Vision of a Microbiology Laboratory of Excellence using Lean Methodology

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Abstract *- The outstanding growth and development at a pharmaceutical manufacturing company in Gurabo, Puerto Rico is leading it to become a laboratory of the future. They are receiving, analyzing and delivering results for microbiological tests have created a high demand on available space. Focusing on Lean processes in a laboratory will be the focus of this project concerning the best storage equipment options to create needed spaces in the Microbiology Lab. Lean processes are a form of continuous improvement focusing on testing products and materials to deliver efficient results in identifying and eliminating "waste". The utilization of the Lean Six Sigma concept was found to be the best tool to conduct the development of the research. Positive results were found in the use of these concepts to free needed space. In addition, logistics of handling microbiological testing processes were improved to avoid delay in product results.*

RESEARCH DESCRIPTION

Research will be carried out concerning the best storage equipment options to create needed spaces in the Microbiology Lab of this manufacturing company in Puerto Rico. This is important because it is expected that the unit become the best supply chain system of Micro Labs in the companies around the world.

RESEARCH OBJECTIVES

The objectives of the research will seek to create a proposal for the implementation of Lean Storage to provide available space to introduce new testing equipment. Also, part of the goal is to improve the operational logistics using quality tools after the "Lean Storage" implementation.

RESEARCH CONTRIBUTIONS

The main contribution of the research development in the Micro Lab will be to become more competitive in acquiring more Analytical testing. In addition, this research will help the chain system of this Micro Lab meet deadlines, improve available space, and be more competitive.

The Issues of Spare Limitation in the Micro Lab

The scope of this research is to contribute to the issue of space limitation in a microbiology lab of a pharmaceutical company. Based on observations of space limitation, it was clear that the laboratory design and layout require some modifications, due to the positive growth of the lab business. By focusing on our customers and quality strategies, some designs proactively support Lean practices that aim at internal work processes. Incorporating "Lean" concepts and tools into pharmaceutical laboratories will deliver significant and needed operational benefits.

What is "Lean"?

The concept "Lean" is a team-based form of continuous improvement which can be applied in the pharmaceutical industries that focuses on identifying and eliminating "waste", with the purpose of providing better organization. Simply to say "Lean" is the key to preserving values with less work. Through the application of the concept of "Lean", it is clear that laboratory design and layout has a powerful influence on processes and "Lean Storage" can also collaborate to reduce the tremendous problems of waste.

The Common Types of Wastes

Waste, in this case, is non-value-added activity from the viewpoint of the customer [1]. There exists 7 types of wastes listed by Japanese founders of Toyota which represent the most common form of issues and are used to improve the performance of a factory. Also, it was introduced as an acronym which is TIM WOOD that involves the 7 types of waste: transportating, inventory, movement, waiting, overproduction, overprocessing and defects.

Initially, there were 4 types of waste identified which added non-value in the procesess or facilities in the micro lab. These 4 wastes are: waiting, transportation, inventory and movement. The first concept of "waiting" is simply time spent waiting on materials, supplies, information, and people that are needed to finish a task [1]. The second concept is "transportation" which can in-

clude transporting, temporarily locating, stocking, stacking or moving materials, people or information [1]. Another concept of waste identified is "inventory". It is both the most visible and is actually an end result of the other wastes. The fourth concept is "movement" which is described as having things you use more often closer to you and things you use, often further away.

The Term "Lean" in a Micro Lab

Lean in Lab environments are not the same as in manufacturing facilities, but the "Lean" principles can also be applied. Pharmaceutical managements have been interested in performance and quality improvement for a long time. For this reason, scientists should be cautious in the moment of selecting which improvement tool is the best and should be the most powerful. Depending on the applications in the area to be collaborated with, one can use different business improvement methodologies. In the beginning, "Lean" techniques were mentioned to eliminate waste from the processes but also then, must be combined with the application of the Six Sigma concepts to reduce variation and balancing of the processes.

Why use the Six Sigma in the Micro Lab?

The Six Sigma is an outstanding process for solving difficult problems and finding answers that are not easy to see [2]. Basically, it must be combined and starts an assessment by studying the business goals following the voice of the customer. The most important goal of the project is where to get started and which tools will be the most productive. The methodology of DMAIC (Define, Measure, Analyze, Improve and Control), is typically to be used to improve in a manufacturing environment. But in our case, this methodology has limitations when faced with product and process layouts. Therefore, this project has to use another methodology for implementation. A methodology that can be used in the Six Sigma is DMADV (Define, Measure, Analyze, Design and Verify). There exists similitude between DMAIC and DMADV. The first three phases will be performed with the same purpose, but the emphasis that will be applied will probably cause changes in the last two phases.

