Production System Improvement:

Floor Area Reduction and Cycle Time Analysis

by

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Abstract

A medical device company challenged a research team to reduce the manufacturing floor space required for an occlusion system product by one third. The team first cataloged equipment location and size, detailed the processes to make the product, and created a model for prototyping designs. The model allowed for multiple proposals of designs to the stakeholders without disrupting the line. The team implemented the new floor layout on August 3, 2012. The layout reduced the footprint by the required one third, removed the waste of extra space and maintenance time. The design was also the lowest cost design for the company. Further suggestions for future reduction in space are also included.

The team was given the additional challenge of improving the manufacturing of the product. My particular focus was to analyze the cycle time. First definitions were given to provide criteria for analyzing different reductions. Processes that were the longest in each subassembly, or bottleneck processes, were specifically analyzed to reduce their process time or delay time. Technical updates to reduce touch time and delay time for other major processes were also considered. Suggestions for future work are included to reduce the production time.

Information regarding the other concentrations, manpower allocation, parts inventory optimization, and visual management, will be found in the other team members' individual theses. [1] [2] [3]

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Disclaimer: All product names are disguised to protect the confidentiality of the company.

Key Words: Lean Manufacturing, Floor Area Reduction, Cycle Time Analysis, Bottlenecks

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Introduction

Overview of Project

There are two objectives of this thesis project. The first, a team objective, is to reduce the area of the assembly line of an occlusion catheter system product. The motivation for this objective is to use the space for a new production line. The second, an individual objective, is to provide analysis and suggestions to reduce the time of production. Other goals given to the team by the company are covered by other team members. These goals include manpower allocation among different subassemblies, a new material replenishment strategy, and the implementation of effective visual management.

Aleisa studied the current manpower and cross training status as well as the lead time for each subassembly [1]. Yang analyzed the strategy and provided a plan to decentralize the supermarket [2]. Chen analyzed the company's current system of visual management and provided revamped visual management system to track key performance indicators to reflect real-time production performance on the floor [3].

This thesis will include, for the two objectives, the specifics of the problem statement, the literature review, the methodology, the results and conclusions, and finally possible future work for the company. Both objectives were accomplished by the end of August 2012.

Background

The company is a global leader in medical technology. The facility in Massachusetts is one of the company's many manufacturing facilities which assembles and produces many different types of medical products. There are approximately 500 employees at the Massachusetts facility.

Emboli are the debris dislodged by catheter products in the arterial system. Embolic protection catheters are used to prevent emboli from moving down the bloodstream. The product is an occlusion type protection system. Occlusion blocks the artery beyond the target site and prevents emboli from passing by. A separate catheter is used to aspirate the debris from the artery. The product is used for both heart and brain applications.

There are four main components to the product, the catheter, the sheath, the syringe, and the accessory. The catheter consists of many different materials and even subassemblies. It is the most complex assembly in this product. The syringe and the accessory are mainly made of injection molded parts, and require different manufacturing operations than the catheter. The different components, the catheter and its subassemblies, the sheath, the syringe, and the accessory are produced on dedicated manufacturing lines.

All of the manufacturing processes are manual and require a high degree of operator interface and skill. The line measures and tests the product's performance as well as manufacturing the product. Most of the processes require table top machinery and fixtures. There is only one shift operating on this line. The production associates on this line range from four to about nine depending on volume demanded. The current floor space used by this manufacturing line is 1528 square feet. The daily demand fluctuated between 20 to 55 units during the team's time at the company.

The catheter is a Federal Drug and Administration (FDA) Device Class II regulated product. The company would be required to resubmit a premarket notification if significant changes or modifications are made that could extend to the safety or effectiveness of the device. The FDA outlines that these changes "could relate to the design, material, chemical composition, energy source, manufacturing process, or intended use" [4].

Problem Statement

Problem Identification

The primary objective of this project is to reduce the product's manufacturing footprint by one third of the original area before the end of August 2012. The space is needed to introduce new production lines for future products.

This project allows the team to adjust the following:

- Tooling and fixtures.
- Process flow and working benches for the catheter, sheath, syringe, and accessory

There are certain design elements that are out of scope for this project; in particular, those outside the floor layout include the following:

- The coating and packaging areas.
- This product is a FDA regulated medical device. The team must avoid new regulatory filings caused by changes to the design specifications or materials.

The second objective of this thesis project is to provide suggestions to the company about how to reduce the time of production. Implementation of this objective was not requested by the company. Rather, the company wanted the suggestions and analysis for assistance of future work on this line.

Current Layout

The product's manufacturing area fits in the corner of the company's clean room area. The measured area of 1528 square feet includes the necessary aisle space for the production benches. The total production line length is approximately 170 feet, where line length only includes the length of the production benches. Figure 1 shows the original floor layout with the wall and surrounding benches, shown in the figure without equipment.

As shown in Figure 1, the production area's current layout consists of seven rows of production benches, computer desks, cabinets, and shelves. Most of the equipment is placed on the production benches. However some equipment is placed to the side, above or below. Each production bench is dedicated to particular assembly procedures.

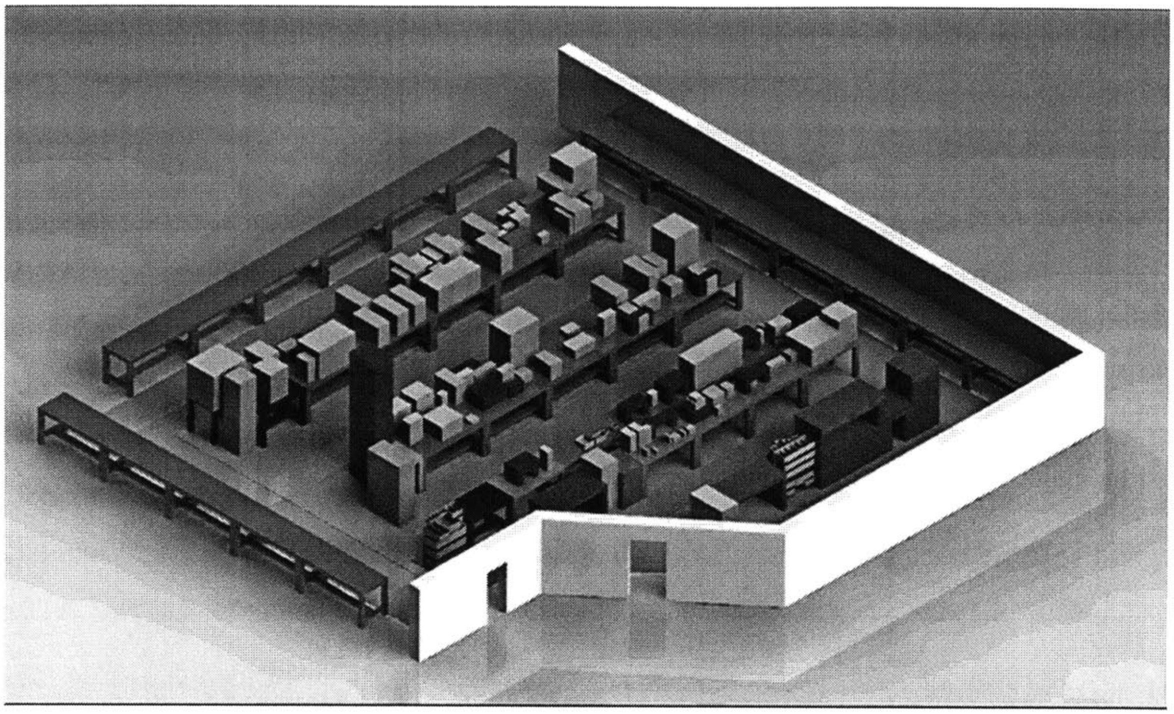


Figure 1: Original Floor Layout with walls and bordering production lines

The catheter line consists of approximately 22 production benches, distributed along four rows of benches. The total line length used for the catheter is 120 feet. The equipment used for the catheter assembly include microscopes, laser micrometers, ultraviolet light source machines, ultrasonic cleaning machines, an electric discharge machine (EDM), hotboxes, and an oven. The current operations require space for the long catheter to be placed on the production benches. Depending on the volume required per day, there are four to six production associates working on this line.

The accessory line has six production benches all in one row, with a line length of 29 feet. The equipment used for the accessory assembly include an ultraviolet curing machine, presses, fume hoods, and screwdrivers. The accessory line has usually one to two production associates working on this line.

The syringe line has three production benches all in one row, with a line length of 20 feet. Equipment used for this line include fume hoods, presses, and screwdrivers. The syringe line has usually one to two production associates working on this line.

The sheath has two production benches for a total line length of 12 feet. Much of the equipment is specialized for just this assembly, including a microscope and hotboxes. There is usually one production associate working on this subassembly.

There are two supermarkets that have a total line length of six feet.

Other areas include computer desks, cabinets, chemical storage areas, along with other miscellaneous items. The total length of these other areas is 30 feet and is split up among all of the rows. Figure 2 is a visual representation of how much space is allocated to each subassembly as well as the major production areas and other areas.

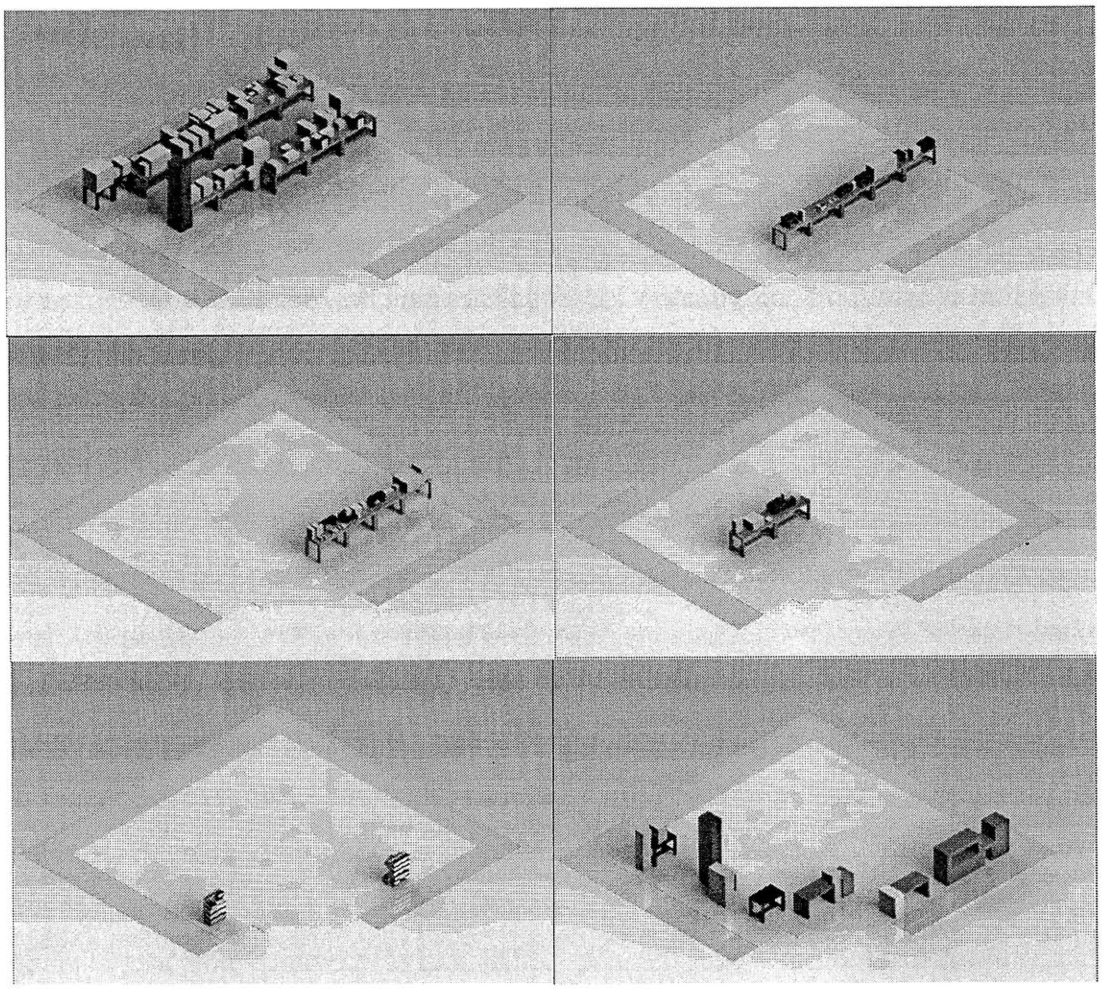


Figure 2: Catheter, accessory, syringe, sheath, supermarkets, and other areas

Table 1 shows a summary of the original layout specifications. Between Table 1 and Figure 2, we outline the details of the original floor layout. It is important to note that the catheter line has the largest and most complex process compared to the other subassemblies. It uses half of the production associates, half of the total line length, and two thirds of the available benches. The other areas, even though they do not create value for the production area, are composed of about a fourth of the total line length.

Table 1: Summary of Original Layout

	Rows Used	Benches	Total Line Length (feet)	Production Associates
Catheter	4	22	270	4-6
Accessory	1	6	73	1-2
Syringe	1	4	50	1-2
Sheath	1	2	30	1
Supermarkets	NA	NA	15	NA
Other Areas	NA	NA	124	NA
Total	7	34	562	7-10

Evaluation Criteria

The main evaluation criterion will be the amount of space reduced in square footage. However, the freed up space must be usable to the company, meaning that the space should be large enough to place production benches. In addition the space saved should be preferably contiguous and on the outside of the design to allow access to the space. The company would prefer a solution that is as low cost as possible. This includes a new layout that requires as few purchases as possible and as few infrastructure changes as possible.

When designing the new layout, all aspects related to the production system are considered to maintain reasonable efficiency of the line. Cycle time should not be compromised in order to fulfill the maximum demand of the product. The second objective of the thesis provides opportunities to reduce this cycle time even further. The time will be the main criterion, while cost of the change will be the second consideration.

My individual concentration will analyze the cycle time of the current layout. I will analyze the process map using metrics like space, batch sizes, and line balancing to explain the resulting cycle time of each process. Suggestions will be provided showing possible ways to improve cycle time and the productivity of the space used.

Other lean manufacturing practices of reducing waste and implementing visual management will also be criteria for a successful design. The parts replenishment method should be as efficient as before to prevent shortages and place inventories at the most accessible locations. The new layout should also provide flexibility in manpower allocation on the line for varying demands. In addition, visual management should be in place to monitor production performance and enhance information flow on the floor.

Literature Review

In order to understand the methodologies used in the manufacturing field the team researched methodologies such as lean manufacturing, Six Sigma, and Lean Sigma. For my individual portion I researched the different definitions of cycle time.

Lean manufacturing

Lean manufacturing is a manufacturing philosophy that focuses on continuous improvement and reduction of waste. The system encourages maintaining a smooth flow throughout the manufacturing process. It reduces the amount of inventory in the system, thus shortening the cycle time and reducing the cost of work-in-progress parts. The concept was derived from the Toyota Production System in late 20th century. It was discussed by John Krafcik [5]. Krafcik introduced two new terms buffered and lean production systems. Krafcik mentions how the production systems of most Western producers after World War II were buffered against almost any problem with high component and finished goods inventory levels. The core elements of lean manufacturing consist of inventory management, set-up reduction for flexible capacity, cells design, Andon, Kaizen, and Poke-Yoke [6].

Inventory management aims at reducing inventory at warehouse and work-in-progress inventory. Process flow is designed to have the same cycle time. Working parts are passed to the next stage at the same time the next process is available. Line balancing is applied in order to achieve the takt time for each process. The system is tuned to be reliable, embedded with mechanisms to self-correct, so that the process flow is smooth without disruption by defects. In order to reduce inventory levels, a pull system is created with Kanbans to indicate the status of the system. As a result, timely replenishment can be achieved and lower inventory levels are required on the floor.

Shorter set-up time reduces the downtime during changeovers, making it less costly in terms of time to manufacture another product, thus increasing line flexibility.

Cell design features sequential operations. Machines and tools are grouped according to the family of parts being produced in the line. One part is produced while moving around the cell. In doing so, one-piece flow is achieved, improving material flow and significantly reducing cumulative lead time.

