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Lean and Current Good Manufacturing Practices in Pharmaceutical Quality System Environment

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Abstract

The present paper aims to investigate the implementation of lean manufacturing concepts and its effects in a pharmaceutical industry, focuses on abolishing or reducing waste. The paper objective is the identification and elimination of waste from the value stream as a central theme of lean philosophy. Implementing lean manufacturing program targeting to improve performance in terms of enhancing productivity, increasing quality, minimizing costs and decreasing lead time to customer order. This in turn improves customer satisfaction and increase profitability and market share.

Despite its vital role in performance improvement and waste removal, it is claimed that lean manufacturing is a difficult change to implement and long-term philosophy, and it takes great discipline from management to obtain the positive results of such a concept. Lean production continues to evolve but the basic outline is clear: design right processes to produce right results, design a production system that will deliver a product instantly on order but maintain no intermediate inventories. Lean cocept seems simple, but beneath this descriptive simplicity is sophisticated sociotchnical systems. Lean is fully integrated management and manufacturing philosophy, many benefits of these are increased by adopting the principles.

The main findings are that lean manufacturing tool has direct positive impact on the productivity and challenges facing pharmaceutical industry.

Keywords: Lean production; Toyota production system (TPS), Pharmaceutical quality system; waste; productivity.

Introduction and literature review

Lean manufacturing process results from the application of a new form of production management.

There is a vast amount of literature on lean concept and has become globally accepted by academics and manufacturers. It is not a set of procedures, but a methodology and continuous improvement mindset and a way of working that includes activities that reduces the waste inherent in any process that adds cost without adding a value and eliminating unnecessary inventory (William, 2000). In 1990 Womack, Jones and Ross created the term lean production, since then, it has become common to use the word lean as a shorthand for lean production.

Implementing such a concept reduces the time from customer order to delivery by eliminating sources of waste in every aspect of the organization. Lean as a concept uses a variety of tools to assist improving quality. To become lean requires a specific way of thinking, philosophy and management system. Toyota production system (TPS) is a series of simple innovations might make it more possible to provide both continuity in process flow and guide variety in product offerings**. Toyota production system is following "4P" model as:**

- Long-term philosophy.
- The right process will produce the right results.
- Add value to the organization by developing people.
- Continuously solve Problems drives organisational learning.

Bhasin, (2012) revealed that less than 10 percent of UK organisations have accomplished a successful lean implementation. The major difficulties encounter the companies in attempting to apply lean manufacturing are the lack of direction, planning, and adequate project sequencing as well as the lack of senior management total commitment.

According to Nordin et al. (2010) failure rate in implementing lean concept was high. Some reported problems and issues regarding the high failure rate of lean manufacturing implementation may be attributed to cultural differences that occur during transition or translation of the concept. A number of studies have argued that efficient communication at all levels must be maintained and sustained in order to ensure success in lean implementation (Angelis et al. 2011, Losonci et al., 2011).

Success or failure of lean manufacturing from worker's point of view can be derived largely via employee's own experience.

Human skills such as effective communication, problem solving, teamwork and leadership debates, are vital for success, hence people and culture change are predominant reasons for lean failure. Whilst lean is concerned with reducing wastes at all levels, it is also about changing corpo-

rate culture (Bhasin and Burcher, 2006). To ensure success organisations need to view lean as a long-term strategy and both culture and strategy should go in parallel to achieve the desired goals. The decision to engage in lean practices is often part of the organisation's manufacturing strategy.

An in-depth description of the necessary changes in organisation's culture, the determination and commitment of the senior management, its role in coaching and empowering the workforce as well as in providing the required means for sustaining the change towards lean concept can be found in (Papadopoulou and Ozbayark, 2005).

Shah and Ward (2003) draw attention that the success of implementation of any particular management practice such as lean frequently depends upon organizational characteristics, and not all organisations can or could implement the same set of practice.

