Abstract

SHAH, ADITYA NARESH. Speeding Changeover in Pharmaceutical Packaging. (Under the direction of Dr. Wilbur L. Meier Jr.)

Pharmaceutical companies increasingly are working to improve productivity and reduce costs in their manufacturing and packaging operations. Expanding markets and innovative marketing strategies have lead to an increased demand in pharmaceutical packaging products. To achieve goals of lower costs, greater flexibility, and increased capacity without substantial investment, pharmaceutical packaging plants are working to streamline their operations by application of lean production and management techniques.

This thesis discusses the background of lean production particularly as it relates to the pharmaceutical industry and presents an actual application in a packaging facility of a global pharmaceutical manufacturer. It describes lean production techniques used to reduce cleanup and changeover time in pharmaceutical packaging operations. The changeover reduction process involved evaluating the process with production associates and developing new standard procedures for performing the changeover. It discusses the unique characteristics of a pharmaceutical changeover and highlights techniques used to deal with potential issues within a pharmaceutical operation. The resulting changeover time was reduced by 65 percent resulting in dramatically increased capacity without addition of facilities, capital investments, or negative impact upon product or process quality.

Speeding Changeover in Pharmaceutical Packaging

By

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Biography

Aditya Shah was born on 3rd November, 1980 in the vibrant city of Bombay (Mumbai), India. He received his Bachelors degree in Production Engineering (B.E.) from D. J. Sanghvi College of Engineering, affiliated to the University of Mumbai, India.

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Chapter 1

INTRODUCTION

1.1 Overview

In recent years, pharmaceutical manufacturing and packaging operations have struggled to respond quickly to market demand while overcoming operational inefficiencies. An increase in the number and complexity of product configurations, coupled with the demands of compliance with regulations in a time of growing market pressure, has made it a challenge to maintain a stable performance in the marketplace.

New marketing strategies adopted by pharmaceutical companies have initiated the introduction of more packaging configurations to facilitate meeting customer requirements with greater precision. As more configurations are targeted to subpopulations, the number of products increases. This results in smaller manufacturing volumes and more frequent changeovers between production runs. As the frequency of changeovers increases, the related downtime has become a major concern as it influences line capacity and per package cost. In an effort to compete under these circumstances, pharmaceutical manufacturers have seen the need to become lean and flexible, streamlining their operations and achieving a significant increase in quality, process and compliance management. To achieve goals of lower costs, greater flexibility, and higher throughput, many managers have turned to the application of lean production and management techniques in their plant sites.

Lean production aims to develop a robust operation that is responsive, flexible, predictable and consistent. It creates a manufacturing operation which focuses on continuous improvements through minimizing non-value added activities while performing the critical activities efficiently. Setup time reduction is a widely used lean manufacturing tool and is a cornerstone of any lean operation. Smaller setup times can produce many benefits, including added flexibility, lower inventory costs, improved quality, increased equipment utilization, and faster production turnaround (Leschke, 1998). This study describes techniques used to reduce the planned changeover time on a pharmaceutical packaging line, thereby increasing existing capacity, reducing standard cost and adding flexibility to the packaging operation.

1.2 Research

This research is concerned with reducing changeover time and subsequent costs for a multinational pharmaceutical company. Production for this company takes place at different sites in Europe, the Americas, Australia and Asia where a broad range of innovative products are discovered, developed, manufactured and marketed. The site at the focus of this lean production application is a pharmaceutical packaging facility in the USA.

The facility packages different types of pharmaceutical product configurations including hospital unit dose (HUD) to trade and sample blisters, and bulk and sample bottles. The facility houses several lines and each line is designed to package certain types of product configurations including HUD blisters, sample blisters, sample bottles, bulk bottle and trade blisters, and bottles. The packaging facility is responsible for satisfying the majority of the demand for packaging within the company in the Americas.

Chapter 2

LITERATURE REVIEW

2.1 Lean Manufacturing

The concept of lean manufacturing originated in Japan after World War II. In response to declining resources, Japanese manufacturers started to embrace new, lower cost, manufacturing practices. In the 1950s, automobile manufacturer Toyota started to develop the process of developing and refining manufacturing processes to minimize waste in all aspects of their operations (Thompson and Mintz, 1999). Lean production aims to do more with less – less time, less space, less human effort, less machinery, and less material while meeting customer requirements (Womack, 1990). Lean manufacturing is aimed at the identification and elimination of "waste" in every area of production including human effort, inventory, processes, time and space which makes the manufacturer more responsive to customer demand while producing world-class quality products in the most efficient and economical manner (Todd, 2000). Russell and Taylor (1999) define "waste" as 'anything other than the minimum amount of equipment, materials, parts, space and time that are essential to add value to the product'.

Organizations that have successfully implemented lean manufacturing methods have a substantial cost and quality advantage over those still practicing traditional mass production methods (Fleischer and Liker, 1997). The benefits have been evident in the form of improved product quality, shorter cycle times, reduced costs, shorter setup times, reduced inventory, higher levels of production, and increased flexibility. Lean manufacturing uses tools such as one-piece flow, cellular manufacturing, total productive maintenance (TPM), workplace organization - 5S, pokayoke- mistake proofing, and single minute exchange of dies (SMED) – quick setups. These tools improve the business efficiency by making improvements and reducing non-value added activities in different areas of business.

Manufacturing organizations are under continual pressure to increase productivity and improve their flexibility and responsiveness to meet customer demands (McIntosh et al., 1996). Lean production systems have the ability to be responsive and flexible, producing small batches and meeting constantly changing customer requirements. The option of setup or changeover reduction as the means of improving system performance complements the notion of using lean manufacturing techniques to create a more flexible manufacturing environment. Smaller setup times can produce many benefits, including lower inventory costs, improved quality, increased equipment utilization, and faster production turnaround (Leschke, 1997). Rapid setups were pioneered by Toyota in the 1960s (Cusumano, 1986), and many studies of Japanese manufacturing techniques (Golhar and Stamm, 1991) have noted the importance of setup time reductions. Shingo (1985), one of the key figures in the introduction of rapid setups at Toyota developed the single minute exchange of dies (SMED) technique over a period of 19 years. SMED refers to the theory and technique for simplifying and improving operational activities to complete a setup operation in less than ten minutes. Although not every setup can literally be completed such short time, this is the goal for the technique which can be met in surprisingly high number of cases.

2.2 Pharmaceutical Industry

While the pharmaceutical industry aims to invent futuristic new drugs, its manufacturing techniques lag far behind those of other similar industries (Abboud and Hensley, 2003). For decades, the drug industry and the Food and Drug Administration (FDA) have accepted this disparity. To the FDA, with its mission of protecting patient safety, it has appeared more important to manufacture medicines precisely to specification, using tried-and-true systems rather than following the latest trends in manufacturing. As emphasized by Haystead (2003) manufacturing has not been given the same level of attention as other segments of the industry. However the rapidly changing realities of the pharmaceutical industry are forcing pharmaceutical manufacturers to adopt manufacturing innovations.

The top 16 U.S. pharmaceutical companies spend more than $90 billion on manufacturing each year, according to a recent Wall Street Journal article (Abboud and Hensley, 2003). This total expenditure that includes materials, labor, operations, and depreciation of investments is estimated to account for more than 36 percent of the industry's overall expenditures, and is more than double the annual spending on research and development. Since prescription drugs are so profitable, the industry for years has not been motivated to improve efficiency. Now however, the payoff from investing in drug discovery is diminishing due to fewer new products coming out of research laboratories. Therefore, savings from improving manufacturing processes are now looked upon as key sources to help establish profits.

According to a study conducted by the Freedonia Group, Cleveland (Official Board Markets, 2002), the demand for pharmaceutical packaging will steadily increase 4.3 percent annually to $5.2 billion in 2006. Expanding markets and targeted marketing strategies have resulted in more pharmaceutical packaging products. In order to capitalize on this demand, pharmaceutical packaging sites need to have sufficient capacity to handle the increased volume at competitive prices. Drug prices are continuously driven down by competition from generic drug sales, increase in smaller third party vendors, insurance provider subsidies, as well as the creation of government-subsidized prescription drug benefits. Companies are trying to drive costs out of their products, while they ensure stability, encourage compliance, promote safety, and meet regulations.

As discussed in earlier sections, lean production aims to minimize or eliminate the non-value added activities while focusing on performing the value added activities efficiently. For reasons discussed in later sections, the focus of this investigation is to reducing changeover time through application of lean manufacturing techniques. As emphasized in the article by Forcinio (2001), one of the most significant problems affecting productivity on a pharmaceutical packaging line is downtime as a result of changeover between products or packaging configurations. Shortening changeover time adds flexibility and reduces costs while offering more capacity to produce additional product. Previous investigations (McIntosh et al., 1996) in this area have applied setup reduction techniques in pharmaceutical manufacturing. However their research focused on reducing setup times using automated and specialized equipment. Their research also discussed issues observed in sustaining improvements.

This research describes an application of setup reduction techniques in pharmaceutical packaging operations. It describes the tasks used to successfully reduce changeover time on a pharmaceutical packaging line. Unique characteristics of pharmaceutical changeovers are outlined and techniques used to deal with potential issues within a pharmaceutical operation are highlighted.

Chapter 3

PROBLEM STATEMENT

3.1 Current Scenario

Following the trend in pharmaceutical marketing, companies are targeting specific customers, leading to the development of many new product configurations. These new product configurations have led to changes in packaging complexity including variation in components, packaging technique, packaging design, labeling and marketing features. From a packaging point of view, these new products are being introduced at a much faster rate. This increased product mix requires the packaging facility to be more responsive by handling smaller orders at more frequent intervals. Smaller orders at more frequent intervals will lead to more frequent changeovers between production runs on certain lines.

From Figure 1, it is observed that packaging volumes during a typical year often exceed the plant capacity. To address additional packaging requirements, the company is faced with two alternatives. It may resort to awarding volume contracts to external packaging contractors or run the in-house lines during weekends at overtime pay. Both options add additional cost and are therefore undesirable. The contract packagers operate on semi-automated lines with much lower overhead costs which results in lower 'per package costs'. Although contract packagers are cheaper on a 'per package' basis, they require a certain fixed volume guarantee during the year. This could sometimes lead to plant capacity not being utilized during certain months to ensure compliance with contract obligations. Figure 2 depicts the alternatives to meeting capacity requirements that the company has before it. The company sites outside the USA are comprised of slow manual lines that mass produce products at low costs. The tax benefits in other countries provide the cost advantage for operating on slower manual lines. Thus to be able to compete in this environment a packaging facility in the U. S. needs to produce packages at lower costs.

