



ROLE OF LEAN SIX SIGMA IN ADVANCING SUPPLY CHAIN MANAGEMENT – A CASE STUDY

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Abstract

Pharmaceutical supply chain is a complex service system with many independent stakeholders each interacting with the others, requiring both integration and coordination to deal with their complexity. Moreover, the supply chain associated with drugs or pharmaceutical products in healthcare industry is critical in ensuring a high standard of care for patients and providing adequate supplies of medication for pharmacies. The pharmaceutical industry is unique in number of ways because it plays an extremely important role in considering the health of people providing access to health care services, innovative drugs and products. A unique feature of the pharmaceutical industry is that it operates in two very different types of supply chains – one to support the drug development phase and other one intend to sell a successful drug in the market. The main objective of this article is to gain a theoretical understanding of Lean Six Sigma with respect to supply chain management and its role towards achieving organizational goals and to evaluate the importance to advance supply chain management in pharmaceutical industry with the help of a case study.

Key Words: *Pharmaceutical, Supply Chain, Lean Six Sigma, organization.*

Introduction

Supply Chain Management (SCM) can be defined as the planning, management and execution of all activities involved in sourcing and procurement, conversion and all logistics management activities. In today's highly competitive environment acquiring the right product, at the right price, at the right time are the key factors not only for critical success but also to survive. To establish a new supply chain strategy one has to have deeper understanding of the customer satisfaction and market place. According to Council of Supply Chain Management Professionals (CSCMP) Supply chain is considered to be an essential element to operational efficiency and they also claim that SCM (Supply chain management) knowledge and competence can be used to support medical missions, disaster relief operations and other kinds of emergencies, culture evolution which could improve quality of life. By utilizing the tools and techniques of SCM a person will have the capacity to properly diagnose problems work around disruptions and determine how to efficiently move products to those in a crisis situation

Supply Chain in the Pharmaceutical industry

Pharmaceutical supply chain is a complex service system with many independent stakeholders each interacting with the others, requiring both integration and coordination to deal with their complexity (Tien and Goldschmidt-Clermont, 2009, p-258). Moreover, the supply chain associated with drugs or pharmaceutical products in healthcare industry is critical in ensuring a high standard of care for patients and providing adequate supplies of medication for pharmacies (Kazemzadeh et al, 2012, p-2129). The pharmaceutical industry is unique in number of ways because it plays an extremely important role in considering the health of people providing access to health care services, innovative drugs and products. A unique feature of the pharmaceutical industry is that it operates in two very different types of supply chains – one to support the drug development phase and other one intend to sell a successful drug in the market. If we compare the goal and constraints of the above two phases they are quite different in nature and they require different types of supply chain capabilities. The former focuses on facilitating a quick completion of medicines to obtain a quick approval and the latter aims to meet sales targets.

Most pharmaceutical industries have complex supply chains that are under-utilized, inefficient and ill-equipped to cope with the sort of products coming down the way (No author, 2011). In order to meet the demands of a fast evolving marketplace and the shift from patient to outcome, the pharmaceutical supply chain will need to undergo a major change (ibid). Currently global demand for the products are continued to raise many challenges for Pharmaceutical companies. Companies must go beyond their traditional approaches and must adapt to create a more modernized and reactive supply chain with well defined research and development processes to serve



customers of present and the future. They should focus aggressively on process innovation rather than a product innovation. The best pharmaceutical supply chain of future will be known by flexibility and agility of both internal and external workflows.

Any risks affecting the pharmaceutical supply chain, not only can waste the resources but also can threaten the patients' life by hindering access to medicine (Schneider et al, 2010, p-422). Risk management is not only important in the pharmaceutical supply chain, but also is a major player in other aspects of pharmaceuticals such as prescription and uses of medicine (Rodriguez, 2013).In recent years the pharmaceutical sector has been facing pressure from government, employers, payers, and patients to provide safer and more efficient services. In order to sustain in the competitive environment the pharmaceutical industries are striving to reduce total cost, lead times and increasing the product quality. This has created a need to implement lean six sigma methodology in manufacturing organizations which could improve efficiency and gain competitive edge for the company. Different tools and techniques can be applied to develop and sustain in the market. Currently six sigma tools and lean management are recognized as most popular continuous improvement initiatives with many companies using them.

Lean is used to deliver products and services better, faster and at a lower cost. Six Sigma is used to achieve stable and predictable process results, reducing process variation and defects (Laureani and Antony, 2010, p-689). Lean thinking and six sigma have been utilized by manufacturing industries to decrease cost and improve quality and productivity by reducing variation and production problems. There is a developing interest among pharmaceutical companies due to dramatic success in manufacturing area which chooses to implement lean in order to reach goals such as to decrease lead time, reduction of wastage, improvement of communication with customers and raising quality level both in production and in testing laboratories.

The main objective of this article is to gain a theoretical understanding of Lean Six Sigma with respect to supply chain management and its role towards achieving organizational goals and to evaluate the importance to advance supply chain management in pharmaceutical industry. We have taken Alison Ltd as our case study (Anupama, 2014, p-9)

It is privately owned Pharmaceutical company strategically located network of 7 overseas offices (africa,congo,brussels,brazil,india,canada,uae),warehouses,datacenters manufacturing and dealing with pharmaceutical products, niche products including tablets, capsules, injections, suspension powder, gels, creams etc and dealing with many customers (wholesalers, retailers, customers, pharmacies). Alisons ltd group is an expert in manufacturing and exporting pharmaceutical products mainly to Kinshasa and rest part of Africa with main concentration on Luanda, Lobito and Mali where they act as monopoly and to other semi regulated markets where they concentrate in smaller portions (such as Brussels and brazil) and involves functioning of data centers, OEM (Original equipment manufacturer) that is with specialization in private labelling, packaging and customized needles.

