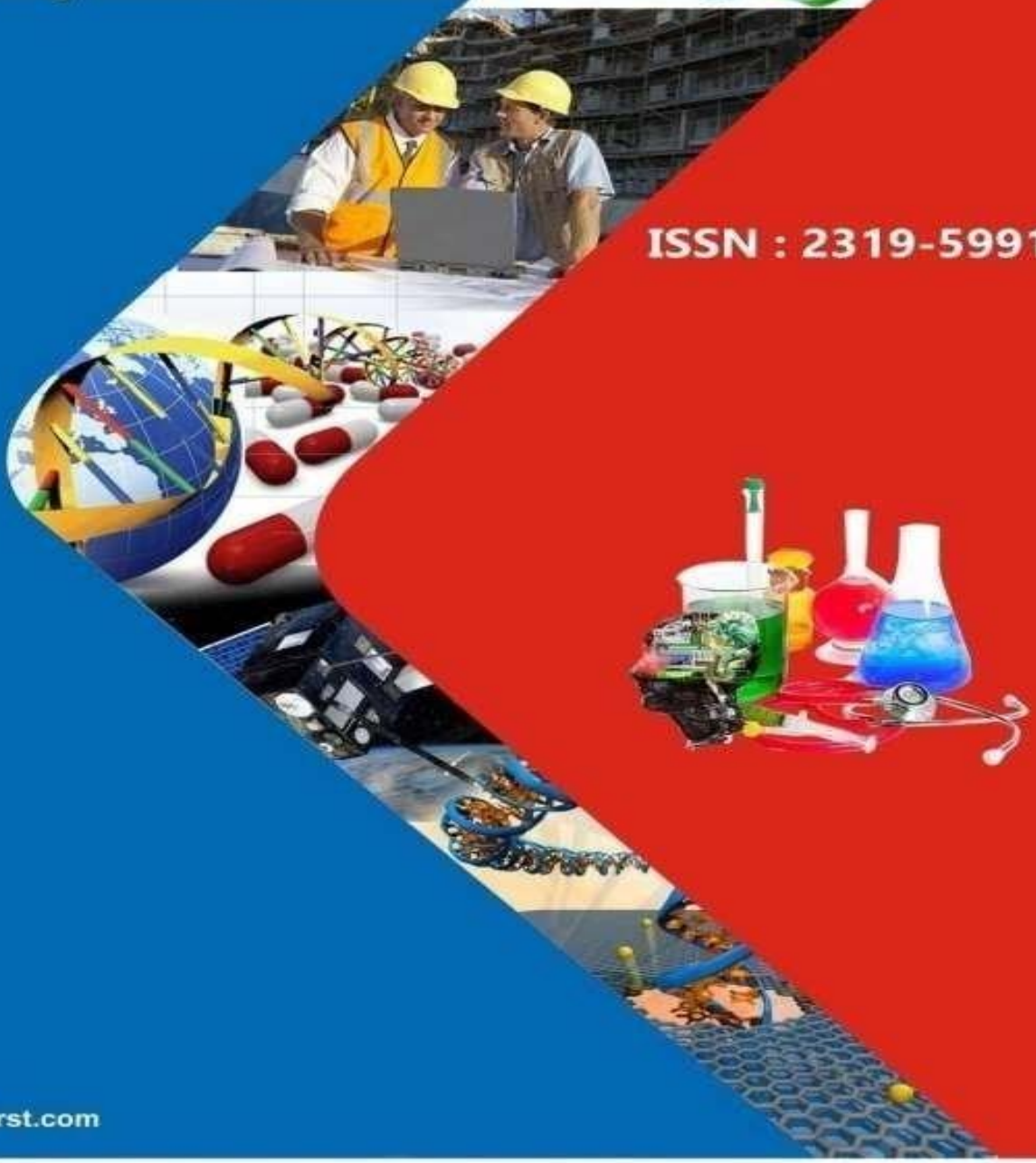
IJERST

International Journal of Engineering Research and Science & Technology

ISSN : 2319-5991



www.ijerst.com

Email: editor@ijerst.com or editor.ijerst@gmail.com

International Journal of Engineering Research and Science & Technology

ISSN 2319-5991 www.ijerst.com

Vol. 18, Issue 1, 2022

Digital Transformation Impact on Pharmaceutical Manufacturing: S/4 HANA and Industry 4.0