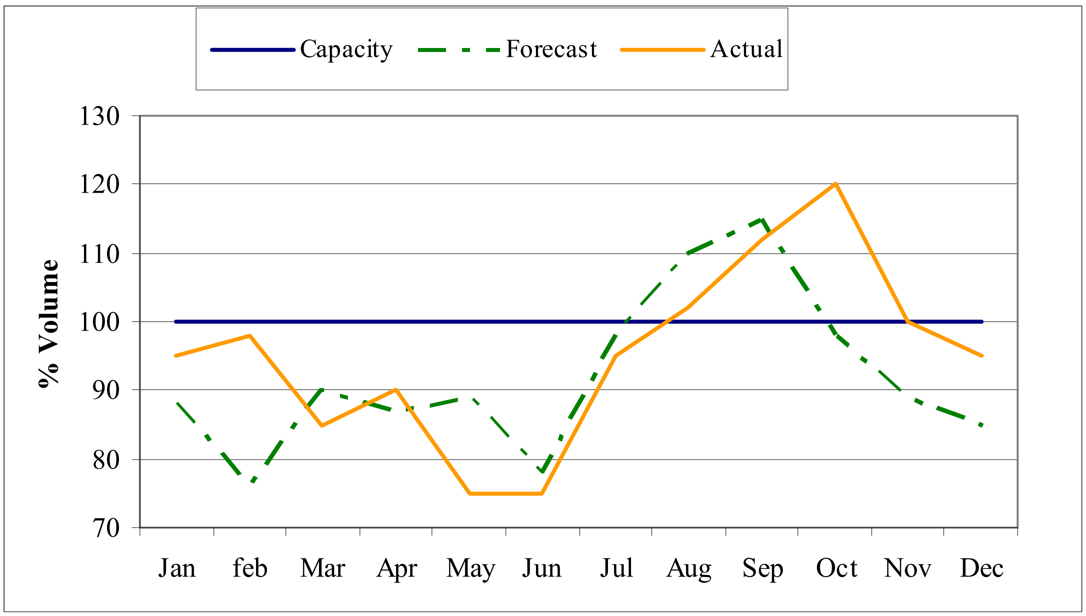

Figure 1 - Variation in Packaging Demand Forecasts and Actual Volumes

Pharmaceutical companies constantly deal with complexities of fluctuating demand from changing patient needs, competition, and economic pressures. Often, sudden unexpected changes can upset carefully made plans. For example, during new product launches, the sales group demands a very high quantity of product for the initial months which would enable them to reach more consumers in the market. Disease outbreaks could increase the demand for a particular drug for a specific time period which could exceed plant capacity. To accommodate such volume surges, additional capacity and increased flexibility become a requirement of the packaging operation.

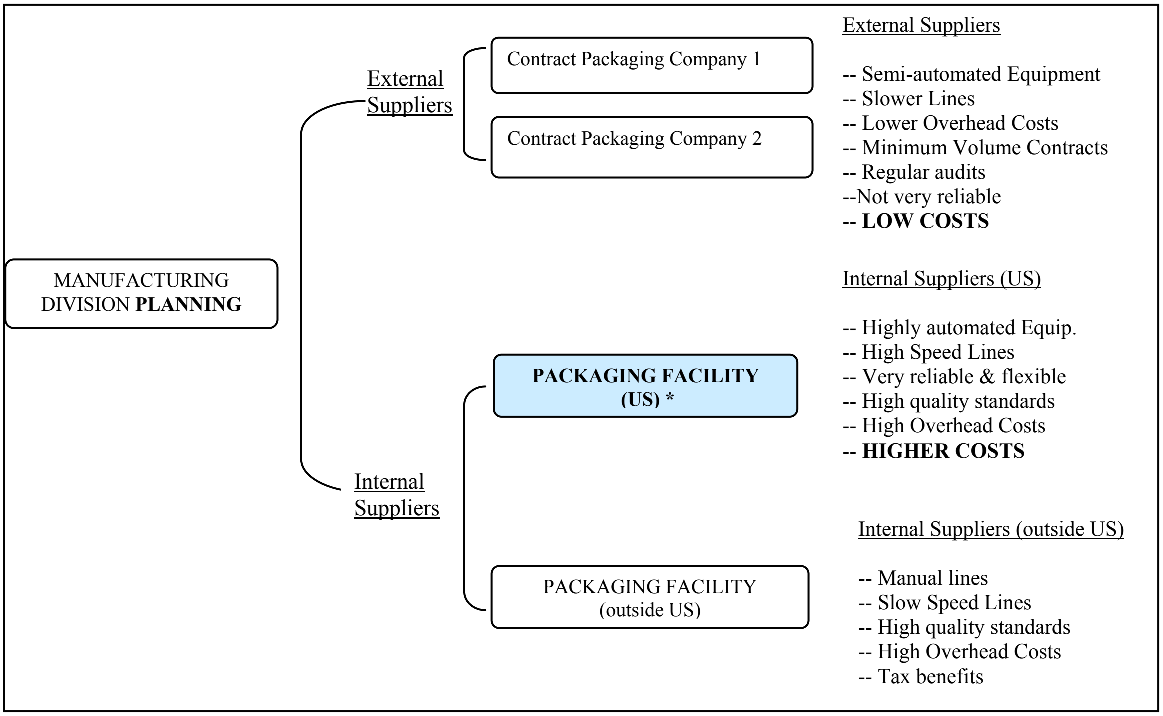

Figure 2- Alternatives in Meeting Packaging Requirements

3.2 Proposed Solution

The impact of such changing competitive conditions on the packaging site has been gradual but by early 2003 serious problems could be observed. Packaging volumes were increasing as were the variations in package type. Faced with increasing packaging volumes and a desire to increase capacity, reduce unit packaging cost and increase the flexibility to meet changing requirements for packaging, the company began evaluating actions it could take to address these issues. Although the company was eager to tackle the problem of insufficient capacity, it was reluctant to invest in more machines to provide an immediate increase in the production capacity. Large capital investment in new equipment appeared risky at a point when the competitive environment was becoming more uncertain. Thus, a solution was sought that would add capacity without having to make a substantial capital investment. In an effort to find an acceptable solution, an evaluation of the plant performance parameters was conducted. In considering opportunities for improvement in the packaging facility process map as shown in Figure 3, it was observed that the packaging lines were not being utilized to their complete potential.

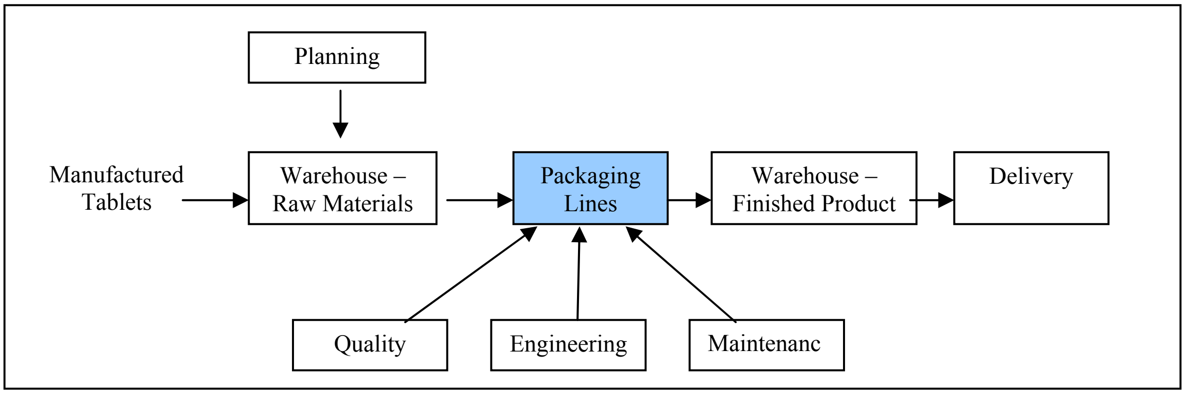

Figure 3- Packaging Operation Process Map

Further investigations suggested as shown in Figure 4, that the packaging facility operated productively less than 50 percent of the time. The packaging lines were producing at this level because of excessive planned and unplanned downtime.

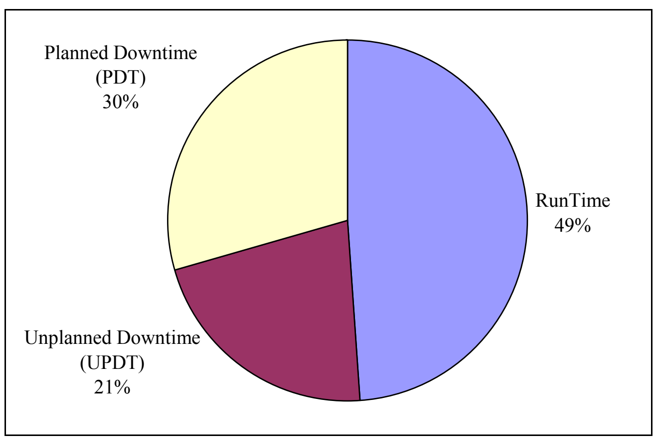

Figure 4- Evaluation of Line Productivity

Unplanned downtime entails unscheduled stoppages during production in the form of breakdown and repair, adjustment delays, minor stoppages, waiting on equipment or stoppages due to uncertain events like injuries. Planned downtime consists of planned breaks and lunches, preventive maintenance, changeovers between packaging runs, and downtime for meetings and trainings.

3.3 Lean Manufacturing Approach to Resolve the Problem

Lean manufacturing tools can be employed at the packaging facility to reduce the incurred downtime. It was observed that unplanned downtime in the form of equipment breakdowns can be reduced by implementing a Total Productive Maintenance (TPM) program. TPM aims to improve the equipment effectiveness by eliminating equipment downtime and reducing defects. A TPM program concentrates on improving equipment availability thereby reducing waiting times.

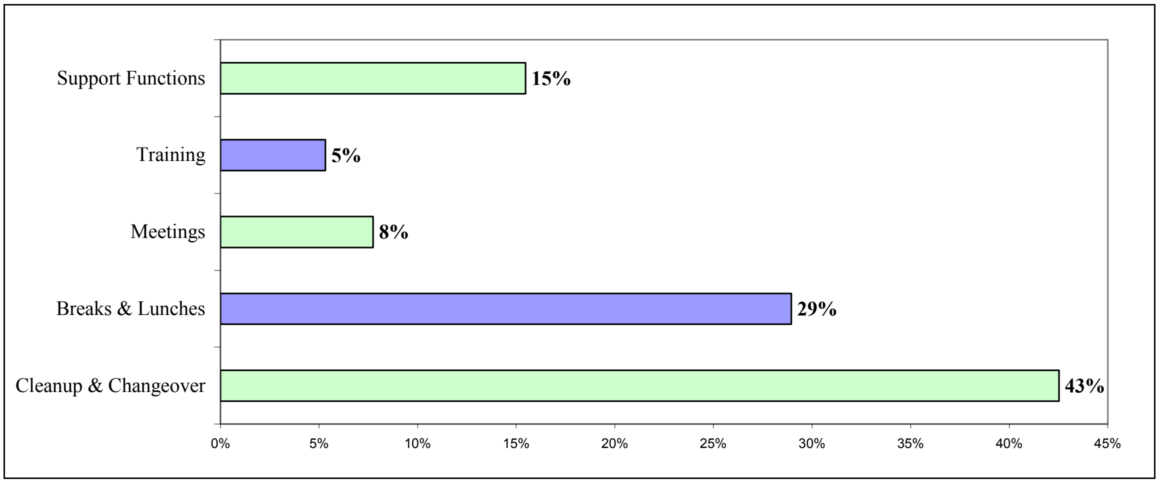

Figure 5- Evaluation of Planned Downtime

A further evaluation of the planned downtime as shown in Figure 5 indicated that more than 70 percent of planned time was involved with breaks, lunches and cleanup and changeover. Breaks and lunches were taken by all packaging personnel at the same time. Staggering breaks and lunches resulted in dramatically reducing their impact from 29 percent to 12 percent of planned downtime. Further reduction of planned downtime can be achieved by focusing on the reduction of changeover time in pharmaceutical packaging. Reducing changeover or set-up times is a common approach to gain uptime in lean production applications. Application of single minute exchange of dies (SMED) methodology (Shingo, 1985) to reduce setup time has been a well known technique in the manufacturing industry.