▪The rise of lean production

Womack et al. 1990 in their celebrated widely read and most cited book entitled "The machine that changed the world", it was a straight forward account of the history of automobile manufacturing and automotive assembly plants. The book provides an essential guide to managers and leaders in every industry seeking to transform their traditional organization to lean. What was new was a term "lean manufacturing". The term is coined to represent half the human effort, half the manufacturing space so that face-to-face communication is easier, half the investment in tools, half the engineering hours to develop a new product in half the time, and the elimination of waste are the basic principles of lean manufacturing. The term "lean" as Womack and his colleagues define it denotes a system that utilizes less, in terms of all inputs to create the same outputs as those created by traditional mass production system.

This philosophy goes by different names, Agile, just – in – time, synchronous, world class and continuous flow are all terms that are used in parallel with lean manufacturing. Historically, the pioneering work of Frederick W.Taylor looked at individual workers and work methods. That resulted in "time study and standardized work". It is one of the earliest ate-mpts to apply science to the engineering of processes and management. Taylor called his ideas "Scientific management" without mentioning the behavioral sciences, later known as "Taylorism". Later Frank Gilbreth added "motion study" and invented process charting. Process charting focused attention on all work elements including those non-value-added elements which normally occur between elements (Besterfield, 1998). As Taylorism ignores the individual difference Lillian Gilbreth brought psychology into the mix by studying the motion of workers and how attitudes affected the outcome of a process Frank Gilberth with his wife Lillian developed the time – and – motion study

as applied to industrial employees to increase their efficiency. These were the people who originated the idea of "eliminating waste", a key of just-in-time and lean manufacturing (Andrea, 2012)

▪The Ford System

Starting about 1910, henry Ford established the first comprehensive manufacturing strategy. Aimed to achieve higher productivity of mass production by standardizing the outputs, using assembly lines and breaking the work into smaller tasks, later known as Fordism. The main goal of Fordism is to lower the manufacturing cost of automobile. This was based on Taylorism.

Ford took all the elements of a manufacturing system and arranged them in a continuous system. Ford is considered by many to be the first practitioner of just – in - time and lean manufacturing. Ford's success inspired many others to copy his methods. Interestingly, it is even doubtful that ford himself fully understood what he had done and why it was so successful.

When the world began to change, the Ford system began to breakdown and Henry Ford refused to change the system. Product Profilation and the decline of mass production in western nations, and the advent of labor union also put strains on the Ford system. The problem with Ford's system was not the flow, rather it was his inability to provide variety and never changing product. This did not cope well with new products.

There are several significant features of Taylorism and Fordism that led to the increase in productivity but both provide means of increasing control over the workers.

▪TheToyota production system (TPS)

The Japanese studied American production methods with particular attention to Ford's original thinking, practices and the statistical quality control practices (SQC) of Ishikawa, Deming, and Juran (Hoyle, 2007)

At Toyota motor company they began to incorporate Ford productivity, statistical process control (SPC), and other techniques into an approach called "Toyota Production System" or just – in – time manufacturing.

Two pillars needed to support the TPS for waste elimination. Just – in – time production and automation (Jidoka) or automation with a human touch (built in quality). For a historical path of the systems and the birth of the Japanese management systems (Liker, 2003; Andrea, 2012).

In the last few years, much more information on lean has become available. One of the interesting sources in that field written from the perspective ofa consultant (Lonnie Wilson, 2010).

He declared that it is not too difficult to design and implement a pull production system that is balanced, operating at takt, and has short lead times and high level of quality. To

sustain this requires a culture that embraces the concept of continuous improvement. Managing the culture makes (TPS) unique among lean organisations. The book offers a great deal of practical advice, theories and "how to" approach for an easy application. More recently (David Mann, 2015) address lean system for management as a concept and advocated that it is crucial ingredient for successful lean conversions. The book includes a clear description on how lean management acts as a driver of continuous improvement beyond sustaining the initial gains from lean production through focusing on processes.