Having won recognition for trustworthiness, reliability and world class standards the company has got a major breakthrough in cross boundary sales. To meet global standards their procurement, manufacturing, inventory, production, planning, testing are given great importance in firm.

Overview of the Pharmaceutical Industry

Looking back in to the history the earliest drugstores date to the middle ages. The first known drugstore was opened by Arabian pharmacists in Baghdad and many more soon began operating throughout the medieval Islamic period and eventually medieval Europe (Nwude, 2013, p-73). During 19th century, majority of the drugstores in Europe and North America had eventually extended into larger pharmaceutical companies. Key discoveries of the 1920s and 1930s, such as insulin and penicillin became mass-manufactured and distributed. Legislation was enacted to test and approve drugs and to require appropriate labelling (ibid). Prescription and non-prescription drugs became legally distinguished from one another as the pharmaceutical industry matured.



The pharmaceutical industry entered the 1980s pressured by economics and a host of new regulations, both safety and environmental. Drugs for heart disease and for AIDS were a feature of the 1980s, involving challenges to regulatory bodies and a faster approval process. Marketing changed dramatically in the 1990s. The internet made possible the direct purchase of medicines by drug consumers and of raw materials by drug producers, transforming the nature of business (No author, No date). Demand for nutritional supplements and so-called alternative medicines generated new prospects and increased the market competition.

The global pharmaceutical industry is expected to reach \$830 billion by 2010 with a growth rate of around 5 to 6 percent. (Addulanaveen, 2011). While the pharmaceutical industry in regions like Latin America, Europe and Japan is growing at a steady rate which is more or less equal to that of the overall industry, the developing regions like China and India are recording corresponding growth in double figures. Industry analysts predict that the pharmaceutical market would reach \$1.1 trillion by 2015 with the average growth rate of around 7 percent (ibid). United States is still the largest pharmaceuticals market in the world with a market size of around \$300 billion and it is expected to reach \$370 to \$390 billion by 2015.

Role of Lean Six Sigma

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. LSS can be described as a methodology that focuses on the elimination of waste and variation using DMAIC (Define, Measure, Analyze, Improve and Control) structure to accomplish customer satisfaction with regards to quality, delivery, and cost. Lean thinking is defined as “*a way to specify value, line up 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*”.

In business terms, Antony and Banuelas (2001) defined Six Sigma as “*a business improvement strategy used to improve business profitability, to drive out waste, to reduce costs of poor quality and to improve the effectiveness and efficiency of all operations so as to meet or even exceed customer’s needs and expectations*”.

The application of Lean and Six Sigma in healthcare sector is relatively new topic and there is very little research has been performed in this area. Six Sigma will eliminate defects but it will not address the question of how to optimize process flow. Lean principles exclude the advanced statistical tools often required to achieve the process capabilities needed to be truly ‘lean’ (Hesami et al. No date, p-2). Each approach can result in dramatic improvement, while utilizing both methods simultaneously holds the promise of being able to address all types of process problems with the most appropriate toolkit. For example, inventory reduction not only requires reducing batch sizes and linking operations by using Lean, but also minimizing process variation by utilizing Six Sigma tools.

Methodology

The author began with qualitative method by conducting a series of interviews and meetings. The main source of primary data is from the operations department and the senior level management. It is primarily a quantitative exploratory approach in which analysis was done to know the problems. They were then subsequently re-analyzed with a few subsequent interviews to understand better the implications of the quantitative results. The secondary data was collected from related books, records and the other reports.

Analysis using the tool Fishbone Diagram

It has been noticed that there is lack or shortage of raw material availability that hinders the production process or manufacturing which leads to delay in on time shipments, lead time problems, inventory management problems (certain material shortage). Ishikawa diagram too has been utilized to illustrate the possible causes of this

problem. In the fishbone diagram Fig.1 the head of the fish defines the effect or main problem where the company faced shortage of raw materials which actually led to many other problems.