This investigation outlines the techniques to develop and sustain an improved changeover process in pharmaceutical packaging. The techniques used complement the SMED methodology and introduce new methods which help to overcome unique concerns that arise in a pharmaceutical operation. In chapter 4, the changeover process and the distinctive characteristics of a pharmaceutical changeover are described. In chapter 5, the methodology adopted to reduce the changeover time is discussed. In chapter 6, the results of the improvement process are presented.

Chapter 4

PROCESS DESCRIPTION

4.1 Pharmaceutical Changeover

Changeover is the process used to prepare the line to run the next product after completing a packaging run. Like setup times in other manufacturing operations, it is defined as the time between the last good product produced in the previous production run and the first good product produced at the start of the next production operation.

Excessive changeover times affect the plant performance in several ways as shown in Figure 5. For example, it was estimated that a 50 percent reduction in time taken to perform a changeover would result in an increase of 10 percent overall capacity of the packaging line. Changeover in pharmaceutical packaging operations possesses unique characteristics when compared with the general manufacturing setup or changeover process.

The two most important characteristics are:

a. FDA's Impact on the Changeover Process.

b. Cleanup - Major Part of the Changeover.

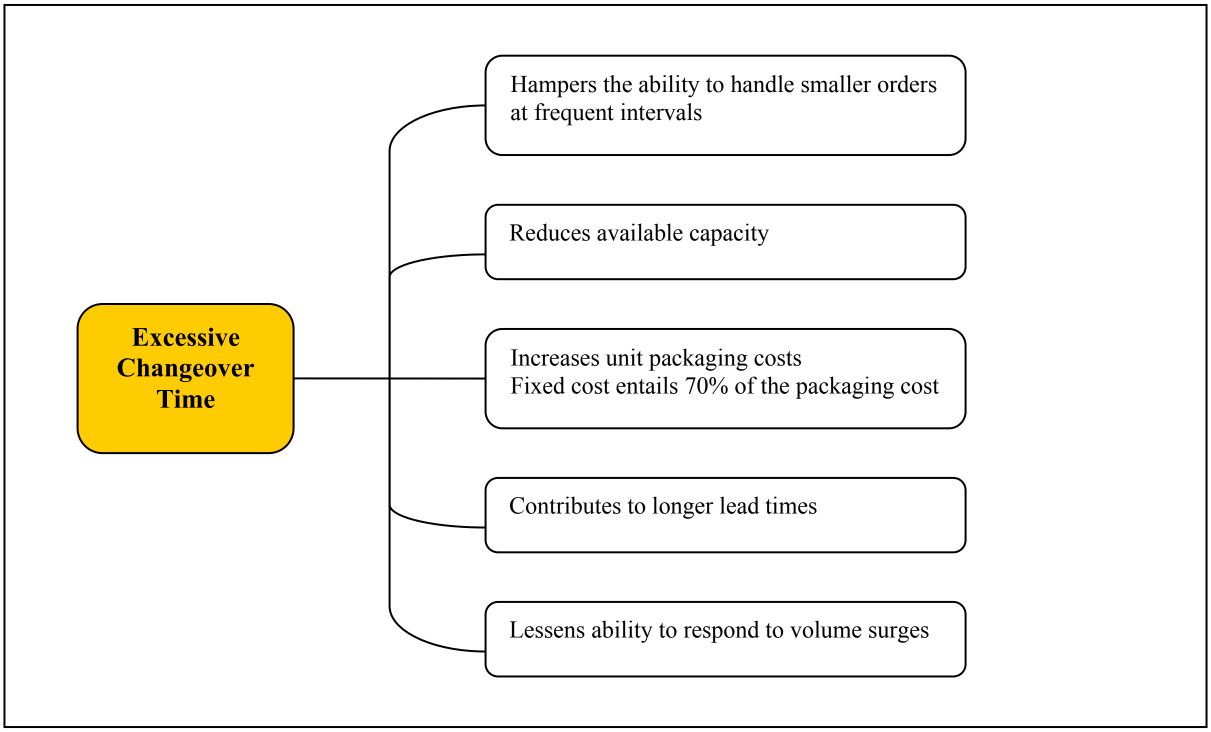

Figure 6– Disadvantages Due to Excessive Changeover Time

4.2 FDA's Impact on the Changeover Process

In most industries, manufacturers are constantly working with their production lines to improve their effectiveness. Due to the perception of stringent FDA regulations, there is little motivation to introduce changes to improve the efficiency of pharmaceutical processes. As part of the drug approval process, a company's detailed manufacturing plan and even the factory itself must gain FDA approval. After approval, even a small change in how a drug is made requires another round of FDA reviews and authorizations, requiring time and effort on the part of the company. The process discourages updating by the companies, who worry they will face a production delay that could cost them heavily. A similar pattern is seen in pharmaceutical packaging operations.

Every pharmaceutical site is made to follow a set of "Code of Federal Regulations" governed by the FDA. Manufacturing and packaging facilities are required to follow the regulations stated in 21CFR Part 210/211 – Current Good Manufacturing Practice (2001). The regulations in the document include the best practices to be used in, and the facilities or controls to be used for, the manufacture, processing, and packaging of a drug. These methods ensure that the drug meets the safety requirements, and has the identity and strength which meets the quality and purity characteristics that it is supposed to possess. The FDA requires that a quality control unit be established in each facility. This unit has the authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products. It also has the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated.

The following section is quoted from 21CFR Part 210/211 – Current Good Manufacturing Practice (2001): Section § 211.22- Responsibilities of quality control unit. (21CFR Part 210/211)

"The quality control unit is responsible for approving or rejecting all procedures or specifications impacting the identity, strength, quality, and purity of the drug product. The responsibilities and procedures applicable to the quality control unit must be in writing; such written procedures shall be followed. Standard Operating Procedures (SOP) for processes that can impact the drug product are controlled by the quality control unit."

Unlike other industries, the quality control unit's responsibilities extend beyond monitoring product quality to controlling the quality of the packaging processes. Changeover standard operating procedures (SOP) are developed by operations and quality control under FDA guidelines and company regulations. The SOP's developed are based largely on the interpretation of the FDA guidelines listed in 21 CFR Parts 210 and 211. Interpretations of FDA regulations are more subjective than objective and are largely dependent upon the quality personnel's evaluation and experience. These interpretations change with the quality personnel changing and are often inconsistent.

The quality control unit tends to be very conservative to ensure product quality, and because of this, any event impacting quality on a line is met with a corrective action. Following a quality event on a line, a check or an additional activity is introduced as a preventive measure to ensure that the failure does not reoccur. This new activity is then introduced on all lines to ensure that a similar event does not occur on other lines. The accumulation of these corrective measures over a period of years has created an inflated process during which many redundant tasks are performed. Changes made to the process need quality approval and have to be reflected in the standard operating procedures before being implemented. Thus any change in the process demands effective communication with the quality control unit and corresponding paper work. The quality control unit thus has a firm hold over packaging processes. The redundant activities are not challenged to avoid confrontation with the quality department. Often, checks are added during the changeover to complement supporting systems in the plant. The systems requiring the checks keep changing but corresponding activities performed in the changeover remain. The process ends up being designed around these additional activities. Often, a stage is reached when operators do not know why certain tasks are performed. They do it that way because it has always been done that way.

4.3 Cleanup - Major Part of the Changeover

An evaluation of the changeover process indicated that cleanup operations between packaging runs mandated for maintaining quality and product integrity comprise as much as 75 percent of the time required to perform the changeover. Thus one of the unusual characteristics of a changeover in a pharmaceutical packaging is the fact that cleanup takes significantly more time than the actual setup. Based upon the dominant role of cleanup in pharmaceutical changeover activities, these cleanup activities were targeted to determine ways to reduce the time taken to complete them.

In order to understand the nature of these cleanup operations, it is important to understand how and why cleanup operations are developed. The fundamental purpose of the cleanup activities is to maintain the integrity of the pharmaceuticals being produced. It is necessary to ensure that no remnant or shred of the previously packaged pharmaceutical product become a part of the next packaged item. Thus, elaborate procedures have been developed over time to wash and "blow down" the packaging area between production runs on different pharmaceutical products, even those of the same product but differing strength or delivery mechanism – i.e. tablet, caplet, gel cap, or liquid. Furthermore, all packaging materials and remnants of the pharmaceutical products from the previous packaging run must be identified, counted and removed from the packaging area.

The following section is quoted from 21CFR Part 210/211 – Current Good Manufacturing Practice (2003): Section § 211.67 - Equipment Cleaning and maintenance

"Equipment and utensils shall be cleaned, maintained, and sanitized at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements.

Written procedures shall be established and followed for cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing, or holding of a drug product. These procedures shall include, but are not necessarily limited to, the following:

1. Assignment of responsibility for cleaning and maintaining equipment;
2. Maintenance and cleaning schedules, including, where appropriate, sanitizing schedules; and description in sufficient detail of the methods, equipment, and materials used in cleaning and maintenance operations, and the methods of disassembling and reassembling equipment as necessary to assure proper cleaning and maintenance;
3. Removal or obliteration of previous batch identification;
4. Protection of clean equipment from contamination prior to use;
5. Inspection of equipment for cleanliness immediately before use."

It was recognized that the activities performed during the changeover can be classified into two categories. i.e. cleanup and setup. As shown in Figure 7, it was identified that cleanup comprises 75 percent of the activities performed during the changeover.

Cleanup activities included:

1. Clearing components (foil, cartons, and packers) from the line,

2. Removing the remaining tablets from the line,
3. Clearing printed material related to the current batch (rejects, trash) from the line,
4. Cleaning (Wipe/ Vacuum/ Blow) the equipment, fill room and backend area to ensure there are no tablets or printed material remaining on the equipment,
5. Performing calculations to account for blister and tablet rejects,
6. Removing batch information from printers, and
7. Staging tablets and components in their respective staging areas.