Author: Puneet Agrawal
Role: Director, ERP
Affiliation: West Pharmaceutical Services Inc
Email: Puneetagrawal1983@gmail.com

Author: Tushar Chaudhari
Role: Senior Manager, ERP.
Affiliation: West Pharmaceutical Services Inc
Location: Exton, Pennsylvania
Email: seetushar@gmail.com

Abstract: ***This research presents the impacts of Industry 4.0 technologies and SAP S/4 HANA on pharmaceutical manufacturing in the context of digital transformation. Secondary qualitative and quantitative data are employed for the research. Case studies, industry reports, and scholarly articles are sources. Explanatory and secondary analyses are carried out to analyse how AI, IoT, and blockchain play their roles in raising operational efficiency, quality, and regulatory compliance in pharmaceutical manufacturing. The findings point to the transformative nature of digital technologies but also note the challenges associated with data integration and workforce readiness. The research concludes by offering recommendations to pharmaceutical companies on the adoption and optimisation of these technologies for sustainable growth and innovation.***

Keywords: Industry 4.0, SAP S/4 HANA, Pharmaceutical Manufacturing, Digital Transformation, Operational Efficiency

I. INTRODUCTION

A. Background to the Study

Industry 4.0 and SAP's S/4 HANA are encouraging the pharmaceutical manufacturing industry to adopt digital transformation. Industry 4.0 or the fourth industrial revolution utilises smart technologies such as IoT, Artificial Intelligence, and Robotics in the production line mainly to gain efficiency, quality, and to meet very strict regulatory requirements [1]. S/4 HANA is a new generation of ERP software which provides real-time data analysis and business process integration, which improves company efficiency and enhances management decisions. The research highlights the way in which these technologies impact pharmaceutical manufacturing processes by making the production process more efficient, cost-effective, and regulated in such a highly competitive business.

B. Overview

Industry 4.0 convergence with SAP's S/4 HANA transforms the pharmaceutical manufacturing paradigm into one that is innovative, efficient, and compliant [3]. Industry 4.0 applies the Internet of Things, Artificial Intelligence, big data, and robotics in the design of intelligent connected production systems, and S/4 HANA brings about an integrated ERP platform through real-time data processing for making the right decisions and automating them [2]. These overcome issues such as regulatory complexity, supply chain inefficiency, and

International Journal of Engineering Research and Science & Technology
ISSN 2319-5991 www.ijerst.com
Vol. 18, Issue 1, 2022

cost pressure. This research discusses how these innovations transform pharmaceutical processes to ensure higher quality, faster production cycles, and better adaptability to the changing needs of the healthcare industry.

C. Problem Statement

Currently, the industry of manufacturing pharmaceuticals is facing problems such as lack of compliance to regulatory requirements, high costs of operations, and inefficient production and supply chain management. Although there are possibilities in Industry 4.0 and SAP S/4 HANA, such problems can be eliminated through them, but most of the time there seem to be issues of weak understanding, high implementation cost and some level of resistance to adoption of the systems [4]. This research identifies the various changes in operational efficiency, compliance, and competitiveness of pharmaceuticals relating to the identified barriers and strategies that enhance the transformative nature of this technology.

D. Objectives

The research objectives are: 1. To evaluate the effects of Industry 4.0 and S/4 HANA on operational efficiency in pharmaceutical manufacturing. 2. To identify the major challenges in implementing Industry 4.0 technologies and S/4 HANA in the pharmaceutical industry. 3. To develop strategies to implement and integrate Industry 4.0 and S/4 HANA successfully into pharmaceutical manufacturing.

E. Scope and Significance

The purpose of this study is to establish how the technology of Industry 4.0 and SAP S/4 HANA can deliver value in relation to efficiency, productivity, and compliance of a pharmaceutical firm. This work relates closely to most of the concerns in the development of pharmaceutical drugs and regulatory requirements with a exploration on IoT, AI, Robotics, and S/4HANA ERP for its contributions on the improvement in supply chain management [2]. It is important for key compliance-related challenges of pharmaceutical manufacturing, such as low efficiency, high cost and complexity. They help in digital transformation of the sector since they highlight challenges to research and the recommendations that can be made.

