Guidelines to choose Operational Excellence techniques/tools for inventory management: the case of pharmaceuticals supply chain

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Abstract

Today's pharmaceuticals supply chain faces an increasing need of flexibility, accuracy and ease of processes management as a minimum requirement. The inventory management process remains a key success for the whole supply chain. The search for Operational Excellence (OE) in inventory management should include a thorough understanding of the nature of the pharmaceutical operations, choice of the right inventory control system and a managerial commitment. The holistic program of Operational Excellence is composed of many waves and relies on specific principles and techniques that aim to stabilize the process of inventory management throughout the supply chain and make it proactive. This stabilization is vital in the pharmaceutical supply chain as it allows the supply chain controlling its stock and then achieves the expected level of Operational Excellence. The objective of this paper is twofold: explore the different waves of Operational Excellence, investigate and analyze its techniques and tools. And then, propose some guidelines to choose the proper techniques and tools that impact the inventory management considering the specific requirements of the pharmaceutical supply chain.

Keywords
Operational Excellence; Lean Six Sigma; Pharmaceuticals inventory management; Pharmaceutical supply chain.

1. Introduction

Operational Excellence (OE) is a broader program of improving and sustaining business performance in which quality management is embedded [1]. Operational Excellence in terms of quick and reliable deliveries, short lead times, high resource utilization and low inventories is desirable for manufacturing firms [2]. The purpose of searching Operational Excellence is to provide quality that could be defined as "Right first time", "What the customer wants", "Conformance to standards", "Value for money", "Right thing at the right time" and so on [1]. When companies fail to take advantage of methods designed to help improve quality, such as total quality management (TQM), Lean, Six Sigma, agile manufacturing and the theory of constraints, manufacturing output is poor. Each organization and improvement program team certainly need to use a large arsenal of tools and techniques in their implementation process. However, organizations should choose techniques and tools that cope with their

environment and respect their constraints. Inventory management knew many applications of continuous improvement and Operational Excellence programs [3] [4]. It is due to the importance of this process and its impact on the supply chain as a whole; an efficient inventory management can positively impact cash flow and liberate valuable floor space. More specifically, the pharmaceutical supply chain is under an increasing pressure to improve quality of the proposed products and services. Due to the market context, the process of pharmaceutical inventory management should allow a reduction of wastes (muda), follow a stable route by elimination of variations (mura) and avoid a wrong use of resources (muri).

Nevertheless, there is a need to know the most suitable techniques and tools to use to get the best results in terms of quality, cost, security and time. Indeed, it is vital that the tools and techniques are selected for the appropriate team and applied correctly to the appropriate process.

Actually, the pharmaceutical sector is characterized by specific characteristics that differentiate it from the manufacturing sector where the Operational Excellence was born. These differences should be taken into account while choosing the suitable techniques and tools of Operational Excellence for inventory management.

In this paper, we provide the most relevant guidelines to choose the suitable techniques and tools of Operational Excellence for inventory management in a pharmaceutical supply chain. In the following section, we present an overview about the waves, techniques and tools of Operational Excellence. Then, we introduce new guidelines to help with the choice of techniques and tools of OE considering the specific requirements of the pharmaceutical supply. Finally, we will close the paper by a conclusion and state future areas of research.

2. Overview of Operational Excellence

Operational Excellence is synonymous to Business Excellence and it also encompasses other excellence programs such as Manufacturing Excellence, Service Excellence, Marketing Excellence and Supply Chain Excellence. Continuous Improvement (CI) is an essential ingredient of Operational Excellence. Four steps could lead to Operational Excellence [1]:
Step 1- Meeting the objectives of operational management
Step 2- Establishing the competitive advantage
Step 3- Achieving Business leadership
Step 4- Sustaining Operational Excellence.

2.1 Waves of Operational Excellence

The OE programs embed many continuous improvement systems such as Six Sigma, Lean processes and FIT Sigma. These programs are considered as the waves of Operational Excellence.