Benefits of Implementation

One can implement continuous improvement and activities to add value to lab facilities and analytical operations. This will benefit the receiving, testing and carrying out of existing drug testing and new product introduction. That is how to actually begin the implementation process and convince management that methodology of a "Lean" laboratory, along with the Six Sigma, can benefit the company bottom line looking for a good design and effectiveness. That is why conducting a "Lean" opportunity assessment is used to support processes including flow, visual management, standard work and excellence in a workplace organization.

Many different techniques and approaches have been taken to elevate the business productivities and performances over a few decades. Some techniques and different perspectives may be beneficial in the lab organization trying to improve efforts. As a "Lean" laboratory effort, the equipment identified must be used to be incorporated in the Microbiology lab facilities in order to eliminate wastes, improve efficiency and create available spaces in the laboratory operations.

The Importance of a Good Micro Lab Layout and Design

The plan of the project needs to be carefully studied as to what will be effective solutions to the current problem. It is important to take into consideration the data on the requirements of the building, which could include floor area, dimensions, safety and the building height, (to know the height that would create the "Lean Storage"). Also, it is important to consider the inches of the main door of the room because of the entrance of the fork-lift when loading with products. The plan will become more important because the number of products for testing per month will be progressively increasing.

A preference of an open space layout in a consumable room and another testing room around the Micro lab is a key for the necessities of the customers. In this case, the customers are the analysts working in the micro lab facilities. The location of some equipment for specific testing or for storage is needed to dedicate work area for specific tasks with all of the necessary materials and equipment close by.

The Equipment Selected

"Lean Storage" equipment (figure 1) was selected to offer a range of storage solutions that can help lab organizational goals. The advantages of "Lean" vertical storage are picking up speed, space-saving, ergonomics, versatile storage, reliable operations and return on investments. The requirements to achieve those

goals are a key to increase work capacity, inventory control, and also improve employee satisfaction. Once the "Lean Storage" is installed as part of the project, there will be better inventory control in the Micro Lab. Furthermore, the methods for materials handling and recording of the location of stored items will be controlled by automatic storage/retrieval systems. One of the advantages in the inventory control is a modern method of record keeping in storage and distribution of electronic data with the objective of eliminating the trail of paper.

Figure 1: Hänel Rotomat®

According by the vendor of "Hänel Rotomat®" the implementation of the "Lean Storage" in the consumable storage room at the Microbiology Lab can help conform to the current necessities. More available space can be obtained using of the available room height and creates up to 60% more storage saving floor space compared to the standard racks.

How does the Lean Storage Operate?

The vendor adapts the vertical storage lifts according to the conditions that apply at each company. This applies to the number of articles and the size and weight of the goods to be stored, as well as the size of the premises and the ceiling height. In all cases, large floor space savings are made and the goods can be handled in a more rational and safe manner. Automatic storage/retrieval systems lend themselves to and, in fact, almost require computer control. Furthermore, modern methods of record keeping in storage and distribution warehouses employ electronic data interchanged with the objective of eliminating the trail of paper. That begins with a purchase order, continues with the record of receipt and the notation of storage location which indicates when the product is removed and shipped, and ultimately leads to the bill of lading and the invoice.

That implementation is what will be validated and developed through the research activities in this project. The costs associated with lab facilities renovation and designs in process excellence can be justified in lab operations to become a "Lean" laboratory.

METHODOLOGY

Using the tool of the Six Sigma and "Lean Laboratory" can provide considerable guidelines to improve micro lab operation processes efficiently. The Lean tools used in different phases of process improvement are: 5S, Visual Management, Value Stream map, Kaizen, etc. Also, managing the Six Sigma as a tool in the project will require a five step process that is going to be helpful for the implementation of the "Lean storage" and the future configuration design of the micro lab facilities. This methodology will ensure the lowest levels of waste and the highest levels of quality. This project will be context oriented to allow the most effective implementation of lab facilities. The methodology identified is DMADV (Define, Measure, Analyze, Design, and Verify). The methodology of DMADV includes the tools as follows: Pareto diagram, SIPOC model, Process Mapping, Ishikawa diagram, etc. This five step methodology can offer more effectiveness in this project environment.

DMADV- Define

The Six Sigma uses the method of DMADV which usually offers an explanation in each of the acronyms that will be challenged in the project. The first is Define: the project goal and the claims of the customers will be determined. Suggestions were collected by listening to customer voices and micro analysts which guided the goals of the project. The Voice of Customer (VOC) Methods: was designed by using a set of questions presented in table 1, based on how the logistics of the Microbiology test processes are affected by necessities of more spaces and more testing equipment. All Analysts were orientated about the goals of the project, which were to improve the flow of the processes to ensure the area to the maximum, acquiring more space to be able to be more competitive and to be able to acquire more microbiological tests of existing clients and future clients. The Survey was generated in one month, looking at how the process works in real time. The interviews were individual meeting with the Analysts where a set of questions are asked and answered to be discussed to understand customer voice. The suggestions of each Analyst were the key to guide the project goals and the observations during the process can provide feedback about the necessities of the Voice of Customer.

