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Challenges to Lean 4.0 in the pharma supply chain sustainability

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Abstract. The Pharma sector is increasingly under pressure to improve the sustainability of supply chains, as consumers and regulators require greater transparency, efficiency, and accountability. Although Lean 4.0 has created a lot of buzz in the organization, the pharmaceutical sector faces challenges in implementing it. The main goal of this literature review is to identify the challenges of Lean 4.0 for the sustainability of the pharma supply chain. A series of papers extracted from the most relevant scientific databases, including the Web of Science, Scopus, Google Scholar, and ProQuest was analyzed and synthesized from 2006 to 2022. 31 articles were used in the study. The findings of the study indicate that challenges include financial, staff experience and specialization, ongoing maintenance, resources for generating new skills and experiences, employees, and partners' resistance to changes in regulations, and cyber-hacking of key information. The results will facilitate future work by practitioners and re-searchers and make an important contribution to existing knowledge.

Keywords: Industry 4.0, Lean 4.0, pharma supply chain, sustainability

1 Introduction

One of the primary goals of the pharma sector is to provide medicines and to be consistent with the goals of the health system. Its supply chain should provide medicines to patients in sufficient quantities with acceptable quality at the appropriate location and time with the lowest possible costs [1]. To achieve this Pharma manufacturers should choose the best raw material and pharmaceutical excipient suppliers, as well as production facilities that are environmentally and socially responsible [2]. Therefore, supply chains are embracing a digital transformation known as Industry 4.0 (I4.0), which refers to the application of a set of digital transition technologies that extend beyond organisational boundaries [3]. "Industry 4.0" refers to the combination of the

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Internet of Things (IoT), Artificial Intelligence (AI), robotics, and advanced technologies to drastically transform the production environment as well as the supply chain [4]. It is consistently gaining attention in sustainability by contributing to long-term economic, environmental, and social development [5]. According to Marodin et al. [6], Lean Supply Chain Management is defined as a group of organisations that are directly linked by upstream and downstream flows of products, services, information, and funds that collaborate to reduce cost and waste by efficiently pulling what is needed to meet the needs of individual customers and also benefit the company's stockholders.

The pharma sector is expected to respond to concerns over the hazardous waste that may harm the environment and human health, the imperative for cost-efficient supply chain practices, as well as the growing need for transparency and accountability in the manufacture and distribution of pharmaceuticals [1]. However, today, Lean 4.0 which combines Lean management and I4.0 enablers has been identified to achieve positive synergies, with the potential for significant improvement in supply chain sustainability applicable even to the Pharma sector [7]. Despite these advances in the pharma sector with small molecule development and manufacturing, significant challenges in the sector can jeopardise the long-term viability [8]. This has prompted the research question: "What are the challenges for Lean 4.0 in pharma supply chain sustainability?". This research objective highlights the challenges of Lean 4.0 to bridge the knowledge gap, allowing practitioners and researchers to better understand these challenges and contribute significantly to the existing body of knowledge, facilitating future work in the field.

2 Literature Review

2.1 Lean Management and Industry 4.0

Industry 4.0 techniques have recently been used in the Pharma sector and have been strictly regulated by several stakeholders to ensure the safety and overall well-being of society[4] Through employing intelligent sensors, energy management techniques allow the monitoring and optimization of energy consumption in areas such as water, electricity, and gas. Pharma companies in developing countries have started to implement basic energy management practices that focus on individual machines, paving the way for an upgrade to a multi-production line or multi-site management system through the use of big data, energy and cost analysis, resulting in precise load forecasting and regulation [9, 10].

Lean manufacturing eliminates non-value-added activities from manufacturing processes to maintain effectiveness, flexibility, and profitability, in the health sector [11]. Vinodh et al. [12] have identified 5S, Kanban, Kaizen, total productive maintenance, total quality management, failure mode and effect analysis, quality function deployment (QFD), value stream mapping (VSM), cellular manufacturing (CM), and other lean manufacturing techniques which are currently being implemented. According to Taj [13], Lean principles are aimed not only at a waste reduction but also at improving

production system efficiency by increasing value-adding activities in product flow and relying on costs [14].

