

Implementation of Lean six sigma For Improving Supply Chain processes in a Pharmaceutical Industry

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Abstract

Lean and Six Sigma are recent developments in continuous improvement methodology that have been popularized by several high-profile companies. The success and complementary nature of these methodologies has led to their combination into a single methodology, commonly called Lean Six Sigma or Lean Sigma. Although there is considerable literature available and many consultants involved with Lean Six Sigma, very little published research addresses the practical experiences of companies that have implemented Lean Six Sigma. The research questions for this research are what extent applying the lean six sigma concept in supply chain process will improve the physical and information flow of the raw materials and finished goods. And what extent improving of the supply chain process by applying the lean six sigma concept will affect Delivery and speed, Quality, Flexibility, and Cost.

Index Terms—Lean; Six Sigma; Healthcare; Pharmaceutical products

1 INTRODUCTION

This research's purpose is to assist the supply chain process in pharmaceutical industry in the term of continuous improvement program that abates or eliminates the negative effects caused by deployment barriers and implementation challenges, and to eliminate the processes waste by using the combination of lean and six sigma in one methodology of DMAIC

Supply Chain is the movement of materials as they flow from their source to the end customer. Supply Chain includes purchasing, manufacturing, warehousing, transportation, customer service; demand planning, supply planning and Supply Chain management

In this research Lean and Six Sigma (DMAIC Methodology) has been applied to improve the physical and information flow for both raw materials and finished goods and in what extent implementation of this integrated approach will improve the supply chain processes in the terms of Quality, Delivery and speed, Flexibility, and Cost.

1.1 Pharmaceutical Supply Chain

The pharmaceutical supply chain will consist of one or more of the following nodes: supplier, pharmaceutical manufacturer, distributor, pharmacy, and consumer or patient [1] A typical structure of these supply chain [2] is shown in Figure 1.

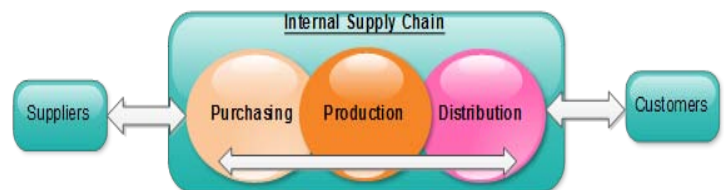


Figure 1 Supply Chain Process

In the past, pharmaceutical industry did not adopt supply chain management concepts [3]. However, now several factors are pressing each component of the pharmaceutical supply chain to change their traditional manners of conduction business [4], [5]. According to Healthcare & Life Sciences Supply Chain Report 2010, controlling cost, globalizing supply chain and improving visibility or tracking are the biggest supply chain priorities, as well as, visibil-

ity or tracking issues are the biggest obstacles to globalizing pharmaceutical supply chain.

2. REVIEW OF METHODOLOGY

2.1 Lean Methodology

The companies' need for constant improvement and evolution leads to the search of management tools and methods to foster the development of customer service and to reduce the costs for all associated processes. Accepting this perspective of management, where the achievement of excellence through continuous improvement of procedures and processes and the search for new management concepts are emphasized, led several companies to engage in management strategies where the assumptions of the "lean" philosophy are key.

The basic concepts of the *Lean* philosophy arose initially from the 50s in Japanese companies and have been developing it up to today. These concepts are centered on just-in-time, where the only goal is the production of products only at the time they are requested [6]. The term "lean" is emerging as a new designation for production / management "philosophy" that opposes the concept of "mass production" [7].

In 1996, they published a second book *Lean Thinking*, and defined Lean thinking as "*a way to specify value, lineup value-creating actions in the best sequence, conduct those activities without interruption whenever someone requests them, and perform them more and more effectively.*

In short, lean thinking is lean because it provides a way to do more and more with less and less – less human effort, less human equipment, less time, and less space – while coming closer and closer to providing customers with exactly what they want". This book provides the conceptual framework for categorizing all of the tools and practices of Lean production into five basic areas, the principle of Lean production can be show in Table 1.

Although Lean production is focused on effectiveness in the production process, Lean thinking is more focused on the efficiency in the company as a whole, including nonmanufacturing: administration, and service [9].

2.2 Six Sigma Methodology

Six Sigma is a methodology to reduce the number of product defects and to reach organizational excellence. It helps the organization to achieve a competitive advantage [10]. This is a structured methodology with systematic statistical-based techniques, which is used to improve the performance of processes / products or quality of a service by reducing process variation [11].

Table 1: The Lean Principle [8]

Principle	Description
Value	Define value from the standpoint of the Customer
The Value Stream	View your product delivery system as a continuous flow of processes that add value to the product
Flow	The product should constantly be moving through the value stream toward the customer at the rate of demand.
Pull	Products should be pulled through the value stream at the demand of the customer rather than being pushed on the customer
Perfection	The never-ending pursuit of eliminating waste in the system such that products can flow seamlessly through the value stream at the rate of demand.

In addition to statistical techniques, the methodology also incorporates other concepts such as financial analysis and project planning [12]. To systematize the application of this methodology in process improvement is often used a formal method called DMAIC (Define, Measure, Analyze, Improve and Control) [13].