First Wave: From Adam Smith to TQM

Organizing labour power in order to improve operations may have started with Adam Smith in 1776; however Industrial Engineering (IE) has a major contribution in the development of Operational Excellence [1].
After Second World War and due to the rapid growth of industrialization especially in the 1950's and 60's, the general manufacturing attitude was focused on producing as much as possible without paying attention to waste or the cost of waste. Thus, there was a need to improve quality beginning by Ad'hoc improvement to achieve the Total Quality Management approach. However, the TQM should be tailored to an organization's needs. This implies that every organization has to develop, its own and unique way to implement TQM. This situation initiated the second wave of OE [1].

Second Wave: From TQM to Lean

The economic success of Japanese companies in the eighties can be attributed to the successful application of TQM and its customized integrated application.
The visit of Eiji Toyoda to USA to study how automobiles were manufactured in the world's largest and most efficient manufacturing plant– Ford's Rough plant in Detroit changed the trend of quality movement in Japan. Actually, he realized many wastes (muda) in the Ford's manufacturing system [5]. For instance, there was high inventory cost to keep a large number of parts that were later found to be defective, when installed at the assembly plant.

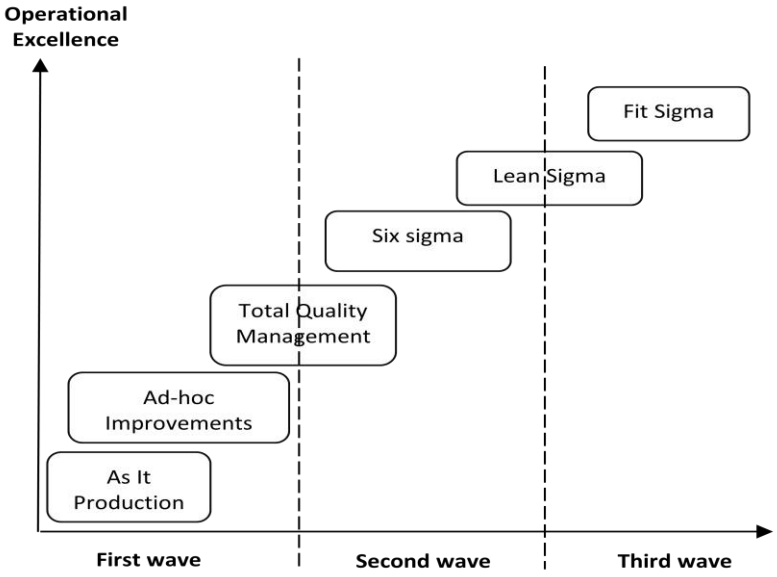

Figure 1. Evolution of Operational Excellence

He also understood that mass production as running at Ford system could never work in Japan. Thus, when he returned to Japan, he established the famous systems to reduce *muda* (waste) such as: the Just-In-Time System and Total Quality Control[5]. During the 1980s, the TQM became the buzzword and seemed to be everywhere but it was viewed as a quality concept that promised more that it could deliver and thus became almost *cliché*. Thus, the Six Sigma appeared to establish itself.
In 1985, Bill Smith, an engineer at Motorola, proposed to insert hard-nosed statistics into the blurred philosophy of quality. The Six Sigma approach expanded to other organizations such as Marconi, Invensys, Bombardier Shorts, General Electric…Then, the Six-Sigma programs have moved to the Lean Six Sigma philosophy which integrates Six Sigma with the complementary approach of Lean enterprise. This is the beginning of the third wave.