-Voice of the Customer (VOC)				
Who is the customer?	Materials far away?	Testing machine is always available?	Do you wait long for the other analyst to finish?	Do you take too long to perform the test?
Analyst 1	Deficient	Regular	Regular	Productive
Analyst 2	Deficient	Regular	Deficient	Deficient
Analyst 3	Deficient	Regular	Deficient	Deficient
Analyst 4	Regular	Deficient	Deficient	Excellent
Analyst 5	Regular	Deficient	Deficient	Productive
Analyst 6	Deficient	Deficient	Regular	Productive

Table 1: The Voice of the Customer by Five Questions

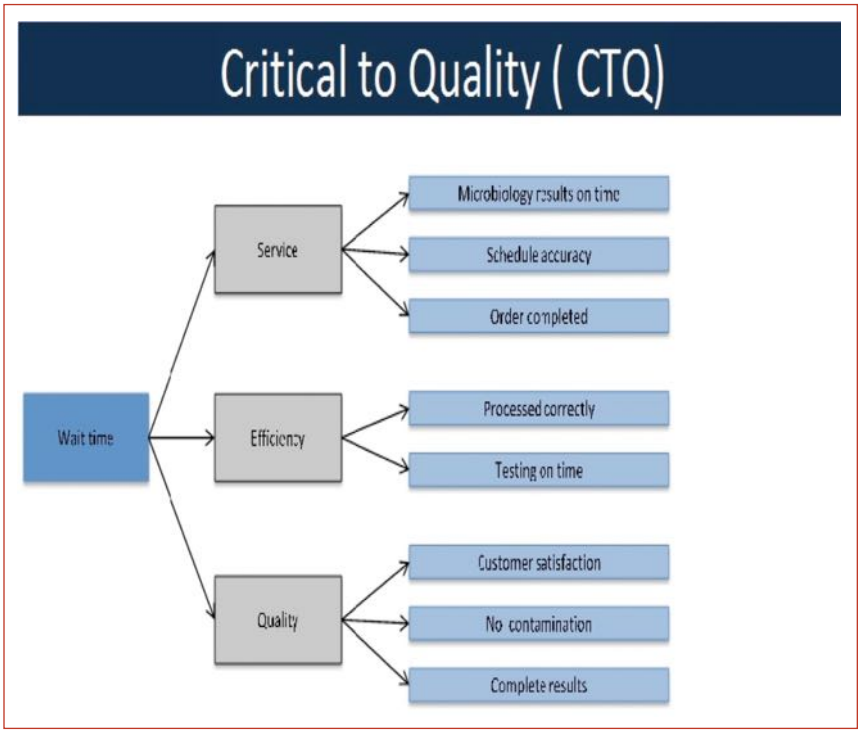

Figure 2. Critical to Quality Diagram

The meeting held was another tool to determine the problems. The Analysts were called together and the discussion was on specific topic about the space limitation and the equipment needed to be addressed. These Analysts were excellent for identifying the CTQ (Critical to Quality) [3]. The Critical to Quality diagram (figure 2) guide part of the research about the critical quality parameters that relate to the demands and necessities of the customer. This team work defines specific ways that help to predict the ability to deliver those requirements.

SIPOC

The tool of SIPOC diagram is an effective tool to study the process which can identify key activities as outputs and inputs throughout the process. It's able to give an overall view of the Lab business scope and help the analysts in views of processes in an equal panorama to be studied. In phase of the Define SIPOC will help transition into a key activity, being that it is a tool to identify preliminary requirements of the customers for those outputs. The Lab team has translated the Voice of Customer data into customer requirement, determined the scope of the project identifying the problems very qualitatively at first. This was qualitatively orientated at first because it is focusing on the quality, instead of quantitatively which focuses on quantity.

After identifying the problem statement, the team was determined that the first assessment is to implant the Lean storage which helps to reduce the space limitation. Also, the implementation of Lean Storage will obtain additional space in one of the unavailable room in the Micro Lab which is occupied by alcohol storage that can be relocated to the consumable room.

After the implementation of the available room in the micro lab, it can be utilized to perform multiple testing. As a second assessment, a functional area will