This method is a closed loop that allows for the elimination of certain phases of a process (those with no added value to the product or service) and allows concentration on new metrics and application of different technologies for continuous improvement. The use of DMAIC steps causes the realization of actions in a sequential and logical way, and in accordance with the scope of the project [14].

Many of the tools and techniques may be applied in more than one stage of the methodology, since their purpose may coincide with the objectives of the

tasks of each phase [14]. The Six Sigma is a philosophy that has evolved gradually with the results obtained in various organizations (industry and services) [15].

One of the main factors when selecting a Six Sigma project involving services is positive financial impact and increased customer satisfaction [16].

Like any quality improvement methodology, there are limitations in its implementation. Moreover, the service sector exhibits an increased difficulty, since this sector has highly dynamic processes [10, 17]. There are many possibilities of implementing Six Sigma projects in the service sector. But it is important to strictly define the characteristic of the process that will be measured, to ensure that it is critical for customer satisfaction and for the level of service quality.

2.3 The Integration of Lean and Six Sigma Methodologies

Lean and Six Sigma are the two best continuous improvement methodologies widely used by various industries [1]. Lean is used to deliver products and services better, faster and at a lower cost, meanwhile, Six Sigma is used to achieve stable and predictable process results, reducing process variation and defects. Lean is developed within the Toyota Production System in the 1970s based on the teachings of Ford, Japanese experts and others, while Six Sigma originally introduced within the Motorola Research Centre in mid-1980s [1], [18].

Lean and Six Sigma methodologies are different but complementary, both attempt to improve the process: Lean assumes that waste removal will speed up the process by which improving business performance, Six Sigma assumes that process variations result in process problems and the reducing process variation will improve business performance [1], [19].

LSS can be described as a methodology that focuses on the elimination of waste and variation using DMAIC structure to accomplish customer satisfaction with regards to quality, delivery, and cost. The relationship between the five Lean principle and Six Sigma DMAIC is shown in Figure 2.

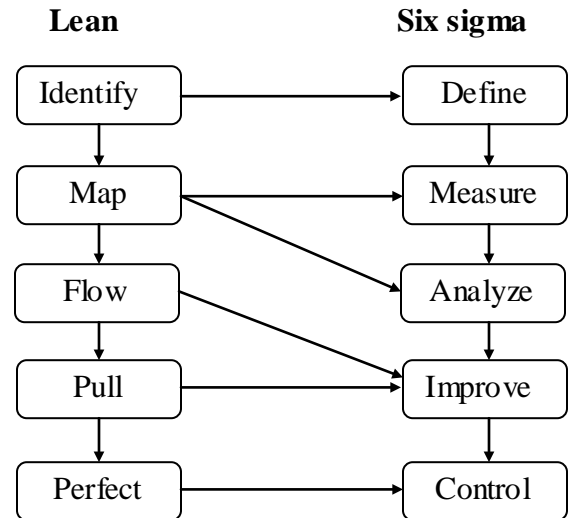


Figure 2: The relationship of Lean and Six Sigma

Modified Approach for Lean and Six Sigma Implementation

In this section, we combine Lean principles and Six Sigma methodologies within a modified approach based on the main concept of DMAIC structure that successfully used to improve several processes in the previous literature.

The problem-solving approach for Lean and Six Sigma implementation is shown in Figure 3.

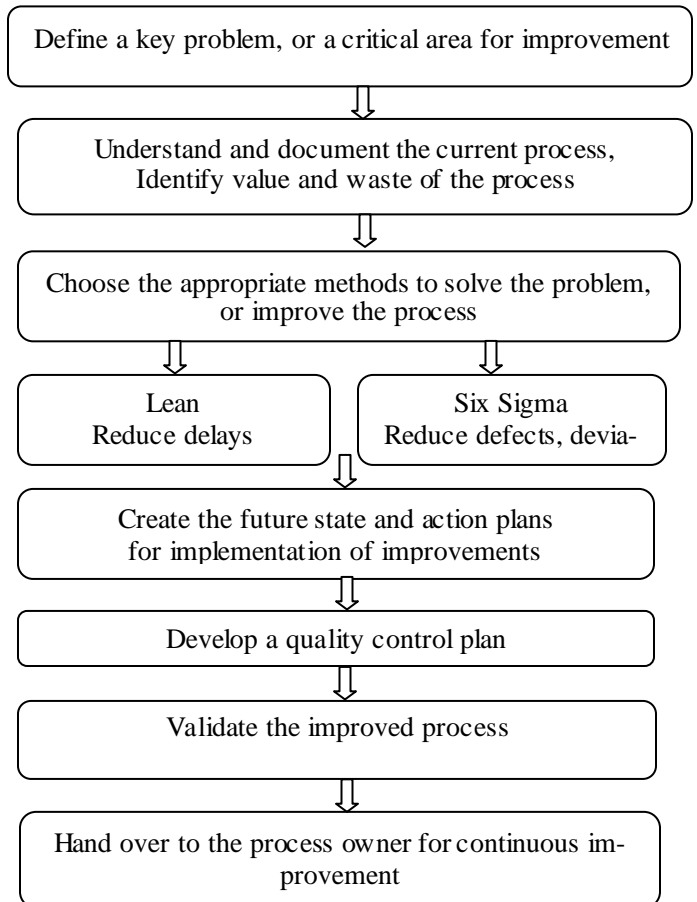


Figure 3: Modified Approach of Lean and Six Sigma

Case Study

Research Problem

As a result of monitoring the efficiency working circle of supply chain process of the raw materials and finished goods, there are some of Current problems:

1- Raw Materials flow:

Stock out of some of raw materials, which affect efficiency of the production plan.