Third Wave: From Lean Sigma to FIT Sigma
The combination of Six-Sigma and Lean promised speed and agility for doing faster and better. The systematic identification and eradication of waste and non-value added activities lead to optimum value-flow, reduced cycle times and eliminated defects. Many firms have experienced the concept of merging Lean and Six-Sigma such as Allied Signal (Honeywell now), BAE systems, Maytag Corporation, TBM Consulting group and Northrop Grumman. The main achieved improvements were in term of enhancement of lead time, reduction of error rate, saving in scrap and manpower, reduction of new product introduction time and saving in million dollars.
To achieve a longer term competitive advantage of a company, the best practices of Six-Sigma and Lean Sigma and other Operational Excellence should constitute the basis blocks of FIT Sigma. To create FIT Sigma, three fundamental features concern Six-Sigma and Lean Sigma:
1-Fitness for the purpose
2-Sigma (∑) for improvement and integration
3- Fitness for sustainability.

2.2 Techniques and tools: Lean, Six Sigma and sustainability
All improvement programs, along the three waves of OE, rely for their processes on techniques and tools. The success of Lean Six Sigma as one of the best–known hybrid continuous improvement methodologies has led many organizations worldwide to adopt it for achieving operational and service excellence. To reach different targets and waste elimination or reduction, a plethora of different tools and techniques has been developed [6]. Techniques and tools constitute an important component of a process. They can be a double edged sword; they are beneficial when they are well used else they can be destructive. For this reason, OE techniques and tools should be used in a sustainable and safe way. Hence, they are the set of methods and skills applied to specific activities to implement, manage, sustain and improve the sustainability performance. On the other hand, to understand the relationship between tools and techniques, a technique could comprise the application of several tools that have different roles. A

tool is very narrow in focus and has a clearly defined application to tackle a specific problem. For instance, Six Sigma methodology utilizes the tools and techniques for fixing problems in business processes in a sequential and disciplined fashion. Each tool and technique within the Six Sigma methodology has a role to play and when, where, why and how these tools or techniques should be applied is the difference between success and failure of a Six Sigma program [7]. The tools for achieving Lean [8] are basically the same as the tools promoted under JIT. However, techniques and tools of both systems could be implemented in a way that maximizes profits, minimizes negative environmental impacts, conserves natural resources and energy, and safe for employees, consumers, and communities. Table1 presents the most prominent and commonly used techniques and tools in companies practicing Lean and Six Sigma[9].

Table 1. Lean and Six Sigma techniques and tools

		Just-In-Time (JIT)	Kanban	Poka-Yoke	Quality Circles (QC)	Value/Process stream Mapping (VSM)	Spagetti Diagram (SD)	5S	One piece flow (OPF)	Tack-time	ISHIKAWA	Kaizen	Statistical Process Control (SPC)	Control charts(CC)	Regression Analysis (RA)	Tagushi methods (TM)	Measure capability (MC)	Correlation studies(CS)	Benchmarking	Quality Function Deployment (QFD)	Failure modes and effects analysis (FMEA)	Design of experiment (DOE)
Lean	Technique	y	n	n	y	n	n	n	y	n	n	y	n	n	n	n	n	n	y	y	y	n
	Tool	n	y	y	n	y	y	y	n	y	y	n	n	n	n	n	n	n	n	n	n	n
Six Sigma	Technique	n	n	n	n	n	n	n	n	n	n	n	y	n	n	y	n	n	y	y	y	y
	Tool	n	n	y	n	n	n	n	n	n	y	n	n	y	y	n	y	y	n	n	n	n

