International Journal of Engineering and Advanced Technology (IJEAT)
ISSN: 2249-8958 (Online), Volume-11 Issue-5, June 2022

Digitalization of Pharmaceutical Cold Chain Systems using IoT Digital Enabler

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Abstract: ***Compared to the other classic supply chain, the pharmaceutical supply chain has many critical challenges, such as cold chain transportation, temperature monitoring, long lead time, and counterfeiting prevention. Pharmaceutical products, such as medicines, drugs, vaccines, and specialty treatments, work as intended within a specific specified temperature. Below +25°C (controlled temperature), +2°C to +8°C (temperature-sensitive products), -20 °C to -40 °C (negative temperature), and -70 °C (ultra-low temperature) are some of the precise and regulated storage thresholds for various types of pharmaceutical products. The cold chain includes production, transport, and storage. It requires a reliable infrastructure to maintain a precise temperature when transporting from manufacturers to patients. This multiple qualitative case study aimed to investigate the role of the Internet of Things (IoT) in the pharmaceutical cold chain. The study involved interviewing various pharmaceutical managers with proven digital strategies for implementing IoT-based digital enablers. The theory of constraint was used as the conceptual framework for this qualitative multiple case study. Data from interviews and supporting documents were analyzed using data triangulation to discover themes. Two main themes emerged from data analysis: (a) Known or unknown constraints in the current cold chain system and (b) implementation of IoT-based digital enablers. Six key strategies were developed pertain to these two themes.***

Keywords: IoT, Pharmaceutical, Supply Chain, Digitalization.

I. INTRODUCTION

Pharmaceutical organizations continue to lose millions because of spoilage from temperature fluctuations and potential hazards for patients and subsequent regulatory actions [11]. Pharmaceutical manufacturers produce the majority of biologics products, which are highly sensitive to storage conditions. Temperature monitoring of some pharmaceutical drugs must be done by following cold chain processes, whether they are in storage or in transit [13]. Biological products have a large proportion of high-value active ingredients with shorter shelf lives and carry strict temperature requirements. Cold chain processes consist of (a) cold storage, (b) cold storage, and (c) cold transport [13].

Manuscript received on 27 May 2022.
Revised Manuscript received on 30 May 2022.
Manuscript published on 30 June 2022.
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These drugs must be kept in temperature-controlled containers during transport, like reefers, to avoid the spikes in ambient containers. IoT is a framework based on the availability of objects, heterogeneous devices, and interconnection solutions that provides shared information based on a global scale to support the design of applications involving people and the representation of objects [2]. The IoT deals with integrating and enabling information using technologies, such as radio frequency identification, wired or wireless sensors, mobile apps, and machine-to-machine system and may allow device-enabled decision-making in supply chain systems with no or minimum human intervention [4].

II. PROBLEM STATEMENT

The most important challenge of pharmaceutical cold chains is temperature control for maintaining the desired quality of the product to reach the final consumer. The general business problem is that Pharmaceutical products that are not well-produced, stored, or transported can cause a major problem for patients when consumed. The specific business problem is that some pharmaceutical managers lack strategies to implement IoT-based digital enablers for efficient cold chain processes.

III. RESEARCH QUESTION

The primary research question for this study was: What IoT-based digital enablers do pharmaceutical supply chain managers use to improve the cold chain process to remain profitable?

IV. RESEARCH METHOD

The purpose of this qualitative multiple case study was to explore the artificial intelligence digital enabler biopharma managers uses to mitigate demand forecasting issue in the biopharma industry to remain profitable. strategies used by supply chain managers to reduce the likelihood of disruption and remain profitable. Our target population included biopharmaceutical managers who implemented AI digital enablers to improve their demand forecasting system. The Purposive sample is used to select supply chain managers.

V. THEORETICAL FRAMEWORK

The conceptual framework selected for this study was the theory of constraints (TOC). Eliyahu Goldratt's (1990) TOC is a system-based management philosophy to understand and identify the root causes that limit a system from achieving higher performance [12].