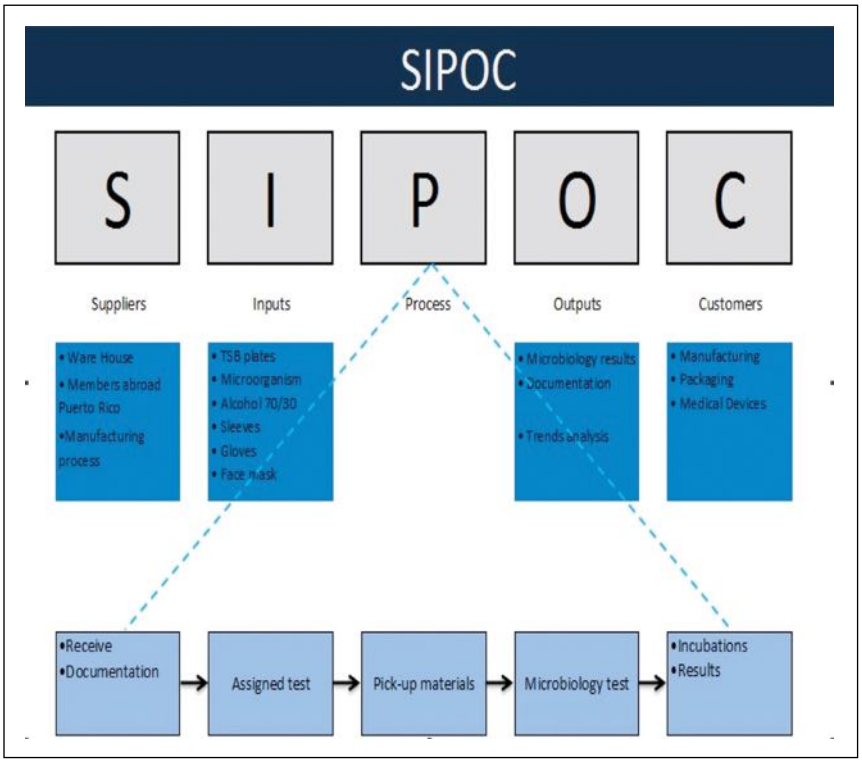

Figure 3. SIPOC another Tool to Define

drive the quality of the results by the samples tested in the space provided. This change will improve the availability to increase the testing for specific clients which will boost the profits of the laboratory and customer satisfaction. Also, the inventory and the organization created by the "Lean Storage" will conduct inventory control that can be applied to the 6S to handle the items.

DMADV- Measure

The second letter of the acronym DMADV is: measure in which the specifications will supply and assess customer needs. This approach can guide to determine the amount of the equipment placed in the consumable room before the "Lean Storage" implementation. When the 13 shelf were measured, they also took in consideration the 3 hallways and the spaces used in the consumable room which results in 1374 m^3. The room size was 2870 m^3, when the area was measured by Length, Width and Height. This approach helped to determine the space needed to evaluate how feasible this would be.

Table 2 shows the occupied space in the consumable room that was calculated at 48% of static space used. This measure was assessing the current status to serve as a basis for comparison for evaluating the new design. When measuring how well the "Lean Storage" could be to improve the space necessities were reflected the processes and services would that meet the customers' requirements.

When the team discussed the problems and found a structured way to choose among alternatives, to begin was evaluated one of the injured process with the critical to quality (CTQ) requirement.

Consumable room			
Items	Size(m^3)	Occupied space	Room size
Shelf 1	72	3%	2870
Shelf 2	72	3%	
Shelf 3	72	3%	
Shelf 4	48	2%	
Shelf 5	48	2%	
Shelf 6	48	2%	
Shelf 7	48	2%	
Shelf 8	48	2%	
Shelf 9	72	3%	
Shelf 10	48	2%	
Shelf 11	72	3%	
Shelf 12	72	3%	
Shelf 13	72	3%	
Hallways 1	194	7%	
Hallways 2	194	7%	
Hallways 3	194	7%	
	Total=	48%	

