Arab American University
Faculty of Graduate Studies

Improving the Efficiency of the Packaging Processes at Birzeit Pharmaceutical Company using Lean-Six Sigma Methodology

By
Renad Yousef Housheya

Supervised by:

Dr. Ashraf Almimi

This thesis was submitted in partial fulfillment of the requirements for the Master's degree in Quality Management

July 2021

Thesis approval

Improving the Efficiency of the Packaging Processes at Birzeit Pharmaceutical Company using Lean-Six Sigma Methodology

Prepared by:

Renad Yousef Housheyah

Supervisor: Dr. Ashraf Al-Mimi

This thesis was defended successfully on July 31 and approved by Examination Committee:

1. Supervisor.....Dr. Ashraf AL mimi
2. Internal Examiner.....Dr. Raed Al Shomali
3. External Examiner.....Dr. Yahya Saleh

Declaration

I declare that I have developed and written this Master Thesis completely, and it has been generated by me as a result of my own original thesis, and has not been submitted elsewhere for any other degree or qualification. Moreover, I have not used sources or means without declaring them in the text, otherwise they are referenced.

Name: ..... Yousef Houshreya.

Signature: .....

Date:.....31.7.2021

Dedication

This study is wholeheartedly dedicated to my beloved parents, who have been my source of inspiration and gave me strength when I thought of giving up, who continually providetheir moral, spiritual, emotional, and financial support.

And lastly, I dedicate this Master's Thesis to the Almighty God. Thank you for the guidance, strength, power of mind, protection and skills and for giving me a healthy life and unlimited blessings.

Acknowledgement

First and foremost, I have to thank my parents for their unconditional love and support throughout my life. Thank you both for giving me strength to reach for the stars and chase my dreams. My brothers, and sister deserve my wholehearted thanks as well for always being there for me, I will always appreciate all they have done.

I would like to express my sincere gratitude to my supervisor Dr Ashraf Al-Mimi for his continuous support of my master thesis, for his motivation, enthusiasm, immense knowledge, patience and support throughout this study and specially for his confidence in me.

Abstract

Many factors, including globalization and the significant technological development that have led to global competition in all areas, companies are beginning to look forwhat makes them ahead and distinguished in the field, reduce operational and non- operational costs, and increase customer demand for quality products and services. One of tools to achieve these goals is Lean Six Sigma (LSS) which is a systematic methodology that aims at improving performance and enhancing efficiency through eliminating different types of wastes and reducing variability. LSS employs the five- phase problem solving DMIAC (Define, Measure Analyze, Improve and Control) approach for existing processes. This study aims at implementing the DMAIC-LSS methodology on packaging processes in Birzeit pharmaceutical company (BPC) working in West Bank in Palestine. BPC works at a high level of quality standards andis considered a pioneer in its field. Through several visits and observations, it has been noticed that the production volume is large with high quality standard; all the production steps are automated, except the packaging processes which are mostly performed manually which represents a good opportunity for improvement. It was also noted that there is no designated location for the manual packaging processes which causes chaos and misuse of resources. Moreover, several types of waste are visible inthe packing area such as motion, transportation and waiting, which result in misuse of resources and extra cost to BPC. The DMAIC methodology has been applied to the packaging processes at BPC phase by phase.

.

Table of Contents

List of Tables

List of Figures

Chapter 1: Introduction

1.1 Overview

In this chapter, background of the pharmaceutical in the Palestinian market, the profile of BPC and all the elements of the research are presented. Specifically, the elements include the problem statement, research objectives and question, importance of the research, and research limitations. Finally, the chapter ends with presenting the thesis structure.

1.2 Background

The pharmaceutical industry sector in the West Bank consists of 4 local pharmaceutical manufacturers who have the ability to produce formulations of pharmaceutical raw materials; Birzeit Pharmaceuticals, Jerusalem Pharmaceuticals, Beit Jala Pharmaceuticals, and Dar Al Shifa, while the main consumers are; The public sector "the Palestinian Ministry of Health", the private sector and a small part of the NGO sector. Antibiotics are the most widely consumed medicines in Palestine.

The Palestinian pharmaceutical industries cover about 50% of the local drug market, which is estimated at about $130 million; The rest is distributed to medicines imported from international markets by 35%, and from Israel by 15%. These factories participate in the process of pushing the economic wheel by employing more than 1,000 people, 70% of whom hold specialized certificates, and they have invested more than 52 milliondollars. In the process of modernizing pharmaceutical manufacturing, and developing its infrastructure. (Al nadeem and Agha, 2012)

Local companies focus their production on medicines that do not require complex technology; which would facilitate the production of various types of medicine and

allow them to compete in light of the availability of foreign products. Therefore, any increase in operating costs will definitely lead to higher prices which will reduce the competitive advantage.

Due to the high price of the machines and the high cost of maintaining them, not to mention that the multiplicity of pharmaceuticals and the difference in the packaging mechanism in each category, it is not possible to obtain machines for each product separately. Due to the high price of the machines and the high cost of maintaining them, not to mention the multiplicity of pharmaceuticals and the difference in the packaging mechanism in each category, as the manufacture unable to provide a machine for each product separately. Accordingly, Manufacturers prefer to use manual packaging.

1. 3 Birzeit Pharmaceutical Company Profile

Birzeit Pharmaceutical Company (BPC) is one of Palestine's leading manufacturers of generic medicines. With a broad portfolio of products that consist of more than 300 products distributed among ten production lines and covering different therapeutic ranges, BPC targets all types of customers in the local Palestinian market including Ministry of Health, local health care organizations, international health care organizations and programs, end users (through pharmacies and physicians). BPC manufactures, and markets 300 products distributed among ten lines of production: Ampoules, Capsules, Tablets & Caplets, Syrups, Suspensions & Granules, Ophthalmic, Semi-solids, Powder vials, Suppositories and Powders. ("BPC", 2021)

All the processes of pharmaceutical manufacturing are automated and are run on sophisticated equipment in the various stages of blending, milling, granulation, blistering, coating, pressing, and sealing with the exception of the packaging processes,

in which some of them are performed on smart machines while others are manual. Furthermore, from the researcher's analysis of these processes and interviewing key personal, there is a clear gap that needs to be closed.

The way the company operates is through a weekly production plan for the amount of production based on bids or market demand, with the possibility of adjusting the production plan according to bids or sometimes the requirements of major customers such as the Ministry of Health and other.

1.4 Problem Statement

The packaging process depends more on the human capital which is more likely to fumble than the accurate machines that are more controllable. Furthermore, the layout design of the facility of BPC is another area where many opportunities of improvement exist as they positively affect the performance and efficiency. The poor layout design results in draining resources and causing different types of waste such as time, movement, motion, and mobility. What should be taken in consideration in any manufacturing facility is planning for proper machines, employee work stations, warehouse layout, and the most critical is the material and employee flow which need tobe as smooth as possible.

BPC suffers from the lack of an organized area for the packaging process, there is a problem in the existing layout for the packaging area; there is no designated location; the packaging process serves several lines of production and there is a need for material flow between different floors which result in wasting of resources.

1.5 Research Objectives

The main objectives of this research can be summarized as follow:

- Increase the efficiency of the packaging processes through applying DMAIC LSS methodology.
- Studying the existing layout of the packaging processes for the purpose of improving the material flow.

1.5 Research Question

Based on the problem statement, the research question is formulated as follows:

Would applying the DMAIC LSS methodology improve the efficiency of the packaging process at BPC.

1.6 Importance of the Research

In the pharmaceuticals sector, manufacturers apply DMAIC LSS methodology in order to reduce operating costs and ensure great service to their customers. Because of the specificity of the pharmaceutical industry, these regulatory measures are supported by other regulatory bodies such as The United States Food and Drug Administration (FDA), which seeks to reduce the number of errors and risks in the manufacturing and operation process. (Food and Drug Administration - Wikipedia, 2021)

Since the pharmaceutical industry is under growing pressure from increasing demand and higher competition, as well as adherence to the medical standards in addition to ISO standards, pharmaceutical manufacturers are always looking for opportunity to improve and reduce the different types of waste in their processes.

The importance of this study lies in its examination of whether the application of LSS will result in the improvement of the efficiency of the packaging process at BPC which is considered as a leading manufacturer of generic medicines in Palestine.

1.7 Structure of the Thesis

The thesis is divided into the following chapters:

- Chapter one gives a general introduction and describes the purpose of this thesis project, the issues to be solved, and the methodologies to be used.
- Chapter two presents a review on some literature and previous studies related to process improvement and the pharmaceutical industry. In addition, it presents the LSS methodology in terms of its history and development, and some definitions and concepts that have been used in the research.
- Chapter three presents the DMAIC LSS methodology
- Chapter four presents the results of implementing the DMAIC LSS methodology; This chapter contains five sections that cover the results of the five phases of the DMAIC methodology.
- Chapter 5 presents the conclusions and recommendations of this study.

Chapter 2: Literature Review

2.1 Over view

This chapter covers core definitions, along with presenting some articles that focuses on the implementation of LSS in general, and LSS in the private sector, and LSS and efficiency. Moreover, this chapter covers important topics related to the objectives of this research such as LSS and packaging process improvement, and LSS in pharmaceutical industry, in order to gain enough knowledge to help improve the efficiency of the packaging process of BPC.

2.2 Lean Definition and Background

During the 1920s, Henry Ford was creating something that was known as flow production system that integrated the production system into a process sequence. This was a breakthrough in manufacturing production. Later on, lean principle developed by automobile company called "Toyota" under the supervision of Taiichi Ohno to create Toyota Production System "TPS"; focusing on determining the value of the process, and distinguishing between added value activities and non-value-added activities and eliminating different types of waste, (Miller, 2005).

Lean Enterprise Institute (2000) defines that the main idea of Lean is to deliver more value for customers with minimum resources. In the same lines, Ptac, Sperl, and Trewn (2015) define Lean as an approach for identifying and eliminating wastes and improving flow of a process while engaging employees.

Before any process improvement is initiated, the value of the process should be determined. Value is defined by identifying how the product or service and the cost linked with the product or service in order to meet the customer’s need.

Mega (2016) states that: “there are five principles to Lean thinking: defining the value, identifying the value stream, removing interruptions to the value flow, letting the customer pull the value from the manufacturer, and the pursuit of perfection”. These principles serve as a method to make sure that the customer receives a quality product or service. Each activity related to the product manufacturing process is inspected, whether or not it adds value and usefulness to the process. If the process is classified as non-adding value, the process would be considered waste. There are eight types of wastes which are known by the acronym “DOWNTIME”. More specifically, DOWNTIME stands for these wastes: defects, over production, waiting, non-utilized resources, transportation, inventory, motion, excessive processing.

Some called these wastes as TIMWOODS for: transportation, inventory, motion, waiting, overproduction, over-processing, defects and non-utilized skills. Either using DOWNTIME or TIMWOODS to indicate the eight types of wastes in processes, Table 1.1 summarizes the definitions of each type of eight wastes stated in DPOWNTIME or TIMWOODS with some process examples. Waste is called in Japanese Muda.

