Controlled Environmental Area Room B Relayout for Acuity X4 Subassemblies Manufacturing Line Transfer

Ashley Ramírez Quiles
Master in Manufacturing Competitiveness
Iván Avilés, Ph.D., PE
Industrial and Systems Engineering Department
Polytechnic University of Puerto Rico

Abstract — *Boston Scientific is part of a competitive environment and strives to find methods to reduce cost, waste and improve quality. A methodology for reduction is Lean manufacturing. This methodology is used to reduce "muda" which eliminates waste in a production process and is known as Japanese term in the Toyota Production System. The layout of the manufacturing plays a big role on the maximization of the space resource. This article discusses the optimization of the manufacturing space by using the Lean Manufacturing methodology and the DMAIC (define, measure, analyze, improve and control) tool as a systematic approach. To optimize space layout of the selected manufacturing lines, equipment and workstations tables were consolidated, eliminated, or reduced. The results revealed that 2,080 ft^2 were able to be cleared for new products.*

Key Terms *— DMAIC, Lean Manufacturing, Space Optimization, Wastes ("Muda).*

INTRODUCTION

The problem that will be presented for this research is based on the Controlled environmental Area room CEA-B Relayout development and implementation to have space to move Tachy Reliance IS4 manufacturing line from CEA-C to CEA-B on the next relayout project, making space in CEA-C for Acuity X4 Subassemblies manufacturing line transfer from Boston Scientific's Arden Hills Site to Dorado Site.

At Boston Scientific Dorado site, there is a limitation with space to transfer and incorporate new or existing products from other Boston Scientific's sites. In this case, the specific challenge is that the manufacturing line that needs to be transferred must be in a controlled environmental area, and all the CEA rooms are occupied.

After various problem-solving sessions, it was found that a few manufacturing lines have opportunities for layout redesigns. Throughout time it was noticed that some workstations could be consolidated or eliminated, and some improvements can be made to better the manufacturing lines flow while liberating space in the CEA rooms for new products.

Research Description

The research associated with this project will be related to manufacturing line balancing, spaghetti diagrams, brainstorming, kaizen, 5S audits and cost analysis to determine how much floor space can be cleared and if the results are successful. Analyzing the resulting data from these exercises will show how much of the room can be liberated for the transfer. This project is important since, as a business unit Boston Scientific always strives to keep growing, innovating, and providing our clients and patients with the best medical device products. Right now, the goal is to achieve a space of approximately 2,000 square ft. This will impact in a positive way quality metrics, cycle time and production output. Also, this will not only help with the manufacturing line flow and consolidation, but it will also result in a financial benefit for our business site since it will enable future growth and innovation. It is desired to free as much space as possible not only for the transfer of Acuity X4 Subassemblies but also for future product acquisitions. The VIP (Value Improvement Process) system, which is the system that tracks how much money the improvements save the company, will be the metric used to measure the result of cleared space in money.

Research Objectives

The research has the objective to better the manufacturing lines flow, consolidate workstations, and reduce occupied space for future Acuity X4 Subassemblies transfer. Also, to accomplish the implementation of the new layout while the manufacturing lines perform flawlessly after the results.

Research Contributions

As part of the contributions from this project, approximately 2,000 square ft is the goal to be liberated at the CEA-B for the future transfer of Tachy reliance IS4 from CEA-C to CEA-B. Leaving the space in CEA-C available for the Acuity X4 Subassemblies manufacturing transfer from Arden Hills Site to Dorado Site.

LITERATURE REVIEW

The specific area being improved is Controlled environmental Area room CEA-B at Boston scientific Dorado site. Lean manufacturing and Lean Six Sigma are the main concepts to be discussed. But before continuing the discussion, history of these concepts will be briefly discussed.

It is very important for all manufacturers to remain on their top game on this global competitiveness, their respective markets and to understand the principles of lean manufacturing and the steps to implement them to ensure that they are the leading edge of manufacturing.