Table 2. Measure of Consumable Room Shelf and Hallways

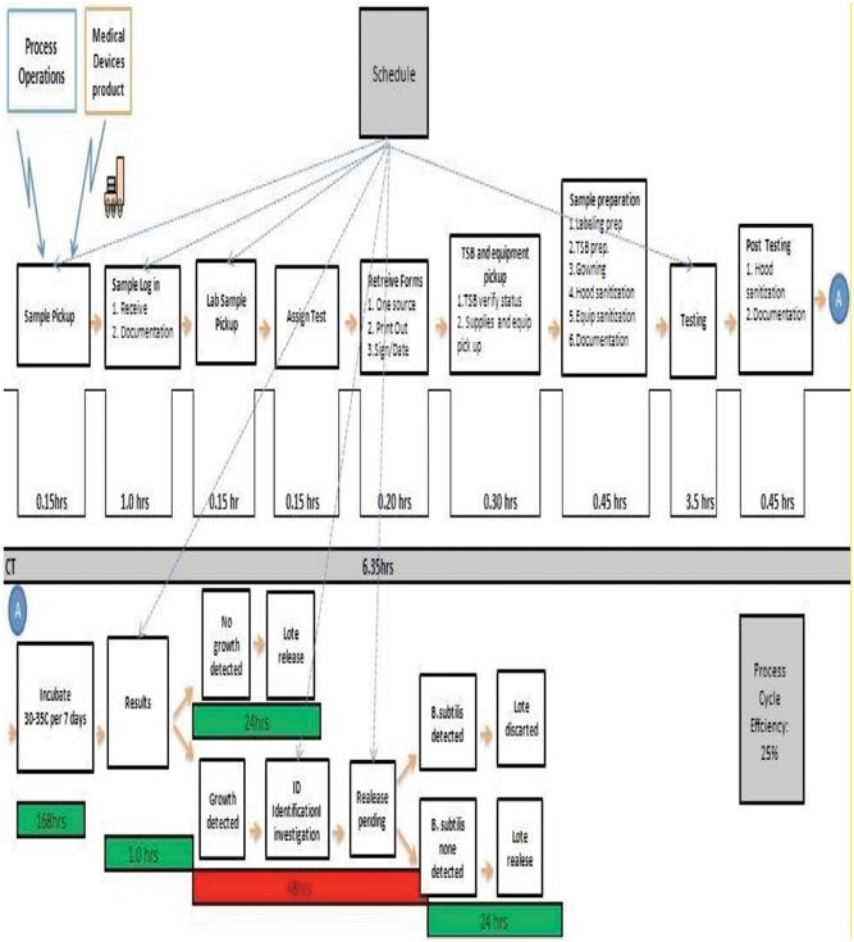

Figure 4. Value Stream Map of the Medical Devices Products

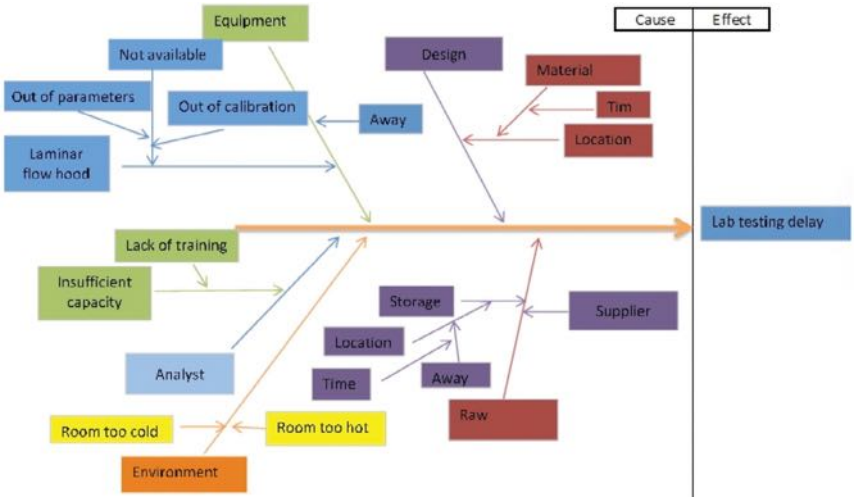

Figure 5. Ishikawa Diagram. Cause and Effect Diagram

In the phase of measure the Critical to quality Indicators (CTQs) is used to predict the ability to deliver on those requirements. Also using a quality tools such as a Value Stream map (figure 4) is possible to see the tour guide with detailed explanation of the individual Microbiology lab process. The reason for that is to support the flow needed to give the customer equipments, the amount of the customers want, when they needed. This individual process is available to show what look at the current state map with all the waste detected to work on this quickly.

DMADV-Analysis

The Analysis, in this step will examine the process options to meet customers' requirements. Applying the Ishikawa diagram (figure 5) is a tool in Six Sigma to identify the cause and effect in a process. Analyzing the diagram of Ishikawa can obtain a lot of the causes in the process such as the waste time, waste motion, waste transportation and waste in the inventory. In solving these complex issues in the Microbiology Laboratory gives a better perspective of the cause and the factors of all these wastes are reflected in lab results delay. This quality tool guides the project to have more evaluation to analyze being that long duration of task is the consequence of disorganized processes. This diagram help the descriptions problems to makes complex issues appear simple in the time of evaluate the root cause.

The Pareto diagram and cause and effect diagram shows the many possible causes of a problem. The problems were identified that are being tried to be solved. The major causes of the problems are the lab testing delay. The root causes of the problems were identified as the major problem was the time to perform and the feet to travel to get the materials. This problem is resolved with the implementation of the Lean storage and the introduction of the laminar flow hood. The Pareto diagram shows the largest number of frequencies to the smallest. The most significant problem stands out and can be targeted first. The results show