Lean production and lean management are closely related methods; lean management is more than just a production management system. It involves improvements within the management.

Liker (2003) presented "The Toyota way" as a set of principles and behaviors that underline he Toyota motor corporation's management approach and production system**. The system can be summarized in 14 principles. In four sections:**

- Long term philosophy.
- The right processes will produce the right results.
- Add value to the organization by developing people.
- Continuously solve root problems drives organizational learning.

The book provides the tools for people to continuously improve their work.

▪ Just– in– time (JIT) production

JIT is an integrated set of activities designed to achieve high – volume production using minimal inventory. According to Ohno (1988) just – in – time means that, in a flow process, the right parts needed in assembly reach the assembly line at the time they are needed and only in the amount needed. The goal is an implementation of a flow production with zero inventory. When trying to work just – in – time, people at Toyota experienced that conventional operation management methods did not work well, which resulted in huge and wasteful inventories (Shingo, 1989). Toyota system discovered that factory workers can share contribution. This discovery originated in quality circle movement and team development (Dale Besterfield, 1998; Donna Summer, 2006)

▪ Automation (Jidoka)

It is a series of technical and cultural issues regarding the use of machines and manpower together, utilizing people for the unique tasks they are able to perform and allowing the machines to self – regulate the quality. This human-machine intelligence led to dramatic productivity imp-rovement. It is the concept that no bad parts are allowed to progress down the production line, whenever a defect product is produced the machines stops automatically. Ohno's theory (1988) lacks the direction that the key to successful TPS implementation is the

total commitment of everyone in the organisation to make it work. Also, Temple et al. (2001) criticized that Ohno's TPS does not deal with complex process control problems and does not give an answer to solve complicated problems across.

For in depth search for the origins of lean production and fall of mass production, it is important to go much farther back in time. Womack et al. (1990) addressed the revolution in manufacturing represented by the Toyota production system (TPS) of the Toyota corporation in Japan. Ohno (1988) the creator of the Toyota production system (TPS) advocated in his book that (TPS) is not just a production system but a management system adapted to day's era of global market. He presented three key statements. Which when taken together define (TPS):

- The basis of the (TPS) is the absolute elimination of waste.
- Cost reduction is the goal.
- After Japan has lost world war II, the main concern was how to produce high – quality goods.

After 1955, however, the question became how to make the exact quantity needed. TPS developed by Toyota motor corporation revolutionized ma-nufacturing method. A great value of the book is to learn how to think about operations and process improvement.

Based on these statements TPS is a production system which is a quantity control system whose goal is cost reduction, and the means to reduce cost is waste elimination (Wilson Lnnie, 2010). A remarkable book (Shingo, 2009) describes approach to manufacturing improvement using what he calls scientific thoughts mechanism (STM). Some of his thought are: respect every individual, focus on processes, assure quality at the source, create consistency of purpose, create value for the customer and seek perfection.

The concepts of both Ohno (1988) and Womach and his colleagues (1990) search for ways to reduce lead time by eliminating wastes. It can be said that they pioneered the idea of applying the concept outside of manufacturing environment.

Lean manufacturing techniques have been around for a long time and can greatly simplify a production process.

It is the identification and elimination of waste from the value stream. Lean manufacturing is a dynamic and constantly improving process dependent on the understanding and involvement of all of the organization employees. Its implementation leads to higher quality, lower cost, and reduced lead time.

The Japanese philosophy of doing business is totally different than the philosophy that has been long prevalent in the west. The traditional belief in the west had been that the only way to make profit is to add it to the manufacturing cost in order to come up

with a desired selling price (Ohno, 1988, Mondem 1998).