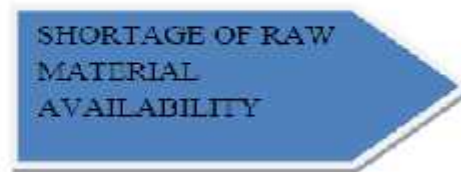


Figure 1: Fishbone Analysis: Issue

1 cause

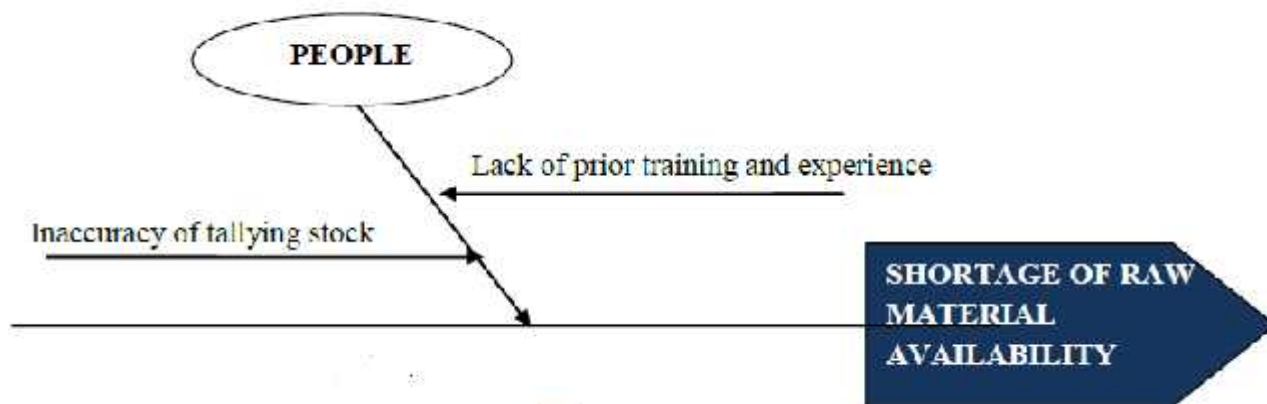


Fig 2. Cause 1

In the above diagram (Fig.2) shows the 1st cause of the problem faced by the company. In fish bone analysis each bone represents the cause of the problem. Here the first bone or first cause is People; lack of training and experience caused problems in handling of raw materials needed that lead to so much of time consumption in manufacturing process of which inaccuracy of tallying stock was the major problem where some employees were not updating the system. As soon as they receive the items in hand they move to stock room directly without entering the items and due to negligence vice versa.

Cause 2

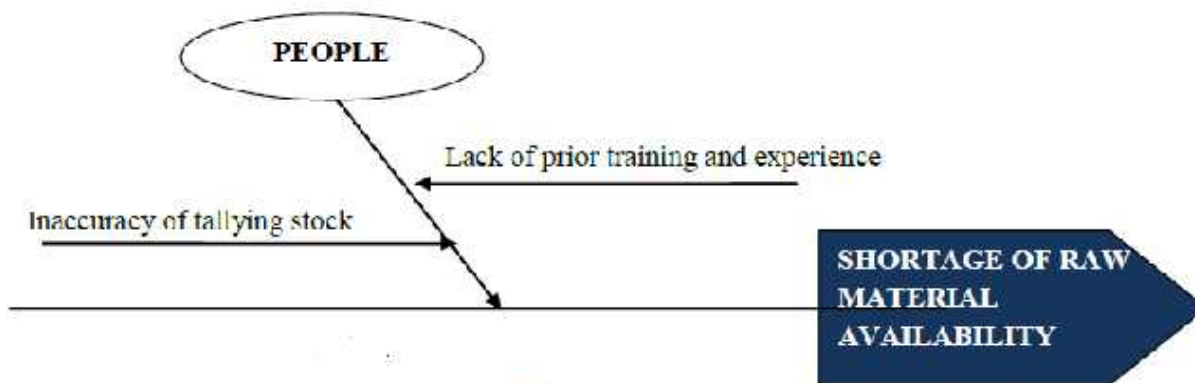


Fig 3: Cause 2

The above fig 3 mentions the second cause for the problem faced by the company. The second cause in the fishbone analysis defines the second cause which is Process. Lack of production planning and scheduling – this category belongs to implementing industry standard practices. In other words a proper check on the standard operating procedure should be implemented. Lack of supplier vendor score card has caused difficulty in identifying the suppliers with the most lead time and taking in preventive actions to reduce the delays.

Cause 3

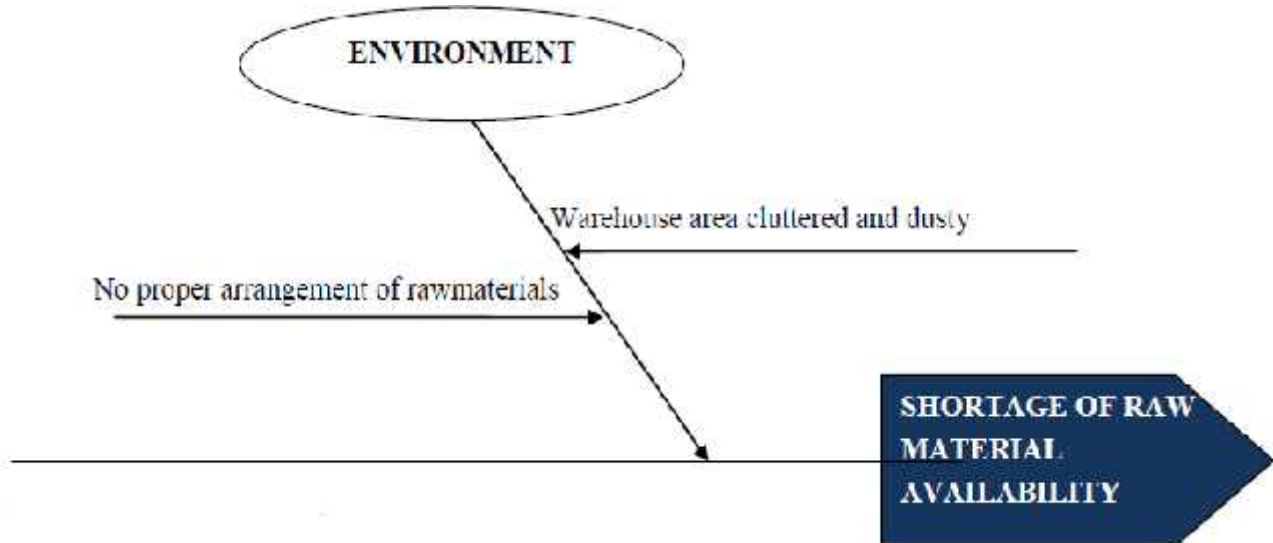


Fig 4 : Cause 3

The above fig 4 explains the 3rd cause for the problem faced by the company. The 3rd cause would be the warehouse area is cluttered and dusty with no proper arrangement of raw materials and manufactured goods which leads to confusion on availability that leads to shortage of raw materials.