For companies practicing Six Sigma in UK for example, the most commonly used tools include cause and effect analysis, Pareto analysis, control charts and run charts. It was found that many companies are not using more powerful techniques such as design of experiments, Taguchi methods, quality function deployment, failure mode effect and criticality analysis, 5-S practice, Poka-Yoke and statistical process control. In other words, the more powerful techniques are less commonly used in these organizations. Lean manufacturing uses tools such as kaizen, value stream mapping, one piece flow, Poka-Yoke, line balancing and standardized work to reduce manufacturing waste. On another side, Lean and Six Sigma share many techniques and tools that can be used in both programs such as cause and effect analysis, 5S and value or process stream mapping. Integration of Lean and Six Sigma is even possible by a full fusion of the Lean philosophy of waste elimination with the Six Sigma mentality of perfection at all times. This integration aims to overcome the shortcomings of both and allows organizations to have the "best of both worlds". Most of popular Lean improvement articles show the relationship between Lean/Six Sigma practices and performance. For example, a study [10] reported that Six Sigma practices are integrated with seven traditional quality management practices to affect quality management and business performance. The results found that Six Sigma element contributes to higher performance improvement. Another study [11] explored the relationship between Lean practices, Six Sigma, and firm performance. The findings also exhibited that the group of plants which implemented Lean and Six Sigma have higher performance than non-implementers. Also, there are many papers that showed the relationship between techniques and tools of Lean/Six Sigma and sustainability to upgrade the level of management techniques to achieve social, economic and environmental improvements without large investments or extensive changes. Finally, the five principles of Lean (Identify value, Map the process, a continuous Flow of products, Pull the process, Perfect the process) and the holistic DMAIC (Define, Measure, Analyze, Improve, Control) structure of Six Sigma could be integrated to achieve a sustainable competitive fitness as shown in Figure2.

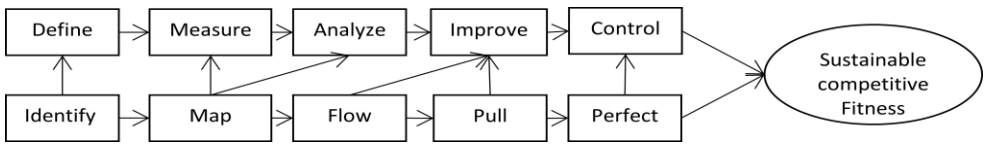

Figure 2. Lean and Six Sigma phases' relationship to sustainable competitive Fitness

There is a need, however, to classify and organize these tools and techniques in a way that will make information about the tools and techniques readily available and will remove ambiguities in definition, purpose, and implementation of the tools and techniques [12].

2.3 Overview on the classification of Operational Excellence techniques and tools

Actually, the use of each technique or tool has a specific requirement according to where and when the tools and techniques can be applied as well as the type of waste and variation the tools/techniques seek to reduce or eliminate.
Shah and Ward [13] identified 22 Lean tools based on their literature review and classified them into four main categories – JIT, total quality management, TPM and human resource management. Eswaramoorthi [14] indicated that there are 36 different Lean tools for machine tool industry. Anand and Kodali [15] developed a consolidated list of around 60 Lean manufacturing tools and categorized Lean tools into ten groups: product design, process planning, facilities and layout, purchasing, production planning and control, quality control, maintenance, human resources, logistics and supply chain management. Pavnaskar [12] stated that there are over 100 Lean tools available and presented a classification scheme for Lean manufacturing tools according to a leveled structure of the organization containing a system level, object level, operation level, activity level, resource level, characteristic level and application level. Alaskar [16] developed a methodology that can help manufacturing small and medium enterprises to select a Lean tool. The methodology is designed by integrating the influence value of factors affecting the KPIs, and the strength of the relationship between these factors and Lean tools, utilizing a selection matrix. Hagemeyer [17] developed a classification scheme in the form of a matrix that identifies, organizes and defines tools of the Six Sigma problem-solving process as taught and implemented at a large manufacturing company.
From the above, it can be noted that the use of tools and techniques of Lean and Six Sigma depend on many factors such as the activity to improve, the environment of the organization, the type of waste, the type of variation…However, the simple introduction of Lean Six Sigma techniques and tools is not sufficient and would not systematically lead organizations to the successful implementation of Lean /Six Sigma and sustainability. The tools/techniques need to be carefully selected and used judiciously, and must fit with the requirements and targets of the organization.