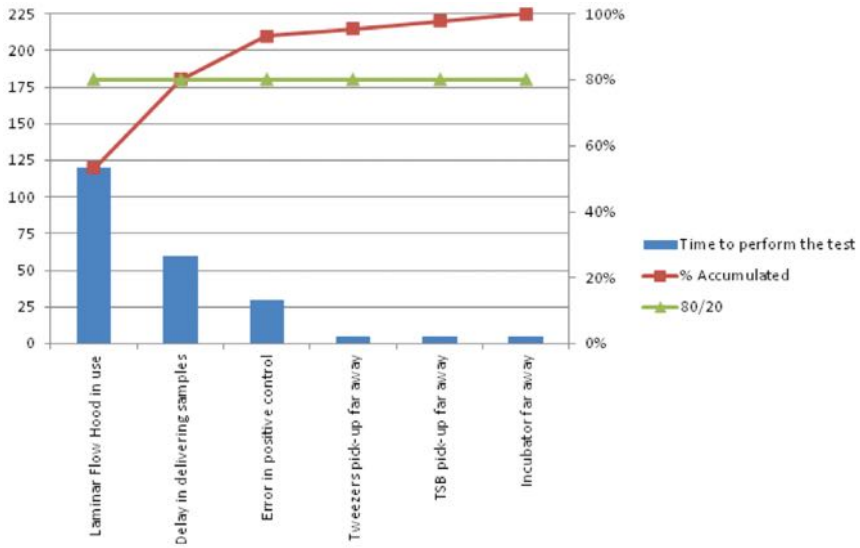

Figure 6. Pareto Chart. Analysis of the Medical Devices Process

(figure 6) that 80% of the problem is the Laminar flow hood, being that other testing requires the use of the hood during the shift.

DMADV- Design

The 4th step in the method of DMADV is design: In this phase, the owner of the project will develop the process to meet the customer's requirements. By studying the capturing of the equipment data used (figure 7) before the implementation, the importance of the equipment and tests to meet the mission of the lab of the future can be better understood. In the design phase here is the key to know how the equipment should be allocated. Using this data gathered can help optimize to support Lean practices in the Microbiology lab operations. Lean storage was identified as high value to use in helping to allocate different equipment in the lab.

The "Lean Storage" implementation changes in the consumable room layout (figure 8) configuration concerning the information gathered.

The data collection of the consumable room establishes that those material organizers in the consumable room are capable of introducing all the material into the "Lean Storage" and be able to reduce almost 70% of the current space used. The space which increased significantly by the "Lean Storage", will be partly used to store 4 incubation machines and to relocate the alcohol storage station as well. Those incubation machines and alcohol storage station, which occupy approximately 15% of the available spaces in the consumable room, are needed to increase the new testing by using a laminar flow hood. The remaining 65% of available space is going to be used for other future implementations. As a result of the movement of the alcohol storage station to the consumable room, the testing capability is increased. This will allow the introduction of a new laminar flow hood for microbiology testing to allocate in the old alcohol storage room, now available. The sum of more testing due to the incorporation of a laminar flow hood in the available spaces is helpful to improve and handle schedules and organize tasks. The satisfaction of our analysts and customers are

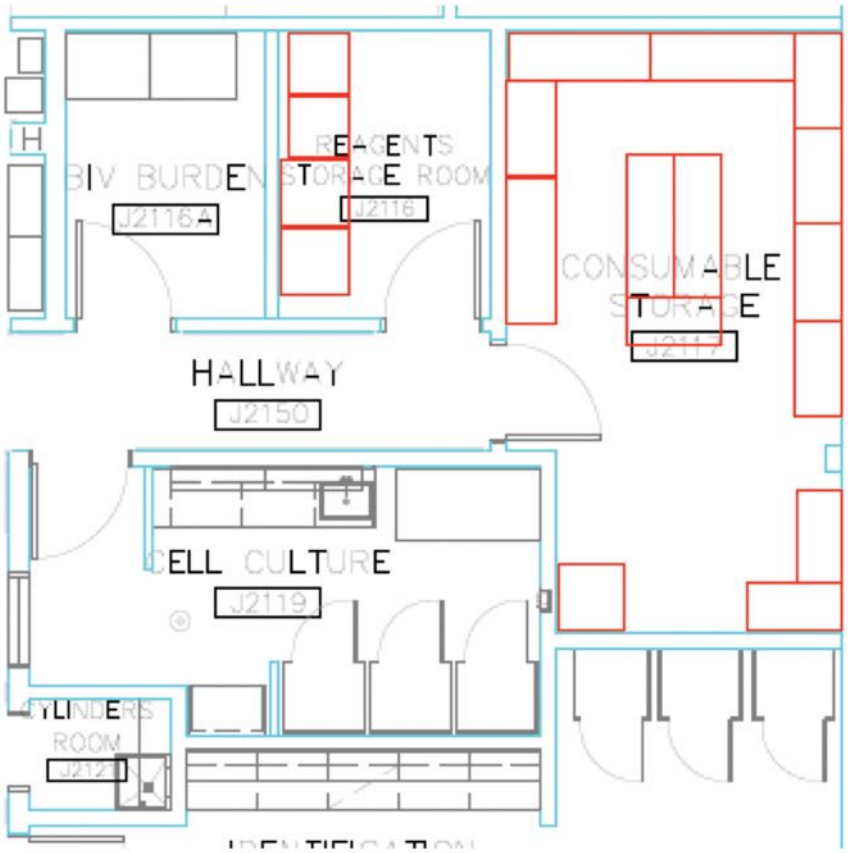

Figure 7. Old Consumable Room Lay-Out. Before Implementation of the Consumable Room