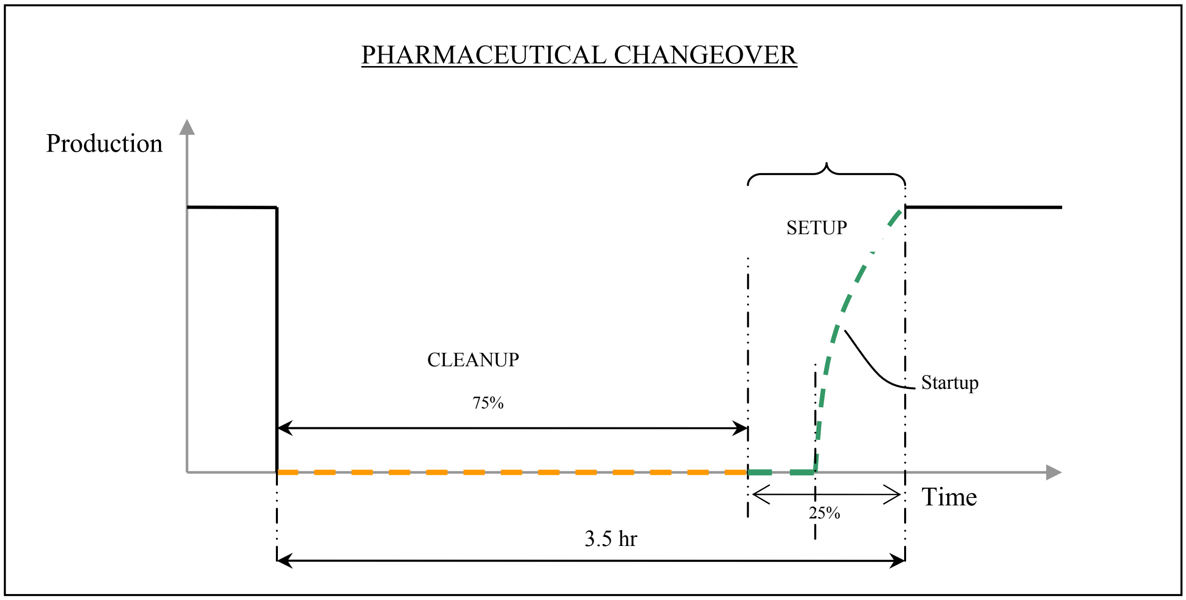

Figure 7– Pharmaceutical Changeover

Setup which forms a smaller part of the changeover includes:

1. Changing equipment on the line,
2. Aligning the print mat with the lid foil,
3. Setting up the printer to print on blister cards/cartons/packers,
4. Preparing and performing sampling tests,
5. Checking settings on equipment, and
6. Making good blisters with correct print.

Since cleanup formed the bulk of the time required to perform the changeover, it was important to reduce changeover time caused due to cleanup activities.

Chapter 5

METHODOLOGY to REDESIGN THE CHANGEOVER PROCESS

5.1 Methodology

Pharmaceutical manufacturers intending to implement lean production must have the ability to be responsive and flexible to produce small batches to meet constantly changing customer requirements. The option of set-up reduction to gain uptime to create additional capacity complements the concept of lean manufacturing that focuses on creating a flexible manufacturing environment. Smaller setup times can produce many benefits such as additional uptime, lower inventory costs, improved quality, increased equipment utilization, and faster production turnaround.

The setup reduction process as applied in this investigation was composed of six phases as shown in Figure 8. The process was designed to identify and assist production associates to reduce the non-value added activities performed during the changeover. The activities performed during the changeover were observed and measured to establish an actual baseline. Every task in the changeover process was challenged in a brainstorming and task evaluation activity to identify activities into the following categories:

1. Necessary activities required to complete the changeover while the line was shutdown,

2. Necessary activities that can be performed external to the changeover process, either before or after the changeover while the line is running, and

3. Redundant and unnecessary activities that could be eliminated altogether.

As the activities were subdivided into these three categories, each process change was discussed with the quality team to ensure that the change would not impact quality in a negative way. Standardized activity schedules were developed to train production associates so that the new method would be followed by personnel on all shifts. Tests were conducted to investigate the schedule and to ensure a standardized, achievable process was developed.

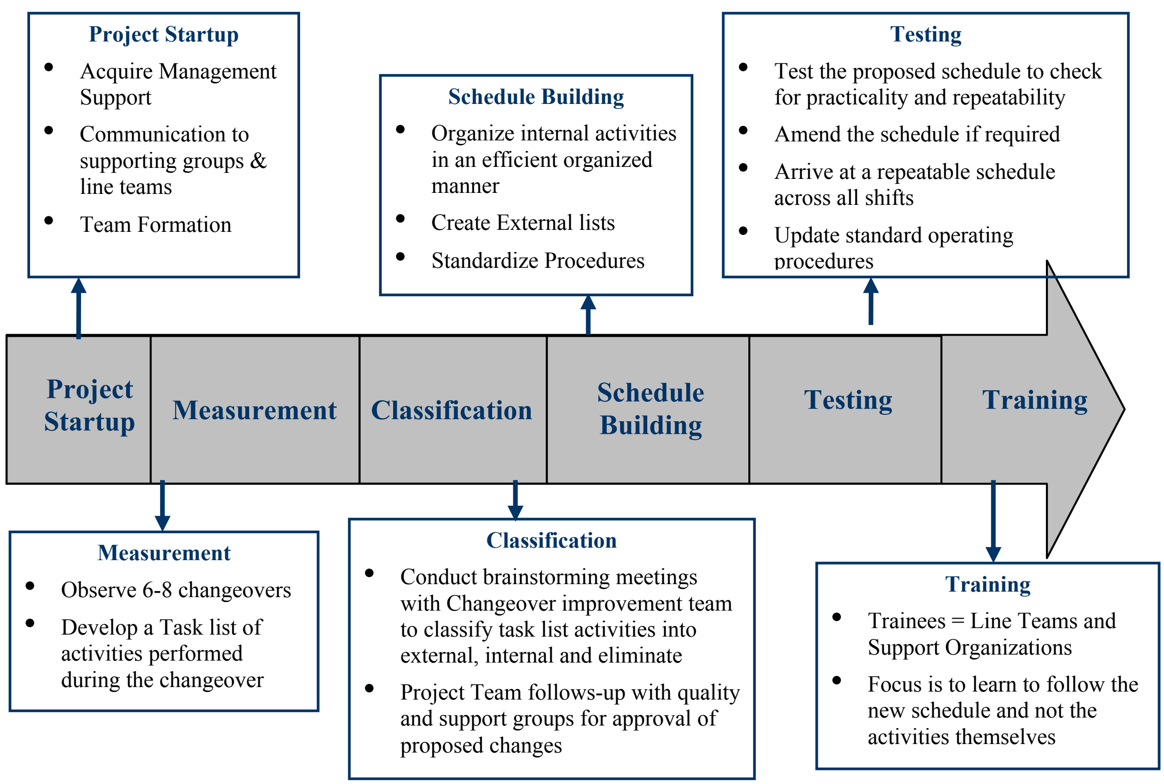

Figure 8- Setup Reduction Process

5.2 Project Startup

A study by Moxham and Greatbanks (2001) suggests that there are a number of prerequisites that need to be in place prior to the setup reduction implementation. The tasks performed prior to implementation would differ for different industries and would also vary according to the plant or factory culture. For example, the packaging facility where the process was implemented has a strong employee involvement and empowerment initiative. According to Forcinio (2001), projects like setup reduction require a cultural focus and commitment from the organization's key players, beginning with senior management and extending through to other departments like purchasing, packaging, marketing, engineering and quality control and validation.

In order to facilitate and implement a setup reduction project, there must be a strong level of management attention and support. The project challenges current business practices which may require the management personnel to change their current way of thinking. Management must be ready to take acceptable risks and change systems that have been in place for many years. Resources required include operators and mechanics and may require the line to be shutdown to conduct meetings. This demands a strong commitment from management because the area of focus is already operating in a capacity constrained environment. The management personnel need to realize that the setup reduction process is not a quick fix and it will take time before positive results are observed on the shop floor. To achieve success, management, operators, quality groups, and other support functions must be prepared to challenge and change their habits.

Training sessions have to be conducted to communicate the following:

1. The need for redesigning the changeover process,
2. The procedural details of the improvement process and identified milestones, and
3. The required involvement of the support groups in the process.

Cooperation on behalf of the support groups is an important aspect for the smooth progress of the project. An organized team structure as shown in Figure 9 is required to manage the setup reduction process.

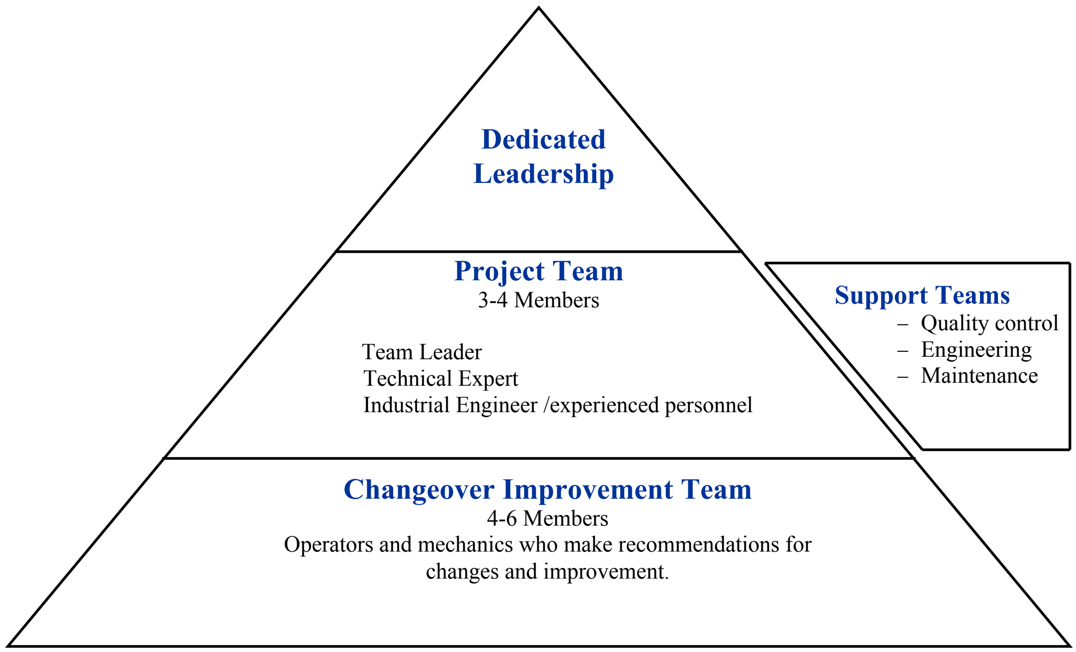

Figure 9- Team Structure

A project team consisting of the in-house stakeholders for the overall project was responsible for the facilitation of the six phases of the redesign process. The project team was comprised of a team leader, an industrial engineer and a line supervisor who had comprehensive knowledge about the line. The project team gathered the changeover data and organized it for analysis. The project team then conducted brainstorming meetings with a changeover improvement team on a weekly basis to analyze the data collected and classified the data into:

1. Internal activities which are critical activities required to be performed while the line is down,
2. External activities which are necessary activities that can be performed before or after the changeover while the line is running, and
3. Eliminated activities which were identified as redundant non-value adding activities.

The changeover improvement team consisted of experienced operators and mechanics from the line. The changeover improvement team typically extended over two shifts. The mechanics provided the technical support during meetings which was helpful in equipment related discussions.