3. Guidelines to choose Operational Excellence techniques/tools for inventory management of pharmaceuticals

Recent years have witnessed phenomenal pressure on the pharmaceutical financial resources. Hence, managers tend to find methods for operational improvements through rationalization strategy, maintaining the care services required by the population and reduced costs. Moreover, considering the important budget dedicated to the pharmaceuticals inventory management, this area constitutes a good field of application of techniques and tools of innovative programs.
Actually, inventory management "*is a set of techniques and methods employed to assure in each moment, in the best economic condition, the conservation of the materials availability for the user*"[18]. Selection of an appropriate process improvement methodology depends on the culture of the organization. When considering Lean, Six Sigma, or integration of both, one main concern is the speed at which the methodology will be accepted by the organization. Moreover, there is a need to select the proper techniques and tools that ensure an efficient inventory management to create economic benefits and achieve accurate healthcare services.

3.1 Guidelines to choose Operational Excellence program

There are some general guidelines for choosing an improvement program and then achieving Operational Excellence. Three main types of decision could be made regarding the improvement programs [19](Figure3):
- If the organization values analytical studies (and their associated data, charts, and analysis), then Six Sigma may be a great program to lead off with.
- If the organization values visible progress and immediate change, Lean may be the best way to initiate a process improvement program.
-If the organization is seeking a systematic decision-making approach with employee participation, then the integration of the two approaches will work well. The company should be sure that the requisite skills to use the decision-making tools are developed.
Actually, some authors find that the ideal solution is to combine Lean and Six Sigma approaches [7]. The success of Lean Six Sigma is one of the best–known hybrid continuous improvement methodologies. This has led many organizations across the globe to adopt it in order to address their operations and become more competitive.
Furthermore, it is important to keep in mind that the purpose of any improvement program is to improve performance of the processes by increasing efficiency and developing customer satisfaction, leadership, and bottom line results by improving quality, speed and costs. For instance, the target of a Lean program is to reduce waste of the process while Six Sigma aims to reduce variations. Combining the two programs leads to process improvement

and efficient use of resources. This can be achieved by applying the tools and techniques from both Lean and Six Sigma.

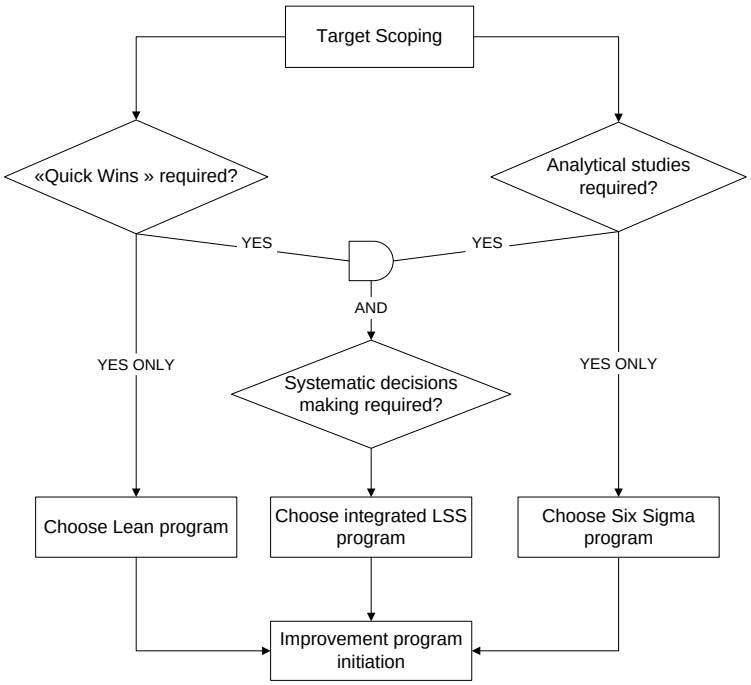

Figure 3. Some considerations inherent to improvement program decision situation.