On the contrary, the Japanese approach believes that customers are the generator of the selling price. The more quality one builds into the product and the more service one offers, the more the price that customers will pay. Therefore, the lean manufacturing discipline is to work in every facet of the value stream by eliminating waste in order to reduce cost, generate capital, bring in more sales, and remain competitive in a growing global market. Again (Womack and Jones, 2003) in a subsequent volume entitled "lean thinking" summarized the ideas of lean manufacturing based within (TPS) approach to the elimination of waste in every aspect of an organisation's operation.

▪ Lean thinking: the principles of lean manufacturing

Lean thinking consists of a continuous cycle of five basic guiding principles highlighted by Womack and Jones, 2003, **the goal is to eliminate waste:**

1. **Specify value desired by the customer**

Every organization needs to understand what value the customer places upon products and services. It is the organisation's job to eliminate waste from the business processes so that the customer's price can be achieved at great profit to the organization.

2. **The value stream for each prod - uct**

It is the entire flow of the product's life – cycle from the origin of the row materials used through to the customer's cost. Studying and understanding the value stream and the value-added and waste can an organization specify the waste associated with manufacture and delivery of a product/service.

3. **Flow without interruption**

If the value chain stops moving forward for any reason, then waste will be occurring. This implies to create a value – stream where the products never stop in the production process, and fully synchronized with the other elements. Carefully designed flow across the entire value chain will tend to minimize waste and increase value to the customer

4. **Pull approach between all steps**

It is the way to ensure that nothing is made ahead of time based on forecast. Pull approach states that the organization do not make anything until the customer orders it. To achieve this requires great flexibility and very short cycle time of design, production, and delivery of products/services. It also requires a mechanism for informing each step in the value chain what is required of them based upon meeting customer's needs.

5. **Manage towards perfection** (number of steps and amount of time needed to serve the customer falls)

A lean manufacturer sets his target for perfection. The principles of total quality management are to systematically and continuously remove the root causes of poor quality from the production processes so that the organization and its products are moving continuously towards perfection. Also, perfection is sought through the use of standards, Kaizen, 5S, 5 why's, 5 M's and similar methods for continuous improvement. Lean production employ teams of multi-skilled workers at all levels of the organization and use highly flexible, increasingly automated machines to produce volumes of products in enormous variety. Organisations that have mastered lean design will offer a wide variety of products and replace them more frequently than mass-production. The next section presents a brief overview of pharmaceutical quality system.

Pharmaceutical Industry

Pharmaceutical Industries include the manufacture, extraction, processsing, purification, and packaging of chemical materials to be used as medications.

Pharmaceutical manufacturing is divided into two stages:

(i) The production of active ingredient.

(ii) The conversion of the active drugs into products.Pharmaceutical have become indispensable part of–health care system and considered to be one of the largest growing global industries. Also, it is a major source of intensive labor generation and foreign exchange earning in many countries. However, despite all these extraordinary achievement, millions of people mostly in low income countries die due to unavailability and in an accessibility of necessary medicine (WHO, 2011).

▪ Current good manufacturing practice (cGMP)

World Health Organization (Who, 2011) issued a primary regulation to pharmaceutical industries entitled good manufacturing practice (GMP) for pharmaceuticals. The objectives of the regulations are to deliver high quality, safe medicines manufactured and distributed following controlled procedures to treat diseases. GMP has evolved gradually, however the recent scientific risk – based framework and the process analytical technology (PAT) supported the innovation of current good manufacturing practice (cGMP). A comparison of cGMP with lean suggest that they belong to two conflicting families. While cGMP focuses on manufacturing to produce safe effective product for the patient, lean focuses on manufacturing focusing on customer's perspective. One of the characteristics of a cGMP manufacturing environment is the abundance of documented processes such as standard operating procedures (SOP), testing methods, environmental

controls, and training programs. This documentation can be divided into technical standards and operational procedures.

The food and drug administration (FDA) has issues regulatory guidelines known as current good manufacturing practice (cGMP) – reminding manufacturing that they must employ an up-to-date technological systems and good laboratory practice (GLP) to assure that the market of drug product has been properly manufactured and clinically tested.