The quality control unit played an important role in developing a successful redesigned changeover. A quality team was established to make decisions on behalf of the quality control unit. The project team held meetings with the quality team to discuss the changes suggested during the brainstorming meetings. The quality team then analyzed the suggested changes before allowing the project team to implement these changes during the testing phase. This ensured that the required level of quality was maintained during the changeover process. Ongoing engineering projects planned to be implemented on the line were communicated by the engineering group to the project team. These projects resulted in the some additional activities to be performed during the changeover. This form of communication from the engineering group helped to incorporate the additional activities in the redesigned changeover. This ensured that activities were not abruptly added after the new changeover was designed.

5.3 Measurement phase

The purpose of the measurement phase was to observe the tasks performed during the changeover and measure the time taken to complete these activities. This phase helped establish a baseline of activities performed during the changeover.

5.3.1 Introduction to Measurement

Prior to the measurement the line team was introduced to the setup reduction process. The project team held training sessions to acquaint the line team about their involvement in the process. Benefits from the improvement process and the need for additional line productivity were addressed during these sessions. It was important to help them to realize that the developed changeover process would help them perform their activities in a more efficient manner. Insecurities about their jobs needed to be addressed in a positive and honest manner. It was made clear that the focus of the measurement was on ***WHAT*** was being done and ***NOT ON HOW*** it was being done. Developing trusting relationships with operators was critical for gaining their active participation in the improvement process. The project team reviewed the line with a member of the line team before starting measurement. This assisted the project team in learning the line terminology which helped to facilitate the classification phase since it ensured that everyone talked about the same piece of equipment during meetings.

5.3.2 Measurement

Measurement and time studies are often videotaped for analysis. However, in this investigation the concerned operators were uncomfortable with the idea of being videotaped. The measurements were recorded by members of the project team who shadowed the operators during the changeover. The recording members documented the observations on forms as shown in Appendix A. These observations were then entered into the computer to create a Task list. The measurement was comprised of activities implemented by all involved groups (warehouse personnel, mechanics, and line supervisors) in the changeover process. Measurements were carried out over all shifts to collect a reliable set of activities. After measurements the average times and standard deviation were calculated to analyze the reliability of the process. It was necessary to ensure that the operators were comfortable when the process was being recorded. As a best practice, operators in the changeover improvement team should participate in the measurement phase themselves. This will help the operators to recognize the redundant activities and best practices implemented by co-workers during the changeover. This results in more operator participation encourages them to come up with optimization ideas.

5.3.3 Task List Preparation

A task list was created to organize the activities performed during the changeover. The task list was developed after two measurements. Observations were added to the list after each measurement thereafter. After eight measurements, a reliable set of steps and their respective times was gathered. The list detailed the steps in the process and was a good method of presenting these activities. The task list served as an excellent communication tool during the classification phase as it helped to identify the time and frequency of tasks performed during the changeover. From the task list, it was identified that a total of 400 activities were conducted. These 400 activities were grouped into 35 main tasks as shown in Table 1.

	TASK DESCRIPTION	Time
1	RUN OUT THE PRINT	05:30
2	VACUUM TABLETS FROM FEEDER (using portable vacuum)	14:00
3	REMOVE INK MAT / PRINT MAT FROM PRINTER- RETURN TO CAGE	04:45
4	CLEAR ALL TABLET WASTE	06:15
5	REMOVE PINK AIM'S ID'S FROM COMPONENTS	05:00
6	REMOVE COMPONENTS FROM FILLROOM	07:15
7	SEPARATE END OF TICKET BLISTERS / SEPARATE EMPTY'S OUT	03:30
8	RETURN PREVIOUS TICKET BULK TOTES FROM FILLROOM TO BACKEND	19:00
9	DISASSEMBLE THE INTERMEC PRINTER	03:45
10	FILL OUT END OF TICKET PAPERWORK	08:15
11	BLISTER WASTE	1:10:45
12	BLOWDOWN THE FILL ROOM & SIGN CLEANING CARDS	43:30
13	2ND BLOWDOWN OF FILL ROOM / INSPECT & SIGN CLEANING CARD	27:45
14	PERFORM TABLET WASTE	09:30
15	INK TRAY CLEANUP	19:45
16	INK TRAY ASSEMBLY	09:30
17	"1ST BLOW DOWN" BACKEND & SIGN CLEANING CARDS	10:30
18	"2ND BLOW DOWN" BACKEND INSPECTION & SIGN CLEANING CARDS	03:15
19	WAIT FOR NEW CAGE TO COME ON LINE	38:00
20	PAPERWORK AT BEGINNING OF TICKET	15:30
21	SETUP INTERMEC PRINTER - TO PRINT PACKER LABELS	14:45
22	CHECK-IN COMPONENTS ON BACKEND OF LINE	28:30
23	PREPARE FILLROOM/ MOVE COMPONENTS TO FILL ROOM	40:30
24	PREPARE NEXT PRINT MAT & PRINTER ASSEMBLY	23:30
25	PREPARE / PLACE NEW PINK AIMS ID'S ON TOTES & EQUIPMENT	07:15
26	PREPARE NEXT EH&S BOX	04:00
27	PERFORM / PREPARE IN-PROCESS SAMPLING	06:00
28	PREPARE CHALLENGES	05:00
29	PREPARE BLISTER PRINT SAMPLES	15:45
	SETUP DIAL IN STARTS	
31	TURN ON THERMO & GOTTSCHO TO START DIAL-IN & CLEAR ERRORS	19:30
32	DIAL IN (ADJUST THE PRINT ALIGNMENT TO RUN GOOD EMPTY BLISTERS)	17:00
33	LOAD TABLETS INTO HOPPER---TURN ON FILLER	13:45
34	PREPARE PACKERS FOR NEXT TICKET	10:00
35	PREPARE FOR FIRST GOOD PACKER-RUN GOOD FULL BLISTERS	15:00

Table 1– Sample Summary Task List

5.3.4 Assessment

After preparation of the Task list, the tasks were further categorized to study the activities performed with regard to the source and nature of the activity. The activities were categorized by the nature of their function i.e. cleanup, calculations, paperwork, material handling, and actual setup. The results are as shown in Figure 10. It was observed that the majority of the time was consumed in cleaning the line while actual setup activities comprised just 25 percent of the activities.

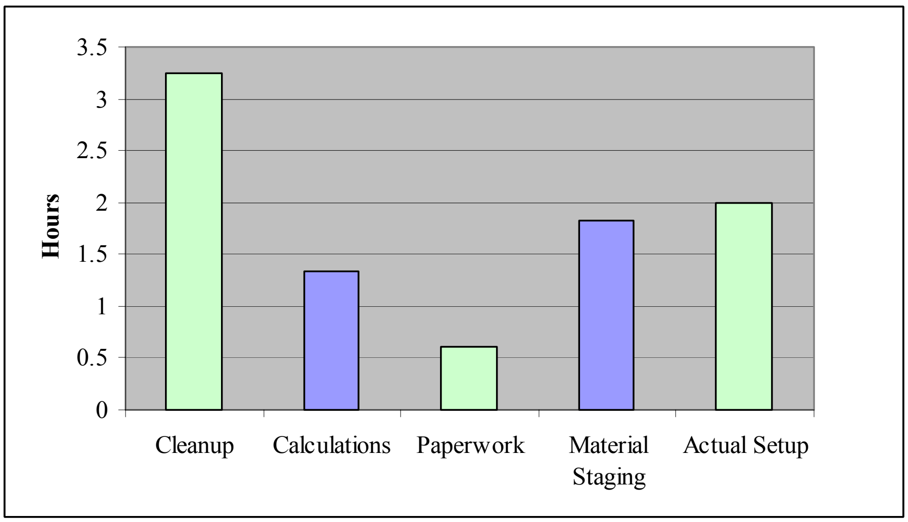

Figure 10- Classification by Nature of Activity

Thus, the majority of the changeover time was involved in cleanup activities. Therefore, the focus of the study was thus directed to reducing the time required to perform cleanup. The changeover activities were reviewed with the changeover improvement team to identify non value-added activities and were categorized into three categories eliminate, external and internal. These categories are explained in further detail in the following sections.

5.4 Classification phase

During the classification phase, the changeover improvement team consisting of operators and mechanics met with the project team on a weekly basis to review the activities that were recorded in the task lists. In the observed changeover 400 activities were performed by three operators in 3.5 hours. Every task in the changeover process was challenged in a brainstorming and task evaluation activity to categorize them into one of the following categories:

1. *Internal activities* are those critical activities which are required to be completed during the changeover and require the line to be shut down.
2. *External activities* are necessary activities that can be performed external to the changeover process i.e. either before or after the changeover, while the line is running,
3. *Eliminated activities* are identified redundant activities that could be eliminated altogether. This includes activities where small changes can be made to eliminate a step.

Each activity was audited to understand why it was done, who should perform it, and when it should be performed. The six questions of Kipling as shown in Table 2 were used as a guide to help identify whether an activity should be performed externally, internally, or should be eliminated.

Primary Questions	Secondary Questions	Decision
What is the goal of this activity?	Why is it needed?	Operators cannot answer >> **Eliminate**
Where will it be performed? When will it be performed? Who will do it?	Why is it performed there? Why does it happen then? Why does this person do it?	If the operators agree these things can be reorganized >> **Externalize**
How will it be done?	Why do we do it this way?	If Operator can provide answers >> **Internalize**

Table 2 – Six Questions of Kipling

As the activities were subdivided into these three categories, each process change was discussed with the quality team to ensure that the change would not impact quality in a negative way. Table 3 shows the application of the Task list during the classification meetings.

The role of the changeover improvement team was to brainstorm about the current process and propose new ideas for improvements. The operators were asked to think beyond their current methods to come up with innovative improvement ideas for the process. The project team was responsible for working in collaboration with support groups to determine how these new ideas could be implemented. This process was an operator based approach that required their active participation and input.

	TASK DESCRIPTION	Time	ELI	EXT	INT	REMARKS
1	**RUN OUT THE PRINT**					
a.	Turn Fill room line status indicator to RED	00:30			X	Necessary as a visual aid for support groups
b.	Turn off the Gottscho printer using the Pac controller	00:30	X			Not required
c.	Keep punching until all print is gone	02:30			X	
d.	Cut and pull of forming film from the thermoformer	00:30	X			Not required
e.	Clear blister waste in grey bin to trash	01:00			X	
f.	Clear Waste from scrap accumulation area	02:00		X		Housekeeping
g.	Turn off thermoformer	00:30	X			Not required – Takes 5 mins to restart
h.	Turn off Air supply	00:30	X			Not required- Maintenance feedback required
i.	Open Punch Station, pull punch station out , blow down	2:00			X	Important- Critical area
2	**VACUUM TABLETS FROM FEEDER (using portable vacuum)**					
a.	Put on latex gloves	00:40			X	
b.	Remove remaining tablets from hopper, put in tote	00:40	X			Run ticket will empty
c.	Run the feeder to empty the filler cassette	02:00		X		

Table 3– Application of the Task list During the Classification Meetings

Facilitating the classification phase was a challenging task which required patience and active listening. Often, operators became uncomfortable with the changes that were being proposed. When certain tasks were placed in the eliminate category, they questioned the value those tasks had added to the organization over time. Their responses suggested that they performed these tasks on the basis that they had always been done that way. It took several meetings to change their traditional mind sets and push them to think beyond their current work habits.