Over inventory of other materials, that has the impact on the cash Flow, return rate, inventory risk, and inventory capacity.

Data error and duplication, differential between the actual and theoretical stock.

Over transportation, over motion, Inappropriate Processing, poor manual recording system.

Dissatisfaction of the production peoples due to low performance of the Raw materials Store.

2- Finished goods flow:

Delaying in the implementations of sales orders. over inventory of some products.

Shortage in the availability of some other products.

Dissatisfaction of the distributors and the sales teams, Data error and duplication, differential between the actual and theoretical stock.

Over transportation, over motion.

Complexity and Inappropriate Processing in Documentation Cycle, Poor manual recording system

Research KPI'S

Raw Materials flow

- Lead Time Variation availability of Raw Materials.
- Preparation time of raw material of the sampled product Safety stock value.

Finished goods flow

- Preparation time of sales order.
- Safety stock Value.
- Working man hours.

Define

The purpose of the first phase of the DMAIC process is to identify and refine a process in order to meet or exceed the customer's expectations. The Define phase includes developing the team charter as shown in table 2, critical to quality characteristics, problem statement, communication plan, project scope, and goal statements.

In this stage the following points will be addressed:

- Define & Scope Problem.
- Determine Project Objectives & Benefits.

- Create Project Charter.
- Create Value Stream Mapping.

Project Charter

Table 2 Project Charter

Project Name:	of Implementation of Lean six sigma in Supply Chain of the Pharmaceutical Industry		
Business Case:	Opportunity Statement (High Level Problem Statement):		
improve the performance of the physical and information flow for both raw material and finished goods supplying process, that avoiding shortage and non-availability of many items	Reducing preparation lead (cycle) time, Establish Safety Stock calculation, Enhance the monitoring system By applying Lean six sigma in this process Which have some of expected business impacts in the terms of: - Delivery and speed, Quality, Cost, Flexibility, Moral.		
	Defect Definition: Time waste and Variation		
Goal Statement:	Project Scope:		
1- Establish safety stock calculations in both finished goods and raw materials stores.	Process Start Point: Begin from receiving the annual sales plan which is translated into production plan		
2-Enhance the documentation system, and improve the monitoring system of stock.	Process End Point: The distributors receive the finished goods as the end of sales orders.		
3- Eliminate the non-Value added to improve the cycle time of the preparation time of production and sales orders.			
4- eliminate the Non Value added in the distribution process flow			
Expected Savings/Benefits:	In Scope: the information and physical flow of raw materials and finished goods		
	Out of Scope: All the production stages		
Project Plan:			
Task Phase	Start Date	End Date	Actual End
Define phase	1-7 -2011	31-7-2011	31-7-2011
Measure phase	1-8-2011	31-8-2011	31-8-2011
Analyze phase	1-9-2011	30-9-2011	30-9-2011
Improve phase	1-10-2011	23-1-2012	23-1-2012
Control phase	23-1- 2012	3-3-2012	3-3-2012

Defining the Process with SIPOC:

It’s important to get a high-level understanding of the scope of the process first. A SIPOC Process definition helps the Process Owner and those working on the process to agree the boundaries of what they will be working on. It provides a structured way to discuss the process and get consensus on what it involves before rushing off and drawing process maps, as shown in table 3

Table 3 SIPOC Diagram

Process: Supply chain					
Suppliers	Input		Outputs	Customers	
Sales (Abbott)	Forecast Plan		Production plan	Planning TPM Dep.	
TPM (Abbott)			Purchasing Plan		
Planning TPM Dep.	Production Order			Raw materials	Production Departments
Production TPM Dep.	Production order			Finished Goods	
Store of R.M	Preparation R.M Order			Product R.M Order	Dispensing Center
Store of F.G	Preparation F.G Order			F.G receipt	Distributors
				Distributors Sales Sheets	Finance(Abbott)

Measure

In this phase, it will be focused on how to reach the main (Non-Value Added) How long it takes for any work item to make it through the process from beginning to end in the Supply Chain process in both Loops Raw materials and finished goods In this stage the following points will be addressed:
 Measure performance standards.
 Measure system analysis.
 Measure process cycle efficiency.
 Time value analysis.