Andon refers to a system that notifies all personnel, such as management, maintenance and engineers, responsible for a quality or process issue on the floor. A signaling system can be activated either by manually pressing a button by a worker or automatically by a monitoring system. It assigns workers the responsibility to stop production in the occurrence of a defect and calls for attention. As a result, problems can be resolved once they occur [7].

Kaizen is a daily process, focusing on continuous improvement of business. The current operation is reviewed on a daily basis to eliminate waste and improve process reliability. It requires constant engagement of workers as well as management in the organization. The culture of continuous improvements leads to significant overall productivity improvement.

Poke-Yoke is a mistake preventative system to avoid defects and human errors, thus improving quality yield. Workers are responsible for the machine they use and parts being produced. Together with Andon, part quality is checked at every cell, problems are made visible to whole working team immediately.

Womack stresses the importance of creating value for the customer [8]. All these tools and methods outlined above, including flexible capacity, cells design, Andon, Kaizen, and Poke-Yoke can help to create value. The objectives of the lean enterprise are to correctly specify value for the customer across the firm, to identify all the actions involved in the product, and to remove any actions which do not create value. In addition in the continuous process of lean manufacturing, once you fix a process, fix it again.

Six Sigma

The Six Sigma approach name comes from that in a normal curve, six standard deviations or sigmas, from the mean on each side constitute 99.9997% of the sample. There would only be 3.4 defects per one million. Motorola's Bill Smith introduced the Six Sigma method in 1986 [9]. According to Motorola University, Six Sigma is a metric, methodology, and a management system. Six Sigma started as manufacturing effort that was then applied to other business processes to reduce defects. It became even more popular when General Electric Corporation adopted Six Sigma in the mid-1990s as part of leadership development. The Six Sigma approach also introduced and supported the idea that improved quality pulls down the overall cost.

The focuses of Six Sigma are to understand and manage customer requirements, align business process to achieve those requirements, utilize data analysis to minimize variation, and drive rapid and sustainable improvement to these business processes [10]. The data analysis involves statistical techniques, such as control charts and statistical process control. The second generation of Six Sigma has taken into consideration situations where Six Sigma does not apply as well, particularly human intensive processes such as marketing and human resources [11].

DMAIC

DMAIC was developed as a problem-solving procedure in the Six Sigma approach that guides a project by evaluating root causes of problems and implementing best practices to improve those processes. DMAIC consists of five steps, namely define, measure, analyze, improve and control. The five steps are conducted in sequence and can be used as milestones for project management. The define phase is to identify valid improvement opportunity, clarify critical customer requirements and establish a project charter to define project goals. The measure phase is to determine what variables to measure, collect data in a planned manner. In the analysis phase, collected data is analyzed to determine process capability, throughput and cycle time. Hypotheses are made to verify root causes for variation. After hypotheses are established, the improve phase generates potential solutions based on data analysis and actions are taken to evaluate the validity of solutions. The final solution is reached in this phase and approval for implementation takes place. In the control phase, attentions are paid to monitor and control critical outputs. Continuous improvements are made to avoid mistakes in the system [12].

Lean Sigma

Lean Six Sigma is an approach focused on improving product quality, reducing variations in production and reducing cost at the same time [13]. It is a combination of two process-improving techniques, Six Sigma and lean manufacturing as described above. The outcome of these two combined contradicts the prevailing view at that time this method was introduced that quality is at the expense of extra production cost.

A lot of studies have been done on Lean Six Sigma applications in private sectors. Maytag Corporation designed a new production line using the concepts of Lean Six sigma in 1999. The production lines space was reduced to one third of the original lines. Maytag also cut production cost by 55% [14].

Concerns about Lean Six Sigma Approaches

In 2000, the board of 3M selected James McNerney as the new CEO. McNerney was trained in the Six Sigma practices taught by Jack Welch at General Electric. McNerney implemented these Six Sigma practices cutting costs and improving productivity, however at the risk of new projects. 3M had been successful because of its innovation and creativity. The statistical analysis did not apply well when in the research and development process there are few facts and the nature of the problem is undefined. If unchecked the culture of Six Sigma can stifle creativity because the motivations of each culture are very different. Six Sigma stresses analysis, while innovation stresses creativity and new projects [15].

The lasting impact of lean manufacturing and Six Sigma projects can be questioned as well. Almost 60% of companies to implement one of these programs fail to yield the desired results. The program's success can be declared too soon and the managerial emphasis is lost leading to increased discouragement. The gains made using these methods can then slip away. Ways to continue the successful use of these projects can include keeping the involvement of improvement experts, lining up incentives with improvement initiatives, small teams and small time frames for the projects, and finally maintaining direct involvement from the executives [16].

The Company's Lean Sigma

The company began focusing on their use of lean sigma techniques in 2006. From the company's training manual it says "In Lean Sigma there is a saying: blame the process, not the people." The Lean Sigma method combines the waste removal, process efficiency thinking of Lean, with the variation reduction and quality improvement techniques of Six Sigma.

The method that the company uses usually follows the pattern of first balancing the flow of the processes using lean manufacturing methods and then using Six Sigma practices to reduce the variation of the process [17]. This process is shown in Figure 3.

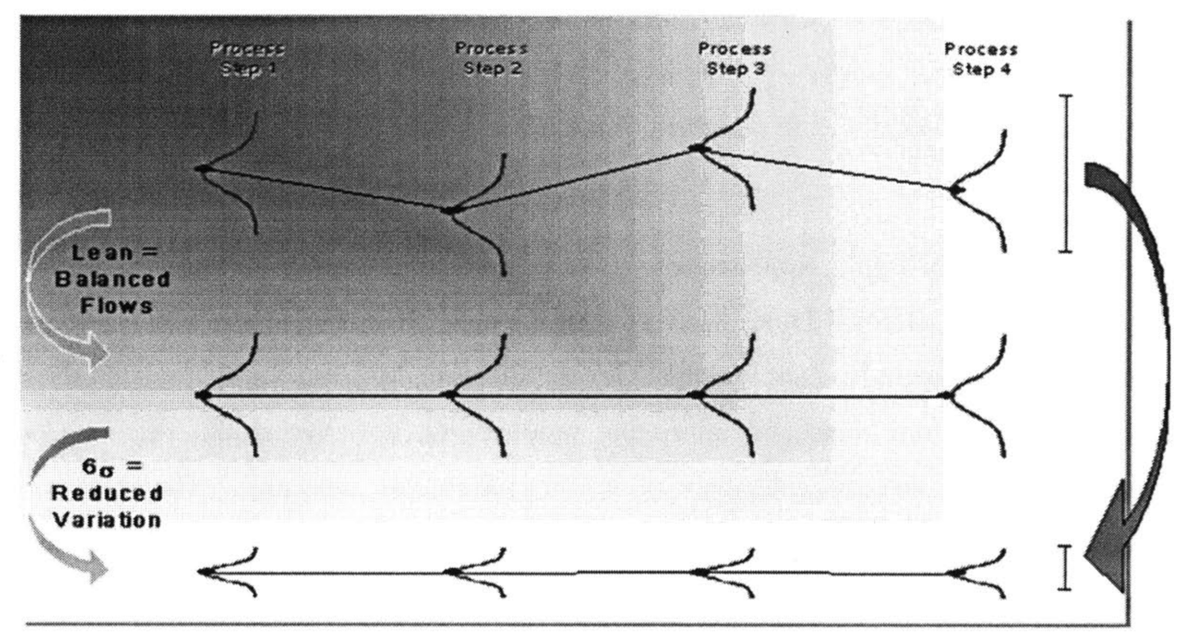


Figure 3: From Normal to Lean to Lean Sigma

An example of a successful Lean Sigma project at the company was another catheter product. In 2007 the company implemented these practices. In the period between 2007 to 2010 the average yield increased from 89% to 94%. The productivity increased which reduced labor costs per unit from $5.04 to $3.07. There was a decrease in lead time as well from 5.4 days to 3.7 days. The sales increased as well as a decrease in customer complaints [18]. The company uses many lean and Six Sigma tools, including the DMAIC methodology.

Cycle Time Literature Review

Queuing Theory Overview

Queuing theory is the mathematical study of waiting in lines. This theory is often applied to manufacturing lines as parts are often waiting to be made. Figure 4 shows the common diagram outlining the flow of the parts through a manufacturing system with the appropriate variables, λ and μ.

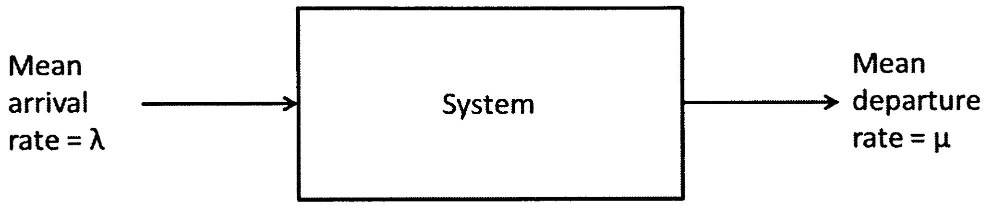


Figure 4: Queuing Theory System

Little's Law

Little's Law relates the average waiting time and the average number of items waiting for a service through the average rate of arrivals. This law is part of queuing theory. The law states, in steady state conditions, the average number of items in a queuing system (L) equals the average arrival rate of items (lambda) multiplied by the average waiting time spent in the system (W). The law summarizes to Equation 1.

$$L = \lambda W$$

Equation 1: Little's Law

Little's Law can be rewritten in terms of throughput (TH), work in process (WIP), and cycle time (CT). Throughput is the average rate of a production process, work in process is the inventory of the parts on the line, and cycle time is the average time the parts spend in the system as work in process. The relationship is shown in Equation 2 [19].

$$TH = \frac{WIP}{CT}$$

Equation 2: Little's Law Rewritten

The last equation reveals that there are many terms used to describe cycle time and confusion can arise. The different definitions and commonly used terms for the time spent in a process are explained in the next section.

Definitions

Many definitions and terms are used interchangeably when it comes to describing the time it takes to make a product. The following definitions specify which definitions are most appropriate for this project and these definitions will be used throughout the thesis.

Process time, Touch time, Run Time

The process time is the time that the manufacturer actually works on or touches the product to bring it closer to an output. Touch time and run time are other terms often used to describe this time period.

Delay time

The delay time is the time that the product has to wait for the next process to occur on it, during which there is no manufacturing action being taken on the product.

Cycle time, Flow time, Throughput time, Sojourn time

Cycle time is the period required to complete one cycle of an operation including process time and delay time. In other words, cycle time is the time it takes to complete a job function or task from start to finish [20].

Cycle time is known by many other names and for the purposes of this discussion, flow time, throughput time, and sojourn time will all refer to this definition of cycle time.

Cycle time is not the same as lead time, takt time, or touch time.

Takt Time

Takt time is derived from the demand required of that product. Dividing the number of units by the available time to produce the unit will result in the required takt time. The takt time will fluctuate based on the demand [21].

SAP Time

SAP stands for Systems, Applications, and Products in Data Processing. The software was developed by SAP AG, a German company. The company uses this system to monitor the cycle time, the demand requests, and to predict a lead time. This time can equal the lead time, however it can depend on when the product is entered into the system [22].

Lead Time

Lead time is the period between when a manufacturing receives an order from a customer and the manufacturing fulfills the ordered item to the customer [23].

There are often discrepancies in these definitions as companies use different definitions for each term. One reason for the different definitions is how time can be "lost" on a product due to waiting for non-manufacturing activities. Figure 5 shows how the different definitions outlined above add together to create the SAP time. The shaded time on the left represents how it can take time to create a work order to actually start building the product. The shaded section on the right represents the time it takes to ship and package the product or the processing time it takes to record the product back into the SAP system. Depending on the company these shaded sections of time could be significant, while in other companies the time differences are not significant leading to the tendency to misuse the terms.

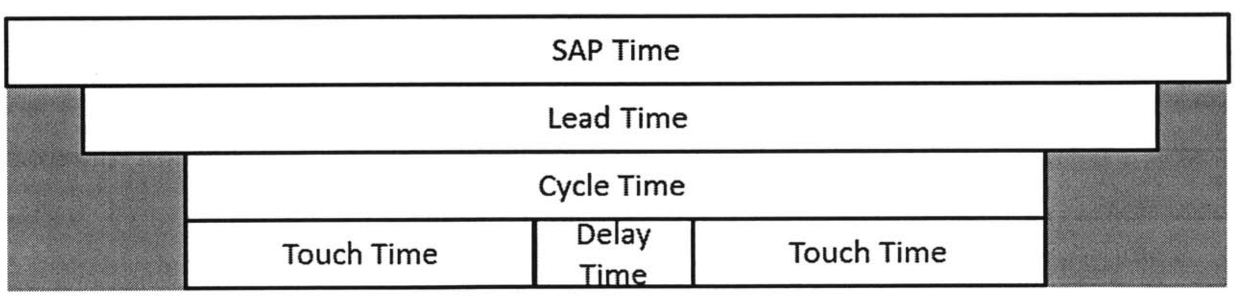


Figure 5: Representation of Manufacturing Time Periods

All of these time periods are affected by the need to expedite a certain build, quality problems delaying a build, or demand levels fluctuating. Lean manufacturing tries to mitigate those changes by building to the takt time required by the demand and eliminating delay time and the shaded sections of Figure 5Figure 5.

Methodology

This section outlines the process the team took to analyze the original floor layout. The team first benchmarked the original layout by creating a system and a model to locate the equipment. The team also focused on understanding the technical aspects of the processes and equipment. After the team analyzed the floor layout, the team developed guiding strategies. These strategies were used to develop the different designs.

My individual methodology for the cycle time included analyzing the process time, the delay time, and the lead time for the particular bottleneck processes. Design improvements to the fixtures, equipment, and space were considered for each bottleneck process.

Cataloging Equipment

The first step taken to reduce the floor space was to catalog the equipment on the floor. The team developed a bench numbering system to accurately locate benches and equipment. The team cut pieces paper to represent a scaled version of the floor, with benches, cabinets, and even some equipment. Putting this physical representation up on the wall helped the team to visualize the floor and think of possible movements. Afterwards using the information gained by numbering the system the team created a three dimensional model which allowed the team to practice different proposed movements.

Bench Numbering System

The original numbering of the system is following the manufacturing process sequence and has different prefixes for the catheter, the accessory, and the syringe. For example, the first workbench in the catheter line following the process is named CT1; the third workbench in accessory line is named AC3.

In the new design of the layout, bench sizes will be changed and some workbenches will be taken away from the line. Each bench is renumbered to simplify bench moving and supermarket replenishment processes. According to the row number and the sequence in the row, each bench is numbered with two digits. Rows are numbered from left to right. Benches are numbered from top to bottom. For example, the third bench in the fourth row is numbered 4.3. The Instron machine table besides the office is named separately as 8.1. The renumbered layout is shown in Figure 6.