Cause 4

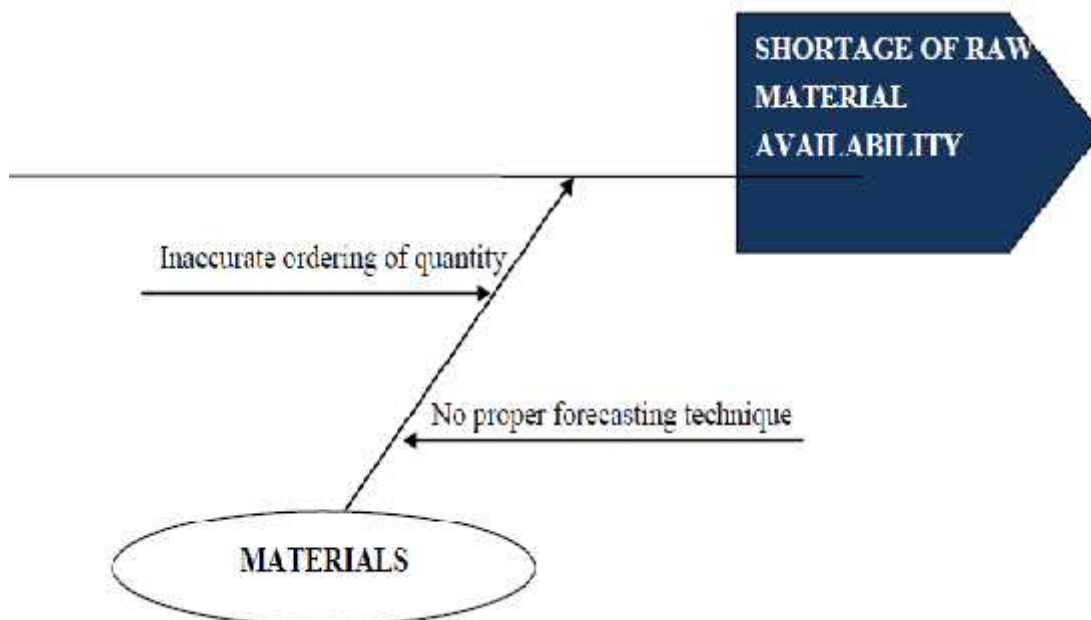


Fig 5 : Cause 4

The above fishbone diagram fig 5 explains the fourth cause which is the material. No proper forecasting techniques in order to know the future demand of the drug which leads to demand uncertainty of raw materials. Inaccurate ordering of quantity leads to wastage sometimes or shortage of raw materials and then the manufacturing process would be held up until you get the necessary raw materials in hand.

Cause 5

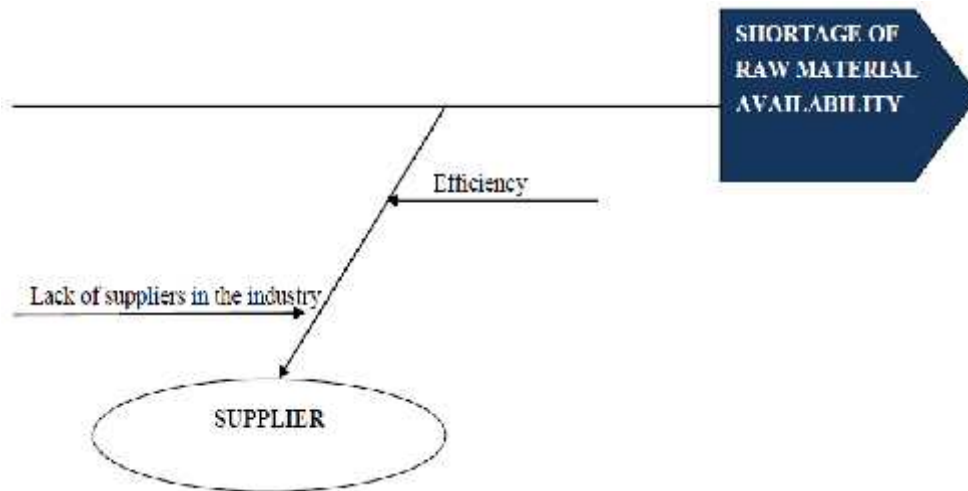


Fig 6 : Cause 5

The above fishbone diagram fig 6 explains the fifth cause of the problem which is the supplier. Here the Lack of suppliers in the industry implies that it not necessary that suppliers would always be the manufacturer of the raw material. In few cases he would be getting it from the original manufacturer or other supplier which then causes lead time and problems. Efficiency here also would lead to the main effect that actually arises by bringing in wrong quantity or wrong raw materials which again cause delay in the manufacturing process.