Lean Six Sigma is a philosophy and methodology that combines Lean Manufacturing with Six Sigma and establishes how to improve processes in a way that involves poor quality costs, out-of-control processes, waste, and critical factors of customer requirements. The convenience of the joint application of lean thinking and Six Sigma is to be able to achieve the best results offered by each of the quality methodologies [1]. Lean Six Sigma projects focus on specific problems for which economic feasibility studies are conducted, use powerful data collection techniques, data analysis, and require unequivocal leadership commitment. All this aimed at improving actions are finally reflected in profits in the company's economic balance sheet. The Lean philosophy manages to eliminate waste and optimize the value chain therefore it is understood that the proper use of both approaches will achieve [2]: minimization and elimination of waste in processes which consists of analysis tools that, together, improve and efficient processes to offer quality services with reduced costs and times. Increase productivity where the application has increased the productivity rate of each employee and processes in general. Improve Collaboration and Communication which consists in collecting data and analyzing it through reliable metrics brings common language to employees. Increase the overall competitiveness of the organization and the satisfaction of customers and consumers which results in reducing costs and process failures. These costs are reduced by eliminating internal errors. Lastly, reduce process times and lead times, this, allows a higher level of flexibility to meet customer demands in real time through process rationalization and simplification [3].

Lean thinking can be summarized in five principles which are, precisely specify value by specific product, identify the value stream for each product, make value flow without interruptions, let the customer pull value from the producer and pursue perfection.

Essentially, it seeks to make a product that is exactly what the customer wants and needs, while minimizing all non-value-added activities in production. Lean manufacturing can be described as eliminating waste in a production process (known as Japanese term “muda” in the Toyota Production System) [4]. The seven type of waste in a manufacturing process are overproduction which to manufacture an item before it is required. Waiting (time on hang) were workers merely serving to watch an automated machine or having to stand around waiting for the next processing step, tool, or supply. Unnecessary transport or conveyance which is carrying work in process long distances, creating inefficient transport out of storage or between processes. Over-processing or incorrect processing

which is taking unneeded steps to process the parts, inefficiently processing due to poor tool and product design. Lastly, excess inventory which is excess raw material [5].

Non-value-added activities are generally understood to be either waste, or incidental activities that are necessary but add no value to the product. For example, quality inspections do not add value to the product; they merely detect defects before they reach the customer. When “Muda” (waste) elements exist, they will increase the cost and add zero value to the manufacturing process. To eliminate “muda” the company must be able to look at the value stream of the manufacturing process. The value stream is simply going through the entire manufacturing process and looking at the things that add value to the product and things that not. The “spaghetti diagram” gives the true path of how material is flowing through the process. Lean Six Sigma is a methodology that maximizes shareholder value by achieving the fastest rate of improvement in customer satisfaction, cost, quality, process speed, and invested capital [6]. Lean Six Sigma combines the two most improvement trends of our time: making work better (using Six Sigma) and making work faster (using lean principles). “Process Improvement” refers to a strategy of findings solutions to eliminate the root cause of performance problem in processes that already exist in your company. In term of Six Sigma, Process Improvement finds the critical causes that create the unwanted defects produced by the process. The Six Sigma DMAIC (Define, Measure, Analyze, Improve, and Control) methodology can be thought of as a roadmap for problem solving and product/process improvement. These tool lead team logically from defining a problem through implementation solutions linked to underlying causes and establishing best practices to make sure the solutions stay in place.

Finally, Boston Scientific is very committed to eliminate waste and reduce cost, that is why Lean Manufacturing and Lean Six Sigma was selected to achieve the objective of this project. By combining methodologies such as Six Sigma and Lean Manufacturing, it is possible to accelerate specific processes for companies to solve problems faster, while creating value for their customers. On the one hand, Lean aims to reduce waste, while Six Sigma allows to reduce defects and possible variations in processes; continually removing them and correcting inefficiencies [3].

For this project, the goal is to use these methodologies to reduce the current occupied space at CEA-B, at least 2,000 square ft for future growth. The current need of space is causing a great loss to the company since it is preventing it from expanding and producing new products.

This is where the Lean Manufacturing and Six Sigma tools will be used to achieve the project goal, which has been used before in other projects like [7], where it was managed to save the company $62,400, and [8] were it was managed to reduce defects by more than 50%.

The current layout for the manufacturing lines at CEA-B room that will be re-arranged to achieve the goal is shown in Figures 1 and 2.