With TOC, digital supply chain managers can formulate a robust design strategy in the early phase, continuously improving the digital processes by identifying and analyzing constraints and solutions for every step of the digital supply chain system [12]. The TOC may help in providing the insights needed to determine why a non-digitalized cold chain system fails to achieve the organization's goals.

A constraint is defined as an element of the factor that limits the system from doing what it was designed to accomplish [3]. Constraints hamper the progress or increased throughput of an organization. Thus, the firm's failure to manage this constraint leads to declines in its productivity. The same TOC analogy can be made to the supply chain, where a weak non-digitalized demand cold chain system can limit the entire supply chain's effectiveness and efficiency.

VI. LITERATURE REVIEW

The IoT signifies smart devices connected through sensors and the Internet that performs tasks and exchange real-time data [9]. The IoT application, such as cold chain monitoring, resources (man and machine) tracking, packaging, and warehouse management, is very much suited to pharmaceutical supply chain management. The IoT can help manage supply chains, improve services, and manufacture products, so pharmaceutical industries have a compelling opportunity to adopt and profit from the IoT, the game-changing technology [10].

The rapid expansion of IoT devices provides enough potential to organizations by harnessing and using data collected through smart devices in the supply chain lifecycle [1]. IoT is defined as a network of uniquely identifiable endpoints or things that communicate without human interaction using I.P. connectivity, whether locally or globally [8]. The IoT is also defined as the extended development of internet services to consider smart objects that exist [8]. Supply chain integration is critical for improving business performances and can be achieved through cost reduction, improving responsiveness, increasing service level, and streamlining organizations' decision-making processes [8].

The IoT has a significant role in the manufacturing, warehousing, and distribution cycle of the supply chain. Smart objects are connected to the Internet using their communication protocol and are continuously collecting and processing the data [8]. The role of IoT mostly starts from manufacturing for shop floor visibility and then moves to the warehouse for real-time inventory visibility, and then finally during distribution toward higher fleet management for real-time cold chain processes.

Drugs and vaccines are susceptible to temperature variations and may lose full potency if the temperature is not maintained even for a shorter duration during transportation [5]. Pharmaceutical manufacturing companies outsource their logistics business to a third party having optimal cold chain solutions to improve core competitiveness. IoT solutions can help pharma manufacturers remotely monitor cold chain environments in real-time by embedding sensors on tracking equipment with auto-start and shutdown mechanisms in warehouses, vehicles, or shipments using smartphones and tablets. Hasanat et al. (2020) suggested an IoT model that can provide information, such as (a) vaccine carrier information, (b) continuous monitoring using sensors, (c) location tracking using GPS, and (d) regular and urgent notifications containing carrier temperatures, humidity, and location information with a timestamp [5].

A smart manufacturing factory's communication system comprises a wireless sensor network for connecting sensor module and gateway, and then sensor and sensor module is distributed to the necessary position in the factory [7]. Smart equipment using IoT solutions collects operational data and status, allows visibility across equipment, and real-time dynamic scheduling of shop floor activities [10]. The solution helps in reducing equipment downtime, and the utilization rate improves. Sensors can also help collect metadata to identify and reduce process variability and improve production yield to enhance productivity, efficiencies, and cycle time [7].

IoT also helps visibility into human and material movement across the shop floor through tracking and monitoring technologies, increasing production yield, and reducing variability [7]. Hasanat et al. (2020) suggested that business managers build an optimal automated warehouse using IoT [5]. The warehouse is an important area for the pharmaceutical industry. The business managers manage many storage facilities globally to ensure a continuous and timely supply of essential medicines in a cost-efficient manner. Real-time visibility and three-dimensional view of warehouse operations allow warehouse managers (a) monitor and track the storage of sensitive drugs in controlled zones, (b) optimize warehouse floor space, (c) track inventory of finished goods, and (d) identify problem areas and assign resources to deal with issues requiring human interventions [7]. The business managers of automated warehouses using IoT may help organizations save nineteen % of the initial cost [5].