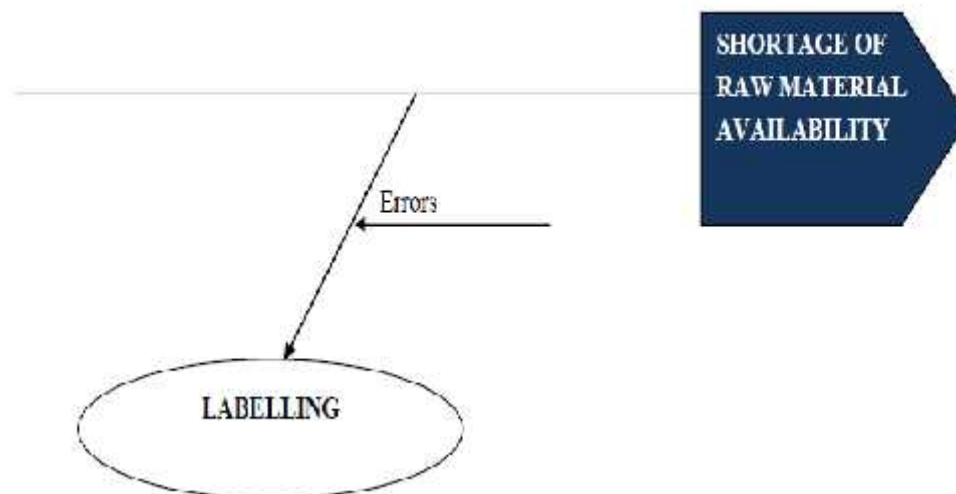
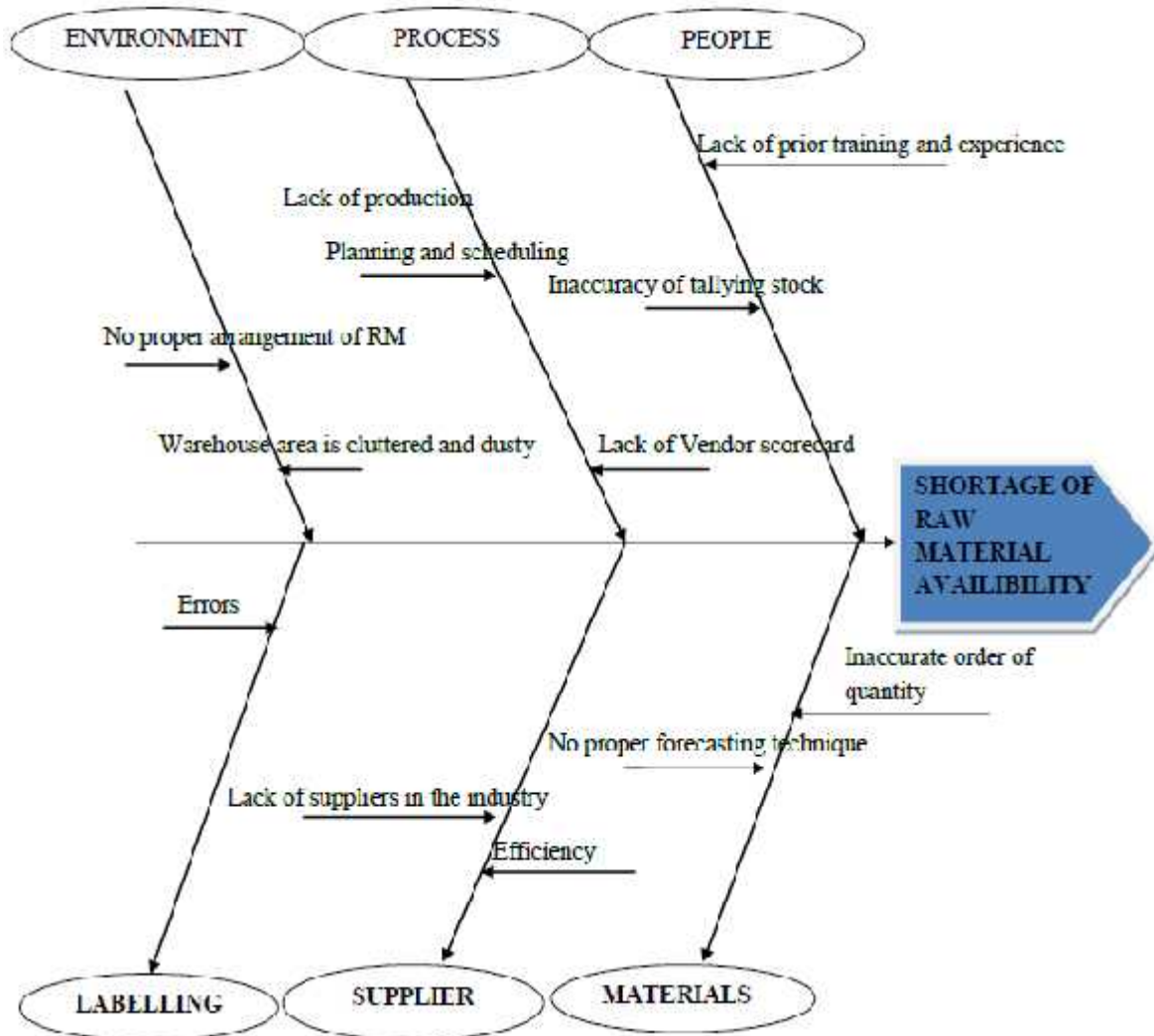


Fig 7: Cause 6

The above fig.7 mentions the sixth cause of the problem which is the labelling. Labelling errors happens at least twice in five packaged items. The wrong Label would be actually put on another product. The description contains the ingredients of chemicals used which then go to bar coding and records the raw materials. Deducting the specific chemical from the system which again causes confusion in the raw materials.



**Fig 8: Complete Fish Bone Diagram
DMAIC Methodology**

DMAIC methodology involves 5 steps Define, Measure, Analyze, Improve, and Control. It is a systematic and continuous methodology used by company professionals for solving problems, improving the quality of products and reducing the defects or waste within an organization. Each phase of the DMAIC has questions that need to be answered. By answering the questions, deliverables or outcomes are produced. Each deliverable provides a path for completing the DMAIC methodology.

Define Phase: The goal of define phase is to define the project by understanding background information about the process and its customers. It identifies key stakeholders, time lines, improvement priorities, and improvement targets at the beginning of project.

Measure Phase: The goal of measure phase is to focus on improvement effort by gathering information about current state of the process. In measure phase team can gather historical data to come up with baseline for improvement. Measure phase data collection effort leads to more focused problem statement.