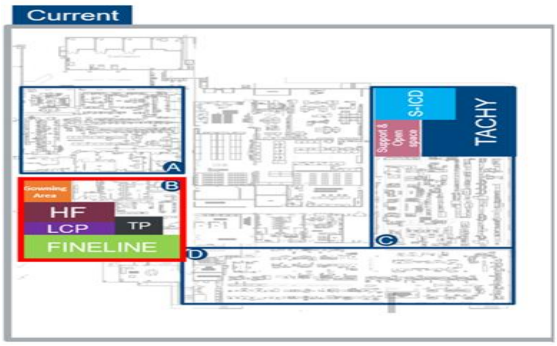

Figure 1
CEA-B Current Layout in Red Square

These are HF (Heart Failure), Fineline, LCP (Leadless Cardiac Pacemakers) and TP (Tray Pack). Also, gowning area for CEA-B room will be arranged to maximize potential space to be liberated. While in CEA-C room the manufacturing lines to be arranged in the next layout project for the Acuity X4 Subassemblies manufacturing line transfer are S-ICD (Subcutaneous Implantable Cardioverter–Defibrillator) and Tachy (Tachycardia). All manufacturing lines are independent from each other and manufacture different BSC Products.

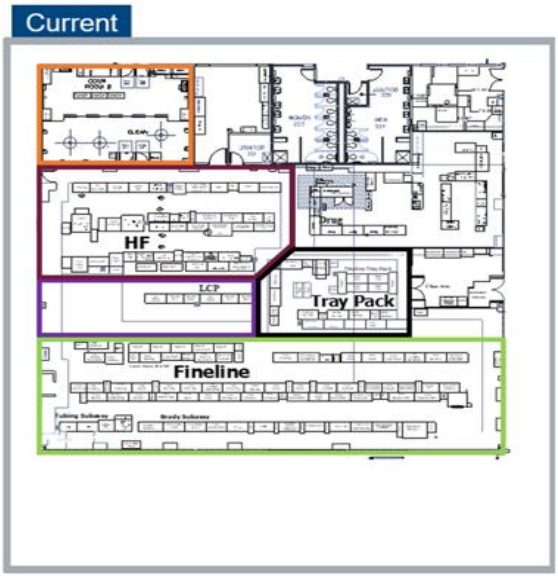

Figure 2
CEA-B Current Detailed Layout

To achieve the final goal, the proposed layout is displayed on Figures 3 and 4.

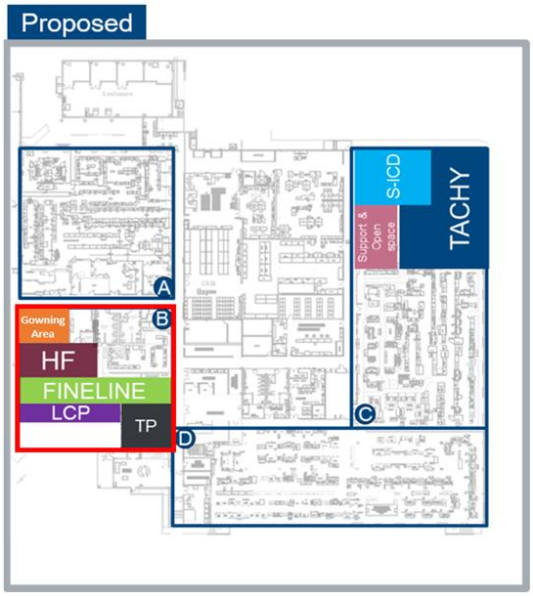

Figure 3
CEA-B Proposed Layout in Red Square

The reason to arrange these specific manufacturing lines and areas is that, through time production volume for these products has decreased giving the opportunity to reduce the output required from each product, relocate overheads needed on other areas and eliminate duplicated workstations, among other improvements. This current issue is causing the company to lose money since it is unbaling BSC to expand and acquire or develop new innovating products which keeps the company competitive and offering their patients the best care.

By implementing these changes Tachy manufacturing line will be able to be transferred to CEA-B room leaving available space to also transfer Acuity X4 Subs manufacturing line from BSC Arden Hills, Minnesota to Dorado, Puerto Rico site.

Also, lead time will be improved since the mainline will no longer need to wait for subassemblies to be shipped to Dorado. Directly supplying mainline and allowing to react immediately in case of any inconvenience.