Table1 ("8 Wastes & Downtime Using Lean Six Sigma - GoLeanSixSigma.com", 2021)

Waste Type	Definition	Examples
Over production	Making more of something or earlier than needed	Batching processes resulting in additional output; producing more to avoid running out of product; providing more information than the customer needs, making additional copies
Waiting	Waiting for information or equipment, parts or people	Parts; Inspection; Information; Machine repair; Faxes; Technology; Copy Machine; Customer Response

Non-utilized resources	Not utilized people experience, skills, knowledge or creativity	Assigning workers to wrong tasks; requiring unneeded or wasteful administrative tasks; poor communication; lack of solid leadership or good teamwork; inadequate training
Transportation	Unnecessary movement of materials or equipment	Moving parts to and from storage; Moving materials from work station to work station; Retrieving or storing Files; Takings files to another person; Going from person to person to collect signatures.
Inventory	Accumulation of parts, information, or equipment	Raw material; Work in progress (WIP); Finished goods; Consumable Supplies; Files waiting to be worked; E-mails waiting to be read; Unused records
Motion	Any movement of people that not add value to customer	Sorting through materials; Reaching for tools; Lifting boxes of parts; Searching for needed items; Searching for files; Extra clicks/key strokes; Clearing away files from work area; Looking through manuals/catalogs; Handling paperwork
Excess Processing	Any steps that not add value from the customer view	Cleaning parts multiple times; Paperwork; Awkward tool/part; Design.; Creating reports; Repeated manual data entry; Use of outdated forms/software

2.2 Six sigma Definition and Background

Six- Sigma is considered as a technique or set of quality management tools that is aimed at process improvement and reducing variability, in order to reach perfection from quality point of view.

The term Six Sigma was introduced for the first time at Motorola in 1986, and it was defined as a set of techniques and tools for process improvement (Webber, 2006). However, Bevan et al. (2006), defined Six Sigma as a process improvement methodology developed at Motorola in the 1980's to reduce defects in its processes. Its goal is to achieve a level of performance equal to a defect rate of 3.4 defects per million opportunities, this is a virtually defect free environment Six Sigma performance.

Ptacek, Sperl, and Trewn (2015), defined Six Sigma in terms of statistics and process improvement. In terms of statistics, Six Sigma is a measurement that captures the variation of a process. The Six Sigma metric focuses on defects per million opportunities (DPMO) defined as follows: DPMO = DPU X 1,000,000/opportunities forerror, where DPU is defects per unit.

The measurement associated with six sigma (6σ) is based on Defects per Million Opportunities (DPMO). A defect consists of any product or service that does not conform to quality standards. An opportunity consists of any time a product is made or service is rendered. A Six Sigma level of performance is considered to be optimal performance. "A six-sigma process should operate within 6σ limits, which implies that 99.99966% of the products are within specification. (O'Connor & Keener, 2012, p. 446).

Improving sigma level requires essential steps in order to be achieved, like the responsibility of everyone who is engaged in the organization. Improving the sigma

level of a process is reflected in reducing costs, and exceeding the utilization of resources, creative ideas, maximizing customer loyalty, job satisfaction, in addition to profitability. For successful implementation of Six Sigma, several steps are required (Stern ,2016):

- Understanding the commitment of high leadership.
- Having access to current data with reference to client desires.
- Having a method management system so as to live current performance and determine areas that require to be improved.
- Proper resources who are sufficiently trained to assist with the design and improvement of processes.
- Consistent management involvement and review to enforce method management, improvement, and design.
- Communication to confirm that customers focus and six sigma strategies and embraced throughout the complete organization.

Companies that have adopted Six Sigma have managed to increase money performance in short term (Thomas, Barton et al. 2009), cost alleviation (Anchanga, 2006), and raise customer satisfaction and cost saving (Sharma, 2003).

2.3 Lean Six Sigma Toolkit

There are several effective tools that can be used for implementing the LSS methodology. Namely, we have the following tools:

1- SIPOC: This acronym stands for Suppliers, Inputs, Processes, Outputs, Customers. These steps have highlighted the various inputs and outputs of the process, in addition to clarifying the flow of operations. This tool usually exists in the define phase, as it is

used to define a new process or develop the current processes that are being used, (Saxena, 2007).

2- Value Stream

Although this tool is usually used in the manufacturing sector, it can also be applied in the service sector. This tool helps to understand the end-to-end value-adding and non-value-adding activities from customer's perspective. It is often used to analyze the current state of the process. Also it shows the resources that are linked to these processes to give a clear view, and classifies the value-added process and eliminate all the non-value-added process, since the customer willing to pay only for value added process. However, the effort for any other process that is not added value for the customer is useless, (Martin, 2010).

3- Project Charter: the charter consists of the objectives and participants of the project, as well as it defines the responsibilities of the project stakeholders. Moreover, the charter defines the project objectives, with project responsibilities clearly articulated**,** (Pyzdek, 2014).

4- Flow: the flow is created by eliminating queues and stops, and improving process flexibility and reliability, (Sevocab, 2008).

5- Flow Chart: this tool represents a graphical structure for the process, in order to clarify a solution and give all the information related to the steps of the process. Moreover, the flowchart gives a clear view for what steps could lead to improvement byclassifying the essential steps over the non-essential ones, (Sevocab, 2008).

6- Cause-and-effect diagrams are a graphical technique to show the several causes of a specific event or phenomenon, to identify a complex interplay of causes for a specific problem or event., Watson (2004).

7- **Gembawalk:** Japanese terms gembutsu, means “real thing” or “real place,”. It contains the following elements: observation which means watching people perform work in-person; in addition to location which means observing people at the actual location where work is performed. A Gemba Walk is a method used to observe and understand how work is being performed. Moreover, this method is a support for giving an up-view about the performance and –behavior, (Maasaki,1997).

8- Moving Range Chart: Individual Moving Range or as it’s commonly referenced term I-MR, is a type of Control Chart that is commonly used for Continuous Data. This chart was developed initially by Walter Shewhart. The moving range (MR) chart shows variability between one data point and the next. Moreover, Moving Range charts are also used to monitor the effects of process improvement theories, (Bayart, 2001).

2.3 Previous Studies

2.3.1 Leans Six-Sigma for Process Improvement

Process Improvement is the precautionary measure of identifying, analyzing, and improving onto existing business processes within an organization for optimization and to meet new standards of quality, (Hamada, 2015). Whilst Rouse (2013) defines Business Process Improvement as a strategic planning methodology endeavor at identifying employee skills required to lead improvements in order to promote smootherprocedures, more efficient workflow and overall business growth.

The studies above define process improvement as a method used by the organization in order to eliminate different types of waste, minimize variations, and solve both the administrative and productive problems that hinder the organization from achieving its goals and exceed the customers’ expectations.

Jouda (2013) conducted a study about improving process quality. He aimed to implementing Six Sigma in the services sector in the Arab countries. The purpose of the study was to reduce the percentage of the defects in their processes and improving service quality. He concluded that focusing only on the quality of inputs and outputs is insufficient to provide good quality services to the customers, but also include the quality of processes likewise. The study reported several recommendations such as the necessity of training the employees to adopt Six Sigma.

Pojsek (2003) has studied in depth each concept of lean, six-sigma, and lean six-sigma, in an attempt to convey the methodology that should be applied on the basis of culture or organizations as well as the situations being addressed. In this paper, the author stated that lean methodology focuses on reducing the time that elapses between a customer's order and the shipment of the product or the provision of the service that fills the order. He also mentions in that lean helps to reduce cost and cycle time which reflects and enhances the overall. performance He also defined six-sigma as a method that helps solve both process and business problem. To clarify the study, the researcher, uses DMAIC methodology to implement the improvement. He indicates in that firms attempt to use the combination of lean and six-sigma. The researcher concludes that the choice between six sigma and lean in implementation much depends on the dominant culture of the company; if the company values more the analytical study, then Six Sigma will be identified as the best option to implement. On the other hand, if the company values more arriving at visible outcomes, then lean will be the preferred option to implement.

2.3.2 Lean Six- Sigma in the Private Sector

Hea, Zhanga, and Zhang (2014), used the DMAIC methodology to improve services' quality, the purpose of their study is to find out how the use of the DMAIC methodology helps to reduce the turnover rate of the dispatch employee. After finding the root cause and implementing improvements, the result showed that the weekly average turnover rate of dispatched employees declined from 2.5% to 1.4%. This has been accompanied by a reduction in human resources costs, improvements in production quality, in addition to yield stability.

According to Maleyeff (2014), the critical success factors of six sigma projects include organizations' deployment of a sound, consistent, and robust methodology, initiating long-term cultural change and building of trust by removing fear, and communicating the vision to all stakeholders.

Nakhai (2009) published a paper to clarify and evaluate the contributions of six sigma methodology to improve the service quality. He concluded that the strong catalyst to adopt six sigma to services has led to a limited field of applications and to impractical expectations as to what six sigma is truly eligible to achieving, predominately in knowledge-based environments.

One of the successful applications of lean six sigma projects was conducted by Indrawati and Ridwansyah (2015), the aim of the study is to improve the quality performance, since it was around 2.97. The researchers segmented the improvement into two phases; in the first phase the study focusses on wastes analysis by using process activity mapping in order to classify the activities under value added and non-value added, then they evaluated the manufacturing process capability using failure mode and effect analysis tools. The result of the analysis showed that 33.67% non-value-added

activities and 14.2% non-necessary added activities that occur during the manufacturing process. The second phase focuses on analysis in order to detect types of waste; product defects, inappropriate processing and waiting are types of manufacturing waste that frequently occur. A continuous improvement program was developed to overcome that problem. The purpose of the study was to improve production performance of and minimize production waste –by removing non-value-added activities that cost the company and waste time.

2.3.3 LSS in Packaging Improvement

Patel, (2011) focused on the implementation of LSS project at an Indian Packaging Company called Kishan Plastics. This company which wanted to sell products in USA has implemented LSS in order to reduce the variation in processes thereby improving the quality of products for the customers. The study mainly focuses on showing the management of Kishan how to improve its current manufacturing or production process. It also defines the production process from supplier approval through production and ending at the shipping department within Kishan. It has been further elaborated within the boundaries using a SIPOC map. At Kishan, they implemented several LSS tools such as Project Charter, SIPOC, Flowchart, Value Steam Mapping (VSM), and Cause and Effect diagram, which led to increasing Kishan's profit by 23.64%, machine stoppage is reduced by 72.2%, and production is increased by 28.33%. They only have one machine in production line so it was easy to quickly see the LSS results.

2.3.4 LSS and Efficiency

The concept efficiency is defined in Modig and Åhlström (2013) as the most efficient use of any value adding resources that can be gained. For instance, how much can a machine produce or how many calls can a call agent process within a certain time period? Flow efficiency, on the other hand, focuses on the process output or the individual unit being processed and the efficiency of the process flow of this unit withinthe organization, (Modig & Åhlström , 2013).

Tennakoon (2015) studied the application of DMAIC to improve delivery efficiency. The importance of the study was to provide on timely delivered products and services, which has become a milestone and competitive advantage. The conclusion of the study indicates that the most problematic cause behind the delivery failure is poor quality and plant availability.

2.3.5 LSS in Pharmaceutical Industry

Manufacturers in these industries are focused on reducing operational costs while ensuring compliance, in order to ensure a robust market position and competitive advantage. They look to increase the efficiency of their operational processes, improving efficiency, optimizing resources, reducing waste, as well as controlling inventory.

Due to the success of the implementation of combined methodologies of six-sigma and lean in pharmaceutical company, where by lean leads to mitigations of waiting time, decreasing the production waste, and improving communication with end users, and enhancing the quality of productions and the laboratory testing. On the other hand, Six-

Sigma decreases the variation, discrepancies and inconsistences thus arriving at the required the quality of the whole process levels.

This research concludes that the principles of FDA's PAT (Process Analytical Technology) initiative are extremely well aligned with lean manufacturing thinking, suggesting a positive outlook for lean pharmaceutical industry, which has successfully been implemented in companies such as Astra Zeneca, Johnson & Johnson, Pfizer and others.