▪ Process analytical technology (PAT) initiative.

The goal of PAT is to understand and control the manufacturing process, which is consistent with drug quality system: quality should be built in or should be by design.

Pharmaceutical Quality systems

The international council for Harmonisation of Technical Requirements for registration of Pharmaceuticals for Human use (ICH) issued more than 50 harmonised guidelines and provided for quality, safety, efficacy, andmultidisciplinary guidelines (http-:www.ich.org)

Greene and D. O'Rourke (2006) explored the introduction of lean manufacturing into the pharmaceutical sector and identified challenges that result.

The (ICH) guidance assist pharmaceutical manufacturers by describing a model for an effective quality management system for the pharmaceutical industry referred to as the pharmaceutical quality system (ICHQ10). The (ICHQ10) as a model can be implemented throughout the different stages of a product life cycle and based on international organization for standardization (ISO) quality concepts and includes applicable good manufacturing practice (GMP) regulations. It complements pharmaceutical development (ICH Q8), and quality risk management (ICHQ9) (ICH guide line Q10).

The elements of (ICHQ10) should be applied in a manner that is appropriate and proportionate to each of the product life cycle stages recognizing the differences among, and the different goals of each stage.

Implementation of (ICHQ10) model results in achievement of three main objectives that complement or enhance the required GMP requirements:

1. Achieve product realization.
2. Establish and maintain in a state of control.
3. Facilitate continual improvement (FDA) (http://www.fda.gov).

Ohno, 1988 identified several types of manufacturing waste (mada). In order to speed the flow and improve processes work processes are redesigned to eliminate waste through process of continuous improvement (Kaizen). Wastes are not found just in the production processes but can also be

applied to administration and other processes. **Types of waste are:**

1. Overproduction (producing more than needed).
2. Waiting time (idle time when events are not fully synchronized).
3. Unnecessary transport (carrying work in process long distances.
4. Over processing (incorrect processing).
5. Excessive inventory.
6. Unnecessary movement.
7. Defects (repair or rework of product/service – scrap).
8. Unused employee creativity.

Why pharmaceutical waste?

Pharmaceutical waste is classified on the basis of their biological, chemical, and physical properties. These properties generate materials that are either toxic, reactive, explosive, infectious, or radioactive, poisons, even in very small amounts. They may have acute effects causing injury, illness or death.

▪ Lean manufacturing practice in current good manufacturing practices

Elsayed,2016 listed several lean tools, of interest is the process analytical technology (PAT) initiative, its goal is to understand and control the manufacturing process, which is consistent with current drug quality system: quality should be by design.

The principles of FDA's and (PAT) initiative appear to be extremely aligned with lean manufacturing thinking suggesting a positive outlook & lean pharma (Greene and O, Rourke, 2006)

GMP together with risk-based framework and process analytical technology initiatives developed by regulatory authorities to support innovation and efficiency in cGMP environment. cGMP for final medicinal products are clearly defined in each country and region. A common objective is to deliver high quality, safe and effective medicines, manufactured following controlled procedures.

▪ Relationship between Lean and cGMP

In a Lean manufacturing environment, every customer-supplier connection is direct with unambiguous ways to communicate.

As the overall goal is to keep product flowing, consistent cycle time is an indicator of good customer-supplier relationship. In cGMP environment product cycle time is quality driven, while cGMP focuses on manufacturing as a means to produce safe effective products that prevent harm, Lean focuses on reducing waste and balance quality with productivity and decrease cycle time as an improvement and value creation.

Lean and cGMP must be equal partner, both are imbedded into the culture of the organization and business strategy, despite their different implementation tools.

▪ Research methodology and implementation

The research aimed to shed light on the impleme-

ntation of the lean concept in a pharmaceutical industry and the principles of TPS to:

- Determine the most common wastes that pharmaceutical industry focus to eliminate and the suitable used tools/techniques for lean implementation.
- Identify the critical success factors (CSF) for Lean implementation in pharmaceutical industry.
- Determine the most challenges can lean take a part of the problem solving.
- Identify the relation between lean and cGMP
- Identify the relation between lean and pharmaceutical quality system (PQS).
- Identify the relation between cGMP and (PQS).