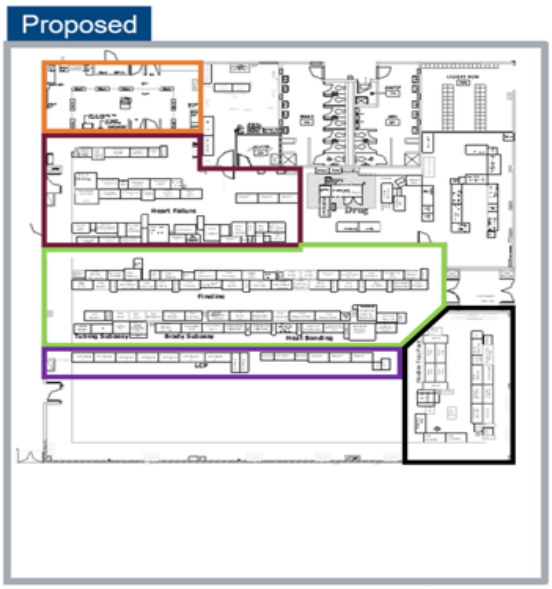

Figure 4
CEA-B Proposed Detailed Layout

PROJECT METHODOLOGY

Productivity in manufacturing industry plays an important role in keeping the company competitive for the market as well as for its survival. Six Sigma is a quality improvement program that looks at processes with a view to analyzing process steps, determining what process elements need improvement, developing alternatives for improvement, then selecting and implementing one. The methodology to achieve the goals of the project that established purpose are the Lean Manufacturing methodology and the Six Sigma DMAIC which is a

data driven improvement cycle designed to be applied to business processes to find flaws or inefficiencies particularly resulting in output defects and to combat them. This tool is defined in the five steps, Define, Measure, Analyze, Improve and Control [9].

This is a statistical-based quality strategy that attaches great importance to information collection and data veracity [8]. Each step focuses on obtaining the best possible results in order to minimize the possibility of error. It can be applied to any production process and if its application leads to control and improvement of the analyzed processes. The basic characteristics of the DMAIC methodology to be used in the project [3] are summarized below:

Define is the initial phase, here are identified the potential projects of the Six Sigma. Properly defining the problem is the most important part of solving the problem. In this phase it is essential to determine factors involved in the quality of the process.

Measure is the next step to set the performance of the current process by measuring the performance baseline before attempting to identify improvements. The goal for this phase was to define the project performance measure, establish the data collection plan, gather data, and establish the baseline. This phase provides a clear focus on the improvement effort by collecting information and relevant data on the current situation in the manufacturing process.

In the analyze phase current and past performance data is analyzed to generate a list of priorities for sources of variation. This phase is used to identify the causes that affect the current process by using the data gathered during the measure phase. During this phase, the team will document potential causes of the problem that are impacting the process.

The improve phase has the objective of performing changes to the process in order to eliminate the root causes of the problem identified during the analyze phase. It seeks to determine the cause-and-effect relationship to predict, improve and optimize the functioning of processes.

The control phase aims to design and document the controls needed to ensure that the benefits of the Six Sigma upgrade are maintained once the changes have been implemented.

As part of the Research, below is the proposed plan were manufacturing line balancing, spaghetti diagrams, 5S audits and cost analysis will be taking place as part of the DMAIC methodology to achieve the goal of making approximately 2000 square ft of floor space for future growth.

DMAIC Methodology Strategy

- **Define:** Here the problem will be defined which it already has been identified since the beginning.
- **Measure:** In this step the current State Map will be taken into consideration. Also, a Spaghetti Diagram which is a visual representation using a continuous flow line tracing the path of an item or activity through a process enabling the team to identify redundancies in the workflow and opportunities to expedite process flow.
- **Analyze:** In this step 8 forms of waste will be taken into consideration which will allow to identify any waste is any action or step in a process that does not add value. Also, brainstorm which is mix of random ideas that comes to mind at the moment of discussing possible approaches or solutions.
- **Improve:** In this step the Future State Map will be taken into consideration which represents the goal of the improvement process and provides shared vision of what the team is hoping to achieve and an objective to work towards. Also, Implementation which breaks down the implementation process into smaller steps, while defining the timeline, the teams and the resources that will be needed.
- **Control:** This phase will evaluate with 5S audits that the changes or improvements implemented maintain.

Each step will be further discussed with its respective results on chapter 4 titled Results and Discussion.

RESULTS AND DISCUSSION

The main problem at Boston Scientific Dorado site regarding this project is that there is a limitation with space to transfer new products. The challenge is that the manufacturing line that needs to be transferred must be in a controlled environmental area, which are occupied.