2.2 Lean 4.0 Enablers

Due to its direct impact on human health and safety, the sustainability of PSCs is far more complex and challenging compared to that of other industries. As a result, the Pharma sector has received increased attention for the impact of its activities on long-term sustainability [15]. The Pharma sector is increasingly sourcing productions and related services to emerging countries with suitable suppliers that are environmentally and socially responsible [2]. According to Schneider et al. [16], the increasing energy prices, the potential impacts of climate change, and the strict regulations have resulted in the Pharma sector focusing more on energy usage and emission reduction throughout the entire life cycle of pharma products. Sustainability is influenced by environmental, societal, and economic factors. Hence exploiting Lean 4.0 technologies facilitates sustainable value creation, which will lead to efficient sustainable PSC designs and management, assisting pharma companies to gain long-term competitive advantages [17].

3 Methodology

In other to identify the challenges in implementing Lean 4.0 in pharma supply chain sustainability, a Systematic Literature review Analysis was used to select and analyse articles. Given this, the Web of Science, Google Scholar, ProQuest, and Scopus were used between (2006 to 2022).

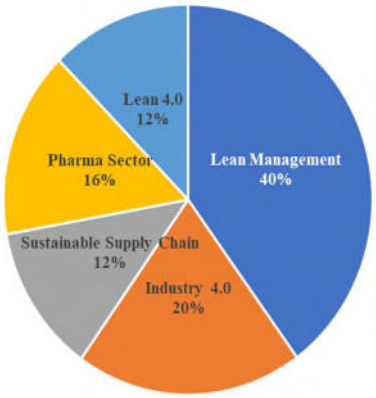
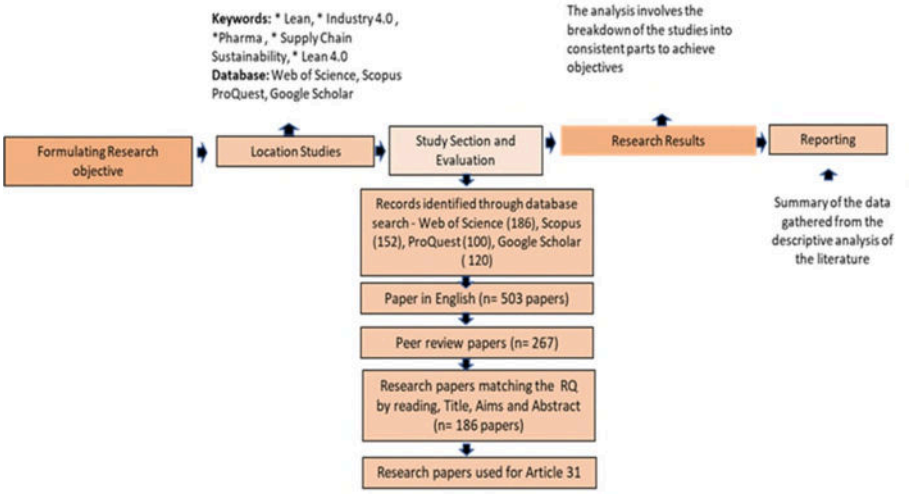


Fig. 1. Article distribution based on keywords.

Fig. 1 shows the percentage of articles viewed in other to achieve the outcome of this paper. Five hundred and three (503) articles were reviewed, two hundred (201) were on lean management, hundred (100) were Sector 4.0, sixty -two (62) were sustainable supply chain, seventy – eight (78) were pharma sector and sixty –two (62) were Lean 4.0. The Search string was (Lean AND pharma), (pharma AND industry 4.0) (pharma Lean

A ND Challenges), (Pharma challenges AND pharma barriers) OR (pharma difficulties AND pharma barriers), (pharma SCS challenges AND pharma SCS barriers) (pharma procurement). Irrelevant title, abstracts and full text was used to reduce the number of articles to a manageable number, the selection process yielded thirty-one articles, which were subjected to an appropriately comprehensive review.



A structure essential to carrying out a secondary inquiry, such as a systematic literature review (SLR), is shown in **Error! Reference source not found.** to reduce study bias. The framework encapsulates the review's thorough plan, including the steps to be taken to produce results and facts that will serve as findings.