Yet, efforts to change and improve operational performance do not seem to be very successful when they are compartmentalized. Most organizations, lead these improvement programs in a functional, operational and/or ad hoc manner rather than in a holistic or systemic way [20]. In trying to achieve improvements in one function, the result may actually be just a sub-optimization or even decrease performance for the organization overall. Functional approaches to change can also lead to fragmentation. A number of Operational Excellence programs not only requires resources, it also requires that organizations manage the dynamic big-picture, not the fragmented pieces.
Moreover, management commitment, people involvement, training skills and education about the Operational Excellence programs answer the questions why the change of the system is needed, how it is supposed to change, and what the benefits will be to the system. This education can also prepare the organization for change and create the readiness for change. Another mandatory issue is to understand the requirements of the system/process. This can make sense to the chosen techniques and tools of the improvement program.

3.2 Requirements of a pharmaceutical supply chain for inventory management

Pharmaceuticals inventory management as strategic products, in any health system, is a top priority. Inventory management in a pharmaceutical supply chain is more complex than in other supply chains because of the impact of product availability on human life. Indeed, there is a set of specific factors and requirements that contribute to this complexity. The first is that physicians are the main decision-makers regarding the procurement of prescription medicines, but they generally are not specialist of operations management and SCM techniques and practices[21] Second, the pharmaceutical industry is under strong institutional and regulatory pressures, such as the number of mainstay drugs that are ending their patent protection tenure, thereby fuelling the growing competition from generic drugs[22]. The regulatory regime of the pharmaceutical industry causes problems in determining accurate sales forecasts. This is due to the difficulty of gauging the magnitude of the competition from generics entering the market place [22].Third, pharmaceutical products are characterized by long developmental cycles that are distinctly different from medical devices. These long lead times have a significant impact on capacity planning and supply chain strategies, particularly inventory management[22].The final challenge with inventory management within the healthcare supply chains is that healthcare institutions are operationally different from the other businesses because it is extremely challenging for them to predict their patient mix and ultimately their supply consumption particularly in emergency interventions. This has major ramifications, particularly for pharmacy departments in healthcare

institutions that carry high levels of safety stock to hedge against uncertainties such as daily demand fluctuations and supply bottlenecks [22]. The net result is that healthcare institutions have to maintain excess stock to insulate them against emergencies and an unpredictable demand. For instance, these factors lead to problems such as stock-outs and drug expiry within pharmacy departments in hospitals.

3.3 Management of pharmaceuticals inventory by OE techniques and tools

Improving efficiency and effectiveness of the operation of inventory management is a far-reaching condition to achieve performance of the whole supply chain. However, investments in inventory management in healthcare are costly. For example, in USA, inventory investments in healthcare are substantial and are estimated to be between 10% and 18% of net revenues [23]. Thus, any cost savings which can be generated through a more efficient management of inventories and can lead to direct increases in profitability. Furthermore, healthcare providers focus on quality of service both from an internal and external perspective. Improving internal service levels also positively impacts patient care and this, in turn, should be lead to increases in the external measures of customer satisfaction and customer perceptions of service quality. To reach a high level of OE, the sustainability of techniques and tools should be taken into account and generally should not be separated from continuous improvement programs. Actually, there are a set of OE techniques and tools that could be used to improve inventory management process (Table 3). The application of techniques and tools for pharmaceuticals inventory management represent many strengths to leverage, weaknesses to monitor, opportunities to maintain and threats to improve. To better explain the role of OE regarding pharmaceuticals inventory management, the SWOT matrix (Table2) identifies some of the most relevant factors which affect the success of inventory management using OE techniques and tools.