II. LITERATURE REVIEW

A. The Role of Industry 4.0 and S/4 HANA in Pharmaceutical Manufacturing

Industry 4.0 and SAP S/4 HANA helps the pharmaceutical Industry to bring efficiency and product quality along with compliance to all related regulations. Industry 4.0 mainly involves adopting contemporary technologies for linking all or several production systems applying the Internet of Things, artificial intelligence, and robotics. On the other hand, S/4 HANA allows for real-time data and automation [4]. As Deloitte indicates in a recent study, manufacturers adopting Industry 4.0 achieve 30 percent less downtime in their production lines [6].

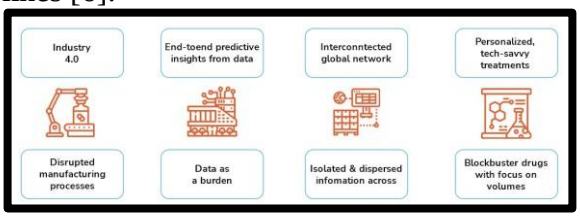


Figure 1: S/4 HANA in Pharmaceutical Manufacturing

[5]

For instance, Pfizer applied information from Industry 4.0 and utilised it on data and quality control in the manufacturing of COVID-19 vaccines [7]. This change can be attributed to the Socio Technical Systems Theory which espouses the use of technology and human activities for the achievement of an organisation's goals [8]. This is very crucial especially in a highly regulated sector where

International Journal of Engineering Research and Science & Technology
ISSN 2319-5991 www.ijerst.com
Vol. 18, Issue 1, 2022

a slightest error could result to severity of the effects. In aggregate, Industry 4.0 and S/4 HANA offer the tools by which businesses within the pharmaceutical manufacturing realm can meet the challenges and implement the changes needed to remain innovative, compliant, and competitive.

B. Adopting Industry 4.0 technologies and S/4 HANA challenges and barriers

The pharmaceutical companies encounter several issues in implementing Industry 4.0 technologies and SAP S/4 HANA. That includes high implementation costs, data integration issues, and workforce readiness [10]. A PwC survey further reveals that 55% of manufacturers face a shortage of skilled workers for digital transformation [11]. For example, Novartis had issues with the integration of IoT-enabled monitoring systems into its manufacturing processes. The company had high initial costs and uncertainty about return on investment.

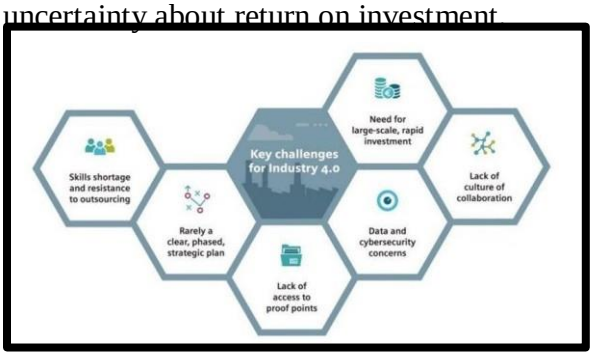


Figure 2: Key Challenges of Industry 4.0 [10]

Another significant challenge is data integration, as many pharmaceutical companies are using legacy systems that cannot accommodate modern technological advances such as Industry 4.0 and S/4 HANA. It is therefore complicated to integrate these new technologies within existing structures, and it can be very time-consuming, thus insisting on complete changes in business procedure and procedures to handle data [10]. Moreover, most pharmaceutical manufacturers face compatibility issues in integration of new technology with legacy system. Also, compliance with standard regulatory requirements, such as GMP, involves a lot of complexity since each new technology implemented must adhere to strict quality and safety standards. In a similar way, Cipla faced a challenge with regard to implementing S/4 HANA, where the workers are not conversant with the system. To address these barriers requires strategic investment in technology, training of the workforce, and integrating processes so that the benefits in the pharmaceutical industry can be achieved from Industry 4.0 and S/4 HANA.