After an idea was proposed, the project team would seek approval from quality, operations or required support groups. The proposed changes were investigated by the project team and discussed with the quality team. The changes included eliminating redundant steps or moving tasks to be performed before of after the changeover. For example, redundant component checks were eliminated after learning that the warehouse performed checks before the components were brought to the line. The project team gathered the supporting information in the form of memorandums and flowcharts to back their case to explain to the quality team. If the quality team was convinced that the changes did not affect the quality of the product and the process still followed the regulations, then the proposed changes were made during testing. Sometimes, feedback from quality control was negative and alternate solutions were sought. The project team shared the results of the meetings with the quality team with the changeover improvement team to maintain their active involvement and confidence in the proposed changes. After the activities were classified, activity schedules were designed to standardize the process.

5.5 Schedule Building

After completing the classification phase, it was necessary to develop changeover standards to train production associates so that the new process would be executed in the same manner by personnel on all shifts. The primary purpose of the schedule building phase was to develop a standardized method for performing the changeover. This led to the development of activity schedules. The schedule reduced the changeover time by strategically organizing the internal activities among the changeover personnel. External tasks lists were designed to aid in performing external activities.

The first draft of the schedule was designed in a meeting with the changeover improvement team. The emphasis while designing the schedule was placed on the critical path. The critical path entails those internal tasks that have to be done in order for the line to be back up and producing product in the shortest possible time. The approach requires one operator to concentrate on the critical activities while the other two perform activities to support the critical path. The project team then analyzed the developed schedule and made changes to reduce waiting times. The changes in the schedule were shared in the changeover improvement team after which testing was done.

A part of the schedule is shown in Table 4. The schedule as shown in Figure 4 is divided into three columns. Each column enlists activities and their approximate times which should be performed by the operators on the line. The starting position of each operator is listed on the column header. The schedule assists the operators to perform activities in the required sequence. It also provides information about activities performed by other operators. This eliminates any chance of redundancy and helps to coordinate tasks to perform a standardized changeover. The complete schedule can be viewed in Appendix B.

OPERATOR 1 BACKEND POSITION		OPERATOR 2 FILLROOM POSITION		OPERATOR 3 ATU/HSM/KG3 POSITION	
Backend Status Indicator to RED; Remove Batch Id	00:15	Fillroom Status Indicator to RED; Remove Batch Id	00:15	CLICK ON PARSEC SCREEN–TCUCO START	00:15
CLEAR INTERMEC PRINTER Remove label roll and place in cage Stick last printed label on the green sheet	5:00 (5:15)	**RECORD GOOD/BAD** blisters information	1:00 (1:15)	**BLOWDOWN ATU** Blowdown Critical Areas Add blisters to EH&S/trash Visually Inspect	8:00 (8:15)
		TAKE PRINT MAT OUT Place base plate in cage	2:00 (3:15)		
EMPTY BINS & MOVE TO THE SIDE	3:30 (8:45)	**PULL PUNCH STATION OUT**	5:30 (8:45)	**BLOWDOWN HSM FLOW WRAPPER** Remove Cross Seal Jaw guard Blowdown Critical Areas Remove film from HSM vacuum bag Add blisters to EH&S/trash Visually Inspect	8:00 (16:15)
VISUALLY INSPECT **1. ECONOSEAL –** Remove Lot & Exp plates **2. CHECK WEIGHER** **3. OVERHEAD CONVEYORS** **4. CASE PACKER –** Remove tablets & blister cards from remaining packages **5. PALLETIZER** **6. COMPONENT STAGING AREA**	14:00 (22:45)	**REMOVE SLIDE BAR CHAIN COVER** Rotate slide bar to remove blisters	3:00 (11:45)		
		REMOVE **BLISTER CARDS** From under the PUNCH STATION	1:30 (13:15)		
		MOVE MATS & BINS TO SIDE	1:00 (14:15)		
		VACUUM FEEDER	3:00 (17:15)		
SIGN FOR FIRST BACKEND CLEAN	1:00 (23:45)	**FIRST FILLROOM BLOWDOWN** Blowdown Critical Areas Visually Inspect	10:00 (27:15)	**BLOWDOWN KG3 CARTONER** Remove Cartoner Lowerator cover Blowdown Critical Areas Add blisters to EH&S/trash Visually Inspect	12:00 (28:15)
WAIT FOR 1ST FILLROOM BLOWDOWN	4:30 (28:15)		1:00		

Table 4 - Sample Schedule

The external tasks were performed either prior-to or after the changeover by operators and line supervisors. Some external tasks needed to be performed at a certain time before or after the changeover by a specific resource. The successful execution of the external activities would ensure a planned reduction in changeover time. The external task lists enumerate the steps to be performed while the line is running. Two task lists were designed to assist operators to perform external activities before and after the changeover. A separate task list was created for the line supervisor to help perform activities at required times. The following task lists were designed:

– External list for activities performed by operators prior to the changeover.

– External list for activities performed by operators after the changeover.

– External list for tasks to be performed by the line supervisor at required times.

Laminated copies of the schedule and external lists were made available on the line for the operators to reference if required. A sample of the external list is shown in Table 5.

Prior-to changeover – Line Team			
Sr. No.	**TASKS**	**WHEN**	**STATUS**
1.	Housekeeping	As needed while running	
2.	Take full EH&S boxes to blister waste area.	As needed while running	
3.	Return Empty totes to backend	As needed while running	
4.	Sort blisters under reject bin in the fillroom	As needed while running	
5.	Clean Deblister Machine	After use while running	
6.	Back PI lifts away for the line to aid with visual inspection	As needed Prior to TCUCO	
7.	Call the Mechanic and the MMS to inform them when the changeover will start	30 minutes prior to changeover	
8.	Get Tyvek, gloves, earplugs, air hoses, flashlight handy & ready to go for the changeover.	15 minutes prior to changeover	
9.	Empty the in-house vacuum canisters and add tablets to the tablet waste	10-15 minutes prior to changeover	
10.	Consolidate trash in the fillroom and backend	5 minutes prior to changeover	

Table 5– External Task lists

5.6 Testing Phase

The primary purpose of the testing phase was to investigate the schedule and to ensure that a standardized, achievable process was developed. The testing phase was conducted to finalize the activity schedule. This phase helped the operators to get familiar with the new method for performing the changeover. The operators were given instructions to follow the guidelines provided by the project team. Members of the project team shadowed the operators and the line supervisor while they performed external and internal activities. The project team measured the times required to complete activities and checked the sequence to ensure the comfort level for the operators. Brief meetings were held after each test to provide operators with the opportunity to give feedback about the new process. Changes were made to the schedule as required during the testing phase. Testing was performed until a fairly repeatable schedule was achieved over all shifts.

The quality control unit’s approval was required to perform testing. A quality deviation memorandum was passed to allow the operators to perform the changeover using the new method. The memorandum guards the operators against not having followed the procedures as stated in the standard operating procedures. Lines were thoroughly checked for quality after the changeover was performed using the new method. This also emphasized that the process did not compromise the quality of the process. The testing phase highlighted the importance of performing external tasks prior-to and after the changeover to able to have a successful changeover. It provided the supervisors and support groups a chance to recognize their roles in the changeover. At the end of the testing phase, the standard operating procedures were updated.

5.7 Training

A training phase was completed next with the focus on creating a standard routine to be followed by all personnel on the line. The purpose was to ensure that the line teams perform activities as listed in the activity schedules and the external task lists. The focus was not on the time taken, since there was an expected learning curve for the operators. The training was focused on the understanding and coordination of the activities and the reduced time was a result of experience. The training phase allowed the operators to gradually move from their old method of working to adopting the new sequence while performing the changeover.

Standard operating procedures (SOPs) were written to help the operators perform the changeover in a consistent and comfortable manner. Best practices for certain activities were included in the SOP. Since SOPs tend to go into the tool box after a period of time, a laminated copy of the schedule and external task lists was made available on the line for the operator's reference. The focus of training phase was about ownership and understanding of the new process. It emphasized the importance of external activities that were required to be performed at appropriate times. This was necessary or the changeover time would be lengthened. Training also created awareness on how future projects on the line would impact the changeover. After a successful training phase, operations resumed process ownership and responsibility for tracking.

Chapter 6

RESULTS

6.1 Results Achieved

The new activity schedules were tested and the line team was trained to execute the changeover using the new methodology.

The setup reduction techniques applied to the changeover process reduced the changeover time from 3.5 hours to 75 minutes, a 65 percent reduction in time saving approximately 2.25 hours per changeover. As shown in Figure 12, 65 percent of the redesigned changeover includes cleanup activities which are required to be performed during the changeover while the actual setup is the remaining 35 percent.

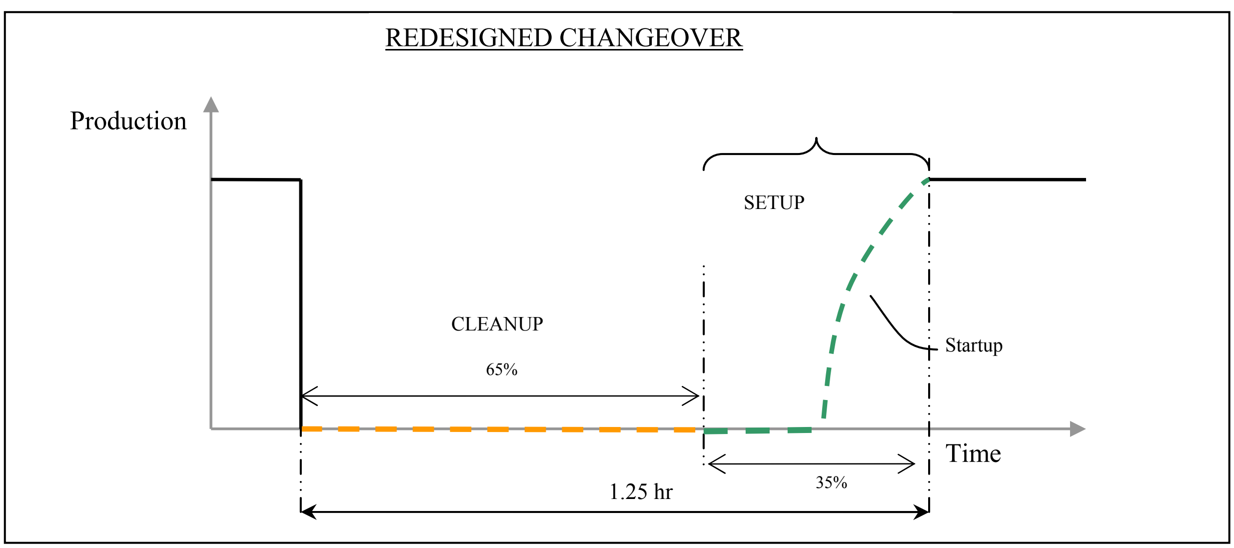

Figure 11– Redesigned Changeover

It was observed that only 32 percent of the activities involved in the changeover process were required to be performed while the line was down. Redundant and unnecessary activities were eliminated while 37 percent of the changeover activities were categorized as external activities to be performed either before or after the changeover. The results of the classification phase are depicted in Figure 12.

