

# *Manufacturing Process Continuous Flow Implementation with Quality Control Inspection and Bill of Material Standardization in a Medical Devices Company*

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*Abstract — The Manufacturing Area was composed of seventeen (17) product families around 191 Stock Keeping Units. Most of these families were manufactured in batch mode, while others in continuous flow. This project improved the value stream mapping, standardized product inspections and simplified the Bill of Material (BOM)/Routing structures. The Quality Control (QC) Inspection Rack, accumulated inventory, the delay caused by QC Inspections, damages and exposure to particle matter due to high manipulation were reduced. The subassemblies were standardized by size and shape in order to simplify the Inventory and the BOMs routings. A Kanban System was implemented to facilitate their deliver to the production area. The actual layouts and the process flows were analyzed using the spaghetti diagrams in order to observe and reduce the waste due to distance between operations and redundancies. Based on all the benefits that will be obtained was highly recommended the three phases implementation.*

*Key Terms — Bill of Materials (BOM), Continuous Flow, Inspection Standardization, Kanban Inventory System.*

## **RESEARCH DESCRIPTION**

A medical devices company was a leading multinational developer, manufacturer and marketer of innovative, life-enhancing medical technologies in the fields of vascular, urology, oncology and surgical specialty products. Expecting the highest levels of quality, integrity, service, and innovation, they were always improving the value stream of DM (Medical Device Product Division name), simplify Bill of Material (BOM)/Routing

structures, and streamline for consistent level loading production throughout the month.

The actual process was defined as a batch process where the materials were processed in finite amounts, discontinuous, interruptions in production between batches. Looking for a continuous improvement, this company was working to change the process to continuous flow using Lean Manufacturing and Six Sigma tools.

The Area was composed of seventeen (17) product families with around 191 Stock Keeping Units (SKU's). Most of these families were manufactured in batch mode, while others in continuous flow. The products BOM and Routings of these families varied much in structure, and were very difficult to maintain a Work in Process (WIP) tracking through all the area for these products. The overall DM Area demonstrated a low efficiency of 66% during the first six months of 2012. Also, the Mean Area Peak Value (MAPV) metric should be maintained above the target of 95%.

## **RESEARCH OBJECTIVES**

The objectives of this project were limited to improve the value stream, standardize product inspection and to simplify the BOM/Routing structures for the fifteen (15) families.

## **RESEARCH CONTRIBUTIONS**

With these changes was intended to: eliminate Quality Control (QC) Inspection Rack and accumulated inventory, reduce the delay caused by QC Inspections, reduce damages and exposure to particle matter due to high manipulation of the units, and facilitate the initiative of implementing

continues flow in the lines. These contributed to the production time reduction and at the same time the cost will decrease too.

Standardizing the QC Inspection with a tighter Acceptance Quality Level (AQL) from 0.65 to 0.40 and avoiding the particle matter due to high manipulation of the units the product Quality was increased. Customer complaints due to particle matter and Non Conformance deviation due to incomplete sampling were avoided.

## LITERATURE REVIEW

On the beginning of 20<sup>th</sup> the Manufacturing went through a revolution [1]. Assembly line were created by Henry Ford to obtain mass production on the Ford Model T. Henry Ford was concentrated on reduce time and waste, increase the quality and decrease the cycle times to obtain the vehicle with a lower cost. The intention of Henry Ford was decrease the model T price year on year, implementing all of these tools that pertain to lean manufacturing and Six Sigma implemented a long time before these concepts were known. All these strategies allowed him to reduce costs, even though he paid his workers well, and provide a great value product to the customer. Toyota later developed the Just in Time Model (JIT) as we know it today. This model is based on the continuous flow of materials through a process with minimal inventory or work in process (WIP) through the different value adding work stations or stages. JIT is pull system which adapts to consumer demand, and is usually implemented with a kanban system.

Kanban is an inventory scheduling system that allows companies to stock only needed components and arts in the production or distribution process [2]. Lean manufacturing systems use the Kanban as a technique to keep inventory levels as low as possible. In lean manufacturing, the process pulls materials through the production or distribution process. The Kanban system provides a signal for reordering or replenishing stock.