The Scope of the Project has two Loops as shown in figure 4

- List of Hot Spots loop 1

- 1- Non accurate Bill of materials; which cause many defects and data errors in requirements plan, the actual stock often is different from the theoretical Stock.
- 2- Bad Communications between planning and purchasing Department about the implementation of purchasing plan; which cause many defect, waiting, shortage and over inventory.
- 3- Non accurate following up the implementation of purchasing process of raw materials which cause many shortages and stock out. High Variation of purchasing orders lead time which causes shortages in availability of raw materials.
- 4- There are three different stores due to bad layout; which cause over motions and waiting through storage process and data errors. No effective coding system of the raw materials; which cause many defects.
- 5- Preparing production orders; there are over motions due to many stores, non-effective storage system, there are many shortage in availability of many raw materials items due to non- available safety stock. There are data errors due to non-effective coding system
- 6- There are data errors due to non-effective coding system, and main store have no feedback about the bill of materials of each product.
- 7- There is data duplication in operation orders; due to Problems in coding system, which causes many defects, waiting, over process.
- 8- Non effective following up for the implementation of production Plan, which cause, waiting, delay in implementation of production plan, Missing data, errors, delaying in decision making.
- 9- Not accurate and non-updated stocks; cause many defects, wrong decisions

- List of Hot Spots loop 2

- 1- Abbott TPM receives sales orders from Abbott Distribution as daily separated Excel sheet; which may cause data duplication.
- 2- Finished goods stores receive sales orders from Abbott TPM by mobile or telephone; which may cause miscommunications, data errors and duplications.
- 3- Non accurate data due to Manual documentation

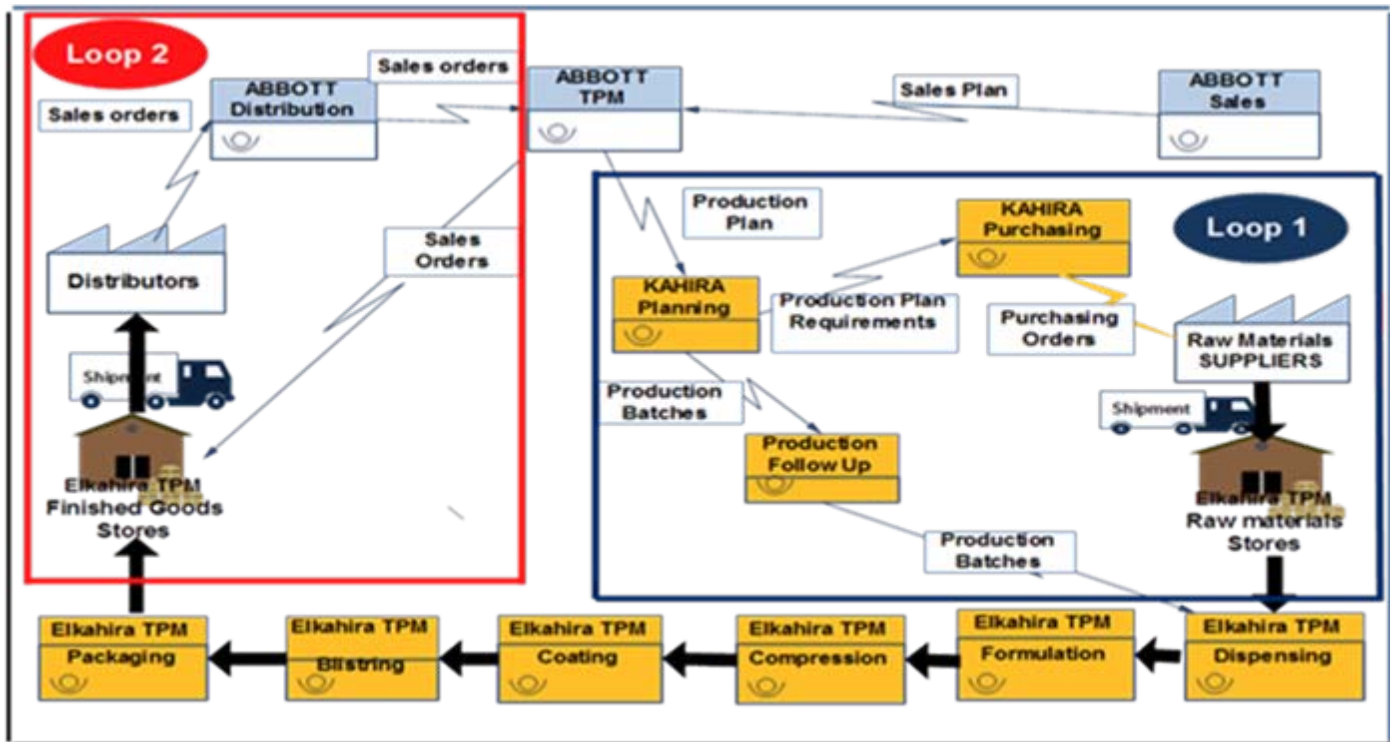


Figure 4 Current stream maps

system.

4- There are three Different stores; Many Different records, over motions.

5- Preparation from three different Stores, Many Different records, over motions.

6- Collects the distribution receipts from three stores; data missing, over motions.

7- Limited deliveries times (one deliveries/ day) by TPM vehicles, there are many breakdowns in Kahira Transport vehicles.

8- Every week TPM Manager Take Copy of the shipping receipts from the store and record the all sales for all branches of the distributors in first sheet; it take about one day man work from him.

Three times in the month TPM Manger collects sales for every Distributors and making the Second Sheet.