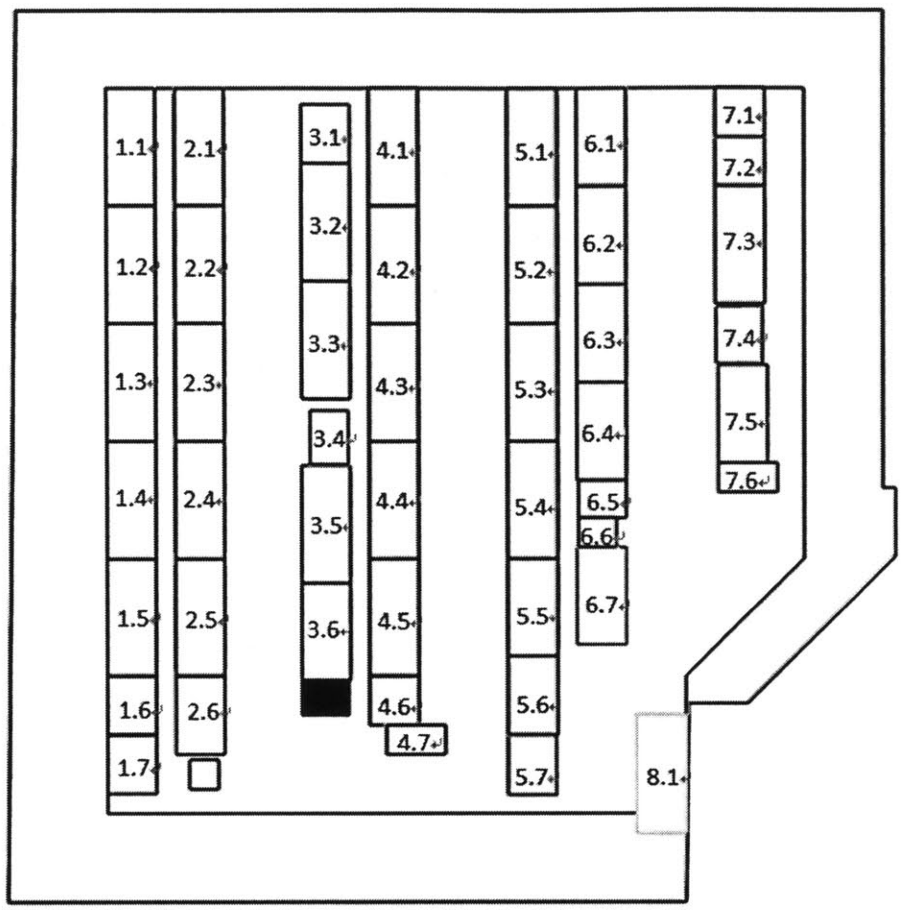


Figure 6: Top view of the original manufacturing floor with bench labeling

Modeling

Computer aided design software, SolidWorks, was used to develop the three dimensional models for the current floor layout to facilitate concept generation and proposal validation. The model was of real scale and included important dimensions like critical aisle distance, back to back distance, and safety width to the emergency exit on the right bottom of the layout.

The SolidWorks model included four categories of parts: production floor area with boundary walls, workbenches, apparatus and nonproduction parts. Figure 7 shows the production floor area with boundary walls: the pink highlighted area represents outer aisle of the production area. The darker floor represents where the benches are located.

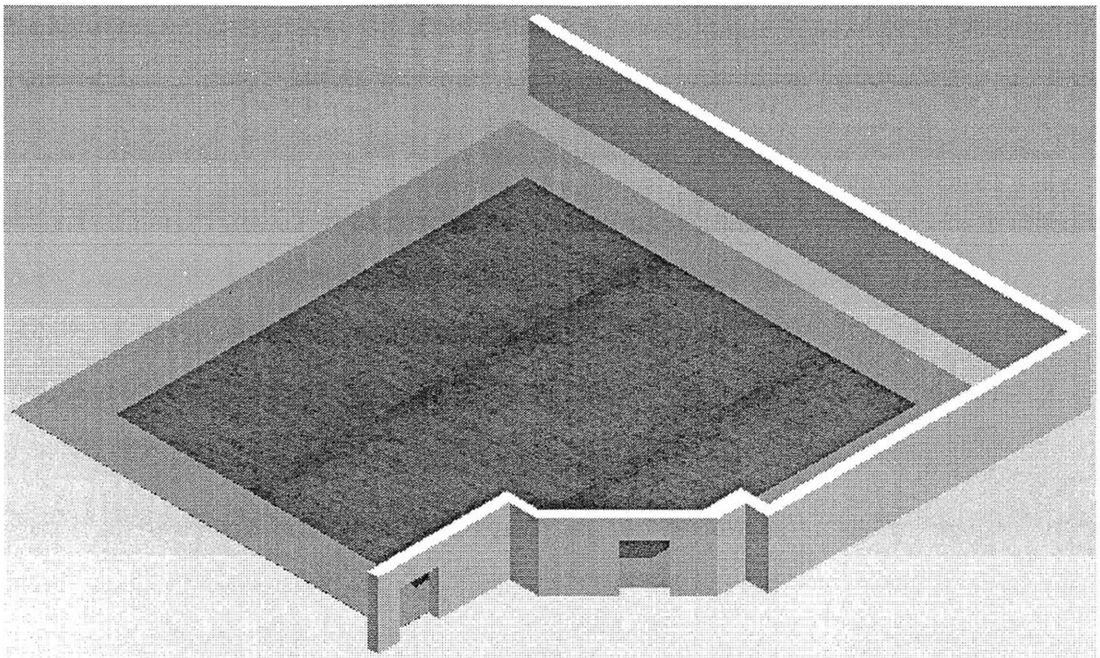


Figure 7: Floor area and boundary model

The production workbenches used are Phoenix Workbenches [24]. Original models were not available from the company so benches were constructed from measurements. Five different sizes of workbenches are used in this production area: two and a half foot, three foot four foot, five foot, and six foot benches. A six foot long bench model is shown in Figure 8 as an example.

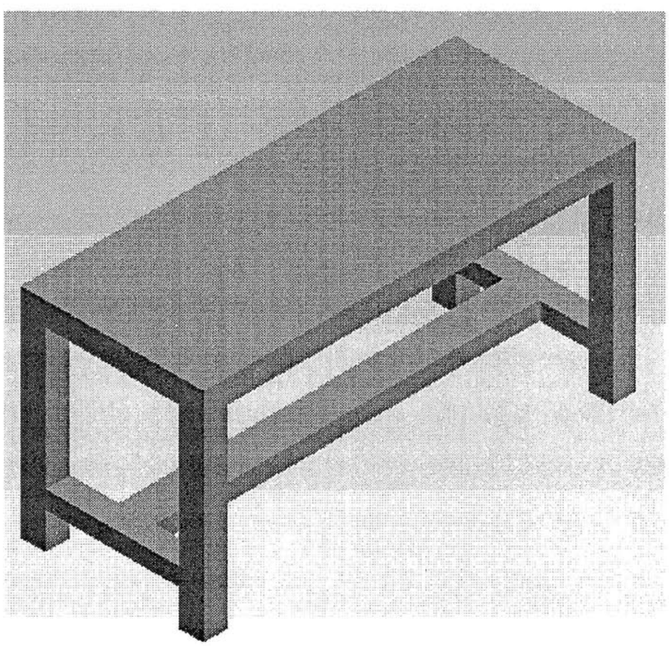


Figure 8: Six foot production bench model

To simplify the modeling process, most apparatus were modeled as a block with length, width and height. Apparatuses included force test equipment, leakage test equipment, microscopes, laser micrometers, and ultrasonic cleaners. All the apparatus were placed in the model on the corresponding workbench as they appeared on the floor. A fume hood model is shown in Figure 9 as an example.

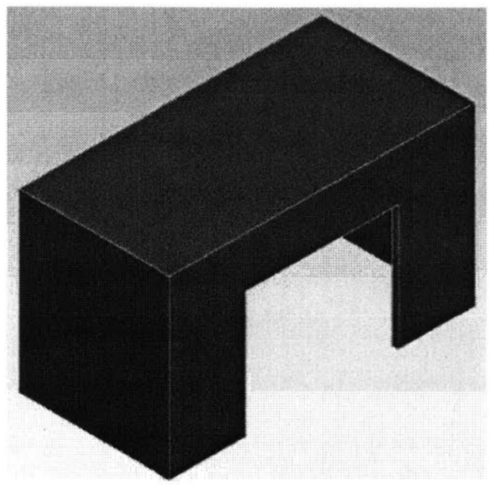


Figure 9: Fume hood model

Nonproduction parts included computer desks, file cabinets, and supermarkets belonging to the floor. A model of one supermarket is shown in Figure 10 as an example.

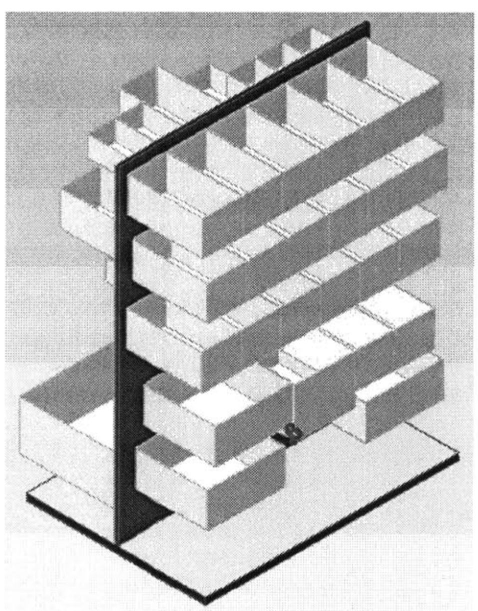


Figure 10: Supermarket model

The whole picture of the original layout of the production floor model is shown in Figure 11. The empty benches are other productions lines indicating the boundary of the production area. The distances between lines are carefully measured to reflect the real operation space for production associates.

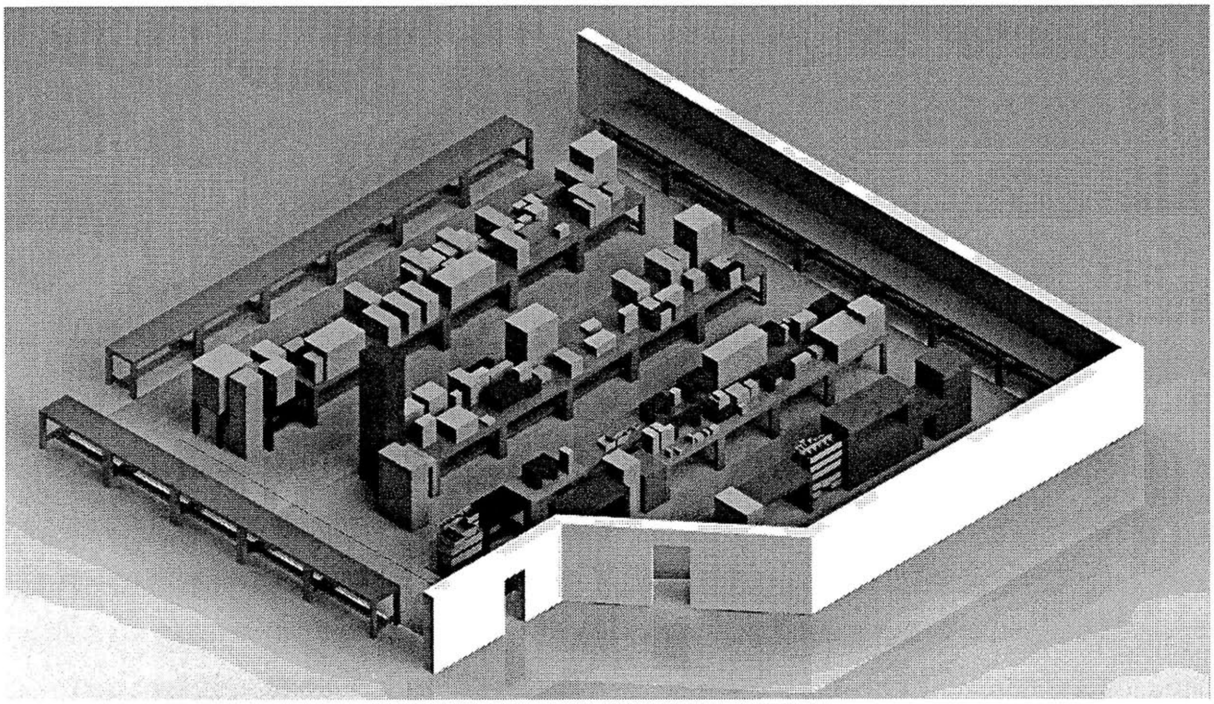


Figure 11: Original layout model

Understanding the Information Stream

After understanding where the equipment was located through bench numbering and modeling the team looked into the information stream of how the company decided to make parts. Through interviews with the warehouse personnel, the line lead, the line manager, and demand planners the team developed the part of the value stream map that showed how information and material flowed before and after the manufacturing process, shown in Figure 12. The supply side and the demand side both have a Kanban system and a planning system that triggers replenishment or production.

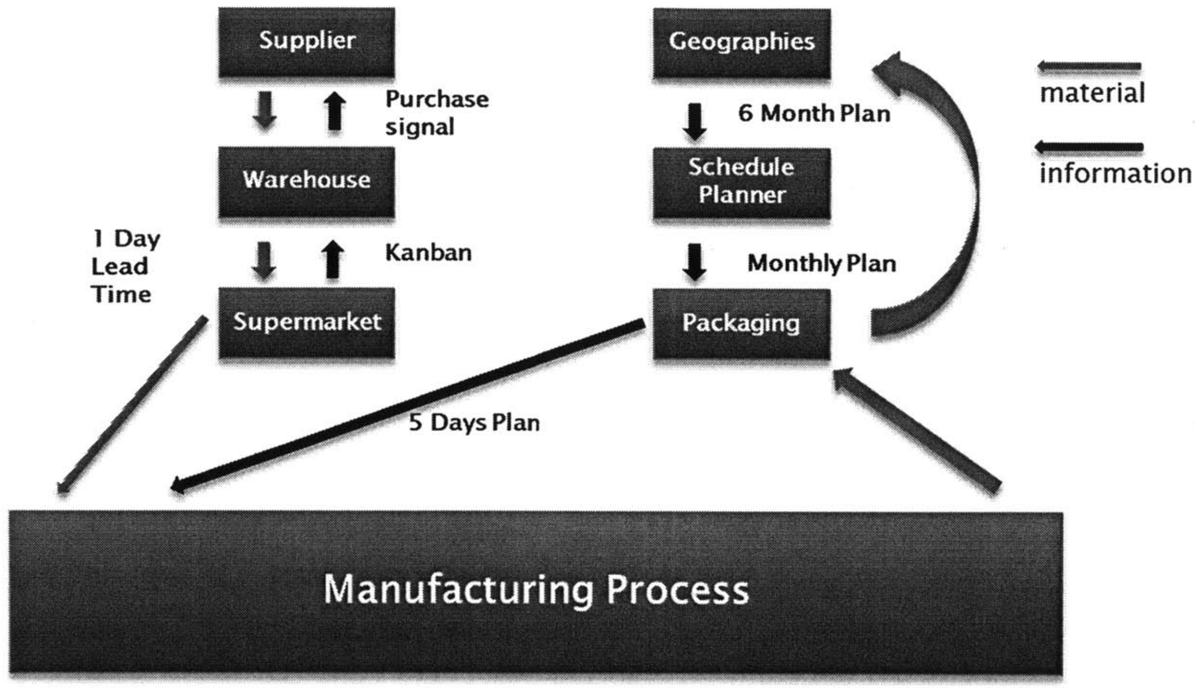


Figure 12: Information stream of the product

Manufacturing Processes

After reviewing the information stream, the team looked at the individual processes to understand the manufacturing methods involved and the time involved for each process. The understanding of the times used will be involved in my concentration of the cycle time analysis, which will be at the end of this methodology section.

Manufacturing Methods

The manufacturing methods for this production line are a mixture of hand tools and manually operated equipment. There are no entirely automated processes. Common processes include cutting components to length, bonding components together, pressing and screw driving components, cleaning, and inspecting visually. The components are currently made in batches, however the manufacturing methods do not prevent one piece flow.

Equipment Used for Manufacturing

There are over 22 different machines used to manufacture the parts of the product. This is not counting the unique machines manufactured just for this line. The common parts are in the matrix shown in Table 2. The matrix allowed the team to look for opportunities to reduce the floor space by combining equipment for two uses or by looking at lines that use similar equipment. The syringe and the accessory use similar machines. The catheter line has 20 microscopes and 11 fume hoods that could be shared. In addition to categorizing the equipment, each piece of equipment on the floor was measured to be added into the model, air and power requirements were recorded, the company's part numbers were recorded, and bench location was recorded. This detailed list is provided in the Appendix, Table 6.

Table 2: Product Family Matrix

	Microscope	Air Blower	Ultra Sonic Cleaner	Laser Micrometer	Hotbox	UV Light Source	Press	Fume Hood	Adhering	Screwdriver
Syringe						1	3	2	2	1
Accessory		2	1			1	2	5	2	3
Sheath					1	1		1	1	
Catheter	20	2	3	5	3	2		3		
Total	**20**	**4**	**4**	**5**	**4**	**5**	**5**	**11**	**5**	**4**

Guiding Strategies

In order to design new layouts, different strategies were considered after the previous analysis of the current situation was performed. These were alternative equipment arrangements, identification and removal of non-production areas from production floor, centralized supermarket compared to point of use inventory, consolidation of equipment, and new bench configuration. The following discussion outlines the strategies and shows how the strategies were linked together to generate different design proposals.