A Kanban system allows a company to reduce inventory levels, which reduces the cost associated

with stocking and storing materials in the organization. Cost reductions occur in the expense of the inventory itself as well as the cost of warehousing and maintaining inventory. Companies that use a Kanban system in a lean environment allow actual customer demand to determine the need for materials and not forecasts of the demand.

Lean manufacturing or Lean is a manufacturing term used to describe a manufacturing, industrial or service operation which operates with little or no type of muda (waste), thus making the operation very efficient and only consisting of value adding steps from start to finish, as can be seen in a value stream map.

The six sigma system is used by businesses to improve their quality management programs. The goal with six sigma is to reduce the number of defects created by a company. The goal is to reduce errors in the end product that the company produces, whether it's a product or service.

A value stream map is a special type of flow chart that is used to depict and improve: the flow of the thing being processed, and information that controls the flow of the thing being processed to be as free as possible of the 7 types of waste (Muda). The seven types of waste defined by Taiicho Onno (Toyota Executive 1912-1990) are:

- Defects;
- Overproduction of things not demanded by actual customers;
- Inventories awaiting further processing or consumption;
- Unnecessary over-processing (for example, relying on inspections rather than designing the process to eliminate problems);
- Unnecessary motion of employees;
- Unnecessary transport and handling of goods;
- Waiting for an upstream process to deliver, or for a machine to finish processing, or for a supporting function to be completed, or for an interrupted worker to get back to work.

The Value Stream Tool is used to graphically illustrate and analyze the flow of the thing being

processed and the information needed to process it, highlight problems and proposed countermeasures - in highly visual ways, to focus direction for your lean transformation teams and serve as a dashboard to monitor and continuously improve [3].

The Value Stream Tools / Mapping are part of our continuous process improvement. The need to implement the continuous flow is intended to reduce cost, time and steps that represent waste instead value added activities. There was a need to improve our process without affecting the quality on our process. Quality includes all the testing, and systems that warranty that products efficacy, patient safety and prove that the industry is capable to produce within the specification consistently. In order to maintain the quality as part of the process a risk assessment was conducted. The risk assessment considered the process flow identifies on every step the error, the defect that this will cause their severity and the occurrence level of them.

The actual Process flow chart will be the following: Ring Cut and Welding stations, QC Inspection, Ring Stock on the Inventory Rack, Sewing, Lamination and Final Cut. The QC Quality Inspections are performed on three different standards, 100% inspection, 0.40 acceptance quality level (AQL) and 0.65 AQL. In the actual process state the inspections vary between the product families. This could ends on sampling errors such as wrong quantity taken for inspection. The acceptance quality level is the greatest percent that is permitted of defective units on our process [4]. The 100% is low risk inspection, in this kind of inspection all the units are evaluated by QC. But is time consuming and the cost is higher. On the AQL inspection, there is always the probability of a defective unit that passes the inspection and be delivers to our clients / patient. For this reason is so important the way of establish the Acceptance levels. The sampling plan to establish the AQL could be develop by the manufacturer utilizing the Operating Characteristics. When the acceptance criterion is established there are two type of error that could be part of the process: Alpha (type I)

and Beta (type II). Alpha is the kind of statistical error that can reject products that are not defective. Beta is the kind of error that can accept product that is defective. On the error type I the producer is affected rejected good material, on the other side error type II can deliver defective items to the patients taking a bad decision.

During the Second World War ordnance tables and procedures were generated in 1940's and these were developed in the Army Service tables. When the war ended the Navy Division perform other tables. At the end of the war, the Navy also worked on a set of tables. The Statistical Research Group at Columbia University performed research and outputted many outstanding results on the sampling corresponding to attributes process. The combination of these three was called Military Standard 105A. This standard are be modified through years and in 1971 they were adopted by the American National Standards Institute as ANSI Standard Z1.4. Also the standard was adopted in 1974 with minor changes by the International Organization for Standardization as ISO Std. 2859. The latest revision was performed on 1989 and is Military Standard 105E. This standard includes three type of sampling: normal, tighter and reduced. The inspector applies the type of sampling according to the scenario and the Manufacturer Operating Procedure that applies. The sampling plans establish the quantity of samples to be taken and the quantity of defects that can be accepted to consider the lot within specifications and not rejected. When a greater sample size is selected the probability of accept lot with the correct or less defect rates and reject lot with higher defect rates.