9- Then he Collect the total sales for all Distributors to make the sales wave in the third sheet to send it to Abbott finance team, that is happening three times in the month

Analyze

The purpose of the Analyze phase is to develop and test hypotheses about the causes of process defects. Therefore, Hypothesis Testing is a common tool in this phase. In the Analyze stage, there are three main Points:

- Estimate Process Capability
- Non-Value added Analysis
- Process Performance

- Identify Variation source

Loop 1 (Raw materials flow):

- Lead Time Variation

There is a high Variation in lead time availability of the sampled raw material as shown in figure 5 and the average lead time is 105 days

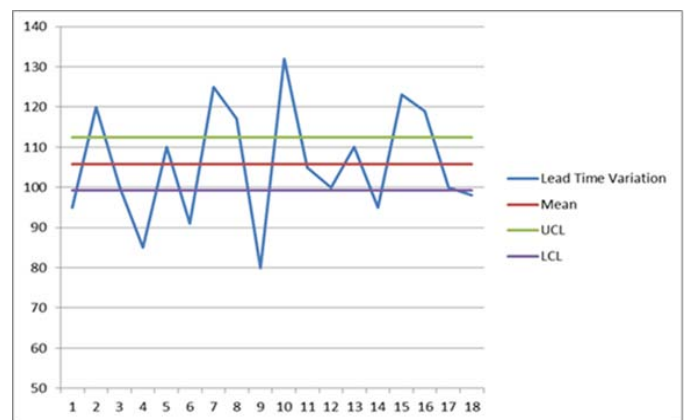


Figure 5 Lead Time Variation of raw material

- Preparation time of production orders

The Average time of Preparation production order is 268 Mins, in addition to high variation as shown in figure 6

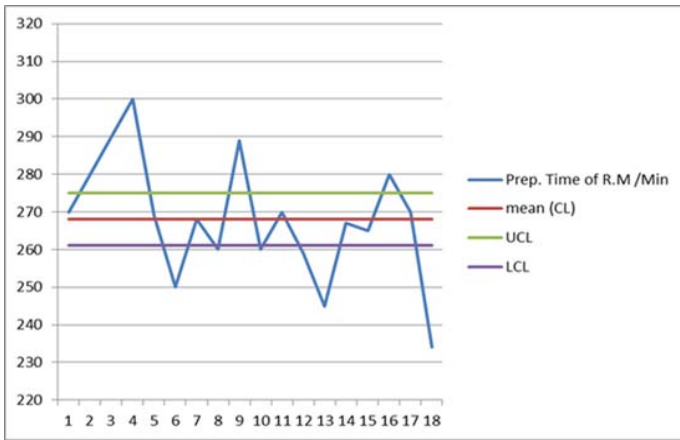


Figure 6 Preparation time of production orders

- Actual Safety stock calculation of sampled raw material:

The reorder quantity is 20,000 kg and the order quantity is 30,000 kg as shown in figure 7

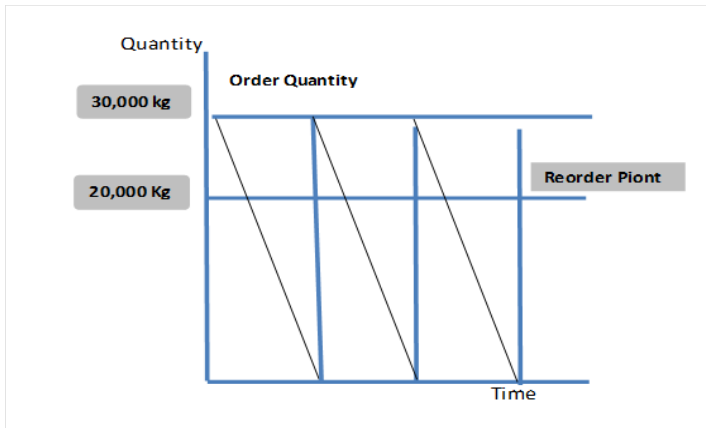


Figure 7 Actual Safety stock calculations

Loop 2 (Finished goods flow):

- Preparation time of sales orders

There is a high variation of preparation sales orders, the average time of sales order is 206 Mins. As shown in figure 8

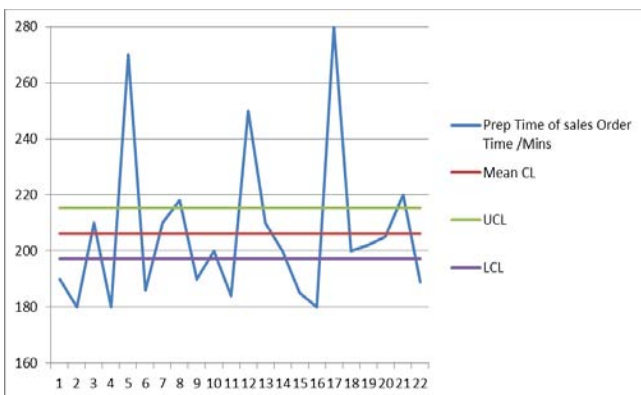


Figure 8 Preparation time of sales orders

- Actual stock of finished products

Days of healthy stock of the sampled product is below the required target as shown in figure 9

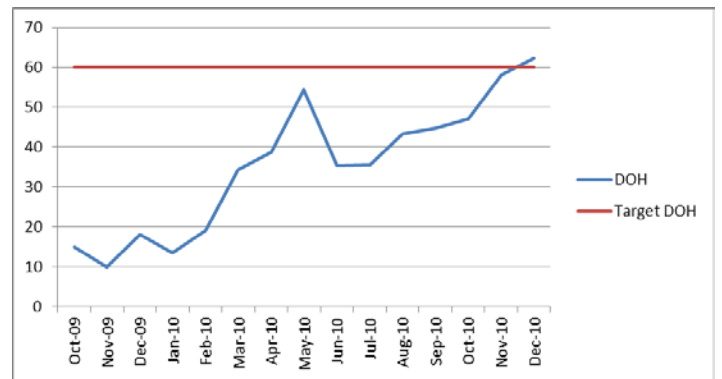


Figure 9 Days of healthy stock

- Working man hours of TPM manager:

The total working man hours for final distributors invoice through three waves per month are 39 hours, as shown in figure 10

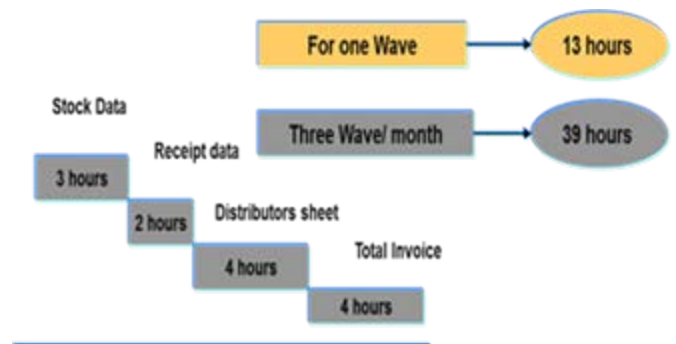


Figure 10 Working Man Hours

- Identify Variation source

Identify the potential root causes of the variation source for poor flow of raw materials and finished goods flow as shown in figure 11

Improve

The Improve phase focuses on formulating and implementing process improvement ideas. Tools in this stage include Multiple Regression and Design of Experiments. In the Improve phase the following points are addressed:

- Creating Ideas.
- Rating of ideas.
- Improvement Recommendation.

Table 4 Safety Stock Calculations

Order No.	Replenishment /days	Replenishment /month	Average Rep	Stdv. Rep.	Consumption/ton/month
1	90	3.00	3.03	0.11	6000
2	89	2.97			
3	89	2.97			
4	90	3.00			
5	91	3.03			
6	10	3.33			
7	90	3.00			
8	91	3.03			
9	89	2.97			
10	90	3.00			
Consumption Rate/Month		6,000	- Safety Stock = Consumption*Stdv.Rep*Service Level - Reorder quantity= Safety Stock * Average Rep. - For 95% Service Level ,Z =1.65		
Stdv.Rep.		0.11			
Service Level		1.64			
Safety Stock		1,076			
Average Rep.		3.03			
Reorder Point		19,256			
Order Quantity		20,332			

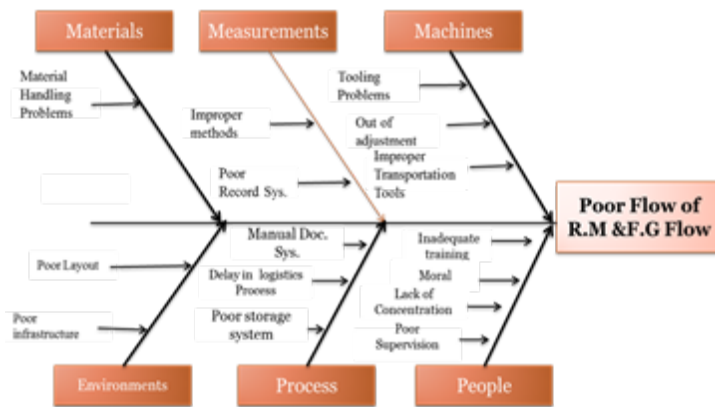


Figure 11 Identify Potential Root Causes

- Raw Material Flow

- 1- Establish One Store for Abbott contains:
 - Specified Abbott raw materials.
 - Separated Stock from Materials which Abbott and TPM participate in it, these quantity for Abbott only and entered the store by Abbott specific code
- 2- Establish new layout for the store, arranging the materials according to:
 - Product Family.
 - The more exit.
 - FIFO; Making three color cards; Red card the most priority for exit, Yellow Card the 2nd priority; Green Card the 3rd one.
- 3- Safety Stock based on the lead time variation.

- 4- Reorder point based on the lead time.
- 5- Plan small deliveries.
- 6- Payment Terms.

- Finished goods Flow

- 1- Establish One Store for Abbott Finished Products.
- 2- Establish new layout for the store, arranging the materials according to:
 - The more exit.
 - FIFO; Making three color card; Red card the most priority for exit; (near expired), Yellow Card the 2nd priority, Green Card the 3rd one.
- 3- Supply the store with Fax machine to receive accurate documented sales orders.
- 4- Supply the store with computer; convert the manual documentation to computerized system.
- 5- Establish computerized system to manage inventory and distribution system; which manage:
 - Daily batches movement.
 - Receipts the distributors.
 - Making invoices.
 - Products Store cards.
 - Campaign invoices.
 - More than seven kinds of reports

Safety Stock Calculations

- (Loop1) Raw materials

- Safety Stock based on the lead time variation.
- Reorder point based on the lead time, as shown in table 4

Table 4 Safety Stock Determination (Raw Materials)

- Plan small deliveries.