The DMAIC process is implemented in order to creating a balance between reducing cycle time and saving patients' lives. In addition, to the high cost of skilled labor, supplies, legal fees, testing and accident and negligence compensation. Healthcare organizations should look at other ways to increase efficiency and reduce cutting costs. The DMAIC process has been implemented in this article. Consequently, maximal utilization of resources has been achieved, fewer redundancies have been noticed, bottle-necks have been minimized. In addition, working conditions have improved for healthcare personnel. Increased patient and physician satisfaction as well as cost savings have been achieved. All of these things point to the success of the LSS process implementation into the healthcare services, (Tanner, Sezen, & Antony,2007)

2.4 Chapter Summary

In this chapter, many terms that were used have been clarified, in addition to a summary of some previous studies. On the other hand, it was found that LSS methodology played a very important role in the development of the operations, as shown in the studies that were considered related to this research.

Chapter 3: Research Methodology

3.1 Overview

The research type that is followed is an exploratory research that explores the application of DMAIC-LSS methodology at a Palestinian pharmaceutical manufacturingcompany. The study was conducted during 2018-2019 at BPC. Both qualitative and quantitative research methods were applied in order to obtain specific and accurate information and facts about the packaging process. In addition to collecting primary data through observing the process, process walk interviews were conducted, and secondary data were collected from previous studies such as articles, scientific researches, journals, and previous master's degree researches. Data gathered wereanalyzed and interpreted using software programs such as PMI Excel Calculation.

3.2 Data Collection

Data are facts, figures and other relevant materials which serve the base for any study and analysis. The sources of data have been classified into primary sources and secondary sources.

Primary Sources: primary data are the first-hand information collected through various methods such as observation, interviewing key persons and GembaWalk, (Douglas, 2015).

Secondary Sources: secondary sources are not only published records and report, but also unpublished records like financial records, minutes of meetings, inventory records, ect. Though, secondary sources consist of a diverse source of material. Moreover, they consist of data which the researcher has no control over collection and classification.

Also, the secondary sources are limited in time and scope; thus, the researcher needs not to present when and where they were gathered, (Douglas, 2015).

The researcher gathered both primary and secondary information for effective and efficient utilization of the method, by interviewing the key persons who are highly engaged with the packaging process and managing the process, in order to have a comprehensive data about the whole process and problems. Moreover, the researcher spent a couple of months observing all process steps in the packaging area and other operations that are related and affect the processes. Furthermore, the researcher used the Gemba Walk Technique; which is one of the most useful tools for collecting data.

3.2.1 Interviews

Interviews are one of the most enriching methods of data collection, as they include different job levels and enable to give a comprehensive and integrated vision of the progress of operations and the problems faced by each job level from its point of view.

Although the researcher was not able to conduct interviews on a large scale, and some administrators were intransigent not to engage the workers and provide information related to the problems, the researcher was able to conduct some of them to understand more about what are the most difficult obstacles and challenges those workers face in the workflow. The following are the interview questions:

1. What are the steps of the packaging process?
2. What are the main challenges facing the packaging process?
3. Which processes face the largest number of issues?
4. From your point of view, what are the root causes of these problems?
5. What kind of waste the process suffers from?

6. How many people work on the steps of the packaging process?7-How many people are shared resources and work elsewhere too?

3.2.2 Observations

The researcher spent two months at the factory observing and monitoring the progress of operations and identifying the problems. A stop watch was used in order to collect cycle time and the essential data. However, the production manager provided the approvals needed to observe most of the operations.

Some procedures were dealt with confidentiality, so they were not granted an approval to be described or mentioned in this research. Furthermore, the researcher used Gemba Walk technique, and filled the process walk form for comprehensive vision of the whole process.

3.3 The DMAIC Approach

The DMAIC (Define, Measure, Analyze, Improve and Control) problem solving or process improvement methodology is considered one of the Six Sigma's approaches for process quality improvement. This model consists of five associated phases (i.e. define, measure, analyze, improve and control) that consistently aid any institute to detect and solve problems and enhance its processes. According to Dale (2007); DMAIC phases are defined as follows:

1- **Define:** In this phase, strategic issues of process improvement, based on customers' requirements and expectations (voice of customers) are identified, team members are identified and their roles are defined. The project scope and boundary, and the

objectives of selected project are defined through filling the project charter, and data are collected by observation and interviews (Gijo, Scoria., and Antony, 2011).

2- **Measure:** this phase includes flowcharting, streamlining and standardizing the targeted process by identifying the detailed flowchart, quality concerns, eight wastes and quick wins. Also, it involves selecting the measurement factors that need improvement and defining a proper structure to asses, compare, monitor and evaluate current performance, (Stamatis, 2003).

3- **Analyze:** this phase focuses on identifying sources of wastes, creating smooth flow and balancing the work. Moreover, it centers on determining root causes of defect and understanding why causes have taken place in addition to prioritizing, verifying and selecting the root causes, (Adams, Gupta, & Wilson, 2003).

4- **Improve:** this phase is defined as a step of testing possible improvements using experimental and statistical tools and gauges, studying and evaluating results and identifying the proper improvements, finally implementing selected actions to reduce the amount of quality problems, (Omicron and Ross, 2004).

5- **Control:** the final phase within the DMAIC process focusses on standardizing improvement actions to ensure that all improvements are persistent, continuous monitoring of performance and finally documenting process improvements.

This study is based on practical research work executed by the researcher and BPC side by side, for improving the packaging process. Figure 3.1 depicts the DMAIC cycle.

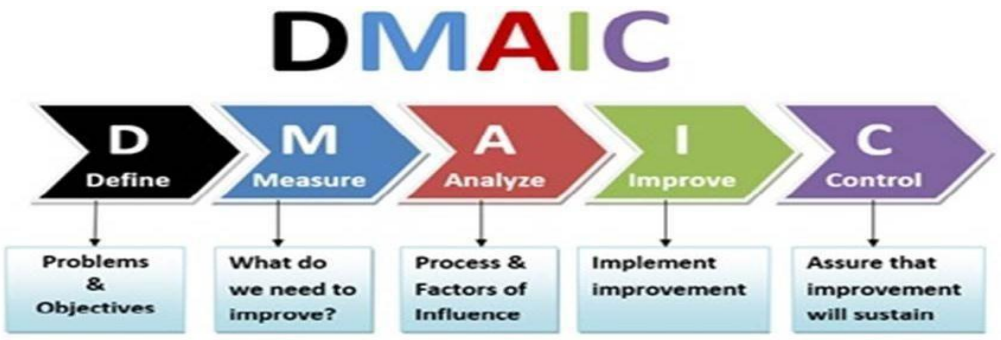


Figure 3.1: The DMAIC Cycle ("dmaic graphic - Bing images", 2021)

3.4 DMAIC Phases Objectives

According to Koning and Mast (2006), they stated that the objectives of the DMAIC phases are as follow:

Define Phase:

- Problem selection.
- Benefit analysis to identify and map relevant processes.
- Identify stakeholders
- Determine and prioritize customer needs and requirements
- Make a business case for the project.

Measure Phase:

- Translation of the problem into a measurable form.
- Measurement of the current situation.
- Select one or more critical-to-quality (CTQs) characteristics and determine operational definitions for CTQs and requirements.
- Validate measurement systems of the CTQs.
- Assess the current process capability.

Analyze Phase:

- Identification of influence factors.
- Identify the causes that determine the CTQs' behavior.
- Select the vital few influence factors.

Improve Phase:

- Design and implement of adjustments to the process to improve the performance of the CTQs.
- Design actions to modify the process or settings of influence factors in such a way that the CTQs are optimized.
- *Conduct pilot test of improvement actions.*

Control Phase:

- Empirical verification of the project's results.
- Adjustment of the process management and control system such that improvements are sustainable.
- Determine the new process capability
- Implement control plans.

3.5 Research Framework

Figure 3-2 provides a summary of the framework methodology for the research and identifies all activities, outcomes, and the results in each phase.

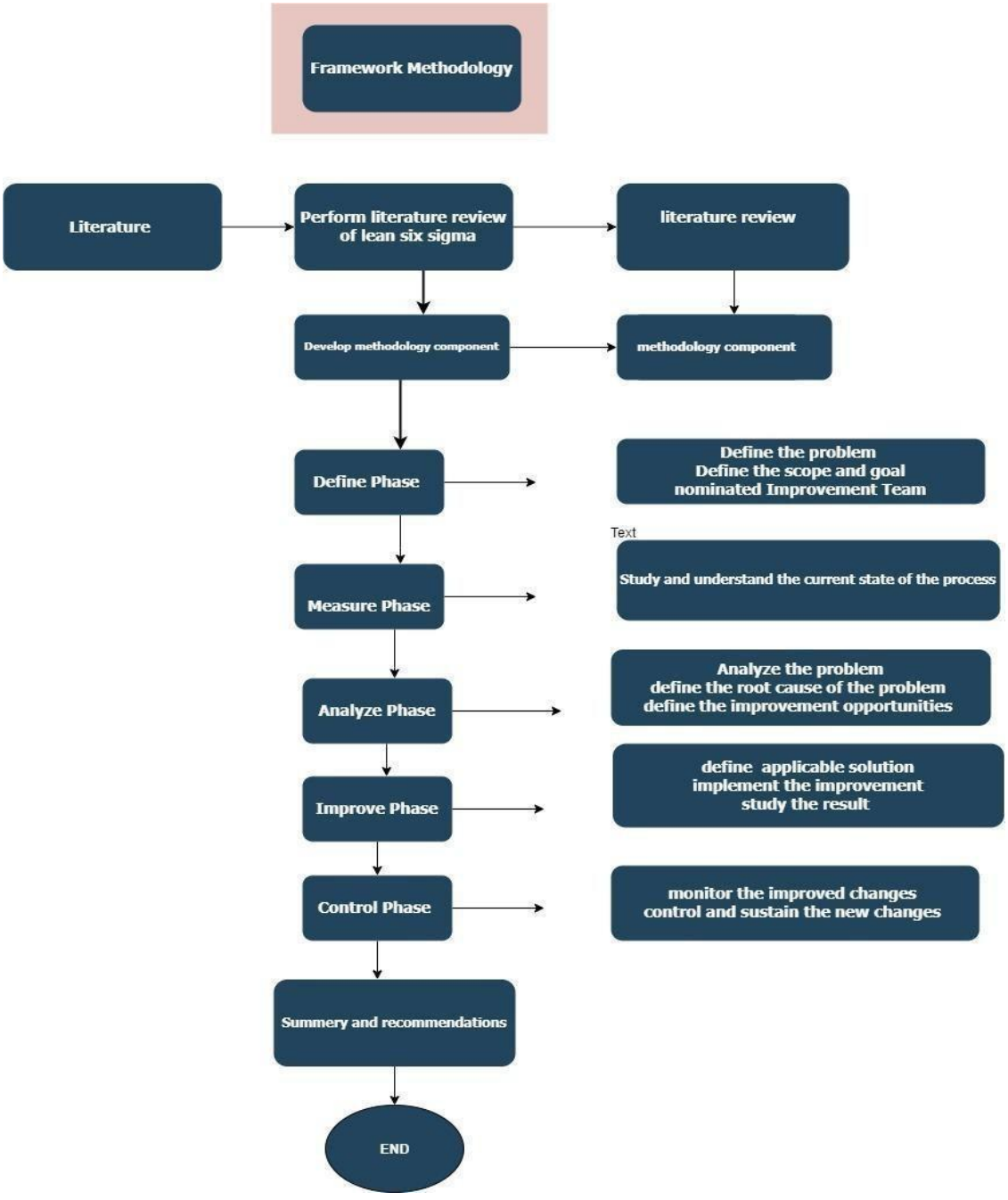


Figure 3.2: Research Framework

Chapter 4: Results and Discussion

4.1 Overview

In the pharmaceuticals sector, manufacturers apply LSS in order to reduce operating costs and to ensure great service to their customers. Because of the specificity of the pharmaceutical industry, these regulatory measures are supported by other regulatory bodies such as the US FDA, which seeks to reduce the number of errors and risks in the manufacturing and operation process. The ultimate goal from LSS projects is to achieve a radical improvement in systematic way by eliminating defects and reducing the variation.