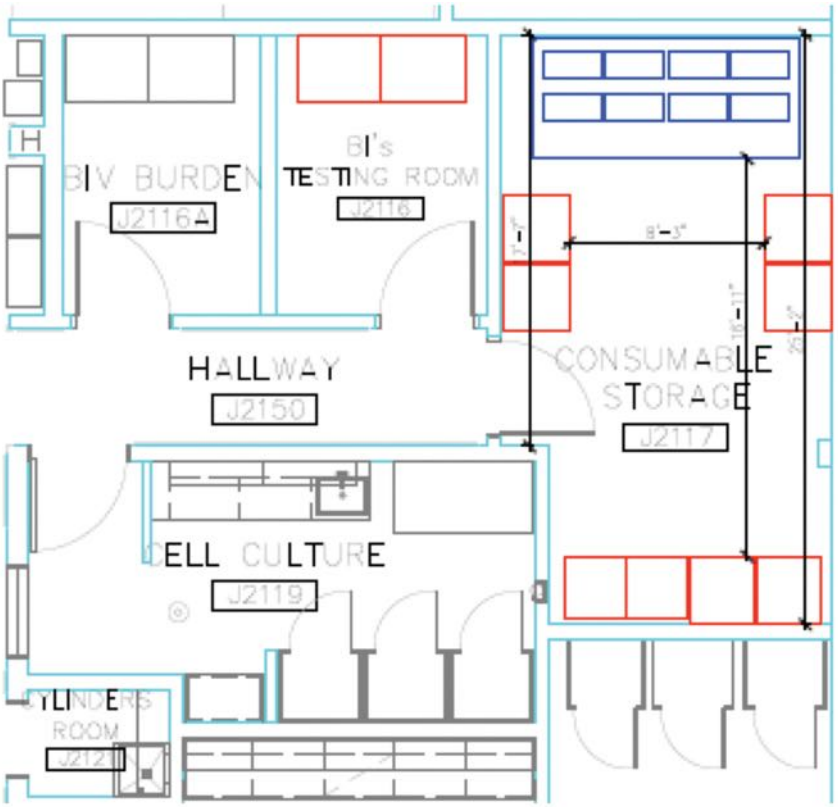

Figure 8. New Consumable Room Lay-Out. After Implementation of the Consumable Room

guaranteed because the times of each testing by the analysts will not interfere and will meet the customers' demands.

DMADV- Verified

The Microbiology Lab map (figure 9) represents the path way of the Analysts to perform each process. The red line represents the number of feet that the Analyst travels throughout the process. Since the Analyst decides what kind of testing and tools are needed to conduct the test the feet were measured 300 feet was the distant traveled. The green line represents the path away after the Lean implementation. The Analyst travels less since a laminar flow hood was introduced closer to perform negative controls or other tests. In addition, the introduction of 4 incubators in the