Analyze Phase: The goal of analyze phase is to establish the root causes of the problem and confirm them with the data points. Braining storming, cause and effect diagram, histogram are some of the tools which can be used in analyze phase of the improvement.

Improve Phase: The goal of improve phase to work on improvement solutions based on define, measure and analyze phase outputs. Improve phase compares before and after process status to develop and implement the process improvements. Improve phase not only generates the solutions but also give feedback mechanism check the effectiveness of improvements.

Control Phase: The goal of the control phase is to maintain and standardize the gains of the improvements. Control phase also require a continuous improvement effort to sustain the change. Customer changing requirements need major changes in process flows; in that case improvement team should be able to analyze the changes for further improvements. The DMAIC methodology, should be used when a product or process is in existence at your company but is not meeting customer specification or is not performing adequately.

Define phase: The tool used here is SIPOC (Suppliers, Input, Process, Output, Customers) where the input affects the output, defective input produces defective output or non-defective input produces non-defective output. A SIPOC diagram helps the entire project team to get a better understanding of the core process that they will be focusing on.

Suppliers	Input	Process	Output	Customers
Biobaxy technologies Triveni Pharma VI exports	Drug intermediates, herbal raw materials derived from fruit, flower, roots etc, chemicals, stainless steel or carbon steel for needles.	Mix the constituents as needed to create necessary formulations as needed by the buyers.	Making drugs available at the best price, syringes	Balpharma, SRS pharma, Medo pharm and other local buyers

Table 1 – SIPOC Diagram for Alisons Ltd.

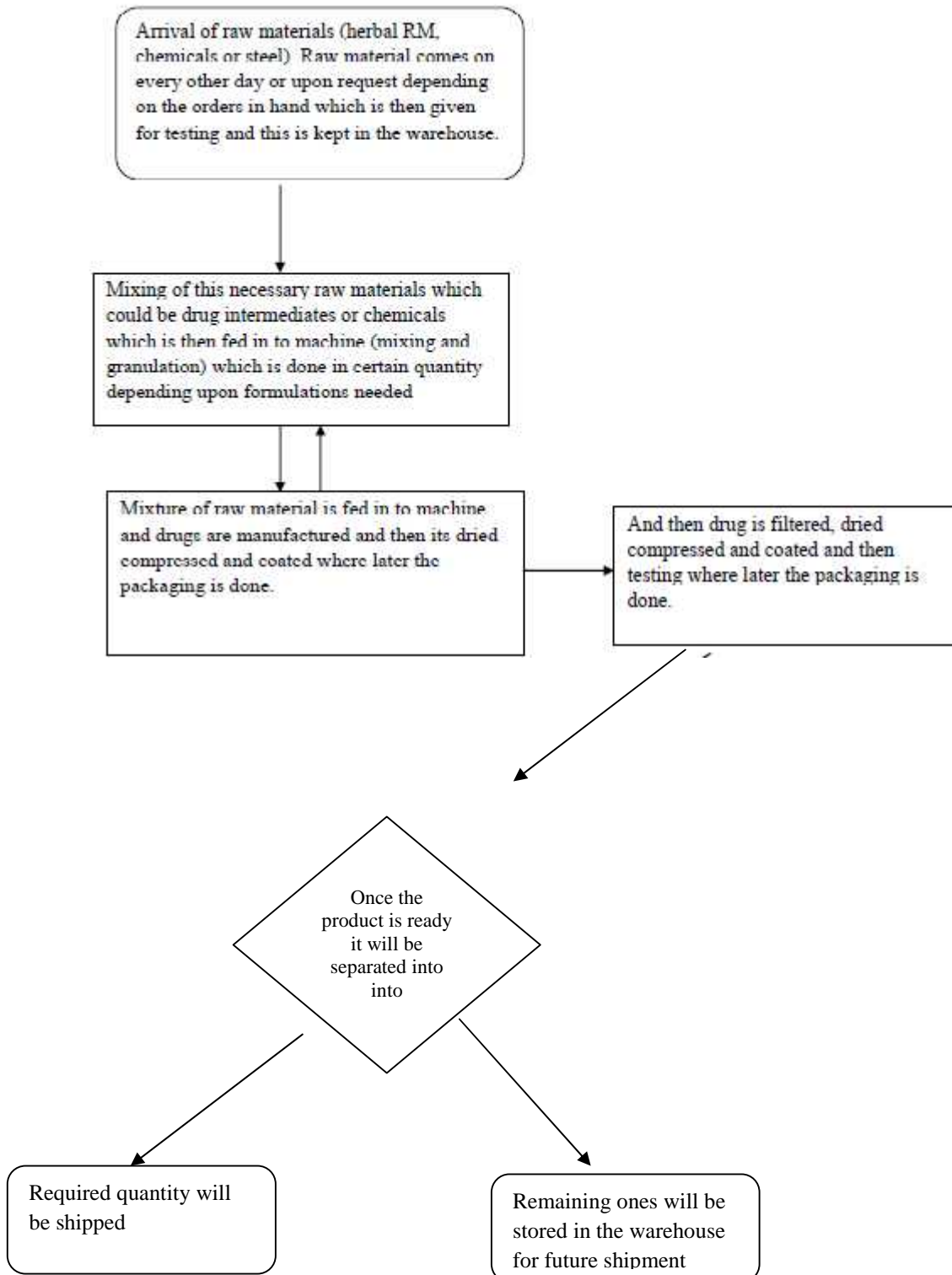
Deliverables – Probable outcome at the end of the project like- increase efficiency, decrease waste and reduce cost.