C. Strategies for Successful Implementation and Integration of Industry 4.0 and S/4 HANA

The successful implantation and integration of Industry 4.0 technologies and SAP S/4 HANA for pharmaceutical manufacturing need to be strategically approached in relation to the adoption of technology and regulatory compliance [9]. The critical strategy is investment in employee training and upskilling. Most manufacturers have a digital skills gap, so investing in comprehensive training programs will help employees be ready to work with the advanced technologies of IoT, AI, and S/4 HANA. This will improve operational efficiency and also help overcome resistance to technological change.

Another approach is through the collaboration with technology vendors in order to avoid some integrative issues. Most pharmaceutical companies use legacy systems that are often not compliant with newer technologies. Working with vendors that offer customised solutions can help address integrative issues and ensure data integration into the system while offering support at each step of the way [4]. Also, it

International Journal of Engineering Research and Science & Technology
ISSN 2319-5991 www.ijerst.com
Vol. 18, Issue 1, 2022

should always have deep pilots and testing before the full-scale stage. This enables manufacturers to identify potential challenges and adjust as necessary before committing to large-scale rollouts. Pharmaceutical companies need to foster a culture of digital transformation and innovation but must also respond to the employees' concerns over the loss of jobs or changing processes [9]. A proper communication and change management plan would make transitions smoother and, hence, improve the overall acceptance of the new technology.

III. METHODOLOGY

A. Research Design

This research adopts an explanatory research design in exploring the impacts of Industry 4.0 technologies and SAP S/4 HANA on pharmaceutical manufacturing. This is because this design is justifiable as it explores the relationship between technological adoption and its impact on operational efficiency, product quality, and regulatory compliance [12]. It establishes causal relationships, challenges, and outcomes by the use of both quantitative and qualitative data. Explanatory design is very useful for understanding the complexity of Industry 4.0 and S/4 HANA and has actionability that is required to implement and integrate successfully in the pharmaceutical industry.

B. Data Collection

This is a study that uses secondary qualitative and quantitative data in comprehending the influence of Industry 4.0 technologies and SAP S/4 HANA on the pharmaceutical manufacturing industry. Sources of the secondary qualitative data include case studies, industry reports, scholarly articles-a source of understanding real-life examples and tangible challenges encountered by the organisation. The sources for the secondary quantitative data are credible databases, government publications, and industrial analysis, providing market statistics, adoption rates, and performance metrics such as graphs, charts [12]. The use of secondary data is justified because it offers a wide, reliable base from which one can understand the trends, patterns, and outcomes of the pharmaceutical sector. It is cost-effective and time-efficient since it enables the researcher to gain access to comprehensive, validated information to draw meaningful conclusions.

C. Case Study/Examples

Case Study 1: Digital Transformation with SAP Hana

The life sciences industry has been slow to adopt digital technologies. However, the integration of SAP S/4 HANA has transformed the sector. The reliance of the sector on innovation and agility was witnessed during the COVID-19 pandemic [1]. SAP S/4 HANA has helped companies in pharmaceutical engineering, biotechnology, and medical device manufacturing modernise processes and increase efficiency. For example, Roche adopted S/4 HANA to improve the global supply chain and gain visibility across all operations. Through AI, IoT, and blockchain technologies, Roche could integrate real-time data, thereby adhering to regulatory requirements while having operational scalability. Pfizer used cloud ERP solutions in accelerating vaccine development, hence reflecting time-to-value benefits [1]. S/4 HANA has capabilities that include integration with non-SAP applications seamlessly through the SAP NetWeaver platform, thereby reducing ownership costs.

Case Study 2: Sustainable digitalisation in pharmaceutical supply chains using theory of constraints

This qualitative multiple-case study explores the strategies pharmaceutical managers in the United States use in digitalising integrated

International Journal of Engineering Research and Science & Technology
ISSN 2319-5991 www.ijerst.com
Vol. 18, Issue 1, 2022

supply chain systems in order to maximise sustainability and profitability. Using the Theory of Constraints as a framework, the study involved semistructured interviews with senior supply chain managers, as well as an analysis of publicly available documents from the respective companies. There are six-step thematic process and three themes as follows: (a) limitations in the supply chain systems available today, (b) enabling digital technologies, and (c) sustainable, resilient, and agile supply chains [9]. The result is a system model developed for this purpose as a structured approach for digital transformation. The manager will identify the constraint of supply chains, take the roadmap to digitise, adopt all enablers like IoT and AI, and sustain the benefits. This change improves the efficiency of operation, utilisation of assets, and responsiveness to customers. The implications of social positive change are better delivery and quality of pharmaceuticals while being environmentally, socially, and economically sustainable for the patients worldwide.