4 Results and discussion

Lean 4.0 manufacturing practices emphasize customer-centricity, which keeps traditional processes focused on efficiency through digitalized systems and processes that cause synergies and help sustainability within the supply chain. However, the pharmaceutical sector seeking to upgrade its supply chains and operations confronts several challenges, as shown in **Error! Reference source not found.**. Management requirement for necessary resources, such as a cross-functional team of experts and necessary investments, is one of the barriers to implementing Lean 4.0 in the Pharma sector [18]. Sustainable Supply Chains Management has its roots in both Sustainability and Supply Chain Management focusing on supply chains is therefore a step towards the adoption of growth on sustainability. According to Linton et al. [19], sustainability must include challenges that extend beyond the core of supply chain management, such as product design, production, distribution, end-of-life products, and recovery processes this is because some drugs have a specific temperature of storage. In addition, building new experiences and competencies would be expensive and take time as employees and supply

chain partners learn over time that they may need to familiarize themselves with the Lean concept and the digital interface [20]. As a result, challenges to its successful implementation include the complexity of the adoption process, evidence of innovation sharing and change embedding, high process variability, a lack of understanding of Lean 4.0, and issues with defining waste [21]. Also, employees' negative perception of Lean 4.0 makes it difficult [21]. Furthermore, a lack of commitment from top management to allow flexibility [22], in changing processes to create fully integrated end-to-end supply chain solutions necessitates close collaboration with partners [23]. Finally, regulatory aspects add another layer of complexity because they include new business requirements and a changing environment in which regulators in the pharmaceutical sector operate [22, 24].

Table 1. Challenges to Lean 4.0 in the pharma supply chain

Challenges	Concept	Author
Management: *Financial *Inexperience staff *Lack of infrastructure *Low management support and dedication *Poor existing data quality	Financial constraints in developing capabilities in terms of advanced equipment and machines, facilities and sustainable process innovations in Lean 4.0. Lack of employee understanding of the concept makes it difficult to implement it effectively. Also, management support and willingness to accept changes are critical for the development and effective Lean 4.0 concept Several interconnected machines, sensors, manufacturing systems and facilities generate huge structured/unstructured data	[18, 21, 22, 25]
Employees 'and business partners' resistance	Unaware of the potential benefits, most industries are hesitant to adopt Lean 4.0 based technology since employees believe that the use of technology would eliminate their job	
Security issues	Cyber hackers have access to vital information	
Regulations	Lean 4.0 is about a cyber-physical network that connects various machines, sensors, facilities, and humans to the internet. This cyber-physical network may raise several complex legal issues with regards to personal and sensitive data	[19, 23, 26]

The problem of coordination and collaboration	Technology integration is critical for effective communication and increases productivity. Industries are struggling to create a flexible interface to integrate various heterogeneous components	[24, 27]
	Lean 4.0 tends to emerge with lean concepts and several complex legal issues	[28]

One of the reasons pharma companies have been hesitant to implement Lean 4.0 is a significant capital investment and a need for skilled labour [18, 21]. Building new experiences and competencies would be expensive and time-consuming because employees would need to be trained due to their unfamiliarity with the Lean 4.0 concept and the digital interface. The complexity of the adoption process due to poor existing data quality [22, 29], evidence of innovation sharing, embedding change, and issues with defining waste need understanding with structural flexibility while adopting new changes [7]. Sustainable manufacturing in the pharma sector involves regulatory compliance with aspects such as the 3Rs (reduce, reuse, and recycle). It extends product life cycles through remanufacturing, recycling, and the use of clean technologies that reduce pollution, reflecting the changing environment in which pharma regulators operate [30]. Also, in terms of regulatory barriers, as well as legal issues [25]operating within existing regulatory frameworks can pose a challenge to technological innovation [30]. Employees are reluctant to accept change because they believe digitalization will eliminate their jobs, which they find comfortable due to fear of the unknown and failure [23]. Also, the absence of commitment from top management to permit flexibility in changing processes creates a deficiency of end-to-end supply chain solutions that necessitate close collaboration with partners [18, 21, 31]. Security issues concerning cyber hackers and data-sharing protocols are on the rise. According to Muller et al. [31], there is a need for a shared ground for a relevant architecture in place before implementation begins, this is because the manufacturing of drugs has a direct impact on human life and raw material, pharma suppliers, and environmentally friendly culture must be established from an early stage of production.

5 Conclusion

The present study conducted an SLR analysis and identified ten challenges of Lean 4.0 for supply chain sustainability in the pharma sector. I4.0 technologies are evolving and the use of Lean 4.0 has the potential to significantly improve agility, efficiency, productivity, and sustainability throughout the entire supply chain. However, the Pharma sector struggles to adopt Lean 4.0 because it is heavily regulated to ensure patient safety, product quality, and data integrity. It also expects smart technology to be fully integrated into the pharma sector as well as incorporate social, economic, and

environmental protection and control within its supply chain. This future is attainable if the challenges are managed effectively.

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