As part of the research, manufacturing line balancing, spaghetti diagrams, brainstorming, kaizen, 5S audits and cost analysis will be performed to determine how much space can be enabled. It is important to address this issue because is causing the company to lose money. Also, lead time and response time will be reduced allowing to address any quality issue that may occur.

By implementing these changes Tachy manufacturing line will be able to be transferred into CEA-B room leaving available space to also transfer Acuity X4 Subs manufacturing line in the near future from BSC Arden Hills, Minnesota to Dorado, Puerto Rico site. With this project it is expected to accomplish the space need no make all the transfers and acquisitions possible.

As for the DMAIC problem-solving approach that drives Lean Six it will be discussed in detail with the actions taken and results obtained to achieve the goal. To properly define the problem is the most important part of solving the problem which is that approximately 2,000 square ft needs to be available to be able to transfer Tachy manufacturing line from CEA-C to CEA-B. All these manufacturing lines need to be in a Controlled environment area and currently there is no free floor space in any of the CEA rooms in Dorado.

To measure, the current state was mapped, providing a clear view of the layout to understand and identify opportunities of improvement. This current state map helped to have a better overall view of the manufacturing lines and identify which workstations and areas could be rearranged, consolidated, or eliminated for better used of the floor space on CEA-B room. Also, the process level analysis tool used for the study are a Spaghetti diagram. This diagram helped to obtain floor space and to eliminate excess movement since it is one of the 8 wastes. Refer to Figure 5.

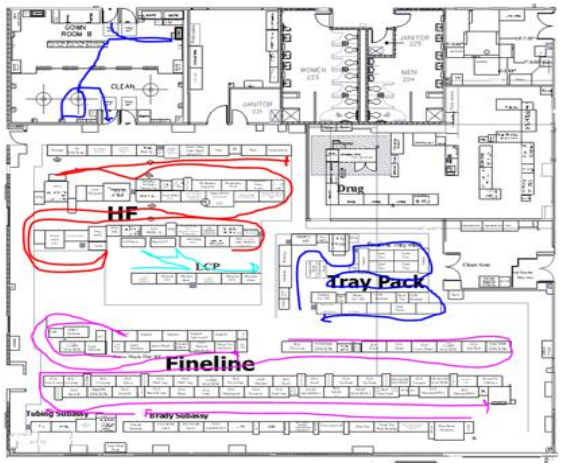

Figure 5
Spaghetti Diagram for each Manufacturing Line

In this third phase different types of waste were identified and analyzed using the 8 forms of waste method which is explained in Figure 6 [10]. As a result of the analysis, it was identified that inspections could be consolidated, gowning could be reduced, meeting areas could be moved and reduced, setups could be rearranged or eliminated and training areas could be reduced or eliminated, among other things.

Figure 6
Eight Forms of Waste "TIMWOODS"

For the gowning area, hand dryers, racks, hanging racks, trash can and waters fountains to wash hands were selected for potential elimination and identified with the color red. Benches identified with the color blue, were suggested to be added to reduce the clean area providing more space to get dress with the gowning while expediting the process of entering the CEA-B room. Finally, clean area perimeter and wall identified with color yellow, were suggested to be moved forward to minimize the

space needed for the gowning and leaving more space inside the CEA-B room for the new layout. Refer to Figure 7.

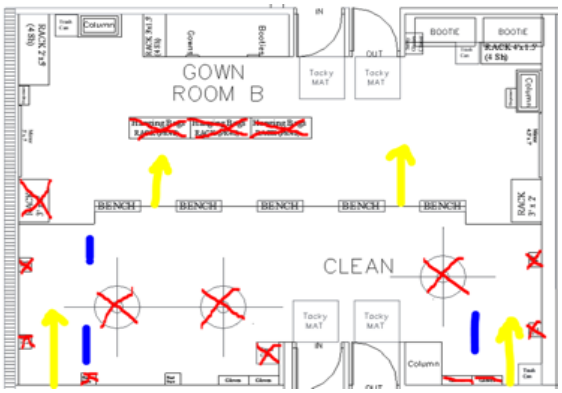

Figure 7
Areas of Opportunity in Gowning Area at EA-B Room

For Heart Failure (HF) manufacturing line, nine manufacturing tables were suggested in color red to be eliminated due to duplication, obsolete, or consolidation. Two manufacturing tables who hold equipment were suggested in color blue to be consolidated into one. Finally, one table was suggested in color green to be reduced from 6 ft to 4 ft. While for the Leadless Cardiac Pacemakers (LCP) two racks were suggested to be eliminated from occupying the HF manufacturing area and are identified in red. Refer to Figure 8.