Removing Non-Production Areas

Production items are those that are directly associated with production and assembly, including working benches at which production associates performed each operation, spaces that production equipment are placed. Those spaces are used to add value to the product itself. Non-production items are items that are not directly involved in value adding actions, but are still located on the floor. One observation on the floor was that there were a number of objects that are not directly related to production activity. Those included cabinets, refrigerators for chemical storage, computer desk and so on. Cabinets were common on the floor. Some cabinets stored files for maintenance technicians, production records while others stored consumables and were used as temporary storage space for work-in-progress parts.

The cabinets took up considerable space on the floor and the majority of things stored were not facilitating production. Refrigerators were placed on the production line to store chemicals, such as glues, that required storage at a lower temperature. Glues were small items compared to the size of refrigerators and the consumption rate was low. Excessive refrigerators were noticed on the floor.

Computer desks were placed on the floor for various purposes. Safety trainers were stationed on the floor using computers to track safety documents. Computers for technicians were placed on the floor as office space. Other computers were used for production associates to log production records. Although each computer serves a purpose on the floor, it was noticed that none of the computers are being used fully. In addition, it is verified by the management that it is not a requirement to keep those desks on the floor. The team identified a cabinet, a refrigerator and some computer workstations as non-production items.

Table 3 below summarizes the number of non-production items and production related items on the floor. The number of production items including working benches and supermarket is 36 and the number of non-production items is 11. That is, non-production items consist of 25% of total objects on the floor. Therefore, sorting out and removing non-production items from the floor will increase the utilization of production space.

Table 3: Non-production items

Type	Working Bench	Computer Desk	Cabinet	Chemical Storage (including refrigerators)	Supermarket	Total
# of items	33	4	4	3	3	47

In order to remove non-production items from the production line, while not disrupting daily production activity, combining storage space, relocating non-production items to less valuable space and decentralizing redundant storage were considered.

There is one refrigerator on the catheter line which is only used to store a small number of glues. After consulting the technician on the floor, the team identified an opportunity to store those glues in another refrigerator on the floor which works under the same setting. By doing so, the refrigerator can be moved for other usage and space is saved. Another benefit goes to the maintenance side, as less equipment needs to be maintained therefore technicians could be freed up for other work.

Computer workstations can be relocated out of "clean room" as those people do not have to work on the floor. The production space should be only used by production associates to make products. Facilitating parties are to be stationed in office area or less valuable place.

Cabinets that are storing files or act as temporary inventory storage should be removed. Files that are not required to be on the floor should be stored in archive place. Those required ones should be stored in smaller cabinets and placed underneath working benches in order to save space. Big cabinets should be eliminated so that they are not used as temporary inventory storage.

Decentralizing inventory to point of use

Currently two centralized supermarkets are on the floor for the product's subassemblies. Bins are placed on a shelf with Kanban cards with part number and name. Production associates obtain parts from supermarket every morning. Warehouse associate collects Kanban cards of parts with low inventory level at the end of the day and delivers replenishment the next morning. The centralized supermarket makes it easy for inventory management. Because all inventory parts are located in one place, warehouse associate do not have to deliver parts to each working bench. On the other hand, centralized supermarket takes up a lot of space: part of row 5 and half of row 7 are used as supermarkets. In addition, since parts are not at the place where they are used, production associates have to go to the supermarket to obtain one day's inventory and store them on the floor. Additional inventory levels are created on the floor.

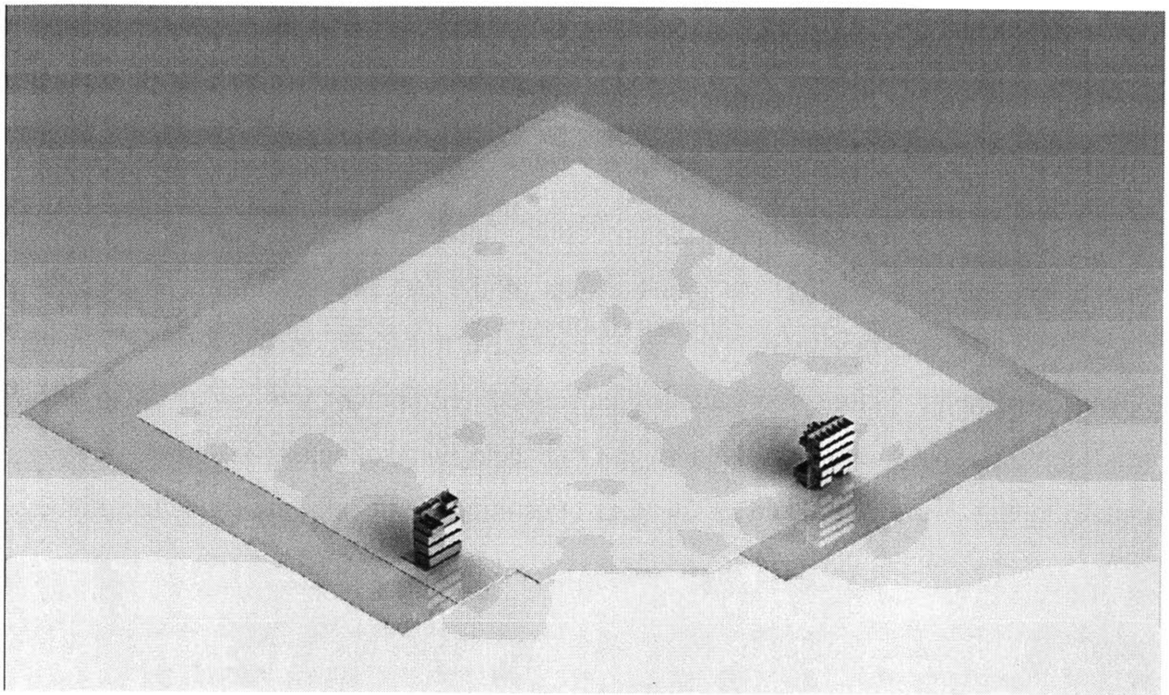


Figure 13: Location of supermarkets on floor

Opposed to centralized inventory, a point of use inventory strategy locates each inventory at the place it is used. For example, a jaw spring is part of the accessory. Therefore, it should be stored on the working bench assembling the accessory. There are two ways of placing inventory bins: on the shelf or attach to bin rail. Each working bench has a shelf for placing documents and bins. It is above equipment on the bench; hence, bins can be stored on the shelf without disrupting operations on the bench. However, the elevation of shelf could require a certain height to reach parts on top of it. Bin rails are long metal strips that are fixed at the back of working benches. Bins then slip onto the bin rails. Bins are therefore more accessible compared to on the shelf in terms of height but they may interrupt operations because they are close to bench surface. A decentralized inventory system meets the team's project objective, as it takes no space on the floor to store inventory.

Consolidating equipment and shortening benches

The current layout of the manufacturing floor is filled with a lot of equipment due to the large number of operations required. One way of reducing floor space is to consolidate equipment and thus reducing number of working benches. For processes that require the same type of operations, one machine can fulfill the same operation instead of having dedicated ones for each process. Table 2 shows the product family matrix that was created to recognize the type of equipment used as well as their quantities on each line.

Microscopes are the most used equipment. Twenty microscopes are placed on the catheter line. The number of production associates on the production line is between six and eight. Most of the microscopes on the catheter line are idle because of the batches and number of production associates. This suggests that there were some excessive machines on the floor which can be consolidated. However, before consolidating equipment, equipment was reviewed to ensure it performs identical operations compared to the one being consolidated. Technical review and specification review were conducted by the team consulting quality engineers and technicians.

The set of equipment required by the syringe and the accessory are observed to be similar. Both lines require UV lights, fume hoods, press machines, adhering mechanisms, and screwdrivers. All operations on the syringe and the accessory lines are manual assembly. This similarity suggests that one set of the equipment can be utilized to perform both the syringe and the accessory operations, although only one can be performed at one time. However, this will eliminate one production space completely and save considerable space for this project. One design based on this finding will be discussed in the next chapter.

Change bench configuration

As discussed in the problem statement, the current layout consists of seven lines of benches. Material flows along lines sequentially. This layout has a simple process flow but the aisle space between each line is significant.

Another strategy is to explore alternative line configurations besides the current layout in order to have a better process flow and increase utilization of space. In common manufacturing practice that the team found in our literature review, other layouts include a job shop, U-cell, and transfer lines. Each layout has its unique characteristic in manufacturing activities and also in terms of space utilization. The team conducted brainstorming sessions to look for alternative configuration and discussed the trade-offs specifically in our project. Detailed discussion is in next section.

Concept Generation

Brainstorming different layouts

Several brainstorming sessions were conducted to come up with different proposals for the production floor layout utilizing the strategies and SolidWorks model highlighted in the previous two sections. Those sessions were conducted internally, the MIT team members, and externally, including the management, quality group, technicians, and production associates from the company. Moreover, the sessions were conducted in the form of informal meetings, floor walkthroughs, or individual discussions.

Desired Layout Characteristics

Although the main goal of the project is to reduce the footprint of the the production line by one third of the original area, there are other factors that are significantly considered before selecting the most appropriate layout. Those factors are:

Saved area

The new layout should save as much area as possible.

Area utilization

The new free area should be useful for the company in a way that it can be utilized for other purposes. In fact, there are no specific metrics to measure this factor, however, the area should have appropriate dimensions to fit new assembly line(s).

Cost of rearrangement

The floor rearrangement should be done with minimum investment cost and with minimum interruption to the production process in the floor for different products.

Ease of rearrangement

The rearrangement process should be done with minimum manpower and paper work requirements.

Tools Maintenance Time

The new layout should be designed to minimize the required time for maintenance of the equipment and tools.

Production Capacity

Despite the current low production demand, maximizing the production capacity is desired for the new layout to account for unexpected demand increase in the future.

Safety

The area reduction should not be at the expense of the safety on the production floor. Maintaining a minimum width of four feet for the aisles between the working benches and 3ft for the aisles toward the emergency exit are vital requirement for any design proposal.

Cycle Time Methodology

Measurements

During the time period of January 23, 2012 to January 26, 2012 measurements were made on the floor of individual processes. The demand was around 50 a day during that time. Batch size averaged 50 pieces for the catheter, 100 pieces for the sheath and 65 pieces for the accessory and the syringe. The measurements taken were both for the operations on one piece as well as the operations on the entire batch size. Some fixtures allow the production associates to perform the same function on multiple pieces at the same time, so both measurements were necessary. The individual and collective data also created a check in the system as to ensure that the individual measurements of the processes were reasonable. These measurements are shown in Figures 14 through 17. The figures shown the measurements of the cycle time in minutes (CT (min)) and the bench the operation is performed on.

There is considerable variability between the different touch times for the different processes, from a few seconds to several minutes. For the analysis of cycle time the processes with the longest touch times, or the bottlenecks, were reviewed for possible reductions.

While observing and measuring the process time, certain fixtures were also looked at to determine the delay time involved with setting up or using the equipment. The equipment was analyzed to provide opportunities to improve the design of the fixture. The location of the equipment and overall ergonomics were also considered as both of these aspects affect the delay time of operating the equipment.

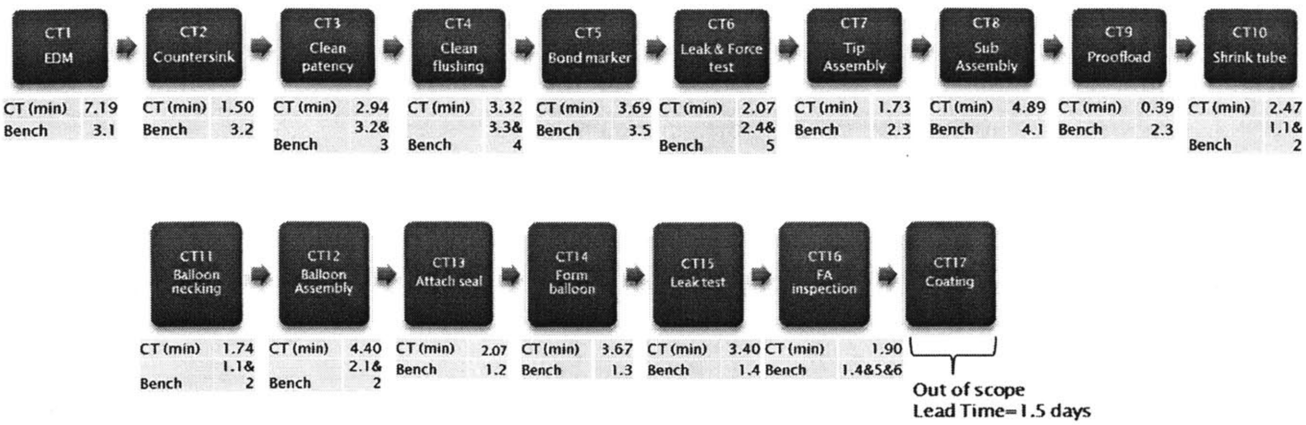


Figure 14: Catheter Process Stream

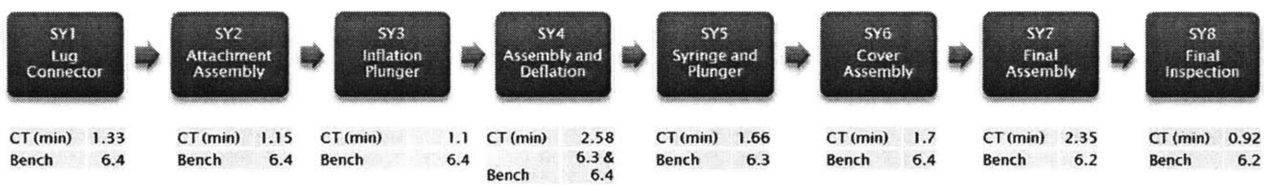


Figure 15: Syringe Process Stream

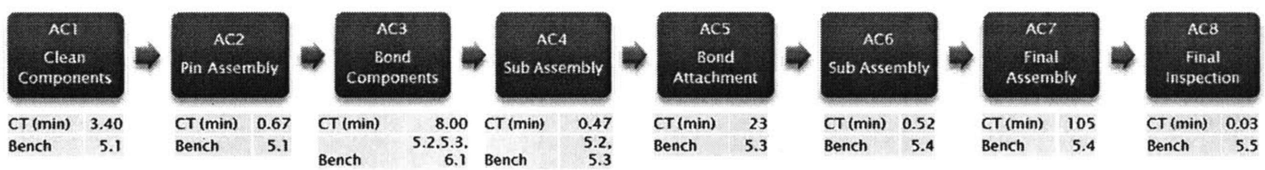


Figure 16: Accessory Process Stream

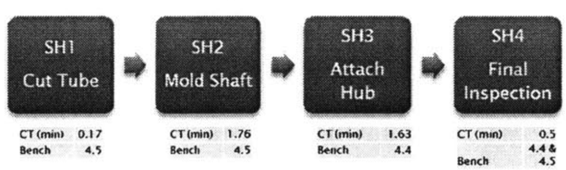


Figure 17: Sheath Process Stream

The team measured the touch times as if the production associates were manufacturing one piece at a time, not considering batch sizes. The company's resources take into account the particular batch size of each process. The thesis will use the times from the company's resources as the batch system will be used on the implemented layout. The bottlenecks were not always the same between the two processes, when different, a brief analysis will be provided. The two numbers are provided in the appendix.

Bottlenecks Analysis

This section outlines the analyses made on the bottleneck processes of each of the four subassemblies, the catheter, the syringe, the accessory, and the sheath.