Table 2. SWOT matrix for pharmaceuticals inventory management using OE techniques/tools

Strengths	**Opportunities**
- High level of support from the top management for introducing OE concepts for pharmaceuticals inventory management - Growing needs to reduce waste and variations in pharmaceuticals inventory managment - Medecines with short shelf-life - Empowerement of medical teams	- Introduction of generic pharmaceuticals - Wide range of pharmaceuticals with completely different characteristics - Low cost of implementation of OE techniques/tools - Need for flexibility (mix flexibility, delivery flexibilty, mix flexibility, new product introduction flexibility) - Positive image of the pharmaceutical supply ch ain - Potential for high demand and stable availibility of pharmaceuticals
Weaknesses	**Threaths**
- Lack of Management Information System (MIS) for pharmaceuticals inventory control - Lack of skill upgradation training and formal training for workers and managers about OE techniques and tools - Anxiety in changing the mindset of employees to adapt varying circumstances - Lack of coordination between the different actors of the supply chain	- Cost of backorders - Misjudgement of OE programs -Training all employes can be time consuming - Inventory managment process improved independently of the supply chain -Takes time to develop the skills to the tools properly - Regulatory pressures for keeping main stay stock

Considering each factor while choosing OE techniques and tools could help the pharmaceutical supply chain to get the best of OE. Moreover, the implementation of OE programs should be managed by OE professionals such as Black belt and Green belt who will involve each team member.

Table 3. Pharmaceutical inventory management targets and their corresponding OE techniques and tools

	JIT	Kanban	Poka-Yoke	QC	VSM	SD	Five S	OPF	SMED	Tack-time	ISHIKAWA	Hejunka	TPM	LB	SW	jidoka	Kaizen	SPC	CC	RA	TM	MP	CS	Bench	QFD	FMEA	DOE
Improved pharmaceuticals quality			x					x					x								x				x		x
Improved inventory flexibility	x	x										x					x	x				x	x				
Improved schedule flexibility		x																x		x		x	x				
Improved coordination		x													x					x			x				
Improved material handling						x	x										x										
Improved time-to market									x	x				x								x					
Improved on-time delivery										x			x										x				
Increased stock control	x	x												x				x	x								x
Increased service level		x																									x
Increased product availibility		x			x																		x			x	
Increased information visibility		x																									
No stock-outs				x							x			x												x	
Reliable deliveries							x																				
Reduced bullwhip effect		x		x																							
Reduced handling costs							x																				
Reduced inventory costs							x	x											x					x			
Reduced inventory levels											x			x													
Reduced labour				x								x												x			
Reduced products obsolescence	x	x	x					x			x																
Reduced safety stock	x	x																									
Imroved Streamlined purchasing		x																x									
Improved quality control at the source																x											
Improved culture and process changes				x													x										
Improves cross-functional training				x													x										
Improved elimination of wrong dispatch			x																								
Reduced forklift movements						x																					
Improved mix flexibility												x															
Improved products flow					x																						

JIT: just-in-time, QC: quality circles, VSM: value stream mapping, SD: spagetti diagram, OPF: one piece flow, SMED: single minute exchange of die, TPM: total productive maintenance, LB: line balancing, SW: standardized work, SPC: statistical process control, CC: control charts, RA: regression analysis, TM: Tagushi methods, MC: measure capability, CS: correlation studies, Bench: benchmarking, QFD: quality function deployment, FMEA: failure modes and effect analysis, DOE: design of experiment.

Finally, the OE programs could be applied with other inventory control systems; techniques and tools of OE may not necessarily offer a solution to all the supply chain's needs, but rather a solid basis to power and influence.

Conclusion

During the past years, the OE knew important but smooth evolution. Effective and efficient choice of OE techniques and tools is a difficult endeavour for every supply chain and should be aligned with its vision, culture and strategies. Moreover the pharmaceutical supply chain has to consider a much larger picture than other supply chains. The inventory management is a critical process that impacts the whole supply chain. By improving its different operations, the supply chain ensures a fluid flow of products to meet patient's demand.

This study raises several important issues that could spark further research. The most important is the evaluation of the different OE techniques/tools regarding the criteria and factors of the pharmaceuticals inventory management. The current work leads to develop a complete model in the pharmaceutical SC context that could support the decision makers and reveal the significance of certain alternatives and criteria.

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