Moreover, for Fineline manufacturing line five spare equipment, six duplicated workstations and two support tables were suggested to be eliminated, all identified in red. Two of the suggested to be eliminated workstations could potentially be consolidated and are identified in blue. Finally, eight tables were suggested to be reduced from 6ft to 4ft, identified in green. Refer to Figure 9.

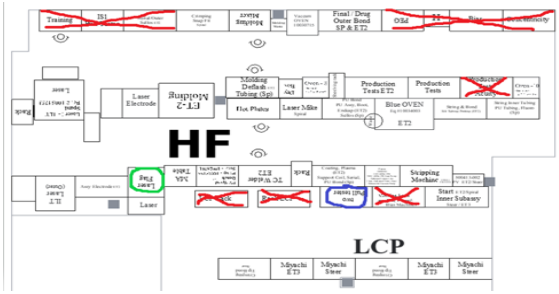

Figure 8
Areas of Opportunity in Heart Failure and LCP at CEA-B Room

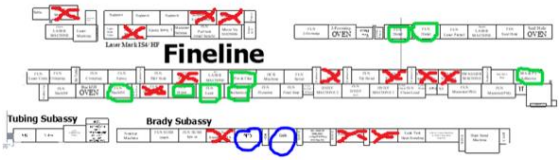

Figure 9
Areas of Opportunity in Fineline at CEA-B Room

Lastly, for Tray Pack manufacturing line, three tables and two racks were suggested to be eliminated, all identified in red. One of the suggested to be eliminated workstation table could potentially be consolidate, identified in blue. Refer to Figure 10.

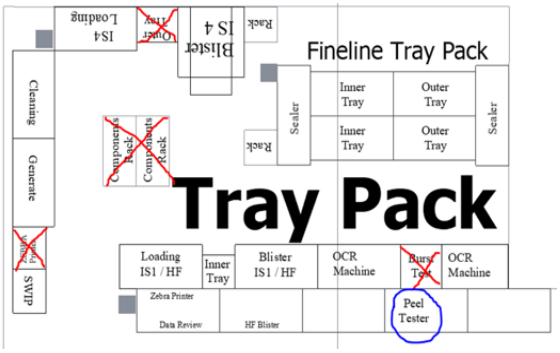

Figure 10
Areas of Opportunity in Tray Pack at CEA-B Room

Also, these were some of the action items in the brainstorming process to make the desired relayout outcome, possible. Refer to Table 1.

In this improvement phase, after analyzing all the opportunities for the improvement on all the selected manufacturing lines in CEA-B room, various arrangements were taken into consideration to make possible these eliminations, consolidations, or rearrangements. The main focused area would be the elimination of the tables or areas identified. Instead of having spare equipment in was decided to only keep the required since the demand of the product is significantly low compared to the product lifetime and three shifts have been reduced to one shift. Also, all the tables identified to be reduced from 4ft to 6ft could also be possible. And since production volume is so low and it is projected to stay that way with the acquisition of new products and technology, the elimination of all the identified areas, tables and setups was also possible.

Table 1
Brainstorming Process for CEA-B Room

Create a list of EZ2 equipment determine which will remain as spare part and which will be discarded
Laser for Tachy SubAssy
Close all calibrations, exit calibrations, and hold at PRIMO system
Business hold at MES to avoid that PB's create orders in system
Send PNs
Business hold form
Perform system transaction
Drug – scrap remaining drug collars after EOL in 2021
Evaluate Spare Parts (67 PNs, 1300 parts)
ECP & EMP Procedures Assessment

In addition, a Kaizen which is a Japanese term that means continuous improvement, was performed with the team including line coordinators, product builders, technicians and engineers to analyze the potential opportunities. The goal was to interview the people that are constantly on a daily basis performing the process and interacting with the manufacturing lines. Their suggestions were very valuable and made de identifying task much easier, maximizing the opportunity of making more floor space.