Catheter

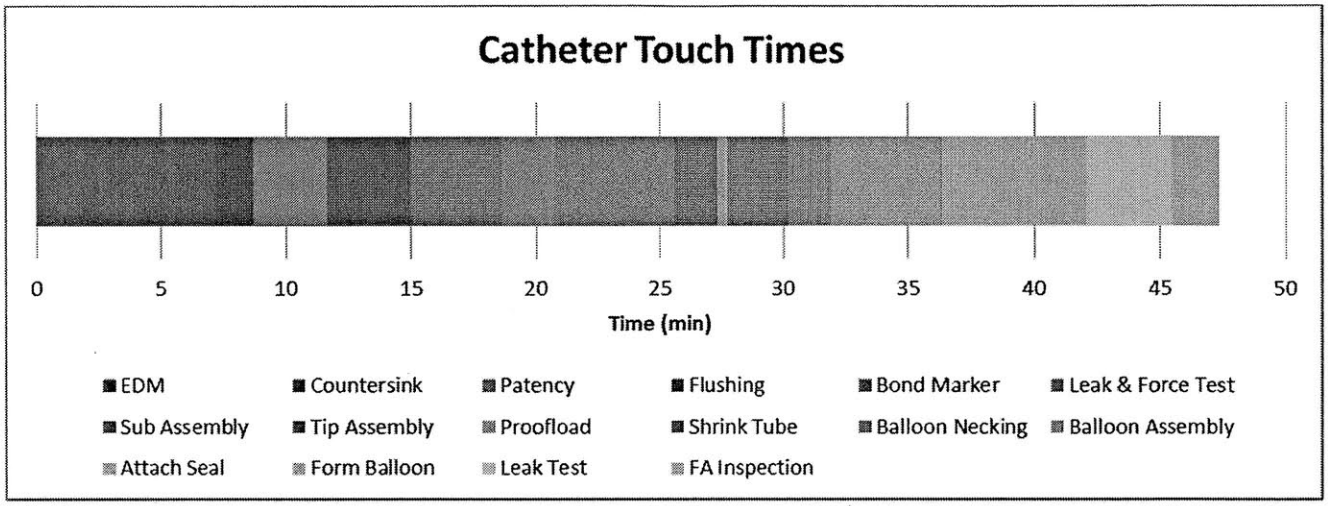


Figure 18: Representation of Catheter touch times

The bottleneck for the catheter is the first process, the process where the EDM is involved as seen in Figure 18. The touch time for the EDM process is 7.19 minutes, while the next two longest processes are the Sub Assembly, with 4.89 minutes, and the Balloon Assembly, with 4.40 minutes. The EDM changes the shape of the catheter. Reducing the EDM process time has the potential to save 2.3 minutes to the entire catheter manufacturing process. To follow the bench numbering references discussed in Figure 6, the EDM is placed on bench 3.1, shown below in Figure 19.

Figure 19: EDM

Fixture Analysis:

The bench for the EDM, bench 3.1, is lower than bench 3.2 to reduce the amount of bending of the catheter between the second bench to the right and where the actual operation is taking place, as seen on the left of the Figure 19 in the black box on the EDM. This reduces the chance for kinks in the catheter. There are no trays or other accessory fixtures that assist the production associates in this operation. The catheter is held by the production associate and threaded into the EDM. Guides to help the production associate to place the catheter in the correct location would decrease the delay time as time is lost in the threading process.

Equipment Improvements:

The EDM can only operate on one piece at a time. An improvement could be to increase the number of catheters that could be operated on a time that would decrease the batch touch time for this process. Adjusting the settings to the lowest time in the machine would decrease the touch time as well. Incorporating the measurements and inspection of the microscope operations into the EDM or moving the microscope closer to the EDM could decrease cycle time. This operation could increase the use of batch sizes because there are no batches used on this process.

Team's Measurements:

The team measured the balloon process to take the longest at 26.58 minutes. This was largely due to the oven time to cure the balloons, of 10 minutes. A new oven that rose to the required temperature faster could reduce this time. Also the fixture to cut the balloons contains eight pieces at a time, so changing the number could reduce the touch time. Reducing the time for the balloon process would decrease the overall manufacturing time for the catheter by approximately ten minutes or more. When the process was measured it took only one minute per piece in EDM, revisiting this measurement revealed the measurement did not included setup times and was a best case scenario.

Syringe

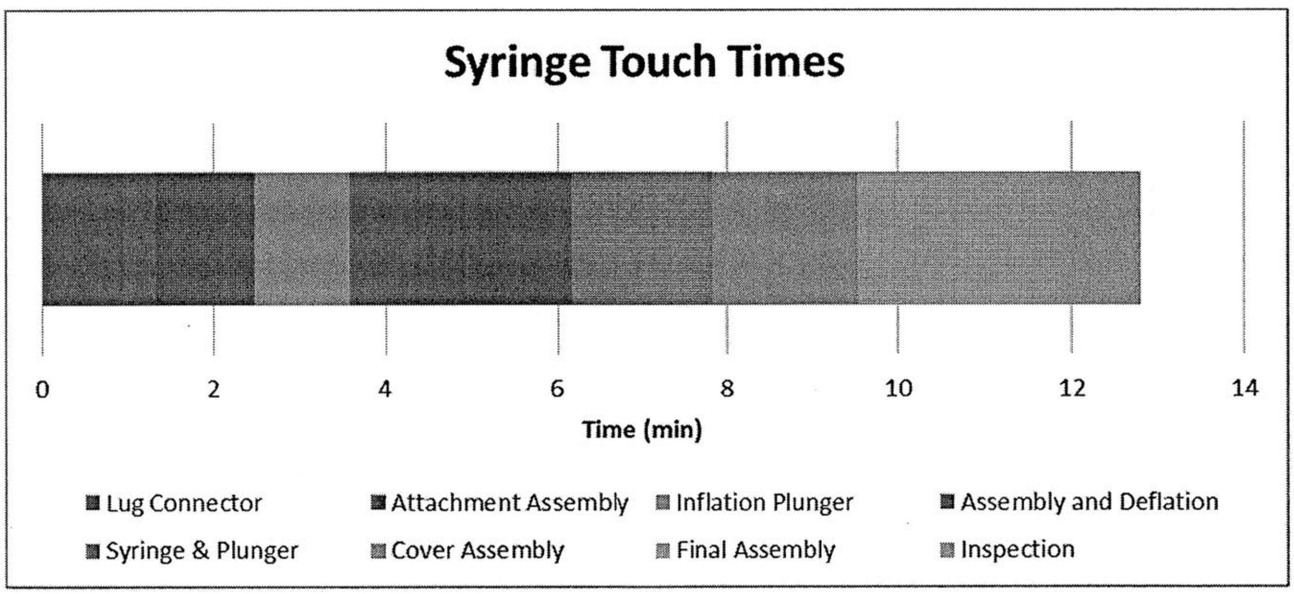


Figure 20: Representation of syringe touch times

The syringe touch times are relatively evenly distributed compared to the other subassemblies, as seen in Figure 20. The bottleneck process is the assembly and deflation process at 2.58 minutes. The second longest process is the final assembly process is 2.35 minutes. Both of these processes take place on the bench shown in Figure 21. Reducing the bottleneck process of the assembly and deflation process would only decrease the overall production time by an incremental 0.23 minutes.

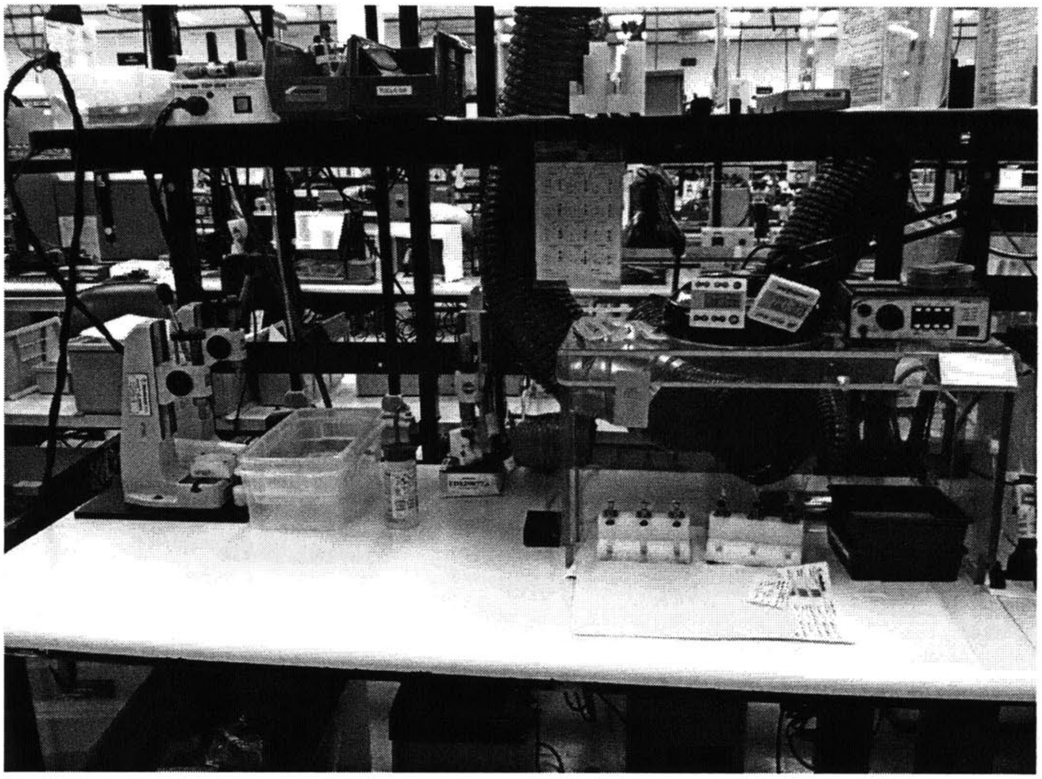


Figure 21: Syringe bench for assembly and deflation and final assembly

Fixture Improvements:

Most of the operations on the syringe line do not have fixtures for the specific operations, most components are held by the production associates. Designing fixtures to hold the syringe while performing the screwing and bonding operations could reduce the required cycle time. The current clamp used for curing the process also requires an uncomfortable amount of force to use, so finding a clamp that uses mechanical advantages would improve the ergonomics of the process. Incorporating the clamp and the holding fixture would reduce time it would take to place the syringe into a new fixture.

Equipment Improvements:

In these two operations, presses, epoxies, and screwdrivers are used. Most of this operation is manual. The screwdrivers are hanging from the ceiling, moving these to the tables could reduce the time spent reaching. Adding a magnetic tip to the bit of the screwdriver could increase ease of placing the screw into the correct place on the plastic injected part. A more drastic change would be fixing the screwdriver and moving the parts to the screwdriver. A similar approach could be made to the applying the epoxy, by fixing the epoxy applier and moving parts to the applier. Both fixing the screwdriver and the epoxy applier would need to be tested to see what takes less time. The presses could include springs to push back up after the production associate has pulled down on the handle.

Team's Measurements:

The final assembly operation is measured to be the bottleneck at 1.97 minutes, not a significant difference considering the similar time of all of the processes. The processes for the syringe manufacturing line are mostly done in piece flow after the epoxy curing time. The suggestions outlined for the assembly and deflation operation could also be applied for the final assembly operation to reduce the cycle time.

Accessory

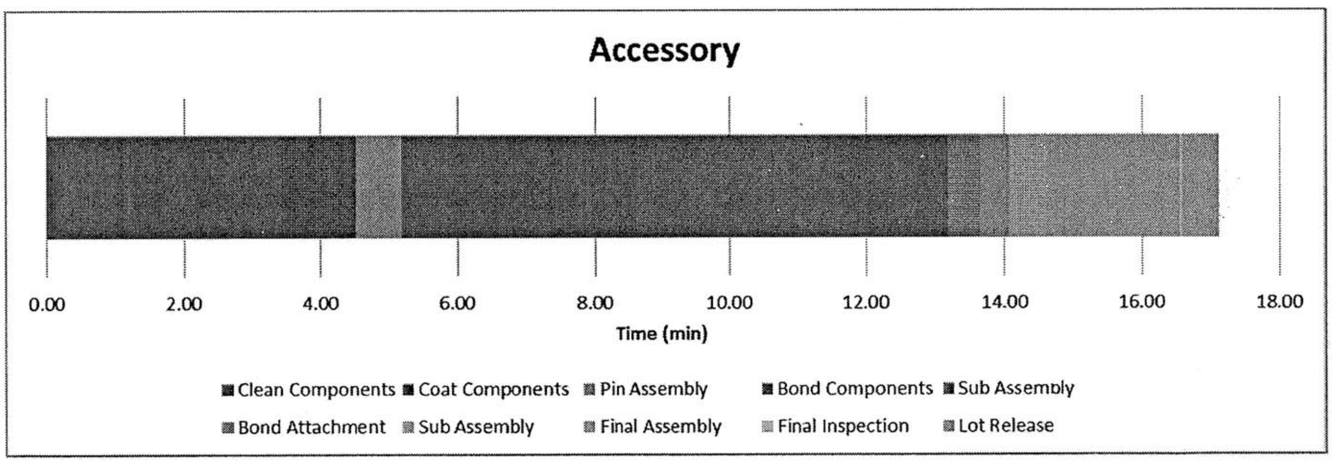


Figure 22: Accessory touch time representation

The longest process for the accessory subassembly is the bond components process, which takes 8.00 minutes. As shown in Figure 22, this process is by far the longest for the subassembly, reducing this time could reduce the overall time for the manufacturing of the accessory by 4.60 minutes, almost 25% of the total time for the accessory. The second longest is the first operation of cleaning the components, at 3.40 minutes. The operation for the bond components process takes place at benches 5.2, 5.3, and 6.1 as referenced in Figure 6. The bonding machine is shown in Figure 23.

Figure 23: Accessory UV Bonding Machine

The process is to put the epoxy on the components, place the components on a tray, and then set that tray on a conveyor belt that goes through the bonding machine. After the components are in the machine, there are some more operations that are performed, and then finally the part is inspected on bench 6.1, shown in Figure 24. This is one of the more space intense operations as the equipment is on three benches. Also this individual process is the bottleneck for the entire occlusion system product with the longest touch time of any operation in any of the other manufacturing operations.

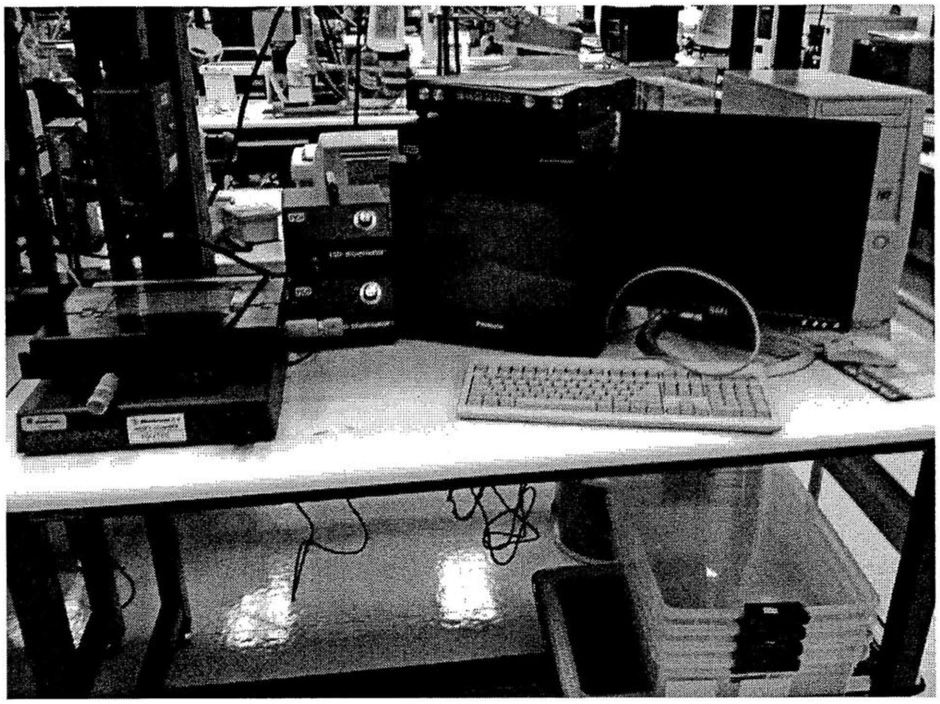


Figure 24: Accessory inspection station

Fixture Improvements:

The tray only allows for six pieces at a time to go through the UV machine, the tray could be improved to allow for more parts to be bonded at a time. The time through the machine would no longer be the restricting time for the batch touch time. Also fixing the last tray so all four trays are in use at a time would help to reduce the touch time for a batch.

Equipment Improvements:

A new UV curing machine could reduce the touch time as well as the equipment space. The machine is about as large as an entire bench. Possibly placing the inspection bench next to the other benches in the process could reduce delay time as the parts are walked from table to another table. Automatic inspection incorporated with the UV curing machine could reduce the transition times between operations as well.