Measure phase

This phase define the baseline performance and also the extent to which the process can be improved. The key defects in the process are identified and defined. Once the key measures for improvement are defined, data is collected to analyze the difference between the current performance and the desired performance. Process variations have been established during this phase.

Phases	Questions	Answers
Measure	What is the current measurement?	Currently company is producing approximately 70 000 medicines a month and approximately 10 to 11000 are getting wasted due to shortage of raw materials.
	What are we going to measure?	
	How will we measure it?	Using process flow chart
	Where do we find data?	Within the company

Table 2 – Measure Phase for Alisons Ltd.



**Fig 9. Process Flow Chart
Analyze Phase**

A root-cause analysis is used to define the possible reasons for the performance gap and quantify the main causes for variation.

Phases	Questions	Answers
Analyze	What are the 6 major causes that can create the problem?	People, process, environment, materials, supplier, packaging.
	What are sub causes for each major Cause?	Mentioned in fish bone diagram
	What are the key deliverables?	Implement 5s, pokayoke and standard production planning and scheduling with accurate demand certainty.

Table 3 – Analyze Phase for Alisons Ltd.

In Analyze phase:

- Through Fish bone diagram (refer Fig.8) or cause and effect diagram the causes that lead to the effects are known and thereby solutions can be implemented.
- Effect known here is shortage of Raw material availability which is understood through fishbone diagram.

Improve Phase

The Improve phase is the fourth step of the DMAIC process is the point where the hard work of defining, measuring and analyzing pays off - the point where the ideas for process improvement are formulated and implemented.

FMEA (Failure modes and effects analysis) tool is taken here during Improve phase.

Failure Modes and Effects Analysis (FMEA) is methodology for analyzing potential reliability problems to take actions to overcome these issues, thereby enhancing reliability through design. FMEA.

Table 4 : FMEA Model

Control Phase

PDCA tool is suggested in the control phase.

Control is the fifth phase of the team's work. The purpose of the control phase of DMAIC is to make sure the new way of working is sustained over time. This phase of DMAIC is complemented by the tools and skills

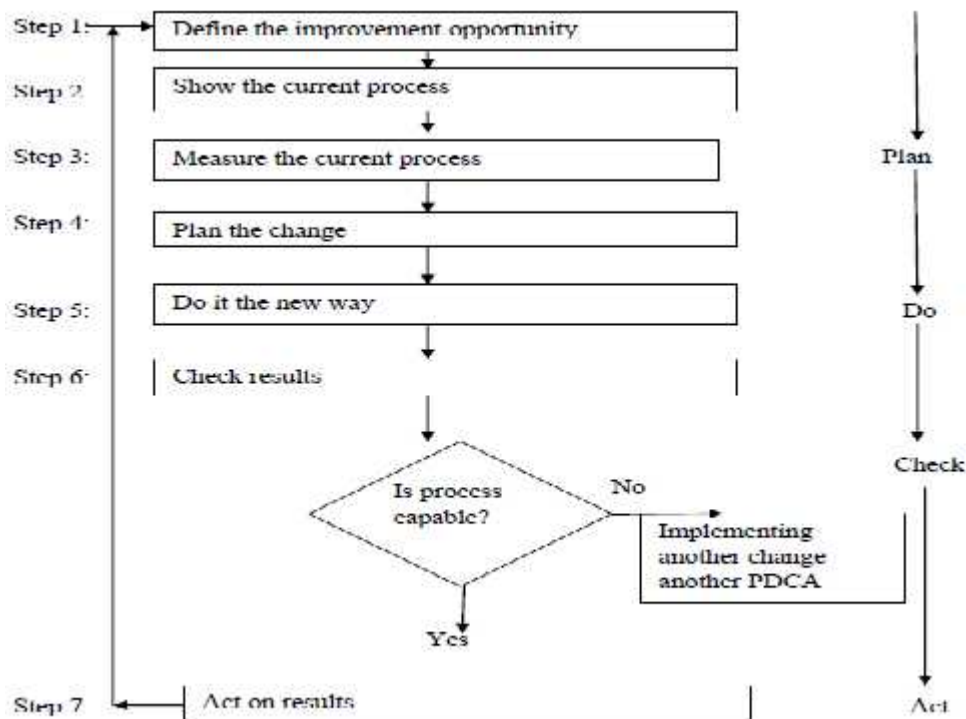


Fig 10 shows the Continues Improvement of Flow Chart
In control Phase:

- Documenting the entire project for future use.
- Lesson learned- whatever team learned from this particular project.
- Set the standard procedure in Alisons LTD for future manufacturing process.

Findings and Recommendations

Certain obstacles that the Organization would be facing in implementation would be as follows;

- Overblown implementation costs. It is possible that, without a tight implementation planning of the initial investment put up for this methodology will require an additional capital.
- Training the functional level executives is mandatory which would be crucial when considering time.
- Post-implementation –Getting used to changes due to implementation of the new methodology will take time for the organization to adapt The problems that has been affecting the organization is not able to manage the inventory, which then lead to problems in on time shipments and that increased the operational hours per unit which then gave way to process variation leading to additional unwanted costs faced by the organization, however the root cause was identified to be non availability of raw material (such as chemicals, drug intermediates etc) to make the drugs by which implementation of lean six sigma would definitely bring a huge change in the current scenario.

From data analysis to ward off certain problems lean six sigma methodology such as implementation of 5s, pokayoke along with process improvement approach is to be considered. A typical process improvement investigation will follow the use the process mapping to show the sequence of activities, flow of information, decision points and the range of possible process outcomes.