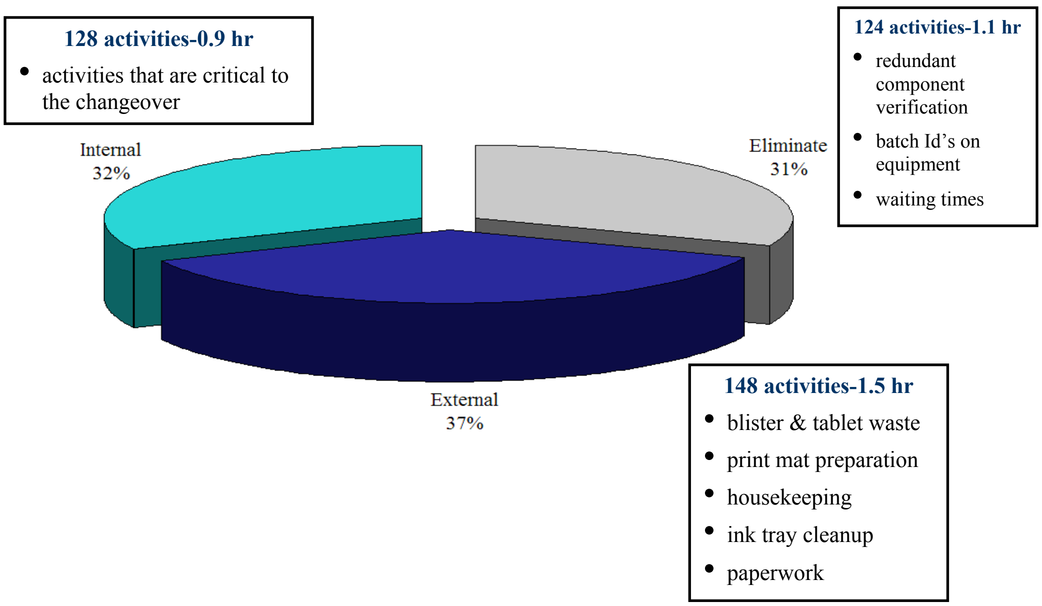

Figure 12– Results of Changeover Improvement

Cleanup activities were reduced by more than 60 percent as shown in Figure13. Critical areas were identified on the line. Activities to clean these identified critical areas on the line were retained whereas unnecessary cleanup activities were eliminated. Housekeeping activities were added to the external tasks lists to reduce the line downtime. Furthermore, calculations and required paperwork were moved to the external task lists to be performed by operators and the line supervisor while the line was running. The setup activities were better organized and operators were trained to perform best practices to ensure a reliable and repeatable setup process.

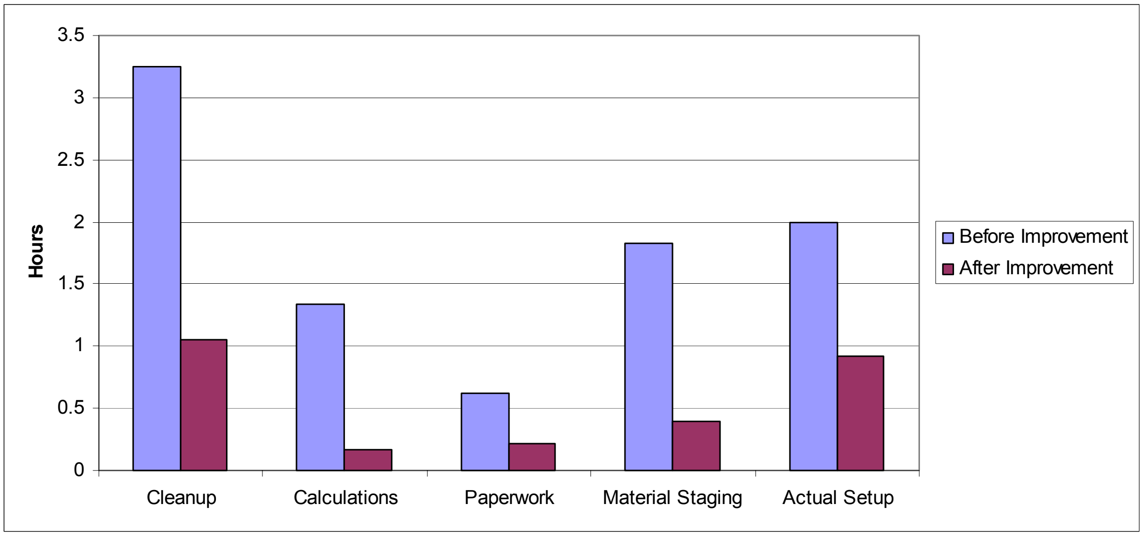

Figure 13– Classification of Activities After Improvement

6.2 Expected Benefits

Given that there are approximately 100 changeover processes performed per year, there is a total time savings of more than 200 hours per year. Thus, the available time on the line was increased by approximately 25 eight-hour shifts without adding any additional capital equipment to the facility. Given that there are 16 packaging line in this facility and applying a 70 percent success factor, an estimated increase of 3000 hours of packaging capacity can be achieved. This will translate into a significant increase in production capacity, cost savings, production flexibility and profit. The additional capacity will help the plant site handle the additional volume which in turn will result in higher turnover. The reduced changeover time will provide the needed flexibility which will enable the packaging facility to accept smaller more frequent batch orders.

The total cost of packaging a product is divided into 2 parts. i.e. Fixed and Variable.

Packaging Costs = Fixed Cost + Variable Cost

Fixed costs are the costs that do not vary with the volume of product produced. In a packaging plant, equipment cost, labor and overhead costs, and plant utilities are considered as fixed costs.

Fixed Cost = Equipment Cost + Man/Labor Cost + Plant utilities

Variable costs are costs which vary with the volume produced. Raw materials used in production are considered variable costs.

Variable Cost = material and component costs

Standard cost per package is calculated as the packaging costs divided by the volume produced.

$$\text{Standard cost per package} = \frac{\text{Packaging Cost}}{\text{Volume}}$$

At the concerned packaging facility, fixed cost comprises 70 percent of the cost per package. Thus, the cost per package decreases with increase in packaging volume. The reduced cost will help the packaging facility to contend with lower costs offered by the other competitors. Thus adding capacity by means of changeover reduction helps the packaging facility to attract more volume at competitive prices with the needed flexibility.

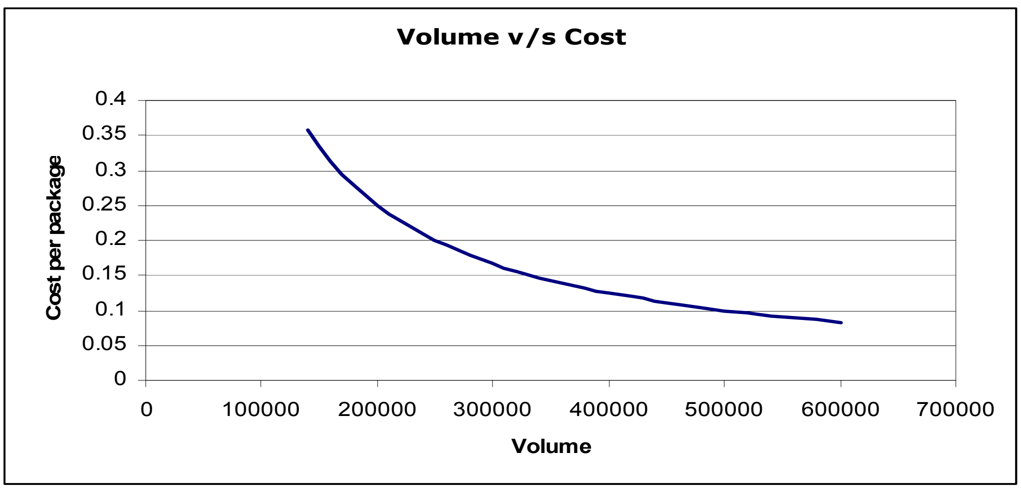

Figure 14– Relationship between Volume and Cost Per Package

The process created a sense of awareness and importance about performing changeovers efficiently in a standardized manner. The standardized process assisted the planning department in their functions since the changeover time durations had become more reliable. Operators tended to participate more in optimization and improvement programs and their motivation increased when their ideas were put into implementation. Overall, the process brought about a cultural change which is required for sustaining and creating new improvement initiatives.

Chapter 7

CONCLUSION & FUTURE WORK

7.1 Conclusion

Lean production processes can certainly be applied productively in pharmaceutical packaging. The problems faced by the packaging facility were successfully addressed by the application of the setup reduction process. Capacity on one line was added without having to invest in new equipment and personnel on the lines. The additional capacity provided the needed flexibility and reduced the cost per package of products produced on that line. Given that there are 16 packaging line in this facility, a large amount of capacity can be added through implementation of setup reduction processes on all lines. This will translate into significant increase in production capacity, cost savings, production flexibility and profit. The additional capacity will help the facility handle the additional volume and enable the packaging facility to accept smaller more frequent batch orders.

In pharmaceutical and other industries in which quality and federal regulations play a significant role in operations, production and quality personnel tend to be conservative and cautious. Dealing with problems that develop in production often results in addition of new tasks and activities for production personnel to perform. Thus processes become accretive and grow over time. It was observed that the perception of the stringent quality regulations in pharmaceutical manufacturing can be addressed through investigations such as the setup reduction process.

Regularly, required tasks need to be reviewed to see if they are still relevant and needed. Furthermore, applying lean production tools like setup reduction can greatly reduce the number of tasks performed during planned downtime.

It was observed that it is important to be able to sustain an improvement made to a process. The potential problem is that the operators have the tendency to drift back to the traditional way of working as shown in Figure 13. Evaluations and audits have to be conducted to control these processes and prevent them from going back to the way they were done until the new process becomes a habit. It is a continuous improvement process which requires monitoring to ensure that planned results are obtained. An organizational structure must be in place to track any deviations in the process to ensure all groups are performing their part in the process.