Team's Measurements:

The team measured the same process, bonding components, to be the bottleneck at 10.07 minutes. This is the longest process for the accessory subassembly. The setup time and the actual operation time add together to make this the bottleneck process for the entire assembly process. Reducing this operation would yield the most benefit for the production capacity of the entire manufacturing system.

Sheath

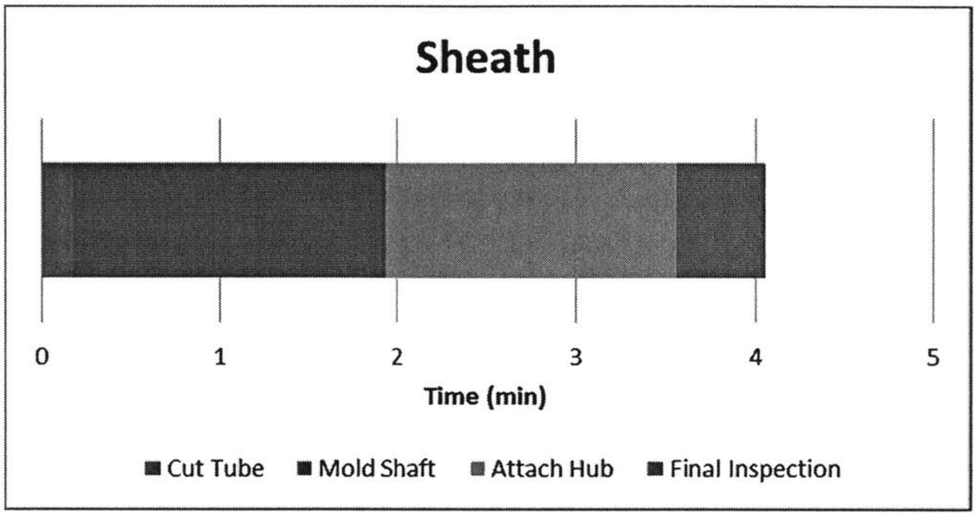


Figure 25: Sheath touch time

The sheath process is balanced between two operations, the mold shaft, which takes 1.76 minutes and the attach hub with takes 1.63 minutes, shown in Figure 25. These operations both take place on benches 4.4 and 4.5, which are the two benches for the entire subassembly. Bench 4.5 is shown in Figure 26. Reducing the bottleneck of the attach hub process would only decrease the entire operation by 0.13 minutes. This is practically enveloped by the variability in each operation.

Figure 26: Sheath bench

Fixture Improvements:

The flow is one piece at a time for this process except for the last operation in the mold shaft process, there two pieces at a time are cleaned. The fixture for removing the molded shafts only works for one shaft at a time. Removing the pieces off of the mandrel takes considerable time as well in this process. There are only 16 mandrels which limits the number cooling at one time.

Equipment Improvements:

Time is lost to setup the machine. The equipment process also takes the longest out of the operations on these two processes. Quicker machines or reevaluating the settings used on these machines would reduce the process time considerably.

Team's Measurements:

The bottleneck the team measured is the attach hub operation at 6.59 minutes. The number of mandrels is also a limiting factor as well as the cooling time. A machine to cool the pieces could reduce the delay time.

Summary of observed times

All of these touch times recorded in the process stream were added together to create a total touch time for a particular component. The lead times of getting the product to the packaging area were also observed. The SAP times were recorded from the company's system. The measurements are tabulated in Table 4.

The differences between the first two columns are due to losses in the cycle time due to delay time and any losses due to communication. The differences between the last two columns the lead time and the SAP time are losses in communication due to the company's system of passing along the information and the lot history reports.

Table 4: Touch Time, Lead Time, SAP Time Comparison

	Touch Time (work day/50 pieces)	Lead Time (day)	SAP Time (day)
Syringe	0.7	1	3
Accessory	1.7	2	4
Sheath	0.8	2	4
Catheter	2.9	5.5	9

Conclusions

This section outlines the floor layout designs the team proposed to the management, the facilities, and production associates to reduce the area. This section also discusses the conclusions from the cycle time analysis.

Proposals

Following the guiding strategies highlighted in the previous section, four different proposals proposed. They are summarized in the sketches and tables below:

Design A

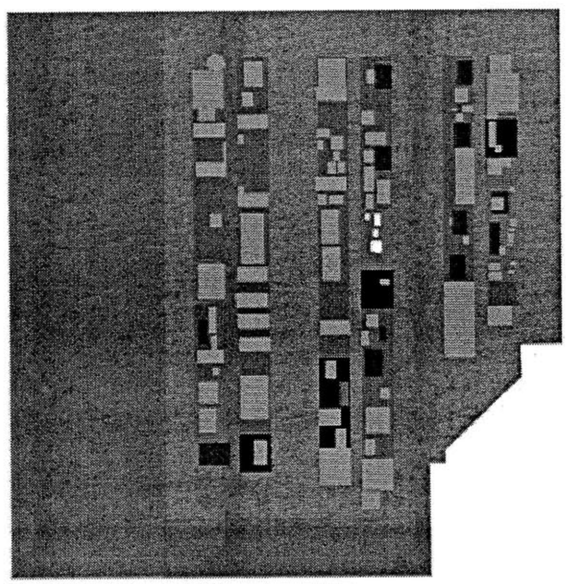


Figure 27: Design A, top view

Design A, shown in Figure 27 and in Table 5**Error! Reference source not found.**, is a conservative design as the configuration is similar to the current layout. The main movements are to remove row seven (the nearest row to the wall on the right), remove nonproduction areas, and then consolidate a few benches and equipment. The production benches will be then moved to the right. The catheter line is still on the outer area on the left side, while the other shorter lines are moved to the right. The area shaded in green in Figure 27 is the new open space.

Design B:

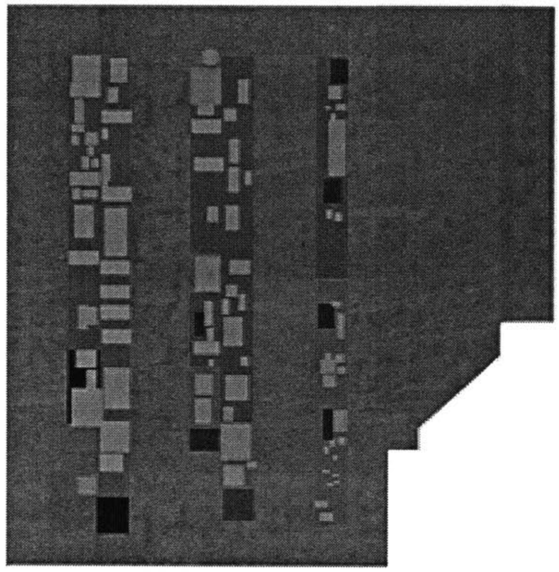


Figure 28: Design B, top view

Design B, shown in Figure 28 and Table 5 takes a different approach than Design A by moving benches to the left, leaving the open space on the right, shown highlighted in green in Figure 28. The area saved is not as large as in Design A. The move is relatively conservative because the bench layout is quite similar as to the original design.

Design C (U Shape Cells):

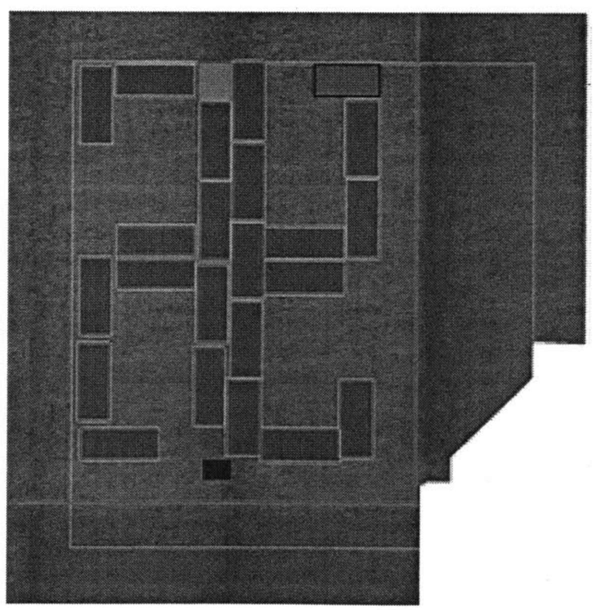


Figure 29: Design C, top view

Design C, shown in Figure 29 and Table 5**Error! Reference source not found.**, is a different bench configuration that creates cell manufacturing lines. This movement is a drastic change from the original design as tables will be rotated and the entire working lines will not be linear. This design increases the potential to use equipment for multiple processes, however the space and product flow would be so drastically different the technical risk would be higher than Design A and Design B. The space saved highlighted in green in Figure 29 is less than both Design A and Design B as well.

Design D (U Shape Cells):

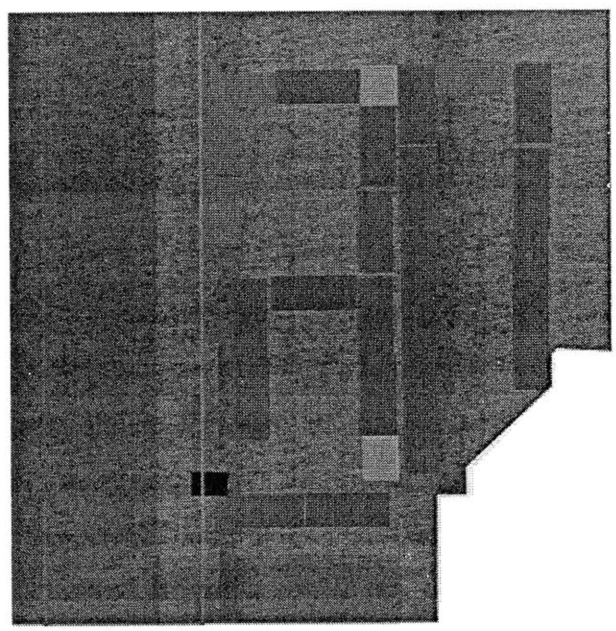


Figure 30: Design D, top view

Design D, shown in Figure 30 and Table 5, attempts to create cell manufacturing lines as well as keeping some areas more similar to the original design. Design D has the same issues as Design C, with the drastically different layout and the high potential technical risk level. This design is able to save more space than Design C. The saved area is highlighted in green in Figure 30.

Table 5: Design proposals summary

	Saved Area	No. of Production Benches	Ease of Movement	Potential technical Risk	Configuration
Design A	476 ft^2	25	Easy	Low	6 rows
Design B	400 ft^2	24	Easy	Low	5 rows
Design C	300 ft^2	25	Difficult	High	6 rows
Design D	350 ft^2	25	Difficult	High	6 rows

Area Results

The MIT proposed Design A to be reviewed by all the stakeholders involved in the project, the engineering team, the management team, the production associates, and the facilities team. The design was met with approval. Suggestions were taken into consideration, including adjusting bench locations, equipment type and locations, and ergonomics for production associates.

The design that was chosen was Design A, the reasons are clear looking at Table 5, as Design A saves the most space, has an easy movement, and a low risk level.

The proposed layout uses the same rule for numbering. The only difference is a prefix N is added to be distinguished from the original design, seen in Figure 31. A matching table will be provided for the proposal package, partially attached in the appendix, to record the changes of benches.

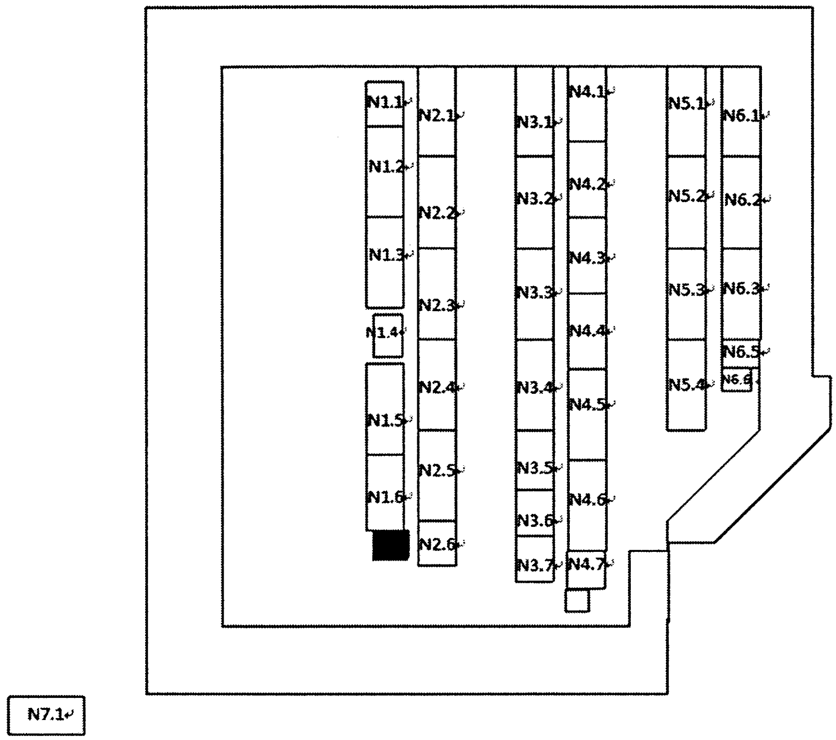


Figure 31: Top view of the proposed layout with new bench labeling

A model of the proposed layout from the concept generation section is shown in Figure 32. Empty space has been cleared out for potentially introducing a new production line. The company did provide a blueprint of the floor layout for the team to confirm their model with. The file is a two dimensional CAD drawing which was modified and included in the final movement package required by the company, attached in the appendix.

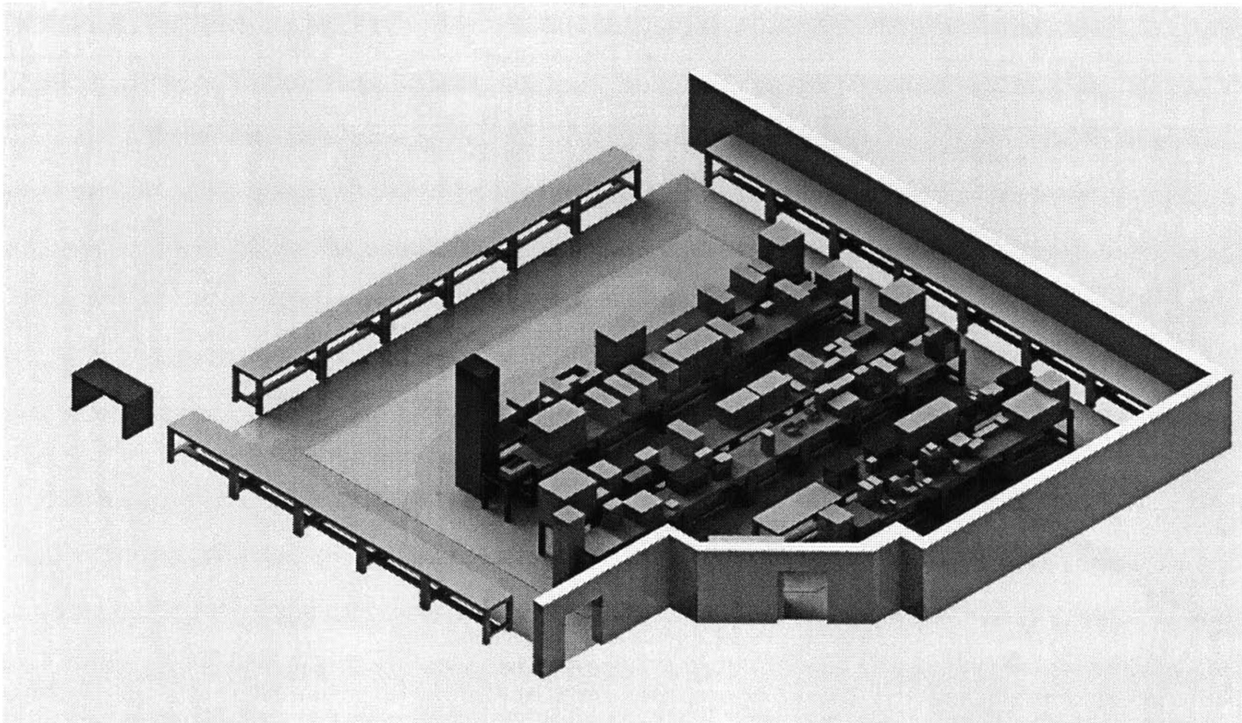


Figure 32: Proposed layout model

Review Process

The team made another paper model to demonstrate proposed movement to the different stakeholders, as seen in Figure 33. The colored papers representing the benches are placed on a drawing of the floor so the original and the proposed layout can be seen at the same time. The tactile representation appealed to more audiences than the modeling, as it was understood by all involved. This format encouraged feedback from the production associates as well as the facility team as the movements were physically represented by the paper cutouts. This representation helped to create a movement sequence as well.