## METHODOLOGY

This project intended to identify the causes of the production output variability per month, the simplification of the BOM / Routing structures, as well as the evaluation for continuous flow and / or mix cells to improve the value stream. This project was divided in three phases. The phase I covered all the changes on the BOM Routings in order to

simply the manufacturing process. A Kanban Inventory system was necessary within this phase to assure the availability of the necessary components and / or sub-assemblies required to accomplish the current productions schedule. Phase II covered the entire necessary layout changes in the production areas in order to improve the value stream mapping and Phase III the standardization of the Product Inspections.

## RESULTS AND DISCUSSION

On Phase I the BOM routings were redesign in order to divide the monofilaments operations as a subassembly from the end item. On this way a Kanban Inventory System was developed and feed with the subassemblies. On the actual BOM routings the monofilament can be at the start of the operations or at the middle. If is at the middle of the manufacturing the process could be stop and wait until this monofilament is created. On the future state the monofilament was stock on the Kanban Inventory System by item number and size. The monofilament was created on its own BOM. The process was continuous flow for the monofilament area and on the end item area. These subassemblies were called on the end item BOM as a component. Following are the actual BOM Routings and the future state for them (Figures 1 to Figure 2).

The subassemblies were be standardized by size and shape in order to simplify the Inventory and the BOMs routings. On the current BOM routings there are thirty five subassemblies with the proposing changes and the standardization of the subassemblies there will be reduce to twenty seven. Following are the Subassemblies (Figure 3).

The Phase II the actual layouts and the process flows were analyzed using the spaghetti diagrams in order to observe the waste due to distance between operations and redundancies. On the current layout (Refer to Figure 4) the area was about 6,340 sq / ft and is divided into a high variety of product flow designs. Some areas worked in batch and others on partial continuous flow. The

movements and the traveling distances were high sources of waste to the daily operations (Refer to Figure 5). The processes became more complex only by its physical flow complexity and other types of waste such as inventory, and overproduction are additional outcomes of this complexity (Refer to Figures from 6 to 9).

On the current Value Stream Mapping (VSM) there were seventeen (17) product families to streamline for better flow. Those were divided into ten (10), the left side VSM picture and seven (7) at the right side (Figure 10). Their manufacturing process and equipment flow were different for these two groups of products. The continuous flow within these two lines depended on their independent cycle time line balancing scenario. There was excess of waste due to the batching process, there was an inventory in between of each step, as well as a line clearance associated to it.

On the future Value Stream Mapping the proposed design improved the following: shorter cycle times, simple process routing to follow, Work in Process (WIP) reduction, increased output due to reduction in changeovers, setups, line clearances and increase quality response time. To achieved this future VSM (Figure 11) the Inspection was consolidated, and the BOM routings standardized implementing the Kanban Inventory System (Refer to Figure 12).

On the Phase III the Quality Control (QC) Inspections were standardized. In the actual process there were three different AQL levels of inspections, 0.40, 0.65 and 100%. The product was inspected for no surface foreign matter, soil, oil, dirt, verify that ring is present, ring shall not be exposed, burned, flattened, cut, damaged among others. The inspections were executed by Quality on Batch process causing delays on the manufacturing process. The manufacturing process included a 100% product inspection for the sub-assemblies by the manufacturing personnel; also there was a QC verification that ensures that the 100% verification is effective and the documentation audit All the QC inspections were standardized based on the AQL 0.40 in order to

facilitate the understanding of the QC Inspection process and avoided the errors of incomplete samplings. QC Inspection was performed during

the manufacturing process or at the end on Batch Process.