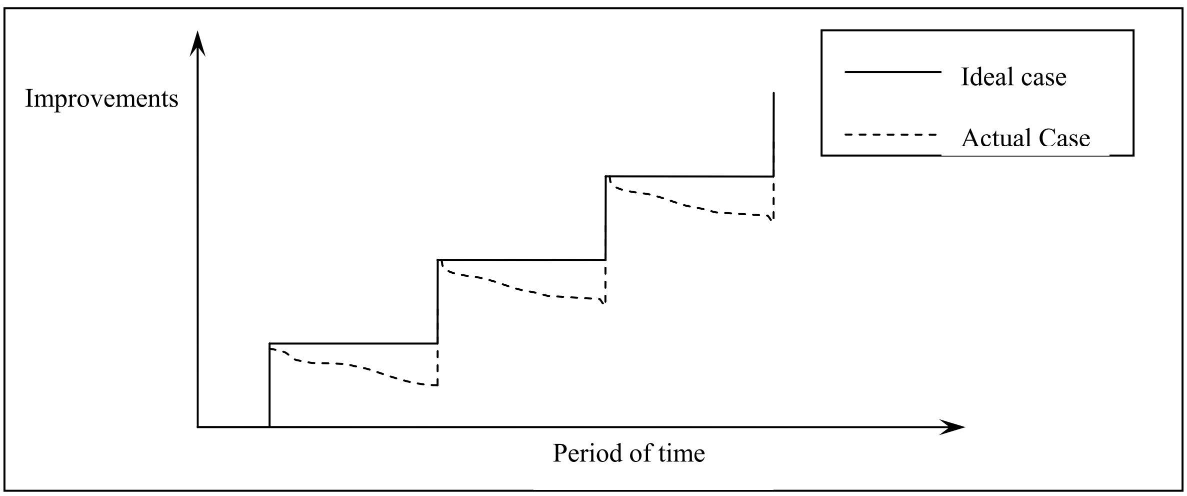

Figure 15– Importance of Process Controls

Leadership at every level is critical to the success of a lean production program. The program challenges and seeks to change many production processes that are intertwined with traditional practices. This requires strong leadership and understanding from senior management. This leadership needs to be shared at every level in the entire operation. All quality functions within the organization must be committed to the project and be open to questioning every task for a project like his one to succeed. This project serves as the beginning of a cultural change of what is possible not only in packaging but also in other pharmaceutical manufacturing operations.

7.2 Future Work

This investigation reduces the changeover time by mainly reducing the time required to perform cleanup activities. As seen in Figure 10, setup comprises 42 percent of the activities performed in the redesigned changeover. The setup activities did not utilize a majority of the original changeover time and hence were not the major focus of this study. Setup activities were organized better while operators were trained to perform these activities in a standard manner. However, it was observed that while performing the changeover using the new method, the time required to perform setup was variable and often the cause of the changeover time being more than expected. As a potential opportunity, an investigation needs to be focused on developing a more reliable setup process. Adjustment pointers can be standardized and operators can be trained to trouble shoot during breakdowns.

The improvement on the packaging lines has had a big impact on the way other departments performed their functions. As shown in Figure 16, the packaging lines are one part of the plant supply chain.

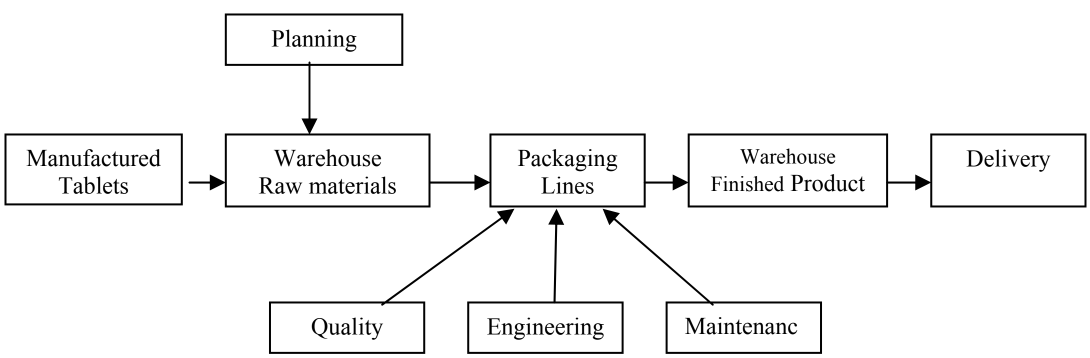

Figure 16 – Packaging Supply Chain

The supporting departments particularly the warehouse and planning department, were finding it difficult to keep up with the speed of the changeovers. It was observed that the lines were left waiting on either paperwork from the planning department or components from the warehouse. Maintenance mechanics that were used to performing their small functions during the longer changeovers now had to schedule times and work during breaks or meetings to complete their tasks. The packaging lines were no longer the constraint in the supply chain and the supporting groups had to make extra efforts to maintain the smooth flow of products. The focus was now moved to making the warehouse and planning operations more efficient. Effective pull systems can be implemented in the warehouse to create a well-organized material transfer system. This would enable the lines to receive products as planned in a repeatable manner.

This investigation has only scratched the surface of possibilities by attacking only the packaging processes, indicating the great potential lean production applications provide in pharmaceutical product processing. Considering just the packaging area, more than 200 hours of time were added on one packaging line. Certainly additional opportunities for improvement exist not only in packaging operations but in other plant areas as well.

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Appendix A: Measurement Form

Recorder :

Operator:

Shift:

Date:

Line:

	Task Description	Time

Appendix B: Activity Schedule

OPERATOR 1
SMED Schedule Rotation:
Filler Rotation

MOVE BINS , MATS AND TRAYS TO THE SIDE (not reserve tray)	00:30	(00:30)
SCOOP EXTRA TABLETS FROM THE FEEDER	1:00	(1:30)
WAITING FOR OPERATOR 2 TO RUN OUT PRINT	03:30	(05:00)
REMOVE ORBITAL WIPER & THROW AWAY CLOTH – Jog tablets from feeder and add to waste – Move reserve tray – Scrap & remove tablets – from the under the filler – Remove orbital wiper	06:00	(11:00)
REMOVE OLD CAGE OFF LINE Collect all documents and place in the cage; Take cage completely off the line	02:00	(13:00)
BACKEND- CLEANING 1st VISUAL INSPECTTION – Visually inspect the backend for printed components – Sign cleaning cards	03:00	(16:00)
WAITING FOR 1st BLOWDOWN	01:30	(17:30)
FILLROOM INSPECTION 2nd BLOWDOWN – Inspect the Punch station –FRONT – Inspect Punch station –BACK – Inspect the SCALE – Ensure trash cans are empty	07:00	(24:30)
INPSECTION - FILLROOM 2nd VISUAL – Visually inspect the fill room equipment and leak test bowl. – Sign the cleaning cards	04:00	(28:30)
Flip FILLROOM line status to GREEN	00:30	(29:00)
INSTALL ORBITAL WIPER & ASSEMBLE THE FILLER – Change orbital wiper cloth – Install the orbital wiper – Assemble the parts of the filler	09:00	(38:00)
FILL THE HOPPER – Load tablet totes on presto lift – Scoop tablets in hopper – Staple tote Id to green sheet	08:00	(46:00)
SETUP THE INTERMEC PRINTER – Take green sheet & go to backend – Program the intermec printer	03:00	(49:00)
ASSISTING OPERATOR 2 TO MAKE GOOD BLISTERS OR AFTER TCUCO OFFLINE TASKS	6:00	(55:00)
ASSISTING OPERATOR 2 TO MAKE PACKERS	10:00	(65:00)

OPERATOR 2
SMED Schedule Rotation:
Thermoformer Rotation

RECORD TICKET INFORMATION – Record Good/Bad blisters information for the old ticket. – Record start time of TCUCO on drag sheet.	00:30	(00:30)
RUN PRINT OUT & CLEAR WASTE – Empty full blisters in the rejection bin to blister waste – Run the print out; Stop thermoformer – Put rejection bin to the side – Sweep out scrap from under the punch station area	04:30	(05:00)
PULL PUNCH STATION OUT	1:30	(06:30)
TAKE PRINT MAT OUT – Place base plate in cage	01:00	(07:30)
FILLROOM CLEANING 1st BLOWDOWN – Blowdown the Punch station –FRONT – Blowdown the Punch station –BACK – Blow the SCALE – Sweep scrap to the side	10:00	(17:30)
PUSH TRASH CAN CONTAINING PRINTED MATERIAL TO THE BACKEND (near the intermec printer)	01:00	(18:30)
INSPECTION - FILLROOM 1st VISUAL – Visually inspect the fill room equipment and leak test bowl. – Sign the cleaning cards	06:00	(24:30)
WAITING FOR FILLROOM GREEN STATUS	4:30	(29:00)
TAKE CAGE TO FILLROOM – Take cage from backed to the fill room – Insert pink AIMS Id on the fill room – line -status indicator; – Fill ticket info on the fill room cleaning card	02:00	(31:00)
INSERT PRINT MAT IN THE PRINTER – Insert print mat in the printer – Take trash can to front side of thermoformer	02:00	(33:00)
PUSH PUNCH STATION IN & THREAD FOIL BACK UP – Place the rejection bins under the punch station	03:30	(36:30)
WAITING FOR THE ORBITAL WIPER TO BE INSTALLED	(1:30)	38:00
CREATE EMPTY BLISTERS (DIALING IN) – Reset the GOOD/BAD blister numbers in the pack control – Check the air on the forming film – Create empty blisters	16:00	(54:00)
COLLECT PRINT SAMPLES Collect and check print samples	01:00	(55:00)
Turn-ON Feeder & Make GOOD blisters **PERFORM ALL CHALLENGES** **MAKE FIRST PACKER**	10:00	(65:00)

OPERATOR 3
SMED Schedule Rotation:
Line tender Rotation

FINISH LAST PACKER OUT – Take last packer out to backend – Take empty packers from fill room to backend; Turn off Intermec printer – Turn Backend Line status indicator to RED and pull off AIMS id – Stick last label on the green sheet – Turn fill room Line Status Indicator to RED and pull off AIMS Id	05:00	(05:00)
EMPTY FULL/ EMPTY BLISTERS – Separate empty and full blisters	02:30	(07:30)
REMOVE BLISTER & TABLET WASTE – Seal the EH&S box – Take EH&S box and tablet waste to Offline Waste Area	10:00	(17:30)
BACKEND- INSPECTION 2nd VISUAL INSPECTION – Empty trash cans on the backend – Visually inspect the backend for printed components	03:00	(20:30)
BACKEND STATUS TO GREEN – Check the cage for "READY" status – Bring cage to the line and position it outside the fill room door – Place the label roll at the intermec printer – Flip Backend line status to green – Insert pink AIMS Id on the backend – Fill ticket info on backend cleaning card	02:30	(23:00)
BRING TABLET TOTES TO THE FILLROOM – Check for red stamp – Load tablets on the pallet jack – Bring tablets totes from the backend to the fill room door	04:00	(27:00)
WAITING FOR FILLROOM GREEN STATUS	2:00	(29:00)
MOVE PALLET OF TABLET TOTES INTO THE FILLROOM	00:30	(29:30)
PLACE BINS, TRAYS, MATS – Put Tyvek on – Position EH&S box in the fill room – Put bins, trash cans, mats and trays in their position in the fill room – Fill ticket info on all cleaning cards – Distribute paperwork on the line	05:00	(34:30)
PROGRAM THE LITTLE DAVID	01:00	(35:30)
GET THE LAPTOP TO THE BACKEND	02:00	(37:30)
PREPARE THE INTERMEC PRINTER – Thread the label roll on the intermec – Connect and start the laptop	03:00	(40:30)
WAITING FOR OPERATOR 1 TO ASSIST	05:30	(46:00)
SETUP THE INTERMEC PRINTER – Put first label on the green sheet	05:00	(51:00)
BRING PACKERS IN THE FILLROOM	1:00	(52:00)
WAITING FOR PRINT SAMPLES	3:00	(55:00)
COMPLETE PRINT SAMPLE VERIFICATION	8:00	(63:00)
AFTER TCUCO OFFLINE TASKS **Record end-of TCUCO time**	02:00	(65:00)