The order quantity becomes 20,332 kg instead of 30,000 kg before improvement as shown in figure 12
Table 4 Safety Stock Determination (Raw Materials)

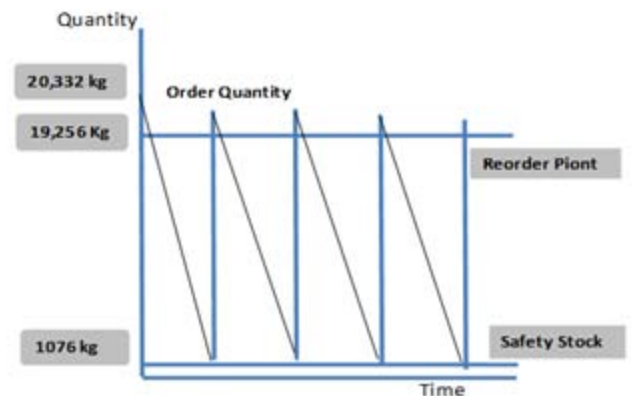


Figure 12 Reorder Point (Loop 1)

**Safety Stock Calculation
- (Loop2) Finished goods**

Safety Stock calculations based on the forecast and the deviation in the last sales, as shown in tables 5, according safety stock rules as shown in table 6

Table 5 Safety Stock Determination (Finished Goods)

Sales			
Month	Quantity	Lead time (months):	3
Oct-10	219,344	Service level:	0.90
Nov-10	300,930		
Dec-10	121,000	Lead time demand:	554,882
Jan-11	100,554	Standard Deviation:	58,056
Feb-11	152,850	Service factor:	0.90
Mar-11	143,042	Lead time factor:	2
Apr-11	160,325	Safety stock:	90,500
May-11	239,221	Reorder point:	645,382
Jun-11	170,815		
Jul-11	183,978	Order Quantity	1,200,264
Aug-11	259,184		
Sep-11	221,109		
Oct-11	270,709		
Nov-11	228,169		
Dec-11	163,232		
Jan-12	140,000		
Feb-12	180,000		
Mar-12	234,882		

Table 6 Safety Stock Rules
By Lokad.com, Copyright 2007

Formulas	Comments
Lead time demand:	Summing the forecasts
Standard Deviation:	Deviation in the past sales
NORMSINV	Inverse of the normal distribution
Lead time factor:	Square root of lead-time to forecast ratio
Safety stock:	Combining factors
Reorder point:	Lead time demand + safety stock

- Define reorder quantity for finished goods

The reorder point is 645,382 units, and the order quantity is approximately 1,200,000 units as shown in figure 13

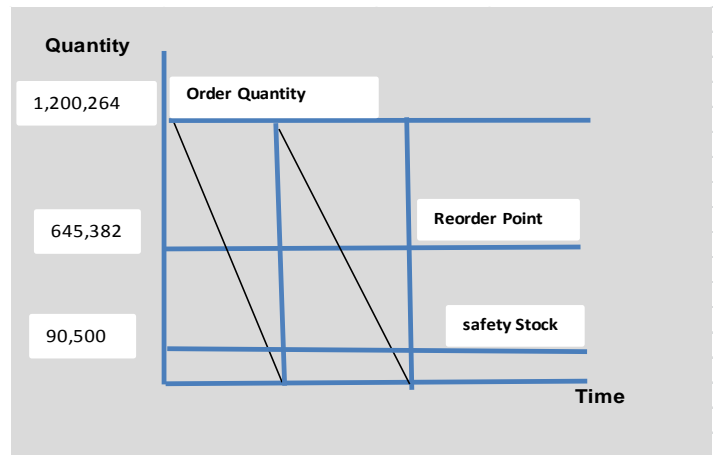


Figure 13 Reorder Point (Loop 2)

Control:

Improvement actions need to be monitored to assess the effectiveness of actions, to maintain benefits over time and to ensure the stabilization of the processes.

In order to verify the effectiveness of the improvements, there is a Comparison between the performance of before and after improvement.

Results:

- Eliminating the variation of lead time of sampled raw materials as illustrated in figure 14
- Decrease the cycle time and the variation of preparation time of production orders, and sales orders as shown in figures 15, 16, 17.
- Eliminate the over motion for physical flow of both raw materials and finished goods
- Implement safety stock calculation for the sampled raw material, and finished good.
- Eliminate the non-value added processes as shown in figure 19.
- Implementing Lean Six Sigma in Supply Chain Processes, large or small, must be a company-wide initiative. That we can improve the performance of supply chain by reducing the causes of defects and Eliminate non value added processes and improving Service and sales causing greater customer satisfaction.