VII. FINDING OF THE RESEARCH

I have used ATLAS.ti and codings were done to identify appropriate themes. ATLAS.ti is a qualitative research tool that can be used for coding and developing themes using interview transcripts, documentation, and field notes. It also provides in-depth insights into data visualization. I have used the word cloud feature in ATLAS.ti to show the visual representation of all the words during interviews with the participants. During data analysis, two themes with six strategies emerged. The themes were (a) Known or unknown constraints in the current cold chain system, and (b) implementing an IoT-based digital enabler in pharmaceutical supply chains. These are discussed in detail:

Theme 1: Constraints in the current cold chain system

The first theme that emerged during the interviews was the identification of constraints in the current cold chain system. Identification of constraints is the most critical factor for implementing IoT-based digital enablers [5]. All participants emphasized the need to work through first and identify the known issue or constraints in their supply chain system.

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Participants' interview data and documentation suggested that an analysis of the current system must be done before deciding on the next step. Identification of all known or unknown constraints must be part of the supply chain system analysis.

All participants also discussed the requirement of creating an organizational vision aligned with the information technology vision to invest in digital enablers, such as IoT.

The following two key strategies emerged pertain to the first theme:

1. Understanding constraints in the current cold chain system:

The major constraints that leaders of a pharmaceutical company face include real-time remote tracking of production, storage, and transportation in third-party logistics, stringent regulations, third-party logistics, and counterfeit products. The corona pandemic has compelled the pharmaceutical sector to move from a just-in-time approach to a just-in-case approach by exposing considerable weaknesses in pharmaceutical supply chains globally [13].

2. Define and develop a vision for IoT digitalization:

Based on all the constraints, pharmaceutical companies need to develop their vision to implement digital enablers in the current cold chain system. Developing vision provides direction and clearly describes the big picture in the short and long term. Managers must have a thorough understanding of the current technological trends based on their specific business requirements. Vision also synchronizes with growth strategies and connects with all stakeholders including third-party vendors that provide support for digital enablers. Developing a vision is also one of the critical metrics for cultural change to bring digital transformations.

Theme 2: Implementing IoT-based digital enablers

The second theme that emerged during the interviews was the need for an AI-based digital enablers agile supply chain system to mitigate the negative impact of disruptions. Participants mentioned the need for AI-based digital enablers to meet their need for the optimized forecast. The Word cloud feature in ATLAS.ti shows the visual representation of all the words during interviews with the participants. Participants also discussed the need for appropriate digital enablers to mitigate the effects of disruptions. The following three key strategies emerged pertain to the second theme:

1. Validation of internal competency for the right skillset:

Implementing IoT can be tricky and require a thorough understanding of business domain knowledge and the technical intricacy of digital enablers. A company must fill its digital skill gap for implementing successful IoT strategies. Pharmaceutical organizations create a matrix team utilizing current business users and plan to either upskill the internal team's capability or hire an external consulting team with in-depth technical skills.

2. Feasibility analysis of IoT-based digital enablers:

Organizations must develop an understanding of and possibilities of IoT-based digital enablers. Choosing the right IoT platform and software is a must as pharmaceutical needs and business is unique compared to other industries. There are so many other factors also to consider, such as how many devices need to be connected, how the data will be processed and stored, etc. Some of the best IoT software and platform available in the market are Google Cloud IoT, New Relic, SAP (ERP), AWS IoT, Wolfram, and Innovation Suite. The most prominent digital enabler as used by pharmaceutical supply chain managers is enterprise resource planning (ERP). A customized ERP version can help managers in integrating all business functions and running the business efficiently. Other IoT digital enablers must have the competency to be synchronized with ERP if already implemented in pharmaceutical companies.

Implementing IoT-based digital enablers also requires organizations to build and support infrastructures. This includes building multiple layers, such as the cloud layer, connectivity layer, and presentation layer. The Cloud layer may include a smart database, platform, applications, and analytical engines. The connectivity layer helps cross-system connectivity. The physical layer generally includes software and hardware. Security and risk management strategies also need to be built before using IoT. There also needs to be provisions for integrating with external business systems. Feasibility analysis needs to take into consideration of all these pre and post requirements of IoT implementation and future supports.