Research hypotheses

Hypothesis (H_1): lean manufacturing tools are seen as an efficient management tool and have a positive impact on pharmaceutical performance towards waste removal.

Hypothesis (H_2): lean tools have a positive impact on the challenges facing pharmaceutical industry.

Hypothesis (H_3): lean tools have a positive impact on continuous good manufacturing practice (cGMP).

Hypothesis (H_4): lean tools have a positive impact on pharmaceutical quality system (PQS).

The research adopts quantitative method, the survey strategy is associated with deductive approach as it seeks to confirm hypotheses about lean implementation in pharmaceutical environment, and emphasize the themes related to lean concept. The hypotheses of the study have provided the basis for analyzing data in a meaningful manner.

A questionnaire was designed to ask all potential participants identical questions in the same order. A pilot sample was distributed for testing its validity and reliability to measure its internal consistency. Furthermore, a focus group performed on two groups to gather data related to feelings and opinion of participants involved in several segments of pharmaceutical industry to get fresh data generated through interaction of participants.

Group 1: classified according to job title from several sectors in a pharmaceutical organization.

Group 2: classified as top management level.

The purpose is that it allows for meaningful comparison of responses across participants from the two groups to get range of possible responses, and to make sure that all segments of the pharmaceutical industry was represented.

Selecting the most appropriate sample

The quality of the sample is an important as its size (Collis and Hussey,2009)

As data collected from a number of organization that applied lean principles have on average more than seven

years of experience in lean practices, it could not be possible to collect data from the entire population. In order to make sure that all segments of the pharmaceutical industry are represented in the sample, stratified random sampling was used (Proportional method). Net sample size of 100 of potential employees from several sectors were asked to fill the questionnaire, it include a combination of open and closed questions. Questions were linked to different variables to test the four hypotheses.

In order to avoid measurement errors, repeatability error was tested (test- re- test). Results of this re-test analysis allowed to understand that no major repeatability issues existed. (Sekaran and Bougie, 2016).

The independent variables (IV) related to different lean techniques will be correlated to four dependent variables (DV) which are:

- Lean performance
- Challenges facing pharmaceutical industry
- cGMP
- PQS

The questionnaire consisted of three major parts, the first included general questions to determine the respondent's profile and to assess their expertise in lean concept (7 questions) and verify if the organization apply lean in the sense of TPS. The second part included (12) questions designed to focus on undertaking a lean concept. In the third part (9 questions) participants were asked to indicate whether they have used the best practices that contributed to most of a lean project's success. The paper will explore their findings.

Results and analysis

Data from a survey from more than 30 published reference cited in (Elsayed,2016) that investigated lean principles showed that the most critical wastes that faced pharmaceutical industry and affect its performance are: waiting time, inventory, and defect.

The most used lean tools/techniques to solve the critical wastes are: Kaizen.5 S, value stream map, just-in-time, Toyota production system, and FMEA.

As for the identified critical success factors**, the survey revealed the following factors:**

1. Management commitment; employee involvement; reward and recognition; education and training.
2. Management support, communication.
3. Link of lean with the strategic objectives to properly utilize lean resources; application of lean concepts in all functions; and creating a lean culture within organization for improvement, and product development.
4. The appropriate application of the process performance measurement system to evaluate lean management.

Analysis of questionnaire's results

The data obtained from the questionnaire were analyzed using descriptive statistics (Sekaran and Bougie,2016) to test the hypotheses to:

- Determine the most common waste(s) in pharmaceutical industry.
- Focus to evaluate the suitable lean tools and techniques to determine waste in pharmaceutical industry.
- Study the synergetic effect among managing pharmaceutical challenges and achieving improvements in cGMP environment and pharmaceutical quality system (PQS).