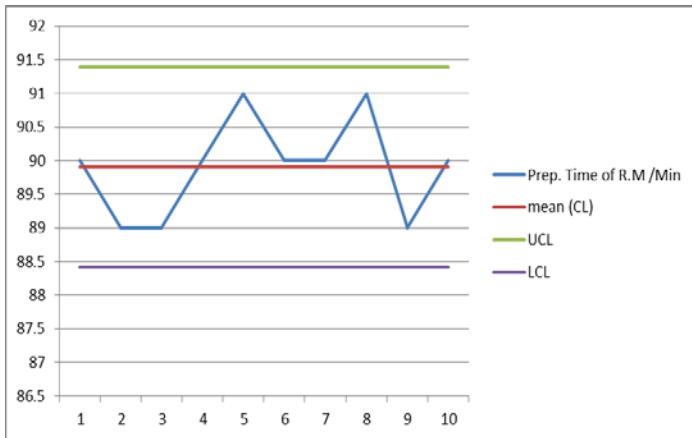


Figure 14 Lead Time Variation of Ibuprofen 38 (After improvement)

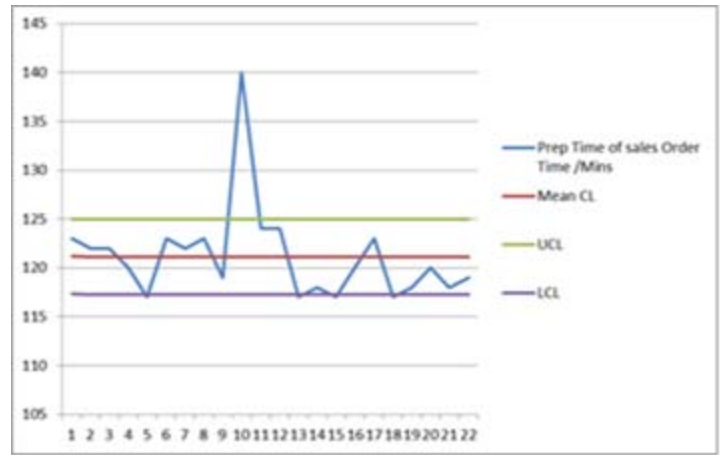


Figure 17 sales order Preparation time Loop 2 (After improvement)

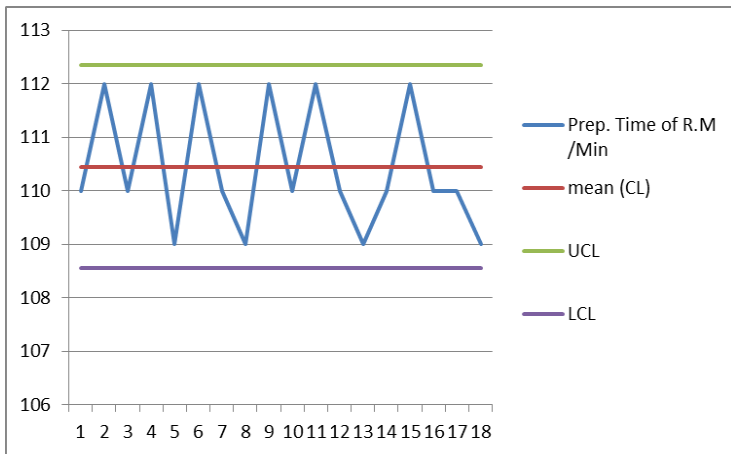


Figure 15 Order Preparation time (After improvement)



Figure 18 Sales orders Lead Time Loop 2

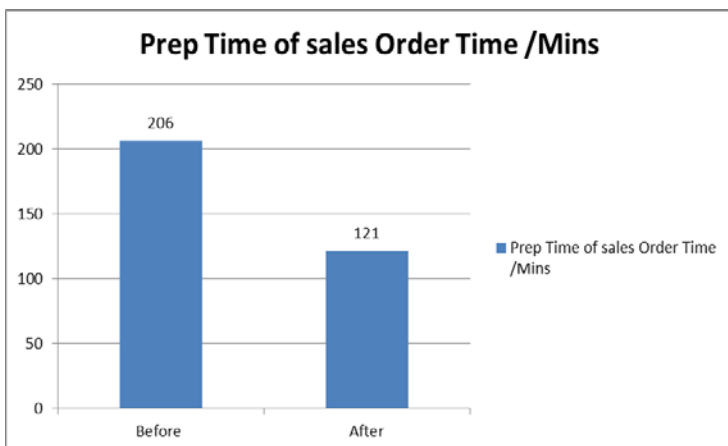


Figure 16 Order Preparation time (After improvement)

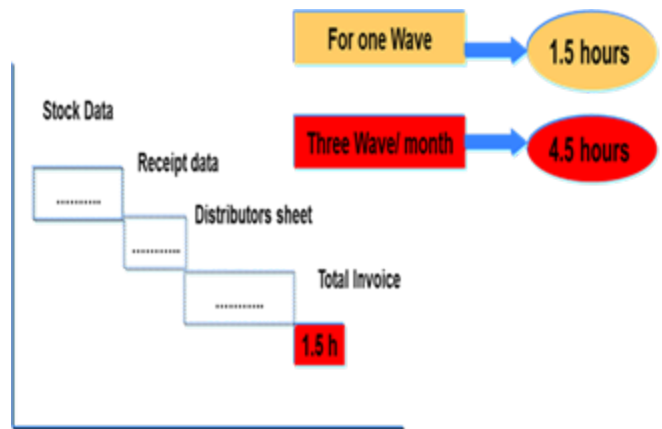


Figure 19 working man hours Loop 2

Conclusion

The research case study is improving the performance of the supply chain processes in the pharmaceutical industry. Through monitoring the performance of the supply chain processes there are many kinds of wastes in; Stock out, over inventory, defects, over transportation, over motion, Inappropriate Processing. The KPI's are identified to monitor and indicate the performance of the case study. Value added results have been achieved after improving the supply chain processes.

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