Usually there are processes that exist and work fairly well and need to be improved. In this case, the focus for considerable improvements can be achieved by using the DMAIC tool. The DMAIC improvement cycle is a data-driven improvement process road map and one of the core tools used for Six Sigma projects.

The DMAIC methodology described in the previous chapter and selected tools from every phase of this methodology were applied in order to achieve the main objective of this research which is to improve the efficiency of the packaging process. In this chapter, there is a section for each of the five phases of the DMAIC methodology which describes the tools that have been implemented. Several LSS tool kits were used to analyze the operation and recognize the causes of the problems, while some other tools were used to improve the process steps and make them more efficient.

During the define phase, the project charter is created and the scope is determined. Also, the team members are selected and work together in order to understand and fill SIPOC template. The second section is the measure phase which is based on measuring the variables based on the existing situation. The importance of this section is to figure out

the process problems that are causing waste and misuse utilization of resources with their root causes. Tools were used in this phase include flow chart, eight wastes, in addition to value stream mapping for the current state. Whereas the third section is the analysis phase; to identify the root causes in order to find the improvement plan by using the result of interviews that were conducted, process walk interviews, cause-and- effect diagram, and Moving Range chart. While the last part summarizes the research and highlighted the results. Finally, the recommended improvements to be implemented were identified.

4.2 Define Phase

During this phase and the creation of the project charter, the scope is determined. The team members are selected. The project is validated by obtaining the sponsor's approval, in addition to establishing a baseline and setting pragmatic goals.

4.2.1 Project Charter

According to Pyzdek, (2014); project charter is used to determine the scope, problem statement, objectives, financial justification and the required resources or members of the project team. It is considered as the baseline of the project since it should contain a clear quantifiable problem statement and how it is aligned with strategic goals. Itcontains project team members and sponsors, scope, time frame, risk, objectives, context and business impact are also defined.

As stated, improving the efficiency of the packaging process at BPC by eliminating the different types of waste and the maximum utilization of resources.

The researcher used to create the project charter and formalize the improvement project by answering three questions.

1- What are we trying to accomplish?

Improve the packaging efficiency of the BPC by eliminating the different types of waste and maximizing the utilization of resources.

2- How will we know that a change will lead to improvement?

The requirement was to measure the percentage value-added for the packaging process. This step gives the exact time for the process itself, and the amount of waste. The baseline must be measurable, once change occurs, the improvement will result.

3- *What changes can we make that will lead to improvement*?

- Defining project objectives, scope and team
- Defining as is process.
- Defining key matrix and goal
- Mapping process and flowchart.
- Baseline data collection.
- Identifying key performance areas and root cause analysis.
- Prioritizing and evaluating potential improvement action.
- Implementation plan.
- Executing improvement.
- Analyzing results and tracking results up until project closure and handover.

The project charter is depicted in Figure 4.1.

Project Charter

Project Sponsor	Younis Alama
Team Leader	Renad Housheya
Project Title	***Improving the Efficiency of the Packaging Processes at Birzeit Pharmaceutical Company using LSS Methodology***

1. Purpose:	
2. Business Case (Issues to be addressed/process to be improved)	
The packaging processes lack of smooth flow, have no designated location, which in turn results in waste of time and other wastes and drain resources.	
Key Players	**Scope**
- Renad Housheya - Aysar Taqatqa - Joseph Sager - Suhad Mashal	Packaging Process at BPC
Enablers/Risk Mitigation	**Barriers/Risk**
- Commitment of top management. - Time availability for the team. - Vision of the company for the purpose ofraising the productivity of workers	- No designated location. - Layout problem. -Tight timeframe. -MOH restrictions. - Lack of funding for plan optimization.

Figure 4.1: Project Charter

4.2.2 SIPOC

SIPOC is one of the useful tools in process improvement that summarizes the process input and output visual form. It helps the people who are not familiar with the process by providing them with a high clear view of the steps of the process and all details of those steps. The SIPOC refers to five important elements as follow:

Supplier: both internal and external suppliers for the process.

Input: inputs to the process such as material, information, and work. Process: the process flow representing the entire process.

Output: the outputs for the internal or external customer Customer: internal or external customer who received final output.

After agreeing and confirming the project charter, the researcher and the improvement team discussed the whole process with all inputs, outputs, in addition to duties of all the employees that are engaged in the process. The improvement team managed to get a clear understanding of their tasks. After that, the improvement team created the SIPOC as shown in Figure 4.2.

Among other things, the SIPOC has highlighted the following Results Measures, Customer Needs, and Results concerns:

Results Measures: Time taken to complete the process, and the exact quantity requested. Results Concerns: Delay on delivery and the variation in weight

It is very clear that there are phases which waste time and resources. The SIPOC tool has been used to start the measuring phase in order to identify the phase that takes the most time to be completed.

Key Business Process Name: Packaging Process

Suppliers	Input	Process	Output	Customers
Printing material (cartoon & brochure) (Production line) I drop production line Ampoule (production line) Quality Department Store (conveyor, packaging box, nylon shrink	Printed cartoon Brochure Released ready medicine (types of medicines) Labour Quality auditor (conveyer, nylon, packaging box)	**Process Purpose:** To package medicine according to specification **Process Owner: packaging department**	Approved i drops medicine Approved ampoules medicine	Store

Process Steps (High Level	Receive weekly production	→ Req of fro isition aterials	→ Receiving and distributing	→ Obtaining quality dep approval	→ Pa p kaging	Delivered the Finished product to the store	**Customer N eeds** Delivering the finished product exact quantity ontime according to quality specification
Process Measures **Present**	- Receiving ime - Accuracy of plan On time	Quantity matching ordered quantity Quality of material received accurate quantity	Received in Time Exact Quantity 100 % on time 100% Qnt	Time to obtaining the approval Approval stamp	Compliance of samples with quality standard 100% on time	Time taken to complete the process "cycle time Exact Quantity 100 % on time 100% Qnt	**Results Measures** Weight Quantity Time Lap testing (quality department)
Data	Accurate plan	Ordering 100% accurate quantity Quality specifications are met	Same quantity within time	Checking approval stamp	Quantity of packaged medicine matching quantity per production plan Quality of packaging 100% meeting packaging specification	Ordering 100% accurate quantity	**Results Concerns** Delay on delivery Variation in weight	**Date**
Goal Performance								

Sources of Variation & Waste	urgent bid	Variation in quantity	Delay on delivery Variation on quantity	Waiting time till the approval	Defects Variation in Quantity	Defects Variation in Quantity		**Version**
Impact on Performance		Delay on the order	Delay on the process Affect the production quantity	Delay on the order	Delay on the order	Delay on the order		

Figure 4.2: SIPOC of packaging process at BPC

4.2.3 Summary and Next Step

In this section, Project Charter and SIPOC have been used in order to define the problem to be resolved. In the following section, the current performance of the process is studied, key measures are identified.

4.3 Measure Phase

The purpose of this phase of the DMAIC technique is to deeply study, understand and document the current state of the process of the packaging process to be improved. This includes estimating the baseline performance of the process with respect to the critical to quality aspects identified during the define phase. In addition to identify the process problems that are causing and waste and misuse utilization of resources with their root causes. In this phase, data were to identify where the waste occurs or where the non - added value activities exist, in order to understand the as-is situation and choose areas where improvements are needed. The following tools were used during this phase: Flow Chart, VSM, and Eight Wastes.

4.3.1 Flow Chart

The researcher created the flowchart shown in Figure 4.3 which illustrates the flowchart for the current process and presents the steps and the relationships between stepsinvolved in the process of packaging to identify bottlenecks, redundancy and non-value-added steps in the process.

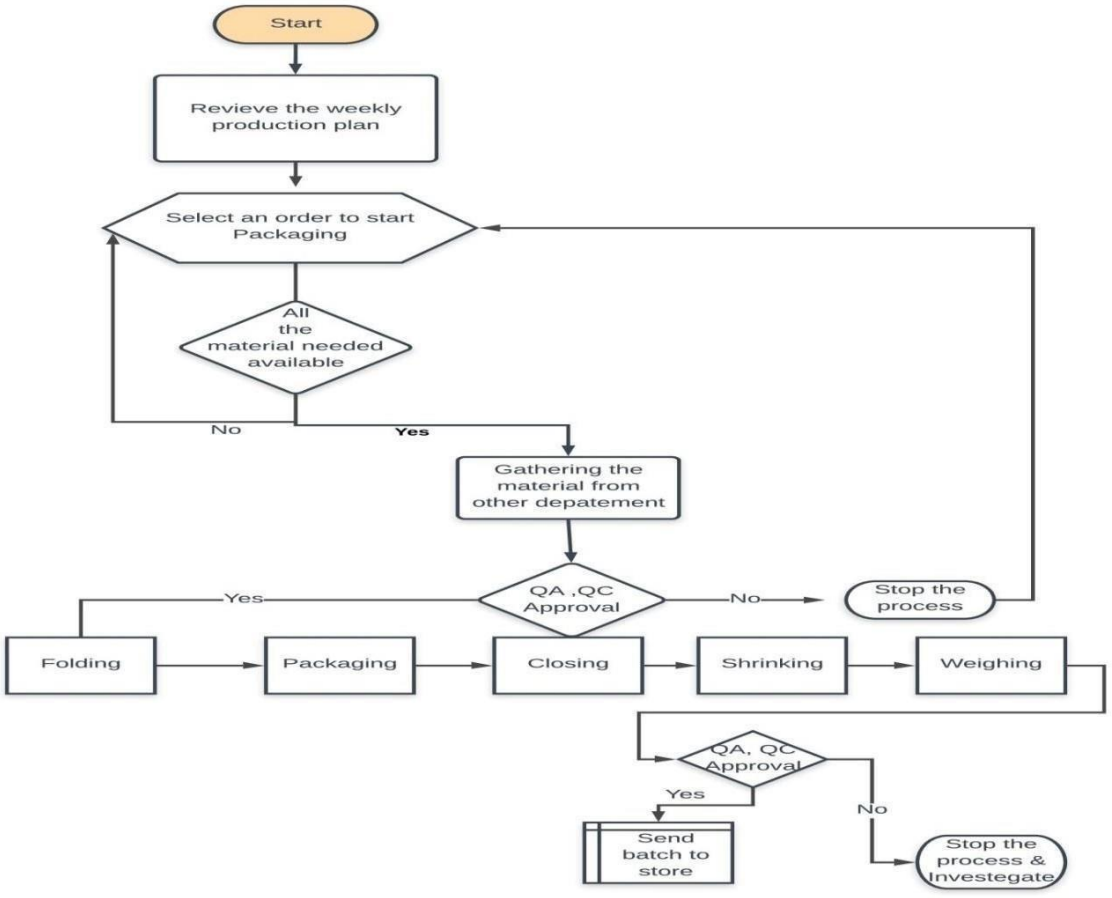


Figure 4.3: Flow Chart

The process starts when the packaging department receives weekly production plan. Once the order is determined, the materials needed are requested, and as soon as the materials are available, the quality department is requested to examine the materials and combine them with their quality standards. Once the quality assurance approved the process; the packaging process begins. Otherwise, the process is stopped.

Upon completion of the weighting process, random samples are taken by the quality assurance and checked for conformance of the specifications. Once obtaining approval from quality assurance, the batch of medicine is moved to the store. Otherwise, the quality assurance investigates the whole samples.