3. Prototyping:

Prototyping or piloting helps managers to understand if IoT-based digital enablers are suiting their business requirements. Piloting also helps in shortlisting a probable business partner, if we have not selected our IoT software, platforms, and implementation partners. It may save their money to identify the software bug in the early stages. A compelling business case must be built by identifying suitable use cases. Prototyping also provides the opportunities to create a strong business case to present in front of senior management.

4. Scaling up:

Scaling up to all the sites can be done once the business case is established and piloting is successful. Senior leadership will also be willing to invest by recognizing the short and long-term strategic significance of digital transformation. The technological shift also requires innovation and cultural mindset shift, and a robust change management process needs to be established for rollout at scale. Organizational ability to scale up and manage the large volume of both unstructured and structured data may impact performance. This needs to be taken care of in advance and strategies must be in place.

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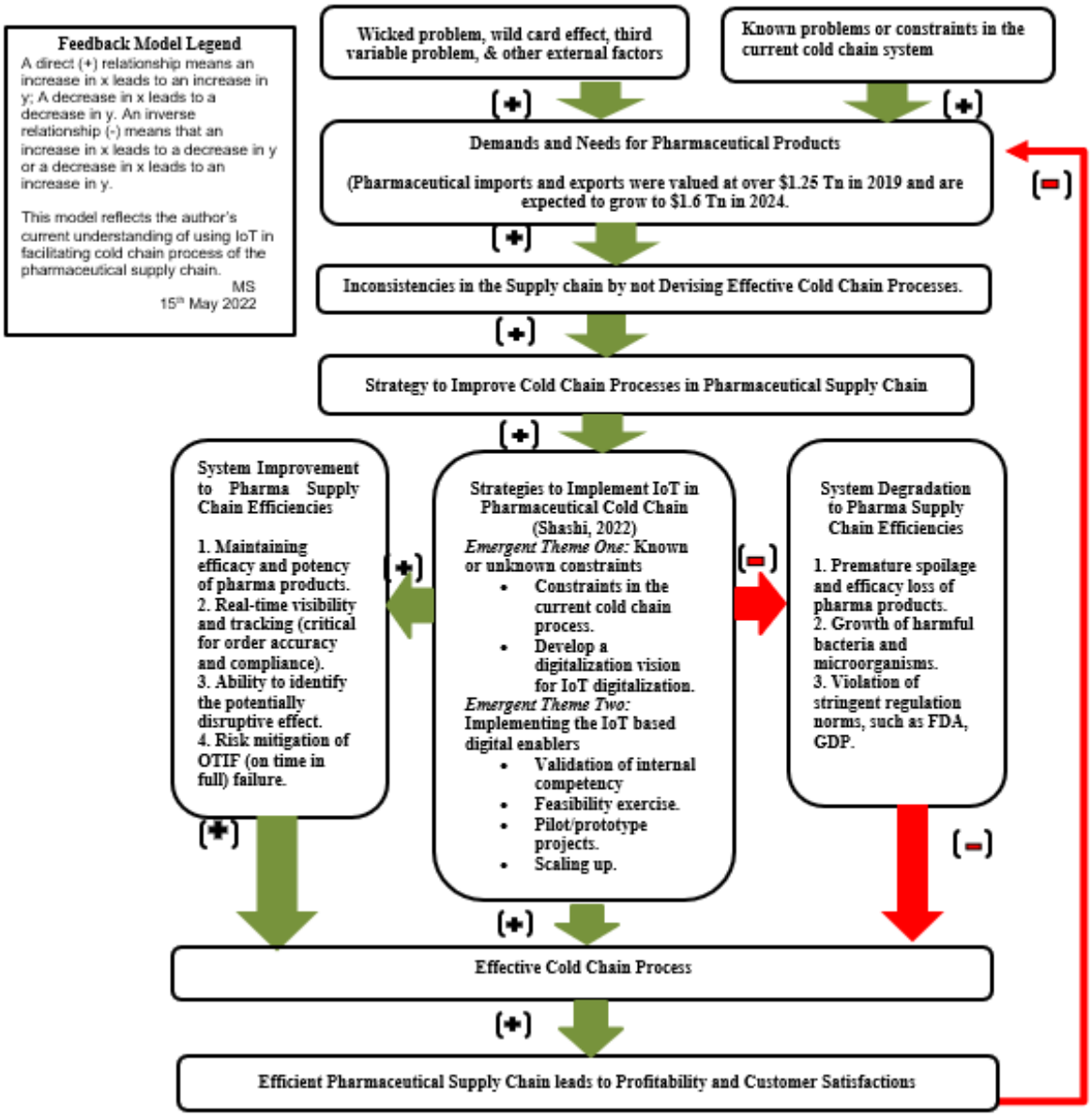