D. Evaluation Metrics

Evaluation metrics for this research include effectiveness in the transformation of pharmaceutical manufacturing through Industry 4.0 and SAP S/4 HANA. Metrics include efficiency in operations through production downtime and process lead time reductions and product quality through compliance with regulatory standards, such as GMP and ISO certifications [3]. The cost efficiency metrics focus on decreases in operational and supply chain expenses after implementation. The success of adoption is assessed based on employee engagement levels, effectiveness of training, and usage rates of the technologies. In addition, the integration performance measures how well new systems align with legacy infrastructure. All these metrics will help evaluate the success of digital transformation in the pharmaceutical industry.

IV. RESULTS

A. Data Presentation

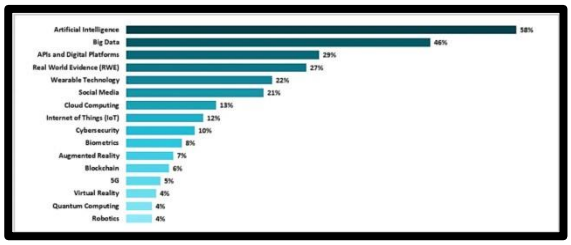


Figure 3: Most disruptive future technologies in pharma

[13]

The graph shows the trends of future disruption in the pharmaceutical sector. The most disruptive is AI at 58%, followed by Big Data at 46%. APIs and digital platforms stand at 29% and real-world evidence at 27% [13]. Wearable technology and social media are impactful as well, with 22% and 21%, respectively [13]. Moderate influences include biometrics, augmented reality, and blockchain, while the lowest ranks at 4% include robotics, quantum computing, and virtual reality [13]. This highlights AI's supremacy and the pharma industry's changing technological environment.

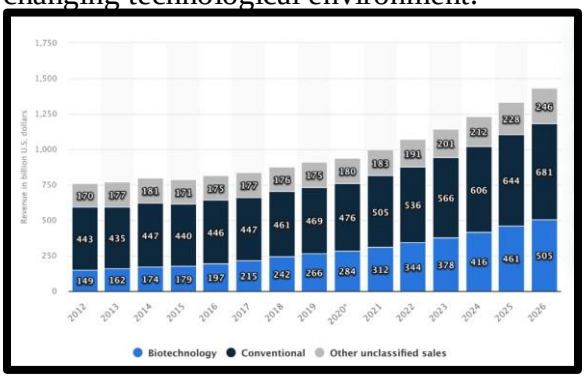


Figure 4: Digital Transformation as Revenue in pharma

[14]

The graph shows the global pharmaceutical sales broken down by biotechnology, conventional, and unclassified sales for years 2012 to 2026. Biotechnology sales grew

International Journal of Engineering Research and Science & Technology
ISSN 2319-5991 www.ijerst.com
Vol. 18, Issue 1, 2022

steadily with $149 billion in 2012 and will continue to do so to an estimated $505 billion in 2026 [14]. The conventional pharmaceuticals have a significantly increasing trend: $443 billion in 2012 to a projected $681 billion in 2026. Unclassified sales are minimal and increase steadily: $170 billion in 2012 and up to an estimated $246 billion in 2026 [14]. These figures underscore the growth in prominence of biotechnology, illustrating improvement and technological integration within the pharmaceutical industry in developing drugs and other pharmaceuticals as well as their overall markets.

B. Findings

There is significant transformation throughout the pharmaceuticals industry, with the influence of the biotechnology sector increasing. An evident shift towards innovation and integration of cutting-edge technologies is driven by the growing relevance of personalised medicine and targeted therapies. Artificial Intelligence has emerged as a prime driver, changing drug discovery, disease diagnosis, and predictive analytics [13]. The traditional pharmaceutical products are still the major market but change relatively at a slower pace than rapid biotechnology advancement [14]. It shows how the industry will pursue digital transformation in order to enhance drug discovery more efficiently and develop better processes in manufacturing to further improve outcomes in the future of pharmaceutical sector.