4.3.2 Eight Wastes

Eight wastes are considered one of the essential tools in the measurement phase. Waste is defined as any step that doesn't add value. The process steps were analyzed by the researcher and studied one-by-one process to determine the types of wastes that exist in each of them. These wastes were categorized into one or more of the eight wastes' categories which are illustrated in Figure 4.4. They include: (Defects, Overproduction, Waiting, Non-Utilized resources, Transportation, Inventory, Motion, and Excessive processing). Determining these wastes helped to identify the improvement opportunities available.

8 Wastes Check Sheet v3.2

8 Wastes Check Sheet

Process Area: Packaging Department **Date:**

	Waste	Definition	Examples	Type "High", "Medium", "Low"	Description of Issues
D	**Defects**	Information, products and services that are incomplete or inaccurate	- Inaccurate amount - Broken parts - The sample does not match the requirements	*Low*	*Any parts or quantities that do not meet the required practical specifications*
O	**Overproduction**	Making more of something - making it earlier or faster- than it's needed	- Extra copies of reports - Redundant storage (hard & soft)/ rare	*Low*	*Rare, usually, where there is a weekly report on the progress of production*
W	**Waiting**	Waiting for information, equipment, materials, parts or people	- Waiting for approvals - Waiting for material - Waiting for ready batches for movement	High	*The main problem is due to facility design*
N	**Non-Utilized Talent**	Not properly utilizing people's experience, skills, knowledge or creativity	- Employees unable to make decisions - Employees not fully trained -Employee overburden	low	*This is due to the lack of clear duties for each employee*
T	**Transportation**	Unnecessary movement of materials, information or equipment	- Hand-offs between functions - Multiple reviews - The flow operations are not horizontal many materials brought from other floor	high	*The main problem is due to facility design*
I	**Inventory**	Accumulation of parts, information, applications, etc. beyond what is required by the customer	- Stockpiling supplies -Low storage space - Keeping batches longer than necessary before storage	low	*Due to layot problem*
M	**Motion**	Any movement by people that is not of value to the customer	Overlapping processes and tasks - Walking between material - Switching responsibility	high	*Material in process , Overlapping tasks, layout problem*
E	**Extra-Processing**	Any steps that do not add value in the eyes of the customer	- Extra formatting, extra fields - repackaging to change the customer holder - Extra formula reports and decuments.	low	*Repacking depends on urgent orders*

goLEANSIXSIGMA.com

Figure 4.4: Eight waste

4.3.3 Value Stream Mapping (VSM)

The packaging process in the current situation has no flow of operations sequentially. On the contrary, it is done spontaneously; each worker chooses to perform a particular task without an estimate of the whole process, and therefore this situation causes Materials in Process (MIP) and impede movement. Moreover, it causes a lot of chaos and wastes time where there is realization of one process at the expense of another.

Through the researcher's observation of all the details of the packaging process and the performance of the workers, it was found that there are no accurate calculations of the time spent in each process individually and how many workers need each process to fit the work smoothly without interruption and waiting. However, supervisors rely on the experience of the time it takes to produce different varieties at the rate previously produced, with a difference in the number of workers and the possibility of requesting workers from other departments for delivery on time. Figure 4.5 below represent the VSM as-is situation.

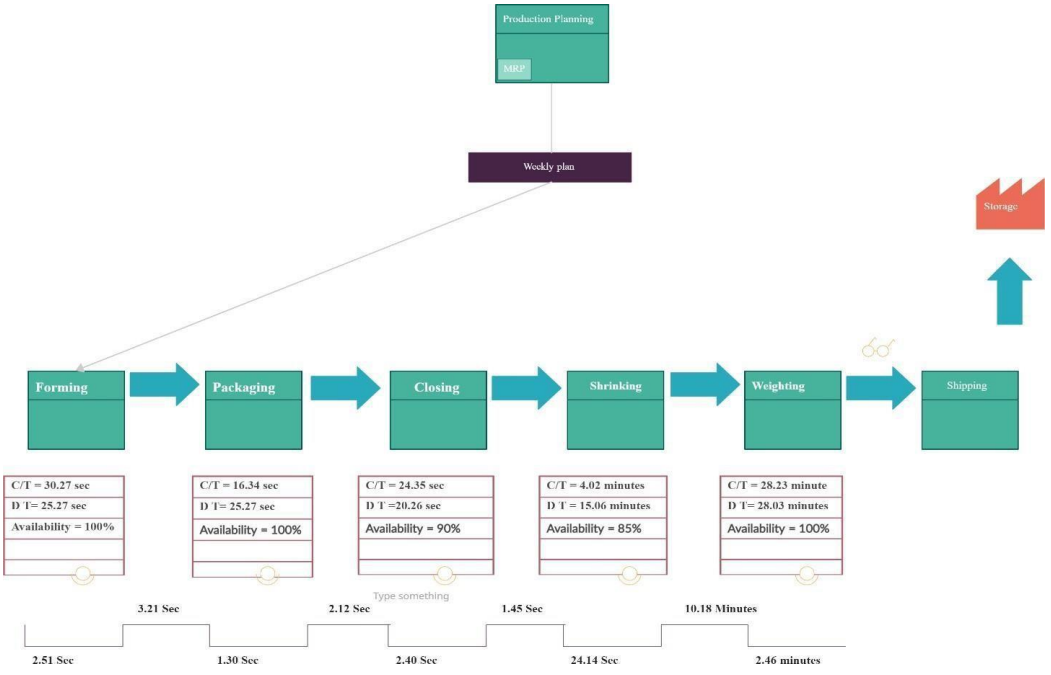


Figure 4.5: Value Stream Mapping as It is

4.4 Analysis of Root Causes and Research Findings

The main purposes of this phase are to analyze the problems, and identify the root causes for both the variation and waste, in order to define the improvement

opportunities. The first activity conducted was a comprehensive study of the process by a brainstorming session with the process operators to identify potential causes.

In this section, the analysis tools used by the researcher are presented. They include: process walk interview, the result of interviews, cause-and-effect diagram and Moving Range chart.

4.4.1 Process Walk Interview

This tool was used to facilitate the concept of the packaging process in a comprehensive way and was filled on the fifteenth of September 2020 with the supervisor of the packaging process. Figure 4.6 summarizes process walk interview results.

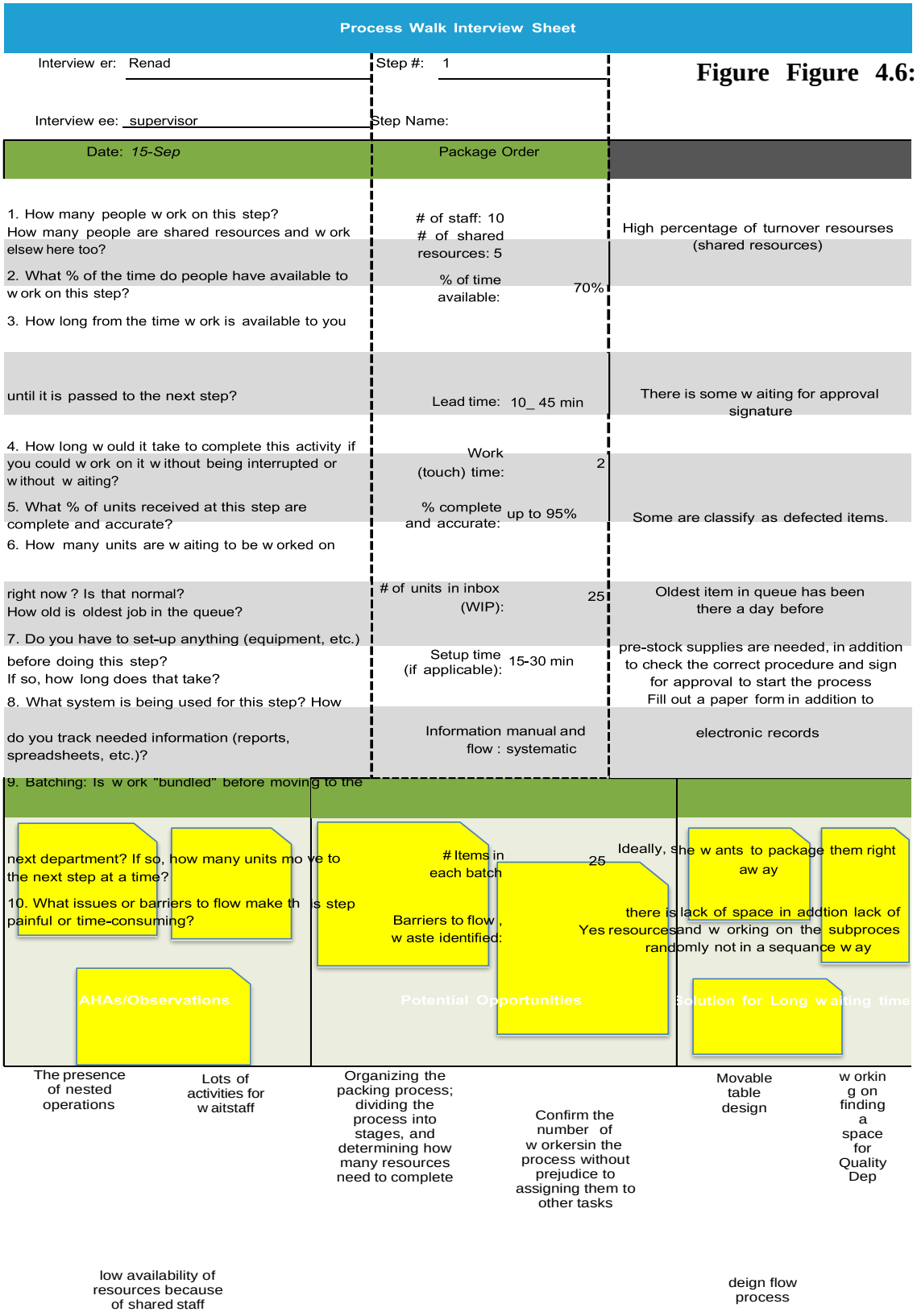
4.4.2 Interview Results

Interviews at various functional levels are important tools for identifying the stages of operations, together with the dilemmas and problems faced at all levels. However, the researcher was faced by many problems due to the reluctance of the majority to cooperate and respond to the interviews; they have their own reservations and inhibition. Interview data were collected and unloaded, and some responses were convergent among employees, the answers are summarized as follows:

- The biggest dilemma facing factories is layout problem.
- The process has many routes between departments because the entire process path is not horizontal, but rather layers.
- The processes are not piecemeal but rather intertwined and there is no organization of tasks among workers “there is no smooth flow".

- There is great pressure on the worker and there are no specific tasks for the worker "overburden" staff.
- There are many overlapping processes.
- There is no real knowledge of how much time each process actually takes and therefore how much workers are required to assign for each process.
- There are many stages for checking and they waste a lot of time since the quality assurance unit is located far from the packaging area.
- There is a lot of motion, transportation, and movement regarding the layout of the factory.
- The material in process impedes movement and operations.
- They are looking for the material for long time since the staff is forbidden from using the elevator, only material moved by floors through the elevators.
- There is no plan in order to take advantage of the waiting time to obtain quality approvals to complete the process, the workers keep waiting without doing any task.

Figure Figure 4.6:



Process walk interview results

4.4.3 Cause-and-Effect Diagram

The researcher used the Cause-and-Effect Diagram to identify possible causes for problems in the process. The goal of this method is to arrange the brainstorming summaryin an effective way, in order to facilitate the process of finding solutions.

Figure 4.6 depicts the cause-and-effect diagram of the packaging process. More elaboration on each potential root cause is discussed.