Fig. 1. IoT Based Digital Enabler In The Cold Chain Process of Pharmaceutical Supply Chain

VIII. APPLICATION TO THE PROFESSIONAL PRACTICE: SYSTEM MODEL

I have developed a theoretical feedback system model as the outcome of this research (see figure 1). A direct relationship variable will help improve the efficiency and inversely related variables will negatively impact the pharmaceutical supply chain systems. Problems in the cold chain system will impact the potency and efficacy of pharmaceutical products. Harmful bacteria and microorganisms can grow if exposed to warm temperatures. Any deviation from the specified environmental condition can violate audit and compliance requirements in a particular country of supply. IoT-based digital enablers can help in real-time visibility and tracking which is a must for order accuracy and compliance. IoT can also help in identifying the potential disruption effect and can be mitigated in advance. The customer today in pharmaceutical companies are working as OTIF (on time in full) model and IoT based digital enablers will ensure that no spoilage happens.

Though IoT can be utilized throughout the value chain, its major significant contribution starts from manufacturing. Remote monitoring, predictive maintenance, and analytics are some of the areas where IoT is exhaustively used in pharmaceutical manufacturing operations. Automatic information data collection (AIDC) with Auto-ID can be used for smart serialization. In warehousing operations, IoT provides real-time visibility and tracking. During transportation, IoT's role gets bigger pertains to maintaining and tracking cold chain conditions. A temperature sensing tag is placed on the container which continuously records temperatures and other environmental conditions. Data can be extracted from the cloud either in real-time or later. IoT also has the potential of changing the delivery of healthcare using the connection of various physical devices, such as patients' vital monitoring devices, weight, thermometers, etc. to the internet [6]. These data can then be transmitted to the healthcare provider's database records.

This will help in patient satisfaction as the number of hospital visits will be less by utilizing IoT in remote monitoring of patients' vital information. Two of the significant IoT implementations in healthcare industries are (i) plug and play used for smooth communications with patients and (ii) smart pill bottles which give reminders for missed doses. The pharmaceutical Industries also need to be prepared for the infrastructure required for supporting their current and future requirements. Data generated by the physical layer transmits to the cloud layer using the connectivity layer. A security and governance framework will help organizations while dealing with external system integrations. Themes were identified based on interview data inputs and documentation provided by interviewers. The model summarizes all the identified themes and strategies. Researchers and industries can utilize strategies to mitigate the risks and issues in the current system and work towards a better future digitalize state

IX. CONCLUSION

Findings from the research study show that IoT is an enabler to spur growth within pharmaceutical organizations. Pharmaceutical organizations were more reactive than proactive in technology adoption, such as IoT despite a positive influence on the supply chain system. The major compatibility issue that hampered IoT adaption was the failure to communicate between IoT devices mapped in the supply chain system. Underlying issues such as privacy, reliability, authentication, access control, and security issues need to be addressed before unleashing IoT applications' unlimited potential and utility in pharmaceutical industries. But increasing customer expectations towards drug potency and non-compliance with regulatory agencies have put pressure on management. Pharmaceutical companies now started implementing IoT to enable value chain end-to-end integration. Big data analytics and cognitive systems, such as artificial intelligence and machine learning helped pharmaceutical organizations by getting inputs from IoT devices and in the process improved the productivity of the cold chain process and the entire supply chain ecosystem. The study recommends further research using different sample populations (other geographies) and different research methodologies (quantitative or mixed). Technology is evolving every day in all industries including pharmaceuticals. The study recommends looking for all possible options in the field of IoT digital enablers.

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