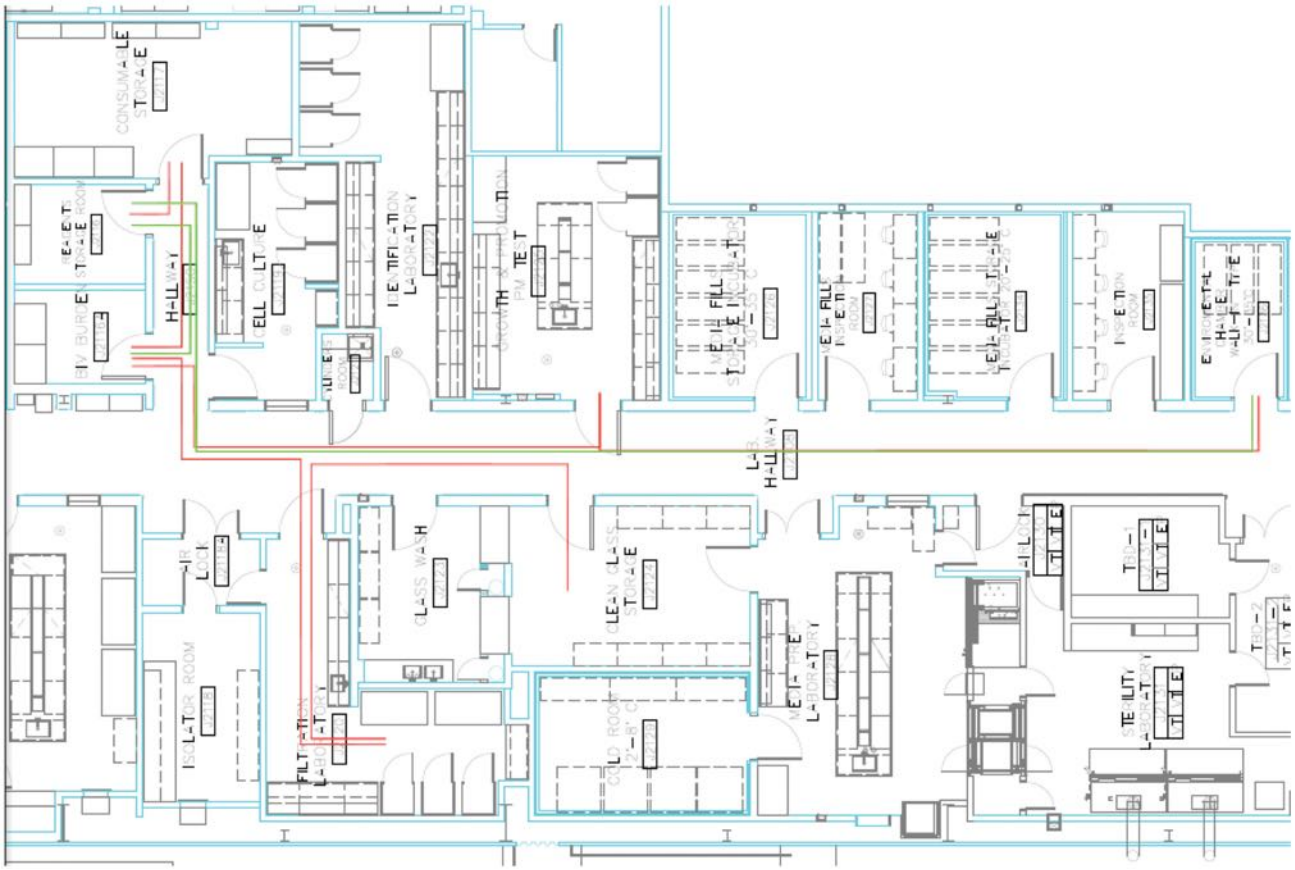

Figure 9. Flow of the Analyst to Perform each Process

consumable room allows shortening the feet to incubate the samples. After the implementation, 150 feet less traveled helping the logistic of the Micro Lab.

Measuring the quality of our tests because of the spending times captured each test requirements can be optimized as high value, avoiding the four types of waste previously identified. The current and future lots of batches demand can be accomplished to high quality because the equipment laminar flow hood provides availability into a planned and flexible schedule for the capacity of microbiology testing and also as equipment back-up. The new space utilization will help us to understand how important the equipment allocation is to accomplish the mission of The Lab of the future when the growing is faster than the facility space capacity. Also, this implementation of the Lean storage was helpful to avoid relocating the Micro lab in the search to have more space and being prepared for the introduction of future tests.

CONCLUSION

One of the key drivers in the Pharmaceutical industry business is the organization as to how to conduct priorities in a changing organization environment. When operating in a highly competitive market, it is more difficult to implement improvements in Lean processes. As laboratories of the future develop to be more competitive, transformation through projects need to be made in order to apply Lean processes. With the proposal implementation of Lean Storage, achieved satisfactory results. In the obtained data of the distances reviewed by Analyst was reduced 50 % of waste. When results were obtained through the analysis of Pareto, was understood that part of the waste founded was the waiting time of the laminar flow in the process. The results are guides to show us the influence of how efficient the laboratory design can be, when maximizing the spaces and equipment avoiding waste. When applying Lean principles in Lab environments, they should be applied to maximize lab processes and operational performance.

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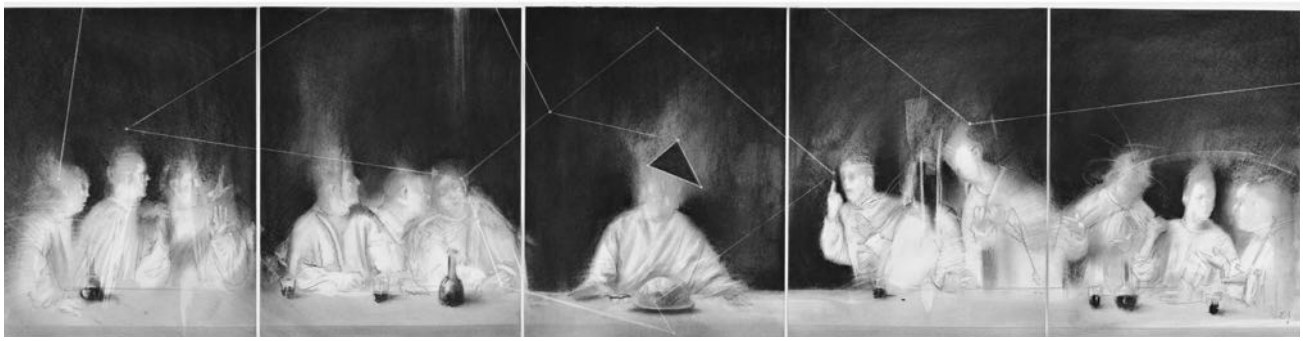

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