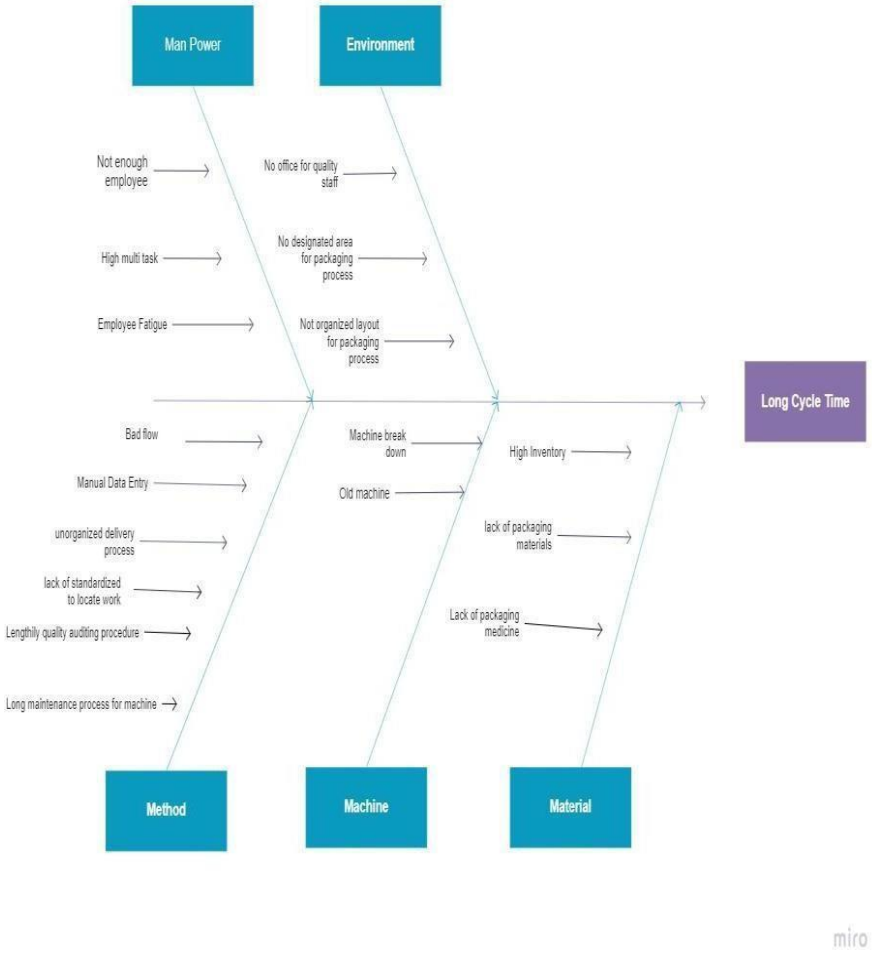


Figure 4.7: Cause-and-effect diagram

- **Man Power**

1- Not enough employees: interference with operation occurs due to the lack of the labors as they are usually requested by other departments in order to perform another job or task.

2- High multi task: It is usually done by companies in general and in various sectors to reduce operating costs and search for higher profit. As long as there are no clear duties for each worker, s/he may be asked for a particular task and leave her/his current task pending.

3- Employee fatigue: as mentioned before, there is no core and clear responsibility for the employee. This makes the staff members exhausted and having responsibilities from different departments. This leads to staff being dissatisfied with the job,stressed, and unorganized which lead to the employee indifferent to completion of their tasks. In addition to all of the above, most of the packaging workers have beenin service for many years. Over time, their performance and motivation decrease significantly.

- **Method**

1- Bad flow: There is no smooth flow in the packaging process as each person does the process, s/her sees fit and separately from the following processes (forming, packing, closing, shrinking and weighing). This way of working leads to chaos and hinders movement as it causes material in process.

2- Manual data entry: The workers write down all the data related to the packaging process on paper forms “manually”, using more than one form. This results in high wastage time, while all the practical systems overall have been transformed into digital systems.

3- Unorganized delivery process: This is due to the layout problem of the factory, and

the horizontal layout of the facilities, which causes materials to be transported through different floors. In some cases, materials are requested before the date of their implementation and placed in nearby places, causing obstruction of movement. This may cause the material to be transferred more than once temporarily and to more than one site until it's processed

4- Lack of standardized and organized work locations: As mentioned previously, due to the problem of space constraints, there is no specific place to complete the packaging process. Sometimes workers have to move their workplace during the process they are doing and wait until they are informed of the place of transfer to complete the process.

5- Lengthy quality assurance approval: There is no dispute about the importance of the role of conforming to quality standards, especially in the field of the pharmaceutical industry, and the seriousness of failure in it. However, the presence of the quality officer in another building requires that every time he comes to take samples, he sterilizes himself, takes samples, returns to his office, and then comes back again and repeats the protocol for entering the packaging process. Hence, sterilizinghimself and signs to complete the process, and this takes a lot of time and causes the workers to be stopped.

6- Long maintenance process for machines: Whereas, in the event of a machine malfunction, one of the factory engineers is called to solve that problem, and while he is unable to fix it, engineers are called from outside the factory, and there is usually no contract with specific engineers, which takes a lot of time. Although this mechanism can be improved either by intensifying the training of internal engineers or contracting with an engineering company so that it has experience in the history

of machine failures and facilitating the repair process.

In some cases, in the event of a malfunction in one of the machines imported from abroad, and one of the factory's engineers does not know how to solve it, the matter needs to be sent to the supplier company of the machine, and sometimes they have to wait until one of the supplier company's engineers arrives to solve the problem.

- **Environment**:

1- There is no location for quality assurance officer in the same building: As it was previously raised and discussed, the quality assurance unit must be located in the same building and in a nearby office to reduce waiting time.

2- No designated location for packaging process: This causes a lot of motion and transportation of materials which leads to resource depletion.

3- No organized layout for the packaging process: The absence of an organized place for the process makes any process liable to be stopped for any reason such as no room for the materials requested, or the ready batches are kept at the same area for a while, until they are transferred to warehouses.

- **Material:**

1- Lack of packaged medicine: Sometimes, the amount of packing materials is not enough to complete a certain order, the supervisor requested to package and handle the available quantity until it is completed later when the materials are available, they are re-certified and approvals are taken on all the quantity by the quality department despite the approval of the first quantity, which causes it to be checked twice and brought back to the packaging area to take random samples.

2- High inventory: Sometimes quantities of pre-determined items are produced or tenders are obtained for the benefit of the Ministry of Health so that they are in large

quantitiesor even for the purpose of exporting them, which makes the warehouses full for a period, and accordingly any quantity that workers complete is temporarily placed in the storage area until the stores are emptied.

3- Lack of medicine: Sometimes there are requests to obtain medicines for the benefit of certain parties, but there is an urgent order, for example, for a certain party, and due to the difference in packaging from one client to another according to certain specifications, the medicines that were previously packaged are brought, unpacked and packaged again within the specifications of the urgent order.

- **Machine:**

1- Machine breakdown: As it was previously explained from the machine repair methodology, there are many and sometimes frequent failures, and therefore a more effective protocol for repair must be developed.

2- Old machine: Due to the high prices of machines and the longevity of the factory, there are many old machines that have existed for a long time, as there are frequent breakdowns and problems.

4.4.4 Moving R Chart

Through the researcher's observation of the progress of operations associated with the ampoule packaging process, a malfunction occurred in one of the ampoule mechanisms that led to the breaking of the ampoules.

The manager stopped the packaging process and gave the instructions to check the whole ampoules, by washing all ampoules, then drying them, and making sure if they are "safe" to be used or classified as "defect". Such a case, when phased, is a drain of time and laborwork. The researcher conducted a search for the root causes of this situation inorder to avoid such an incident in the future, as it was reflected on delaying the

packagingprocess for two working days; as a small span of five minutes in such a situation can spoilthree thousand ampoules.

It was practically impossible for the researcher to investigate so many aspects and elements of all root causes of malfunction, as this lies outside the agreed upon the

jurisdictions of the researcher. The root cause that was pin pointed was the one that the researcher has focused on; the length of the ampoule and how relevant it is for the end product of the process. If it is within the parameters specified by the capacity of the machine, then it would be produced safely, otherwise it would be broken or yielded defect. Random samples (25 ampoules each) of two ampoules categories (1ML, 3ML) respectively, have been selected. Measurements of the length of ampoules were taken, and were examined to see whether they fall within the parameters of the specifications identified in the process. The result of the examination shows the specifications of the ampoules given by the supplier stands at 1 ML length 21 ± 0.5 MML, while the 3 ML length 89±1 MML.

Figures (4.8,4.9) in the graphs below show that the length of the ampoules is appropriate to the specification led by the supplier. Therefore, the length of the ampouleis excluded to be a factor in the defected ampoules output. There has to be another core factor which has to be perused.

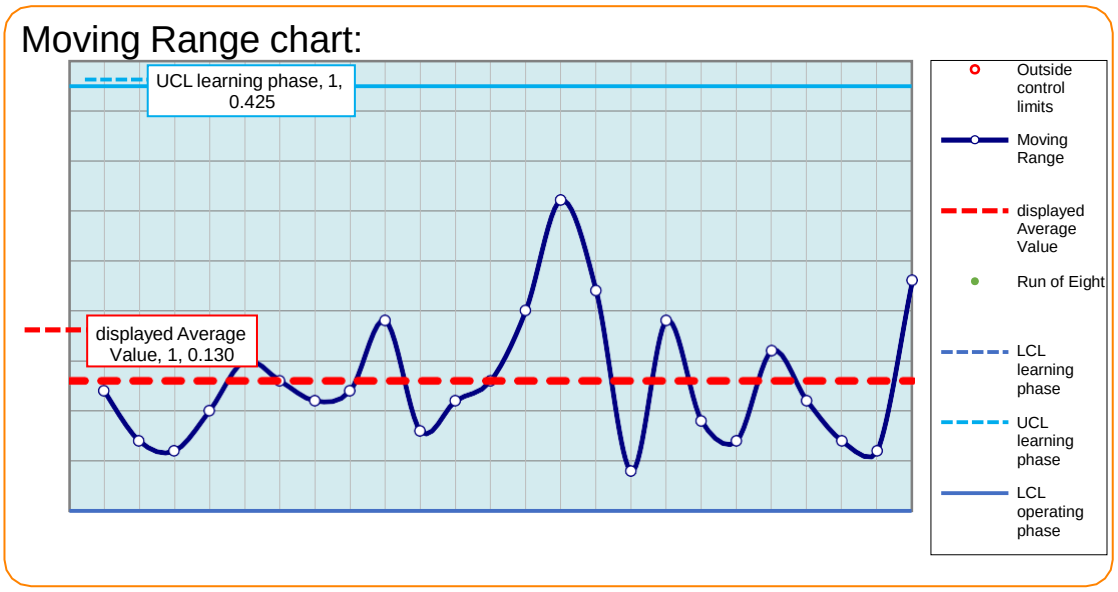


Figure 4.8: Moving Range Chart 1ML

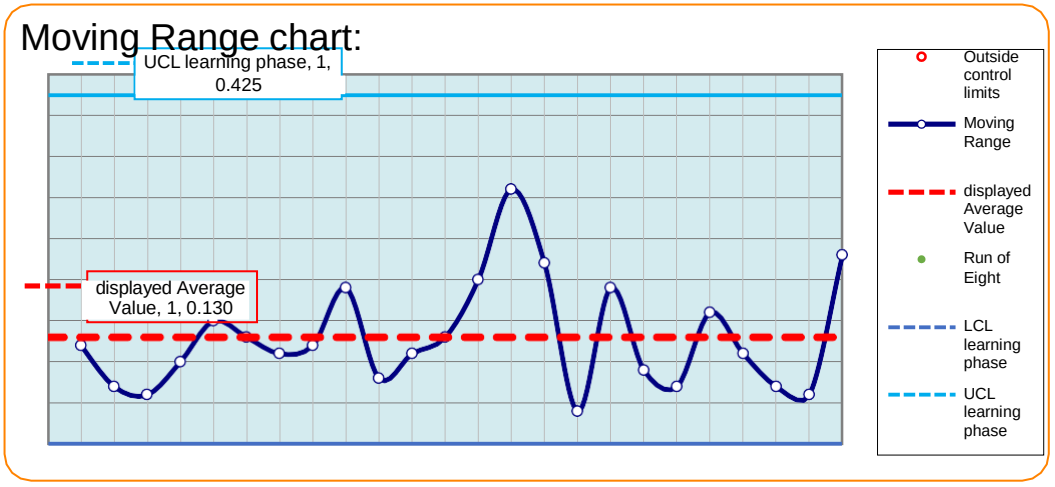


Figure 4.9: Moving Range Chart 3ML

4.5 Improvement Phase and Proposals for Improvement

4.5.1 Overview

The following section addresses both VSM current state, and the proposed improvement.