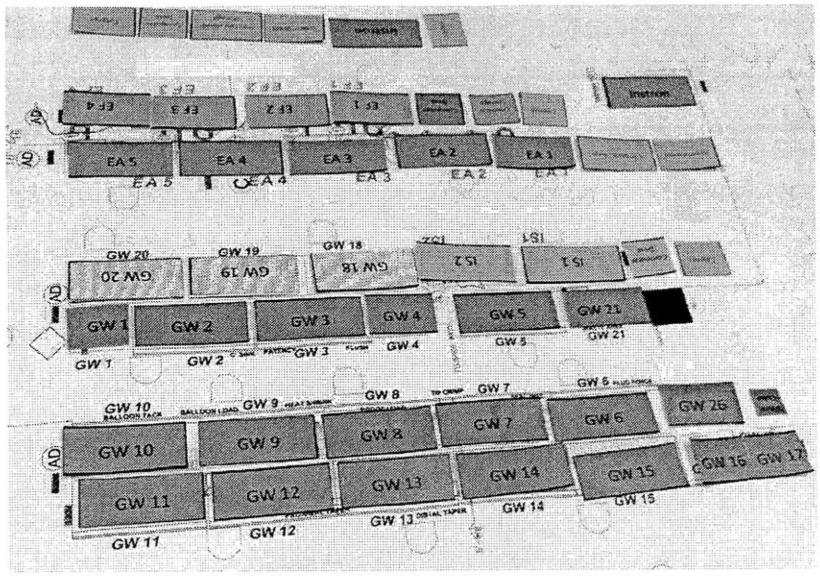


Figure 33: Paper cutouts used for demonstration

The team also presented the technical specifications outlining each move to all the parties involved. These discussions allowed the team to address multiple suggestions and viewpoints. One example is a production associate requested to not combine the operations that occurred on two duplicate machines onto just one machine removing the duplicate. The two machines are seen in Figure 34. The reason the production associate gave was that the setup time was significant and quality issues could be caught earlier with two separate machines. The team realized that the space saved by combining was not significant so the two machines were kept in the proposed layout.

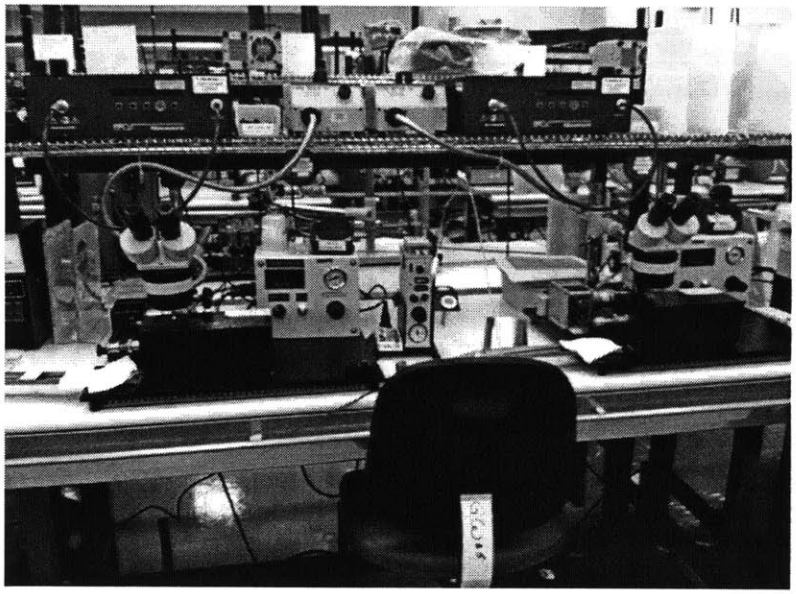


Figure 34: Identical machines on line

Summary of objectives met

The team saved one third of the original area and the space saved allows for ten new benches as seen in Figure 35. These new benches will provide space for the company to introduce a new production line of ten six foot benches.

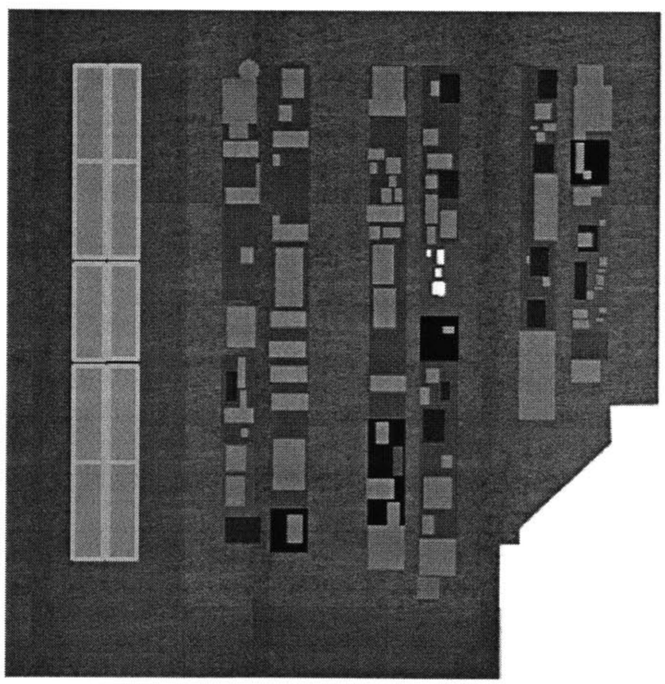


Figure 35: Proposed layout with new benches

The layout also minimized the cost required for the move by requiring very few new benches and equipment. The team, after receiving feedback from the facilities team, did not require infrastructure changes such as duct work to make the move. The team minimized the calibration requirements by not moving an entire row of benches. The design also removed some equipment to reduce the maintenance time. The team by not changing the process location or equipment did not affect the production capacity. The safety requirements were also considered in the final design. All of the desired layout characteristics were met.

Cycle Time Conclusions

No significant changes were made to the process so the process time was not increased, the delay time should only decrease because of the closer location of the components. Recommendations were made on how to improve the cycle time are shown in the section below.

Recommendations

This section provides specific recommendations for the company. These recommendations would improve the manufacturing production system.

Kaizen System for Decentralization Plan

The supermarket decentralization plan placed bins on the benches and shelves. The management responding in a timely manner to the Kaizen system will improve the location by allowing the production associates to change where the bins should be placed. Better locations will improve process time by decreasing the time spent on reaching for the component or finding the component. The Kaizen system will also allow the production associates to improve the bin size or number of components.

Bench Depth

The catheter is a long narrow product. Most of the depth of the benches is not used for either component storage or equipment storage, the space is empty. Using shallower benches would decrease the overall area the production benches take on the floor, reducing the entire floor manufacturing layout area.

Cycle Time Recommendations

My individual methodology for the cycle time included analyzing the process time, the delay time, and the lead time for each of the four subassemblies bottlenecks, the recommendations are outlined below:

Equipment Changes

The catheter equipment of the EDM needs to be changed to see if there are ways to reduce setup or touch time for the EDM operation. The syringe's screwdrivers should be placed on the bench to reduce cycle time. The accessory UV curing machine needs to be adjusted to reduce the cycle time and studies need to be performed to possibly change the type of epoxy used to not require such a lengthy process. The accessory equipment should be the highest priority as that bottleneck is the bottleneck for the entire process. The equipment also takes up the most production bench space for the entire occlusion system manufacturing process. The sheath could be improved by looking at the UV curing equipment used to reduce setup time.

Fixture Changes

For the catheter operation adding fixtures to hold the catheter would decrease cycle time. The cycle time of the syringe would be decreased if fixtures are improved to hold the parts while epoxying or screw driving the parts together. The trays for the accessory operation need to be fixed and improved to reduce the curing time for the entire batch. The accessory trays could reduce the bottleneck for the entire occlusion system manufacturing process. The sheath operation fixtures could be improved by having more mandrels for the production associate to use to reduce the delay time of waiting for an available part.

Future Work

Improve lead time

As seen in Table 4, further studies could be performed to reduce the loss in time in communication that is causing a difference in lead time and SAP time. The process could be analyzed to see where in the information stream the delays are occurring.

Multifunction benches

The order of processes, the batch size, and the number of production associates on this production line contribute to the fact that many of the benches are only used during one part of the day. During any given time, approximately seventy percent of the benches are not being used by the production associates. A time study could be performed to monitor when benches are in use, so the same bench could have one operation performed in the morning, and then once that operation was complete, the bench could be used for a different operation in the afternoon. This study has the potential to reduce the floor layout significantly.

Standardize epoxies

The product is FDA regulated, so new materials would require new filings. There are currently several different epoxies being used on the production floor, some require fume hoods, some require UV curing, and all have different curing times. A study could be performed to reduce the variety of epoxies used on this line to standardize the processes. This could potentially remove some of the bonding equipment thus reducing the area. This could also improve the cycle time by finding an epoxy that takes less time to cure than the current epoxy.

Single piece flow

As discussed in the literature review, a standard practice in lean manufacturing is to introduce pull systems to improve the flow of components on the line. The batch sizes in this line can reduce the cycle time for some processes. For example for the processes where fixtures are involved, like the balloon assembly in the catheter, the fixtures are placed in an oven in batches. This reduces the overall cycle time for a production amount because of only requiring one curing time in the oven. However, these operations that encourage batches prevent single piece flow and a pull system to improve flow. A benefit of reducing the batch size is the increase in flexibility of the line to respond to changes in demand. A study in this area could provide opportunities to increase production capacity of the line.

Lessons Learned

Move Day

Implementing the move of the floor layout earlier in the team's time at the company would allow the team to support and refine the design. The team had the supporting documentation (attached in the appendix) ready and approved by the parties involved a month before the actual move. Moving earlier would allow the team to document the results and the aftermath of the implementation for future moves within the company.

FDA Regulations Involved

A lesson that I learned was how the FDA regulations can really constrain the engineering options available to the company to improve the manufacturing process. If possible the company should try to streamline the manufacturing process before new regulatory filings would be required if changes are made.

Detailed Designs and the Review Process

Another lesson learned was that the more detailed a design was the easier at the end it was to implement. A more detailed design allowed for more concerns to be raised earlier in the process allowing for more stakeholders to be involved. This gave the team a better result in the end where there were fewer surprises for everyone. The multiple reviews in the review process also allowed for multiple designs to be worked on by the research team and the management team.

Appendix

Asset List

Table 6: Detailed Asset List

Description	Asset Number	Dimensions	Bench	Voltage	Other Connections
Oven for Balloon	TD532820	27.5*25.3*35	1.1	Check	Check
Microscope	126736	13*29*20	1.1	110V	N/A
Laser Micrometer	TD581101	24.4*9*9.5	1.1	110V	N/A
Four Fixtures for Balloon	EQ1400C-F	8*13*8	1.1		
EFD	EQ12400		1.1/1.2	110V	Air
Sander	EQ12361		1.2	110V	N/A
Ultrasonic Cleaner	EQ1242I	13*12*11.75	1.2	110V	N/A
Blow Machine	EQ1237K	9.9*6*7.9	1.2	110V	Air
Blow Machine	E-630	9.9*6*7.9	1.2	110V	Air
Panel on top of Blow Machine	TD53381A	11.1*8.3*4	1.2	110V	Air
Microscope	100301	13*29*20	1.2	110V	N/A
Blow Machine	E-630	9.9*6*7.9	1.2	110V	Air
Panel on top of Blow Machine	TD53541A	11.1*8.3*4	1.2	110V	Air
Spare Part for Fixture		8*14*4	1.2		
Microscope Base	EQ2252B	24*18*18	1.3	110V	Air
Microscope Base	EQ2252C	24*18*18	1.3	110V	Air
Yellow Equipment	EQ2423D	6*6*18	1.3	110V	Air
Novacure Machine	EQ1464C	17*11*6	1.3	110V	N/A
Novacure Machine	EQ1464D	17*11*6	1.3	110V	N/A
Microscope with fixture A	89132	32*18*16	1.3	110V	N/A
Microscope with fixture B	126728	32*18*16	1.3	110V	N/A
Yellow Equipment	EQ2423B	6*6*18	1.4	110V	Air

Microscope	126676	13*29*20	1.4	110V	N/A
Laser Micrometer	TD58110V	24.4*9*9.5	1.5	110V	N/A
Tool Box		17*11*11	1.5		
Nikon Measurescope		17*13*22	1.6	110V	N/A
Panasonic Image Equipment		20*10.5*12	1.6	110V	N/A
Ram Optical with Computer	EQ1256D	36*30*34	1.7	110V	N/A
Microscope with a fixture	126621	24*18*17	2.1	110V	N/A
Novacure Machine	EQ1464G	17*11*6	2.1	110V	N/A
Yellow Equipment		6*6*18	2.1	110V	Air
Fixture	EQ2252D	24*18*16	2.1	110V	Air
Microscope	126677	13*29*20	2.1	110V	N/A
Volume Static Eliminator	SDC011	13.5*11*10	2.1	110V	N/A
Heater	EQ2258C	6*14*4	2.2	N/A	N/A
Microscope	126734	13*29*20	2.2	110V	N/A
Microscope	126662	13*29*20	2.2	110V	N/A
Blow Machine	EQ1237F	9.9*6*7.9	2.2	110V	Air
Blow Machine	EQ1237I	9.9*6*7.9	2.2	110V	Air
Laser Micrometer	TD58110N	24.4*9*9.5	2.2	110V	N/A
Proofloader	58075	48*22*21.5	2.3	110V	Air
Microscope	100294	13*29*20	2.3	110V	N/A
Microscope Base	TD54093A	14*10*15	2.4	110V	Air
Microscope	126668	13*29*20	2.4	110V	N/A
Microscope	126738	13*29*20	2.4	110V	N/A
Microscope		13*29*20	2.4	110V	N/A
Seal Insertion Machine	126888	32*24*26	2.5	110V	Air
Chatillon	TD54887	9*4*2	2.5	110V	N/A
Microscope+Machine	126675	41*25*27	2.5	110V	N/A
EDM Machine	TD5325IB	26*26*39	3.1	Check	Complex

Medical Waste Container		d: 17* h: 20	3.1		
Pressure Regulaor	EQ1253E	7*8*4	3.2	110V	Air
Sander	EQ1236B	6*6*7	3.2	110V	N/A
Microscope	126729	13*29*20	3.2	110V	N/A
Microscope	126735	13*29*20	3.2	110V	N/A
EDM Control Panel	TD5325IB	12.3*17*18	3.2	110V	Complex
Ultrasonic Cleaner underneath the table	USC 169	22*31*18	3.2	110V	N/A
Alcohol-Air Supply	TD55786A		3.3	Check	Check
Automatic Cleaner	EQ1477A	14*10*5	3.3	110V	Air
Flushing Patency Space	EQ1305B	33*24*74	3.4	Check	Check
Laser meter	TD58110F	24*7*10	3.5	Not existing	Not existing
Plastic Fume Hood (thicker)	x	24*9*14	3.5		
Humidifier	AOS001	14*7*18	3.5	110V	N/A
Microscope	126764	12*24*18	3.5	110V	N/A
Equipment	EQ1240L	7*6*12	3.5	110V	Air
Acids and Corrosives		20*18*21	3.6		
Waste Rejected		24*16*18.5	3.6		
Microscope in a fume hood	126181	24*11*14	4.1	110V	N/A
USC	USC 160	13*12*11.8	4.1	110V	N/A
Laser Micrometer	TD581101	24*9*14	4.2	Not existing	Not existing
Humidifier	AOS002	14*7*18	4.2	110V	N/A
Microscope in a fume hood	126664	36*19*19	4.2	110V	N/A
Shape Plug a	EQ1280B	23*14*8.5	4.3	110V	Air
Microscope	126730	13*29*20	4.3	Not existing	Not existing
Shape Plug b	EQ1453A	12*20*14	4.3	110V	Air