Process Map Development		
Primary	Why	Selection
1. PURPOSE- eliminate the root cause that incur additional problems and costs	It should be achieved to avoid the additional expenses and to increase customer satisfaction	Customer satisfaction and removal of additional defects
2. MEANS-by implementing lean six sigma methodology. 3. SEQUENCE Implementing 5s, pokayoke with a bit of changes in organization in sequence to shortly remove the defects	This way to get perfect solutions for the current problems To slowly implement this techniques to reduce the defects to achieve organizational goals	Achieved through lean six sigma methodology Should be achieved as soon as possible
4 PLACE- factory, warehouses and other places when needed	These are the place where major defects happen	Should be achieved in areas where frequent defects occur.

Table 5 : Process Map Development

As considering the shortage of raw material availability we basically see that suppliers in this industry is few when compared to another industries because this industry focuses on quality of materials and if compromised can even take a toll on health of an individual to ward off this problem we could recommend :-

- Creation of vendor scorecard.
- Forecasting based on qualitative methods and on time series model.
- Implementation of 5s procedure in the organization.
- Implementation of Pokayoke to eliminate the problems in Labeling.

Vendor Scorecard

A scorecard compares a vendor's current assessment results to previous results or to the results of other vendors, and shows a live feed for the vendor.

Supplier	Key elements analyzed	Benefits
Name Supplier code	Delivery performance. Pricing & reject rates. Lead time variability Response timeliness to quality concerns.	Better delivery performance. Better management of community.

Table 6: Vendor Scorecard Model

This scorecard would help the organization to understand vendor lead times by bringing in incorrect material and quantities which would lead to problems in delay of on time shipments and increase in operational hours per unit leading to additional costs. Keeping a vendor scorecard for each vendor will help the organization to cope up with the problems happening in shortage of raw material availability.

Implementation of 5s Procedures in Organization

Sort –to remove the unwanted items which are not needed for current operations. Eg: to move the raw materials to another section of warehouse which are not needed at the moment.

Set in order- arranging the items which is needed the most and labeling them so that anyone can find them easily without wasting time looking for the desired raw material.

Shine – Keep everything, everyday swept and clean. Turning the workplace in to a clean bright place where everyone will enjoy working and keeping clean in this industry is mandatory as dust particles can be harmful while making drugs to allergic reactions with a probability of being hazardous.

Standardize-Making sure the first 3 phases are implemented and checked.

Sustain- Making a habit of maintaining correct procedures to achieve the organization goals and ward off the present problems.

The above mentioned did correctly would eliminate problems related to shortage of raw material availability which then would help organization to concentrate on their goals.

A **sample** of what could be done:-

- Shelves should be made of steel and strong.
- Drugs or chemicals should be arranged in alphabetical order of generic names such that it's easy identifiable and helps in inventory control too.
- Introducing separate bins for the product that has maximum sales where it contains description and manual entries of what went out of the stock.

- Each form of drug should be arranged in separate areas e.g. 1 area for tablets 1 area for syrup etc
- Store liquids on pallet on the floor on the lowest shelf to be at ease for movement and prevent wastage.
- Keep environment clean
- Storing drugs or chemicals in dry place protected from heat

Next would be implementing Pokayoke another lean six sigma tool to ward off problems in labeling which occurred occasionally in the organization.

Pokayoke .

The purpose of Poka-Yoke is to develop processes to reduce defects by avoiding or correcting. This technique is mostly used in manufacturing industries but now this effective technique is used in many industries as well.

The purpose is to detect what is error? How to prevent error?

CURRENT STATE

Errors : Ibunal forte capsules at times were labeled as ibunal capsules which did not meet customers and Alisons ltd label requirements caused confusion at customers end Heavy costs were incurred on balpharma to pay charges for logistics.

Investigated Causes : These capsules were pulled from finished goods inventory and packed as BP ibunal caps as there were two products of ibunal capsules under ibunal labeling (ibunal forte and ibunal) while applying labels without prior checking especially when applying new labels errors occurred. Errors also occurred due to making the shipment ready in rush hours.

- 1. In order to keep drugs ready for shipping which was done in rush mistakes happened.
- 2. Team decided to improve the process rather than playing blame game with individual employee.
- 3. Team decided to change the format of label were packing and shipping departments will have more checkpoints for applying label.
- 4. Approval on change and explaining the case to assure that improvement will prevent the errors and defects in future.

SOLUTION (Pokayoke implementation)

1. Team in charge decided to change the Label format by adding BP ibunal forte caps Label and to have one more check point before applying BP ibunal caps on top of existing one.
2. Team decided to move the label printing machine closer to packaging department.
3. Team decided to initiate 5S program to increase packaging area allocations.
4. Team requested balpharma to allow giving more lead time.
5. Designing a full proof system that catches all labeling mistakes.
6. Training everyone in using this system.
7. Stressing the importance of labeling to everyone in the organization.
8. Creating a corporate culture where all personnel pay attention to the smallest and simplest step in the process.
9. Open communication and newer ways of improvement are encouraged by management.



Conclusion

This Project suggested improvements that could take care of the present situation. Improved supply chain activities have improved following:

- Increase customer Satisfaction: Increase in on time shipments will increase customer Satisfaction.
- Reduce overall costs: Managing inventory, reduction of process variation and reduce operational hrs/unit will reduce overall costs of the company.
- With 5S program, things get cleaned up and organized in organization by eliminating the problem of raw material availability along with process improvement approach.
- Implementing Pokayoke.
- To ward off labelling problems thus by making customers satisfied.
- Improving workflow and efficiency in the organization to achieve organization goals.

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