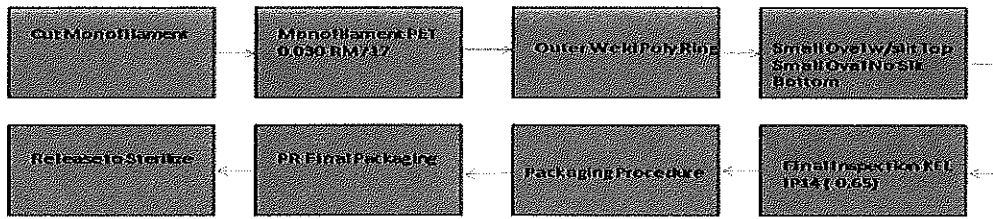


Figure 1  
SKL Actual BOM Routing

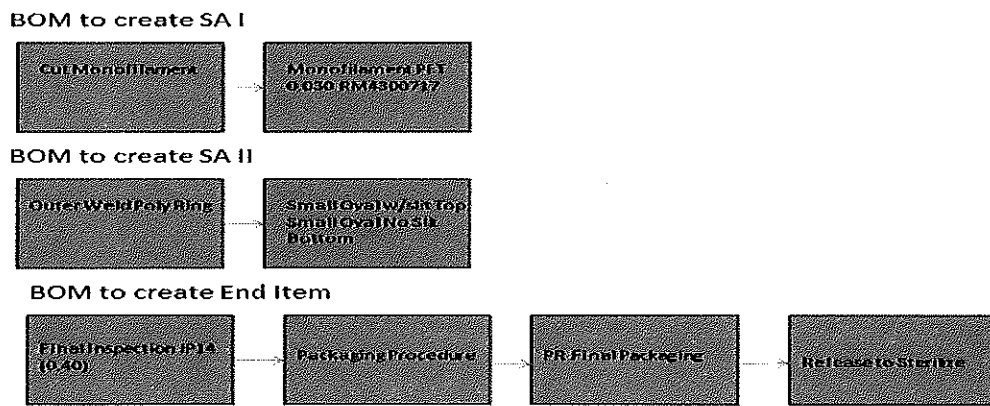


Figure 2  
SKL Future State BOM Routing

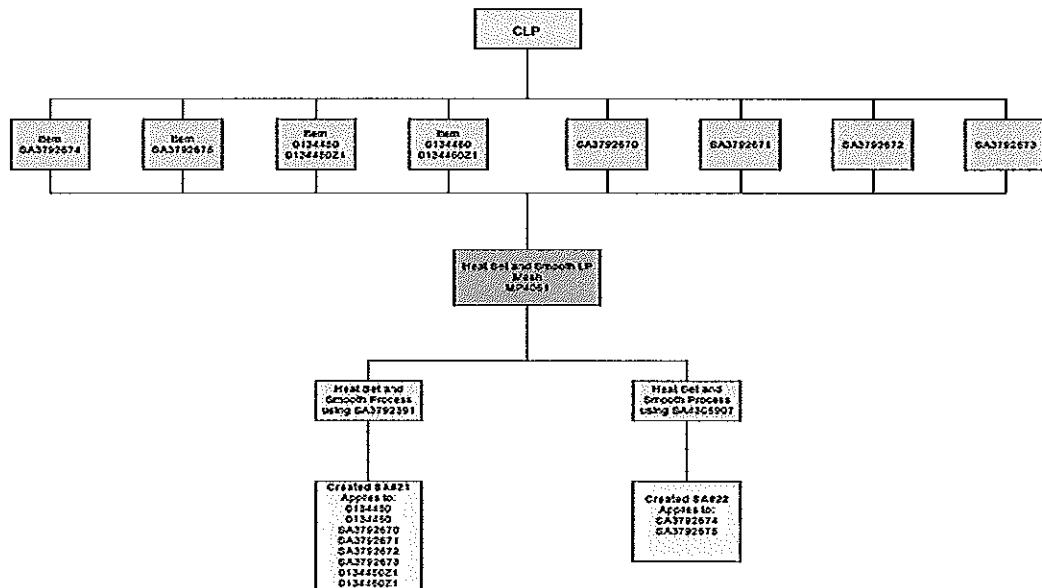


Figure 3  
CPL Subassembly Standardization