Some of the suggestions were consolidating racks that holds the finished product since the volume is very small and it can fit in the same rack without causing any harm to the leads or impacting quality, since they will be handled with the same care, control and properly identified avoiding any mix up. Also, some equipment was able to perform more than one process eve thought each equipment was just being used for one. This gave the opportunity to eliminates as much similar equipment as possible without impacting output or quality. And finally, they also suggested workstations that could be consolidated since the same person performs it and the line clearance process and physical and system controls avoid any mix-up, mismatch or any step being skipped. With these suggestions and the utilization of the resources to optimize production and maximize efficiency eliminating the different types of waste, it was confirmed that there will be a significant improvement.

Moreover, the implementation plan to make the relayout possible is shown in Table 2. These are the tasks that had to take place from all the team to make the implementation of these relayout possible.

Table 2
Implementation Activities for CEA-B Room Relayout

Pre calibration activities begin at HF.
Pre calibration activities begin in Fineline and Drug area.
After Tray Pack shift end, start of CEA-B wall demolition activities. *At the end of the shift each line covers all equipment and workbench & take out all units from room CEA-B.
After wall demolition is finished, CEA-B re-layout activities started. LCP heat sealer movement from CEA-B to CEA-C. Equipment that will be relocated is disconnected.
Continue of CEA-B re-layout activities, and relocation. All CEA-B equipment movement activities done.
All CEA-B utilities connections done. Ceiling tile closed. Ready to go back into parameters of temperatures and humidity. All CEA-B workbench and equipment clean, ready for room sanitization.
Post calibration/validation activities.

After all these tasks were completed, this is how the future state map looks like. Refer to figure 11.

Figure 11
Before and After Layout for CEA-B Room

Also, even though the first spaghetti diagram shows a good workflow this new layout made it even better. Refer to Figure 12.

Figure 12
Before and After Spaghetti Diagram for CEA-B Room

There was improvement and the goal to achieve floor space, was met. Now, is not only improving but maintaining. Therefore, on the next and final phase it is explained how the team keeps track and visibility of these improvements and new opportunities.

For these manufacturing lines 5S audits are performed biweekly not only to assure the improvement is in place, but also to find new opportunities of optimization, maximization of resources, minimization of space used, elimination of wastes, growth, and consolidation opportunities. This audit is performed by qualified personnel with all the knowledge and training required to perform it. It covers that supplies, materials, inventory, documentation, tools, and equipment are in point of use and have a specific location. Also, it verifies that workbenches, chairs, and equipment are in good condition and does not have damaged or peeling and are free of tape residue. All binders, documents, processes are labeled, stored neatly & easily accessible and mobile items have taped and labeled locations, among other things. It has great visibility, and it is a great tool to avoid any chance of losing the implemented improvement.

CONCLUSION

In conclusion, for a company to maintain competitive, continuous improvement is essential. This assure that constant upgrade of the process, technique and utilization is maximized while waste is reduced gaining beneficial results for the employees, the company and most important, the patient. For this project Lean Six Sigma was used because it was the ideal methodology to reach the desired goal.

For this project, the method selected was the current state map and the Spaghetti Diagram which provides a clear view of the problem and four manufacturing lines and gowning area to maximize space utilization, eliminate and consolidate. Also, the DMAIC tool provides overall view to look at it all at once and identify potential opportunities but also divides the project on five different phases which allows to get deep enough in the areas to see those not so easy to identify opportunities. Since the cost on BSC facilities is $350.00 per square foot, each square foot inefficiently used represents a deficiency in the utilization of the space which results in limiting the capacity to increase production output and bring additional volume into the site.

The reutilization of the existing space having a smaller footprint avoids spending additional capital on the construction of new facilities to relocate new products. Also, as additional benefits people flow was reduced due to walking distance shrinkage and material flow reduction. However, since the purpose of this project was to make floor space available for new products that will be transferred to the facility, the cost avoidance was obtained considering that a construction of a new facility was no longer needed.

As a result of the relayout for CEA-B, 2,080 ft^2 were liberated meeting the goal of 2,000 ft^2 required and consequently a cost avoidance of $728,000 was achieved. Refer to Table 3.

Table 3
CEA-B room Relayout Cost Avoidance VIP 72327

Area before (ft^2)	Area after (ft^2)	Available Space	Ft cost	Saving (Cost Avoidance)
9043	6963	2080	$30.00	$728,000

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