C. Case Study Outcomes

Case Study	*Key Outcomes*
Case Study 1: Digital Transformation with SAP Hana	● Modernised processes in pharmaceutical engineering, biotechnology, and medical device manufacturing that increased efficiency [1]. ● This enables real-time data integration using AI, IoT, and blockchain while maintaining regulatory compliance and ensuring scalability of operations.
Case Study 2: Sustainable digitalisation in pharmaceutical supply chains using theory of constraints	● Developed a system model using the Theory of Constraints to digitise supply chains, thus improving agility and resilience ● Utilised enabling technologies such as IoT and AI for sustainable and efficient operations [9].

Table 1: Case Study Key Outcomes
(Source: Self-developed)

D. Comparative Analysis

Author	Focus	Key Findings	Challenges Highlighted	Proposed Solution
[4]	Implementation of	Industry 4.0 technol	Resistance to change	Gradual adopti

International Journal of Engineering Research and Science & Technology

ISSN 2319-5991 www.ijerst.com

Vol. 18, Issue 1, 2022

	Industry 4.0 for productivity	ogies significantly enhance productivity in various industries.	and high implementation costs [4]	on strategy with proper pilot testing to evaluate effectiveness.
[8]	Digital servitisation and socio-technical systems theory	Digital servitisation capabilities enable improved service models in technology-driven industries.	Difficulty in aligning technological advancements with human factors [8]	Leverage socio-technical systems to integrate digital tools effectively with human processes.
[9]	Sustainable digitalisation in pharmaceutical supply chains	Digitalisation using the Theory of Constraints improves pharmaceutical supply chain sustainability.	Identifying constraints in complex supply chains [9]	Apply a digital roadmap, identifying constraints and using technologies to enhance supply chain resilience.
[10]	Sustainable digitalisation in pharmaceutical supply chains	Digitalisation using the Theory of Constraints improves pharmaceutical supply chain sustainability.	Identifying constraints in complex supply chains [10]	Apply a digital roadmap, identifying constraints and using technologies to enhance supply chain resilience.

Table 2: Comparative Analysis
(Source: Self-developed)

V. DISCUSSION

A. Interpretation of Results

The results show a drastic change by the pharmaceutical companies towards adopting digital technology resulting from development in biotechnology and AI. Amongst the technologies mentioned, AI has been the most disruptive one changing the very nature of drug discovery, disease diagnosis, and predictive analytics [13]. Traditional pharmaceuticals still lead but biotechnology sales are accelerating rapidly with evidence of sectoral growth importance in personalised medicine [14]. Case studies show that SAP S/4 HANA is effective in the modernisation process of pharmaceutical manufacturing, improved efficiency, and

International Journal of Engineering Research and Science & Technology
ISSN 2319-5991 www.ijerst.com
Vol. 18, Issue 1, 2022

quickening the production of vaccines [1]. On the other hand, the application of the Theory of Constraints model in the supply chain proves the enhancement of agility, sustainability, and quality of digitalisation. These also signify that the pharmaceutical industry becomes dependent on digital technologies that improve the effectiveness of operational efficiencies, responsiveness of the market, and patients' outcomes.

B. Practical Implications

These results imply that there is a need for pharmaceutical companies to digitalise using advanced digital technologies, such as AI, IoT, and blockchain. Digital transformation through SAP S/4 HANA can thus lead to efficient production processes, decreased time-to-market for drugs, and transparent supply chains [15]. Furthermore, using the Theory of Constraints to optimise the supply chain will help improve resilience and sustainability. Integration of these technologies can drive innovation in pharmaceutical companies. This also ensure regulatory compliance, meet the growing demand for personalised medicine, and improve patient outcomes.

C. Challenges and Limitations

The research was further limited by a lack of proprietary data from the pharmaceutical companies to access, and the case studies could not be analysed in much depth. Further, the fast-changing nature of digital technologies within the sector also means that the findings may go out of date very quickly [15]. The use of secondary data and existing case studies also limits capturing real-time developments within the sector. The research focus on particular technologies may also not capture all aspects influencing pharmaceutical digital transformation.