4.5.2 Value Stream Mapping "current state "

Following the application of modification to the running operations and transformations of the packaging process from somewhat haphazard and interlocked into smooth flow and interconnected operations. Positive result has become clear and average down time, cycle

time have been significantly less. Through this improvement step, we became more knowledgeable of the time average needed for every operation that is i.e., we become aware of what operations need much or less time than others. And how many laborers needed for every operation. Therefore, assignment of laborer can be given on the bases on how many needed according to operation requirement. So, saving can be done in terms of number of laborer and time consumed in every stage.

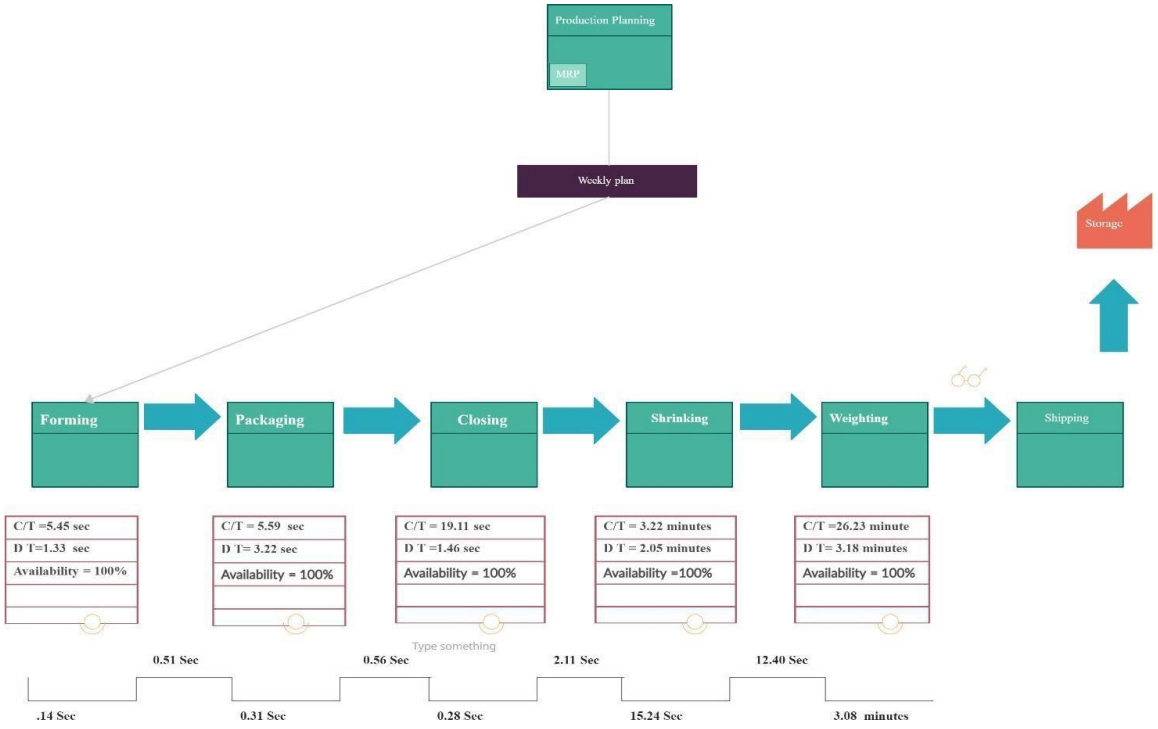


Figure 4.10: Value Stream Mapping Current State

4.5.3 Proposals for Improvement

The various stages of packaging and all interrelated operations have been studied including of which those related to standing. Furthermore, most important steps that cause the wastage whether time or human resources. Steps were suggested that would reduce as much as possible the wastage of all types of resources, and elevate the efficacy and efficiency of performance together with the best use of resources.

The completion of the project was postponed pending the implementations of the forthcoming proposals. Unfortunately, the Corona pandemic in addition to economic situation aborted the realization of most of them. The proposals center on:

The issue of elevator was devoted for the transfer of commodities and items through the various floors without staff accompanying the commodities in the elevator, causing much of delays and loss of materials placed inside the elevator. Sometimes

requirements of the operations were placed inside the elevator and dispatched to the destined floor, but were lost because the absence of somebody at the receiving end. It was agreed with the head of production to assign special laborer to receive and dispatch material through the elevator to predestined locations, and this has helped to resolve this issue. While the problem related to the approval of quality assurance; it has been customary that prior to every operation, quality assurance officer used to come and take samples, examine if it complies with required conditions and parameters. This process was repeated at every stage. This step has been significantly monitored by the researcher who found out that this step frequently caused the total abruption of the whole process for sometimes more than 30 minutes until the quality officer's approval is obtained in order to complete the required process.

This being the case since the quality officer is located in a different building, not in the production and packaging building. It was proposed to the production manager to seriously examine the possibility of finding an office inside the production and packaging building. Since this officer needs to sanitize himself and put on the sanitization overcoat which would facilitate his work.

Allocating space for the quality assurance monitoring in the same building will curb the time loss on behalf of a laborer substantially; 30 minutes saving on behalf of every laborer; if we have ten laborers in the spot, then we would save ten times thirty = 300 of

work time in total.

Regarding to mixing tools issue; The mixing tools are always kept in boxes in faraway distant floor. Whenever these tools are needed, they are brought, used, sanitized, and then returned to those faraway places. This issue was discussed as the packaging labors are assigned to bring and return these tools every time they are needed. This means that their assigned labor in packaging is intermittently breaking. It was agreed with the management to allocate a space in the same floor and allocate a cupboard to accommodate the missing tools.

Regarding of space constrains; the narrow space dictates that the packaged medicine is kept on boards in the packaging hall. The packaging process itself leaves the material in process scattered in the hall. This impedes the flow of the process. In consequence, it was proposed to instate a table with a running bar on the top to facilitate the packaging process and dispatch the material. In addition, to shelves underneath the table to accommodate the packaging medication. Figure (4.11) below presents a table with roller conveyor in addition to bottom storage shelf.

4.11 Photo of a recommended table with roller conveyer with bottom storage shelf

Chapter 5:

Conclusions and Recommendations

5.1 Overview:

This chapter presents the conclusions of this research, and the recommendations.

5.2 Conclusions

This research focused on the packaging process at Birzeit pharmaceutical Company, as it is one of the weakest manual and unorganized processes when compared to other processes in the factory which are automated and digitalized. The researcher spent two months in the factory collecting information and data through interviews with the staff and through observation and monitoring of the packaging process, then had implemented the LSS methodology and tools.

The research methodology adopted was structured around the implementation of the five phases of the DMAIC methodology. At every phase, several tools were implemented and have proven how powerful this methodology is in defining and measuring the problems of the packaging process and identifying the root causes that should be addressed to improve the efficiency of this process. Starting with the Define phase, the SIPOC and Project Charter tools have been used to facilitate the understanding both inputs and outputs, and the mechanism of the process in a concentrated matter. As a result, it has become easier to define the goals and the manner of how the employees got engaged in the process and how to get a clear understanding of the tasks in order to obtain a clear understanding of the packaging process.

In the measure phase, implementing the flowchart for the process provided an integrated comprehensive view of how the packaging process is run every day. This helped the

researcher to set forward solutions and give comprehensive understanding of the operation in order to provide clear vision for the necessary steps needed to achieve the desired improvement. Moreover, the eight-waste tool has been utilized to arrive at all types of wastes in order to eliminate them. Additionally, the VSM tool has been utilized by the researcher for purpose of dividing up all the stages of packaging processes in order to measure sub process individually, to collectively lead to the whole process "calculate cycle time ", and the down time averages have been calculated together with calculating the averages in every sub process.

During the Analyze phase, the results of the interviews with the staff have been studied to understand the scope of the problems facing the laborers during their job operations. Furthermore, the process walk interview has been implemented by the researcher accompanying the supervision. This behavior resulted in getting a deeper understanding of the scope of the problems.

The Cause-and-Effect Diagram tool which was implemented has helped the brainstorming of potential causes for the problems in the packaging process in an efficient manner which helped facilitate finding solutions for the process.

The Moving Range chart tool has also been utilized to analyze the problem of breaking needles. The researcher was able to study one variable only which is the length of the needle and studied whether the length of the needle has a relationship with breaking needle or not. The choice of this variable to be studied as it was the one assumed by the factory managers to be causing the problem of breaking the needles. The outcome of the study shows no linkage between the length of the needle breaking. Consequently, the researcher recommended for management to investigate other variables that lead to the breaking of the needles; such as the raw material, machine settings, thickness of the neck of needles, ect.

The VSM tool has been utilized to calculate the cycle time of the operations and DOWNTIME of the process. The packaging process has been divided into consecutive sub processes and each laborer was assigned a specific task. The identical sub process was assigned to individual laborer. The time every laborer consumed to perform the exact subprocess was calculated. An average for the time all laborer involved was calculated also.This has shown the amount of time needed for the completion of every sub process and the process as whole. And by extension this had help in the process of forecasting as to how many laborers and how much time each process required. The improvement process was welcomed by the laborers and has raised their motivation as it has shown specifically what every laborer is tasked with thus diminishing the burnout of staff and mitigated the burden on all staff involved.

5.3 Recommendations

Most of the improvements recommended in this research were not implemented due to several reasons given by the management of BPC including the intention to build a new building and move the packaging process and other processes to this building, some financial problems faced by the factory, and the outbreak Corona virus pandemic. The following recommendations are proposed for implementation once the conditions change:

1- Layout problem and inadequacy of the space have to be addressed. Further space is needed to avoid wasting time, motion, transportation, and provide flexibility of movement. In addition, adequacy of space would resolve the work in process problem.

2- Lack of job descriptions and duties assigned to the laborer “they are called upon to perform different activities”, this results in over burden and burnout of the laborers affecting their motivations. Management should clearly define the responsibilities and tasks of the laborer with no confusion. So, over burden of laborer is minimized and their motivations will be enhanced.

3- Absence of smooth flow procedure of the packaging process and division of laborer that is required for every sub process, which result in the waste of time for every sub process. Therefore, division of labor and definition of task for laborer and prevention of overlap of tasks should be clearly set by management, so laborer knows well what to do and when. Once this is implemented, it becomes clear how many laborers are needed and can forecast the number of laborer and time needed for each quantity” batch of medicine”.

4- The current quality assurance location is seriously questionable. Therefore, management should seriously consider allocation of quality assurance personal in the same facility of the packaging area. Thus, saving time and effort of roving between buildings.