Gra Lab 545	N/A	10*4*5	4.4	110V	N/A
Epoxy Gray Box	EQ1240E		4.4	110V	Air
Air Blower	126619	12*10*8	4.4	110V	Air
Introducer Sheath a		27*18*13	4.4	110V	N/A
Introducer Sheath b		15.5*7*10.5	4.4	110V	N/A
Introducer Sheath c		14*7*18	4.4	110V	N/A
Introducer Sheath AB			4.4	110V	N/A
Fiber Optic Illuminator	N/A	7*5*8	4.5	110V	N/A
Introducer Sheath 2a	TD52533A	15.25*9*21	4.5	110V	Air
Introducer Sheath 2b		24*22*14	4.5	110V	N/A
Introducer Sheath 2c		8.5*8.5*3	4.5	110V	N/A
Plastic Fume Hood	x	24*16*16	5.1		
Ultrasonic Cleaner	TD53862B	13*13*12	5.1	110V	N/A
Press Machine	EQ20871	6*10*19	5.1		
Epoxy Black Tower, w/o Base	EQ1240G	3*6*11	5.1	110V	Air
Epoxy Black Tower, w/ Base	EQ1240A	7*6*12	5.1	110V	Air
Plastic Fume Hood	x	24*16*16	5.2		
UV Curing Machine	TD51436B	54*18*27	5.2	Check	Check
Plastic Fume Hood	x	24*16*16	5.3		
Slider Pad and Mid Pad	EQ1274D,E	8*6*4	5.3	110V	Air
Black Machine	EQ 1240U	7*6*12	5.3	110V	Air
Plastic Fume Hood (thicker plastic)		24*12*14	5.3		
Press Machine	TD538221/01	6*10*19	5.5		
Plastic Fume Hood	x	24*16*16	5.5		
Testing Equipment	EQ1256G	20.5*20.5*26	6.1	110V	N/A
Accessories for Testing Equipment	na	7*9.5*7	6.1	110V	N/A

Inspection Computer and Monitor	na	36*30*18	6.1	110V	N/A
Fume Hood	na	28*11*14	6.2		
Air Supply/ Press Control	EQ1253C	7*7.5*4	6.2	110V	Air
Equipment	EQ1465A	24*6.5*4.5	6.2	110V	N/A
Equipment Inside the UV Bonding	EQ2449A/ EQ1496A	8*9*9	6.3	110V	N/A
UV Bonding	UVH001	21*16*12	6.3	110V	N/A
EFOS Acticure	EQ1241C	12*11*6	6.3	110V	N/A
Pressure Control above UV Bond	EQ1253A	7*7.5*4	6.3	110V	Air
Equipment	EQ2170A	14*14*11	6.3	110V	Air
Top Gun on Stand Support	TD58103	5.5*4*7.5	6.3	110V	Air
Pressing Machine	EQ2087A	7*12*17	6.4		
Pressing Machine	EQ2087B	7*12*17	6.4		
Pressing Machine	TD 129877A	7*5*15	6.4		
Fume Hood "Thick"	NA	30*9*14	6.4		
Top Gun Shelf	TD50653C	7*5*5	6.4	110V	Air
Small Press Over the Shelf	EQ 2251A	2.5*6*4	6.4		
Small Press Over the Shelf	EQ 2251B	2.5*6*4	6.4		
Small Press Over the Shelf	TD53738A	2.5*6*6	6.4		
Small Press Over the Shelf	TD53738B	2.5*6*6	6.4		
EFD 2000 XL on Fume Hood	EQ1274	7.5*6*3	6.4	110V	Air

Touch Time Measurements

Table 7: Catheter touch times

Catheter				
	Description	Time from Company's Resources (min)	Time Measured by team (min)	Bench
CT1	EDM	7.19	1.20	3.1
CT2	Countersink	1.50	0.50	3.2
CT3	Patency	2.94	4.00	3.2,3.3
CT4	Flushing	3.32	2.87	3.3,3.4
CT5	Bond Marker	3.69	10.33	3.5
CT6	Leak & Force Test	2.07	2.25	2.4,2.5
CT7	Sub Assembly	4.89	6.50	4.1
CT8	Tip Assembly	1.73	2.25	2.3
CT9	Proofload	0.39	0.50	2.3
CT10	Shrink Tube	2.47	1.00	2.2
CT11	Balloon Necking	1.74	26.58	1.1,1.2
CT12	Balloon Assembly	4.40	2.40	2.1,2.2
CT13	Attach Seal	2.07	1.58	1.2
CT14	Form Balloon	3.67	2.77	1.3
CT15	Leak Test	3.40	0.32	1.4
CT16	FA Inspection	1.90	13.73	1.4,1.5,1.6

Table 8: Accessory touch times

Accessory				
	Description	Time from Company's Resources (min)	Time Measured by team (min)	Bench
AC1	Clean Components	3.40	10.00	5.1
AC2	Pin Assembly	0.67	0.50	5.1
AC3	Bond Components	8.00	10.07	5.2,5.3,6.1
AC4	Sub Assembly	0.47	0.08	5.2,5.3

AC5	Bond Attachment	0.42	0.38	5.3
AC6	Sub Assembly	0.52	2.77	5.4
AC7	Final Assembly	1.96	1.75	5.4
AC8	Final Inspection	0.08	0.83	5.5

Table 9: Syringe touch times

Syringe				
	Description	Time from Company's Resources (min)	Time Measured by team (min)	Bench
SY1	Lug Connector	1.33	0.70	6.4
SY2	Attachment Assembly	1.15	0.42	6.4
SY3	Inflation Plunger	1.10	0.22	6.4
SY4	Assembiy and Deflation	2.58	1.00	6.3/6.4
SY5	Syringe & Plunger	1.66	1.50	6.3
SY6	Cover Assembly	1.70	1.17	6.4
SY7	Final Assembly	2.35	1.97	6.2
SY8	Inspection	0.92	1.00	6.2

Table 10: Sheath touch times

Sheath				
	Description	Time from Company's Resources (min)	Time Measured by team (min)	Bench
SH1	Cut Tube	0.17	0.17	4.5
SH2	Mold Shaft	1.76	3.25	4.5
SH3	Attach Hub	1.63	6.59	4.4
SH4	Final Inspection	0.50	0.30	4.4/4.5

Floor Reduction Proposal Package

Abstract from package

This package summarizes the movement plan for the Area Reduction Project. The project's goal is to reduce the current floor area by one third. This package provides the necessary numbering system, dimensioned drawings for current and new layout, needed items for movement, movement descriptions, new replenishment strategy, IQ and calibration requirements, and new layout bench details. This area reduction plan suggests actions that will reduce the floor area used by the product by 31%. This layout will help to minimize the shift distance of the ducts to a maximal distance of 5 feet compared to 8 feet in the previous design. Movement descriptions summarize all movement and changes in the new layout and IQ requirement. In implementation of the new layout, the dimensioned drawings and new layout bench details provide detailed information on the arrangement of benches, equipment, and inventories.

Benches Labeling (Existing Layout):

Table 1: Bench Labeling for Production Line

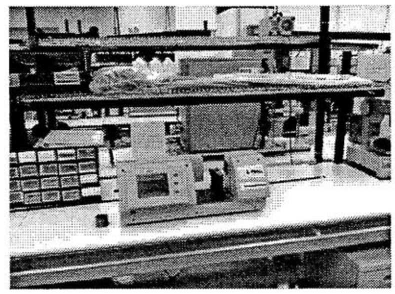
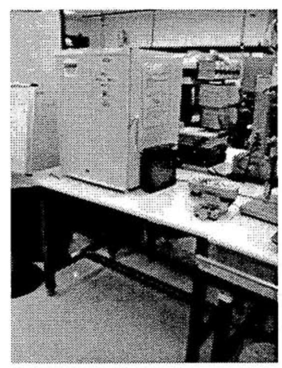
Process Description	Row Number	Benches, Stations & Cabinets (Current)	Benches, Stations & Cabinets (Proposed)
Catheter	1	1.1	N3.1
		1.2	N3.2
		1.3	N3.3
		1.4	N3.4
		1.5	N3.5
		1.6	N3.6
		1.7	N3.7
Catheter	2	2.1	N2.1
		2.2	N2.2
		2.3	N2.3
		2.4	N2.4
		2.5	N2.5
		2.6	Eliminated
Catheter	3	3.1	N1.1
		3.2	N1.2
		3.3	N1.3
		3.4	N1.4
		3.5	N1.5
		3.6	N1.6
Subassembly + Sheath	4	4.1	N5.4
		4.2	Eliminated
		4.3	N5.3
		4.4	N6.1
		4.5	N6.2
		4.6	N6.3
		4.7	Eliminated
Accessory	5	5.1	N4.3
		5.2	N4.2
		5.3	N4.1
		5.4	N5.1
		5.5	N5.2
		5.6	N5.5
		5.7	Eliminated
Syringe	6	6.1	N4.6
		6.2	Eliminated
		6.3	N4.4
		6.4	N4.5
		6.5	Eliminated
		6.6	N5.6
		6.7	Eliminated
Supermarket	7	7.1	Eliminated
		7.2	Eliminated
		7.3	Eliminated
		7.4	Eliminated

		7.5	N6.4
		7.6	Eliminated
Tensile Test	8	8.1	N7.1

Movements Summary

Moreover, Table 2 documents the changes that will take place on the affected benches (other than changing the location).

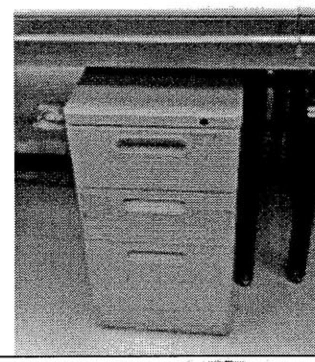
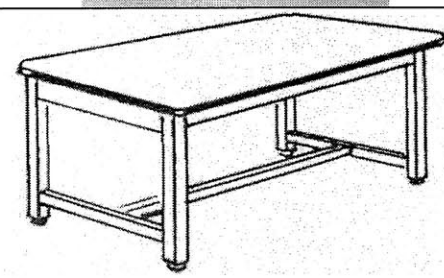
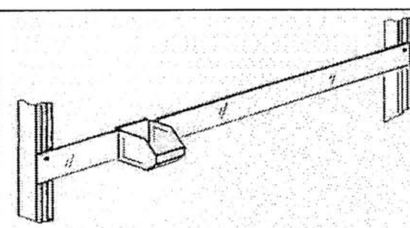
Table 2: Sample of Changes on Affected Benches

Item Description	Production Line	Bench No.	Action	Picture
Bench	Catheter	1.5	Replace the 6 ft bench with a 4 ft one.	
Fridge	Catheter	2.6	Combine it with the fridge at the coating room and eliminate its bench.	
Bench	Catheter	4.2	Replace the fume hood with a cone to be located on 4.3 and remove the 6ft bench (4.2)	
Working benches	Catheter	4.1/4.3	Replace these two benches (6ft) with two 5ft benches.	Refer to Figures 1 & 2.

Item Description	Production Line	Bench No.	Action	Picture
Cabinet	Sheath	4.7	Decentralize the content of the cabinet to 2 small drawers to be placed underneath bench (N4.2)	
Fume hoods	Accessory production line	5.5	Combine the fume hood with the one at 5.1.	
Bench	Accessory production line	5.4/5.5	Replace the 6ft bench (5.4) with a 5ft one. Relocate the benches 5.4 and 5.5 to their new locations shown in Figure 2 (N5.1 and N5.2 respectively)	
Computer Desk	Accessory production line	5.6	Replace it with the other computer desk (6.5) and relocate this desk to row 6 as shown in figure 2 (N6.3).	

Needed Items for the Movement

Table 3: Sample of Parts to be provided

Item Description	Quantity	Picture
Fume Cone to replace the hood on bench	1	
Drawers	4	
3 ft bench	1	
Bin Rail for 6 foot bench	3	

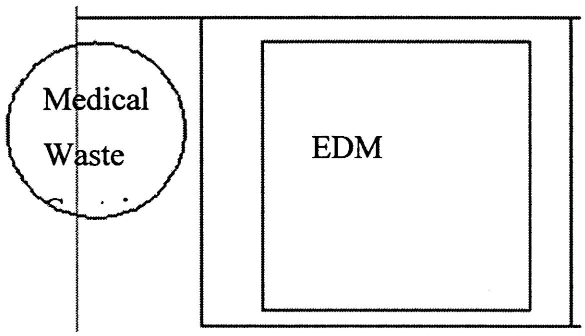
Saved Area

The Product Floor area will be reduced from 1528 ft^2 to 1052 ft^2 (31% reduction).

Sample of New Layout Bench Details

EDM Machine, Bench N1.1 – E831

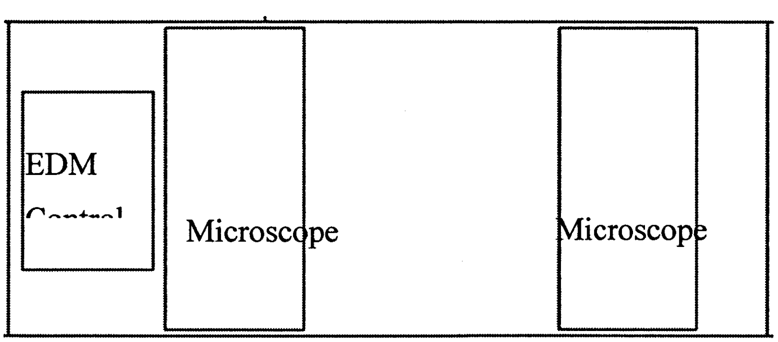
Same bench, initially 3.1



Equipment

Description	Asset Number	Old Bench	Voltage	Other Connections	New Bench
EDM	TD5325IB	3.1	Check	Complex	N1.1
Medical Waste Container		3.1			N1.1

Countersink, Bench N1.2 – E832



Same bench, initially 3.2

Equipment

Description	Asset	Old Bench	Voltage	Other	New

	Number			Connections	Bench
Pressure Regulaor	EQ1253E	3.2	110V	Air	N1.2
Sander	EQ1236B	3.2	110V	N/A	N1.2
Microscope	126729	3.2	110V	N/A	N1.2
Microscope	126735	3.2	110V	N/A	N1.2
EDM Control Panel	TD5325IB	3.2	110V	Complex	N1.2
Ultrasonic Cleaner underneath the table	USC 169	3.2	110V	N/A	N1.2

Supermarket

Stock No.	Description	New Location	above the shelf / on bench
IM1084-03	EDM Electronic Tungsten	N1.2	above
MC1246-01	Coil Balloon	N1.2	below

Sample IQ and Calibration Requirements

Table 1: Sample Catheter Installation Qualification and Calibration Document

Process Description	Equip #	IQ Protocol Status	IQ Report in Agile (Most Recent)	Pre & Post Move Calibration	CAL. #	Comments/ Rationale
Sub assembly 0.014", Plus	EQ1236C (Sanding Fixture)	I.Q. is not required for this project per Q.A. and Mfg. Engineering Review		No	NC1762	
	WD1 Soldering Station	I.Q. has not been required	N/A	No calibration required	6269	Delivered to Metrology Lab for calibration
Shape and Inspect Part	**EQ1453A (Press)**	**IQEQ1453 Rev. A**	**IQEQ1453A Rev. 1A**	**Required**	**5182**	
	EQ1236I (Sanding Fixture)	I.Q. is not required for this project per Q.A. and Mfg. Engineering Review		No	NC-1766	
Part Preparation	**EQ1280B (Seal)**	**IQEQ1280 Rev. A**	**IQEQ1280B Rev. 1A**	**Required**	**5178**	
Seal Placement and Taper	EQ1240O (EFD Dispenser)	I.Q. is not required for this project per Q.A. and Mfg. Engineering Review		No	NC-1794	
Final Inspection						
EDM Inflation Hole	TD53251B (EDM Machine)			Unit is not moving	5051	No relocation
	EQ1253E (Pressurized Air Source w/ Nozzle)			Unit is not moving	5059	No relocation
Countersink	EQ1236B (Sanding Fixture)			Unit is not moving	NC-1741	No relocation

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