D. Recommendations

Pharmaceutical companies should be continually investing in the digital technologies such as AI, IoT, and blockchain in order to further operational efficiency and innovation [16]. In addition, frameworks like Theory of Constraints in supply chain optimisation can add more resilience to operations. It will require workforce training and strategic partnership with providers for successful implementation.

VI. CONCLUSION AND FUTURE WORK

This research has shown that the technologies of Industry 4.0, including AI, IoT, and SAP S/4 HANA, are crucial in improving pharmaceutical manufacturing processes, efficiency in supply chain, and compliance with regulations. Digital transformation is very important for the industry to ensure innovation, sustainability, and competitiveness while facing challenges like integration complexities and high initial costs.

Future research in this area could involve longitudinal studies that explore the long-term effects of Industry 4.0 technologies on pharmaceutical manufacturing. Further research into the adoption of emerging technologies such as blockchain and quantum computing can provide greater insight into their ability to further drive operational efficiency, regulatory compliance, and innovation within the pharmaceutical industry.

VII. REFERENCES

[1] Kagermann, H., Wahlster, W., & Helbig, J. (2013). Recommendations for Implementing the Strategic Initiative INDUSTRIE 4.0. German National Academy of Science and Engineering.

[2] McKinsey & Company. (2017). Industry 4.0 and Digital Transformation in Pharma Manufacturing: Opportunities and Challenges. McKinsey Global Institute.

International Journal of Engineering Research and Science & Technology
ISSN 2319-5991 www.ijerst.com

[3] SAP SE. (2018). SAP S/4HANA for Intelligent Pharmaceutical Manufacturing. SAP Press.

[4] Manyika, J., Chui, M., & Bughin, J. (2015). The Internet of Things: Mapping the Value Beyond the Hype. McKinsey Global Institute.

[5] Russell, S., & Norvig, P. (2016). Artificial Intelligence: A Modern Approach (3rd ed.). Pearson.

[6] Deloitte. (2019). Industry 4.0 and the Future of Pharma: Digital Transformation and Smart Manufacturing. Deloitte Insights.

[7] European Medicines Agency (EMA). (2019). Digital Innovation in Pharmaceutical Manufacturing: Compliance and Regulatory Considerations. Available at: https://www.ema.europa.eu

[8] Ghosh, R., & Braun, G. (2018). "Blockchain and IoT in Pharma Manufacturing: A New Frontier in Digital Transformation." Journal of Supply Chain Management, 54(3), 120-135.

[9] IBM Institute for Business Value. (2020). The Impact of AI, IoT, and Blockchain on Pharma Industry 4.0 Manufacturing. IBM Report.

[10] Xu, L. D., Xu, E. L., & Li, L. (2018). "Industry 4.0: State of the Art and Future Trends." International Journal of Production Research, 56(8), 2941-2962.

[11] SAP. (2020). Pharma 4.0 and SAP S/4HANA: A Roadmap for Digital Transformation in Pharmaceutical Manufacturing. Available at: https://www.sap.com

[12] Accenture. (2019). AI-Driven Manufacturing in the Pharmaceutical Sector: Enhancing Operational Efficiency and Compliance. Accenture Report.

[13] Chui, M., Manyika, J., & Miremadi, M. (2018). "The Role of Digital Transformation in Pharmaceutical Manufacturing: Challenges and Strategies." McKinsey Quarterly.

[14] KPMG. (2018). Digital Technologies in Pharma Manufacturing: The Role of IoT, AI, and Blockchain in Quality Control and Compliance. KPMG Report.

[14] The Role of Artificial Intelligence in Enhancing Data Security and Compliance in Cloud-Based Ecommerce Logistics Integration", int. J. Eng. Res. Sci. Tech., vol. 18, no. 3, pp. 176–185, Aug. 2022, doi: 10.62643/.

[15] Lee, J., Bagheri, B., & Kao, H. A. (2015). "A Cyber-Physical Systems Architecture for Industry 4.0-based Manufacturing Systems." Manufacturing Letters, 3, 18-23.

International Journal of Engineering Research and Science & Technology

ISSN 2319-5991 www.ijerst.com

Vol. 18, Issue 1, 2022