A scale analysis on all variables was performed using the software package for social sciences (SPSS) in order to test the reliability of the variables. This resulted that all variables are reliable with a Crombach's alpha of 0.819 in the top management group and of 0.836 in employees group. This ascertains consistency.

Table 1: A Compendium of correlation and linear regression between groups.

Group	Variables			
	Independent variable	Dependent variable	Results	Interpretation
Top Management	Lean Tools/techniques	Lean performance	0.000	Significant
		Lean & pharmaceutical challenges	0.002	Significant
		The relation between Lean, cGMP, and PQS	0.000	Significant
Employees		Lean performance	0.000	Significant
		Lean & pharmaceutical challenges	0.008	Significant
		The relation between Lean, cGMP, and PQS	0.036	Significant

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- Interestingly table (1) highlights that as all values of the variables in both groups are less than 0.05, this indicates accepted hypotheses, assuming confidence level of 0.05%.

This indicates that lean tools and techniques are seen as an efficient management tools that eliminates waste problems and has direct positive impact on the productivity in pharmaceutical industry.

- Lean tools have a positive impact on the challenges facing pharmaceutical industry.
- Lean tools have a positive impact on lean performance, cGMP, and pharmaceutical quality system (PQS). As all of these have an effective impact on the productivity and quality.

Discussion:

Table 2: Commonalities of previous literature and current research

Item	Literature reviews	Current Research
Successful tools	Kaizen,5s, VSM, J-I-T, SOP, TPM, FMEA	Kaizen,5s, VSM, J-I-T, SOP, TPM, FMEA, DOE
Pharmaceutical performance	Waiting time, Inventory, Defect	Waiting time, Inventory, Defect, over production, transportation

A remarkable result from table (2) is that the current research bears a close resemblance to the previous literature.

Participants showed that transportation often leads to operations having to wait for raw materials or products to be delivered due to delay.

Both top management and employees think that lean tools and techniques have a positive impact on the challenges facing pharmaceutical industry as:

- Reducing the cost and at the same time maintaining the quality of the products.
- Changing commercial business model from indirect to direct marketing and sales
- More responsive supply chain from "Push" to "Pull" driven
- Remain competitive in the market.
- The pharmaceutical quality system (PQS/ICH Q10) can be perceived as "expensive" and non-value adding

by some areas of GMP, while ICHQ10 is supporting the requirements of the quality management system ISO 9001/2015 considering risk-based thinking throughout the organization.

- Pharmaceutical industry already has its own standard correlated to lean concept by applying process analytical technology (PAT) and ICHQ10 principles.

Conclusion

Competition from low-cost countries and faltering home economics has turned the attention of manufacturers to operational costs and waste reduction. The current descriptive research aimed to shed light and provide portrayal of the implementation of the concept of lean production and the TPS philosophy in pharmaceutical industry performance, and how it could be helpful technique that may be used to face challenges in pharmaceutical industry, as well as studying the effect and the relation between, Lean, cGMP, and pharmaceutical quality system (PQS). The findings of the study indicate that the most successful technique and lean tools are Kaizen,5s, VSM, TPS, J-I-T, SOP, TPM, FMEA and DOE.

This conforms and matches literature. It is concluded that design of experiment (DOE) beside the previously identified aspects play more important role towards implementing TPS. The research underlined that lean concept has a positive impact on the challenges facing pharmaceutical industries through maintaining the quality of products, changing commercial business from indirect to direct marketing, and more responsive supply chain from "push" to "pull" driven. In a lean pharma manufactuing environment, cGMP and lean concept must be equal partners and embded into organization's culture. Cultural and design of experiment aspects play important role in the current pharmaceutical industry.

There is no question that the elimination of waste is an essential ingredient for survival in today's manufacturing world for improvement. Improvement is hard work, it requires smart managers, great leaders, and empowered employees.

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