5- Addressing the issue of machine failure; there is no contract with certain maintenance agencies. Management relies on ad hoc maintenance technicians and engineers. With little knowledge of their technical history. Therefore, a maintenance qualified team should be engaged, so that familiarity of the machine and rapid maintenance can be achieved. On the long run, this will prove to be cost effective and time saving.

6- When it comes to time utilization of laborer, much is lost while waiting for the arrival of quality assurance approval, the laborers can be assigned some tasks instead of waiting.

7- Addressing the issue of the mixing tools; the management should seriously consider allocating space in the same floor and allocate a cupboard to accommodate the mixing tools in the same locations. Thus, avoiding the continual transfers of the mixing tools from one location to another. Let alone avoiding the disruptions of packaging whenever laborers are tasked to fetch and dispatch the mixing tools. In addition to time loss, laborer motivation depreciates because of unnecessary labor task alteration.

5.4 Research Limitations

This study was carried out during January 2019 – February 2020. Hence conclusions made from study do not apply to other periods.

This study is limited to the packaging processes at BPC. Therefore, the results cannot be universally generalized due to the extensive differences in perceptions, disciplines, and attitudes.

According to this research, there were many limitations and obstacles that were reflected in the results of the research, which caused the delay in completing the research and the failure to implement many important proposals in the improvement process. These limitations include:

1- Difficulty in obtaining information or accessing a lot of information, in addition to the fear of many employees to provide any information that may be useful in advancing the improvement process based on management decisions in BPC. All

the information and analysis in this research are based on a total effort of the researcher through observations and data collection, although the researcher has obtained full authority to conduct the research.

2- Among the other limitations that were encountered, which would have contributed greatly to the quality and enrichment of the research is not implementing the proposedimprovements that were presented and discussed with BPC's management. There were several reasons given by management for not implementing the results including the intention to establish a new building which would solve the problems in the packaging process and the layout problem, financial problems, and the outbreakof Corona virus pandemic.

3- One of the obstacles that the researcher faced in obtaining data was the difficulty of continuing to monitor a particular process while keeping the same workers for credibility and accuracy in obtaining results, as management was constantly asking workers to perform other tasks, which leads to the suspension of the process and waiting for long periods to be able to complete data collection under the same conditions (with the same workforce, in addition to the same medicine type to be packaged, as there is a protocol for each type).

   Unfortunately, the researcher was not allowed by management to communicate with employees of different levels who have a direct relationship with the packaging process.

List of References:

Abdulmalek, F. A. and Rajgopal, J. (2007). Analyzing the benefits of lean manufacturing and value stream mapping via simulation: A process sector case study. International Journal of Production Economics, 107(1):223–236.

Adams, C. W., Gupta, P., & Wilson, C. E. (2003). Six sigma deployment (Vol. 4). nadeem, W. (2021). الصناعات الدوائة نم ناطرلي. Retrieved 27 September Routledge. 2021, Agha, from https://info.wafa.ps/ar_page.aspx? s., &

Anchanga, P. (2006). "Critical success factor for lean implementation within SMEs." Journal of Manufacturing Technology Management 17(4): 11.

Bayart, D. (2001) Walter Andrew Shewhart, *Statisticians of the Centuries* (ed. C. C. Heyde and E. Seneta) pp. 398–401. New York: Springer. 4th International Quality Conference May 19th 2010 Center for Quality, Faculty of Mechanical Engineering, University of Kragujevac. 85-92. doi:10.1002/tqem.10113.

Bevan, H. (2006). Lean Six Sigma: some basic concepts. NHS Institute for Innovation and Improvement.

Bossert, J. (2003). "Lean and Six Sigma-synergy made in heaven." Quality Progress 36(7):31

BPC. (2021). Retrieved 27 September 2021, from https://www.bpc.ps/#about_us

Cusumano, M. (1994). "The Limits of "Lean"." Sloan Management Review 35(4): 5 Dale, B. G., Van der Wiele, T., & Van Iwaarden, J. (2007). Managing quality. John Wiley & Sons.

Gijo, E. V., Scaria, J., & Antony, J. (2011). Application of Six Sigma methodology to reduce defects of a grinding process. Quality and Reliability Engineering International, 27(8), 1221-1234

Hamada ,A.(2015).Process improvement organizational development. Retrieved from: (https://www.linkedin.com/pulse/what-process-improvement-organizational- development-abdelaziz-hamada)

He, Z., Zhang, X. T., & Zhang, M. (2014). Reducing the voluntary turnover rate of dispatched employees by the DMAIC process. Total Quality Management & Business Excellence, 25(7-8), 842-855.

https://searchcio.techtarget.com/definition/business-process-improvement-BPI Indrawati, S., & Ridwansyah, M. (2015). Manufacturing continuous improvement using lean six sigma: An iron ores industry case application. Procedia Manufacturing, 4, 528-534 Initiatives for Process Improvement. Environmental Quality Management, 13(2),

Juda, mahfoth Ahmad. (0251) . Improve process quality by implementing Six Sigma inthe services sector. Remah Review for Research and Studies .05-5)0270(05 ,

Maleyeff, J. (2014). Sustaining Public Sector Lean Six Sigma: Perspectives from North America. Management and Organizational Studies, 1(2), 92.

Mega, J. E. (2016). Lean Management Using Six Sigma: Proven Strategies That Work!JMB. Retrieved August 10, 2016, from https://read.amazon.com/.

Miller (2005), Going Lean in Healthcare, IHI White Paper.

Modig N & Åhlström P, 2013. Tätä on Lean: Ratkaisu tehokkuusparadoksiin. Rheologica Publishing

Nakhai, B., & Neves, J. S. (2009). The challenges of six sigma in improving service quality. International Journal of Quality & Reliability Management, 26(7), 663-684.

O'Connor , P. D., & Kleyner , A. (2012). Practical Reliability Engineering (5th ed.).Chichester , West Sussex, United Kingdom : John Wiley & Sons, Ltd.

Omachonu, V. K., & Ross, J. E. (2004). Principles of total quality.

Patel, R. (2011). Modeling Lean Six Sigma in the small packaging industry in India.

Pojasek , R. B. (2003). Lean, Six Sigma, and the Systems Approach: Management Ptacek, R., Sperl , T., & Trewn , J. (2015). The Practical Lean Six Sigma Pocket GuideXL: Using the A3 and Lean Thinking to Improve Operational Performance inANY Industry, ANY Time. Chelsea, Michigan: MCS Media, Inc.

Ptacek, R., Sperl , T., & Trewn , J. (2015). The Practical Lean Six Sigma Pocket GuideXL: Using the A3 and Lean Thinking to Improve Operational Performance inANY Industry, ANY Time. Chelsea, Michigan: MCS Media,Inc.

Rouse, M. business process improvement (BPI)-(1-2-2018). Retrieved from:

Sharma, U. (2003). "Implementing Lean principles with the Six Sigma advantage: Howa batterycompany realized significant improvements." Journal of Organizational Excellence 22(3):9

Stamatis, D. H. (2003). Six Sigma fundamentals: A complete introduction to the system, methods, and tools. SteinerBooks

Stern, T. V. (2016). Lean Six Sigma International Standards and Global Guidelines (2nded.). Boca Raton, Florida: CRC Press.

Tanner, M. T., Sezen, B., & Antony, J. (2007). An overview of six sigma applications in healthcare industry. International Journal of Health Care Quality Assurance, 20(4), 329-340. doi:http://dx.doi.org/10.1108/09526860710754398.

Tennakoon, B.M.M.M and Palawatta, T.M.B., A Case Study on Application of DMAIC to Improve Delivery Efficiency (December 22, 2015). 12th International Conference on Business Management (ICBM) 2015 - The Best Case Study Presentation Award. Available at SSRN: *https://ssrn.com/abstract=2706992*or *http://dx.doi.org/10.2139/ssrn.2706992*

Thomas, A., R. Barton, et al. (2009). "Applying lean six sigma in a small engineering company - amodel for change."Journal of Manufacturing Technology Management 20(1);16.

Wastes & Downtime Using Lean Six Sigma - GoLeanSixSigma.com. (2021). Retrieved 27 September 2021, from https://goleansixsigma.com/8-wastes/

Webber, Larry; Wallace, Michael (15 December 2006). Quality Control for Dummies (https://books.google.com/books? id=9BWkxto2fcEC&pg=PA43). For Dummies. pp. 42–43. ISBN 978-0-470-06909-7. Retrieved 2012-05-16.

الملخص

تساهم هذه الدراسة بشكل فريد من خلال توضيح التأثير التآزري لتطبيق منهجية Lean Six Sigmaفي القطاع الخاص وبشكل أكثر تحديدًا في قطاع الأدوية .نظرًا للعديد من العوامل ، بما في ذلك العولمة والتطور التكنولوجي الكبير الذي أدى إلى المنافسة العالمية في جميع المجالات ، فقد بدأت الشركات في البحث عما يجعلها متقدمة ومتميزة في هذا المجال ، وتقليل التكاليف التشغيلية وغير التشغيلية ، بالاضافة الى زيادة طلب العملاء للمنتجات والخدمات عالية الجودة. كان لهذه التغييرات تأثير عميق على رؤية وثقافة وتفكير العديد من المنظمات. استجابة لهذه التغييرات ، بدأت الصناعات إما في تطوير عملياتها أو تنفيذ استراتيجيات إدارة جودة جديدة فعالة وتحويل تلك الاستراتيجيات إلى تنفيذ حقيقي. بعض المنهجيات المفيدة التي تساهم في تحقيق هذه الأهداف تشمل إدارة الجودة الشاملة ، كايزن ، Lean Six Sigma، إعادة هندسة إجراءات الأعمال وما إلى ذلك (عبد المالك ، فواز أ و راجوبال ، جايانت ، 2007) يهدف هذا البحث إلى دراسة عمليات التعبئة والتغليف في شركة بيرزيت للأدوية , حيث انا الشركة تمارس نشاطها على مستوى عالٍ من معايير الجودة والتي تعتبر رائدة في مجالها. ومن خلال عدة زيارات وملاحظات لاحظت الباحثة أن حجم الإنتاج كبير وذو معايير جودة عالية; حيث ان جميع خطوات الإنتاج مؤتمتة ، باستثناء عمليات التغليف التي تتم في الغالب يدويًا ، وقد أدى ذلك بالباحث إلى التركيز على عمليات التغليف كفرصة جيدة للتحسين. لوحظ أنه لا

يوجد مكان محدد لعمليات التعبئة اليدوية التي تسبب الفوضى وسوء استخدام الموارد. علاوة على ذلك ، تظهر عدة أنواع من الهدر في منطقة التعبئة مثل الحركة والنقل والانتظار ، مما يؤدي إلى إساءة استخدام الموارد وتكلفة إضافية للشركة .لذلك ، ينصب تركيز هذا البحث على تحسين كفاءة عملية التغليف باستخدام منهجية .Lean Six Sigma ولتحقيق هذا الهدف قام

الباحث بتطبيق إحدى أشهر طرق التحسين وأكثرها فاعلية وهي ."DMAIC" هذه الطريقة التي تبدأ بتحديد المشاكل ، ثم قياس الأداء الحالي للعملية ، ثم تحليل البيانات التي تم جمعها في المرحلة السابقة ، ثم تنفيذ التحسين ، وأخيراً التحكم في التحسينات المحققة والحفاظ عليها تتضمن نتائج هذا البحث تحديد جميع انواع الهدر الموجودة في عمليات التغليف وقياسها باستخدام منهجية.Lean six sigma , واخيرا تم رفع توصيات لجميع المقنترحات التحسينية والتي تعذر تطبيقها ليتم تطبيقها في اقرب وقت ممكن بهدف تحسين عملية التغليف بافضل استعمال للموارد وتقليل مختلف انواع الهدر.