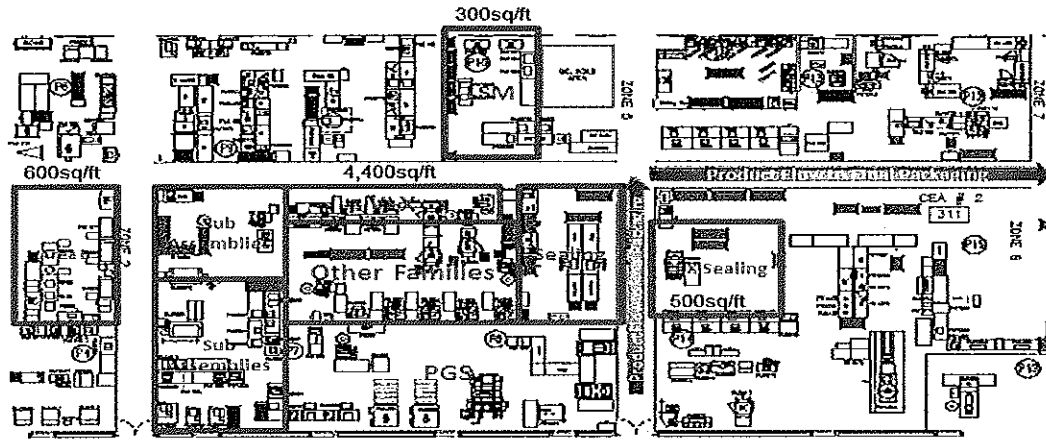


Figure 4  
Current Layout

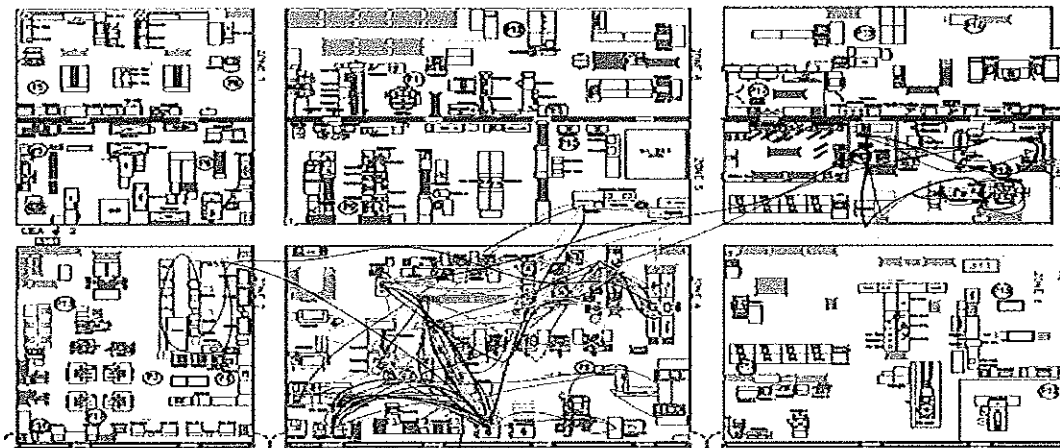


Figure 5  
Spaghetti Diagram

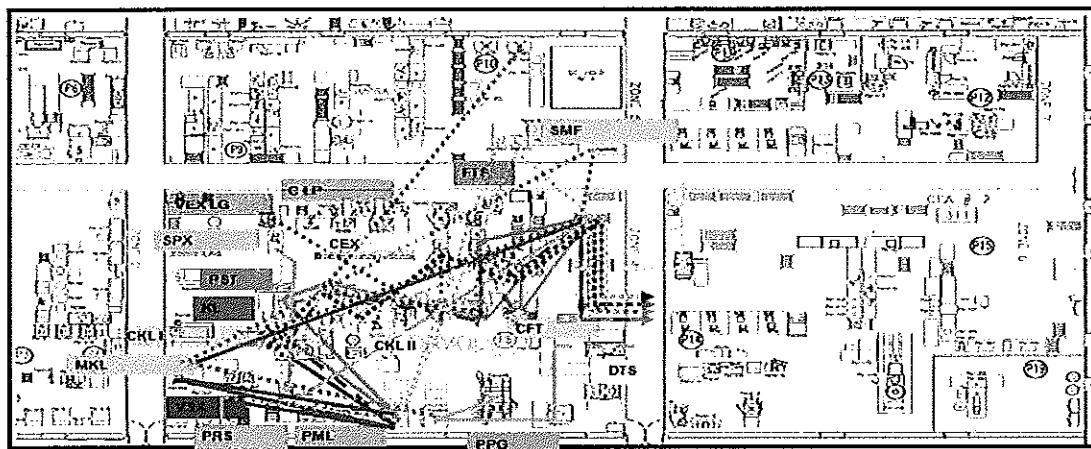


Figure 6  
Product Family Process Routes

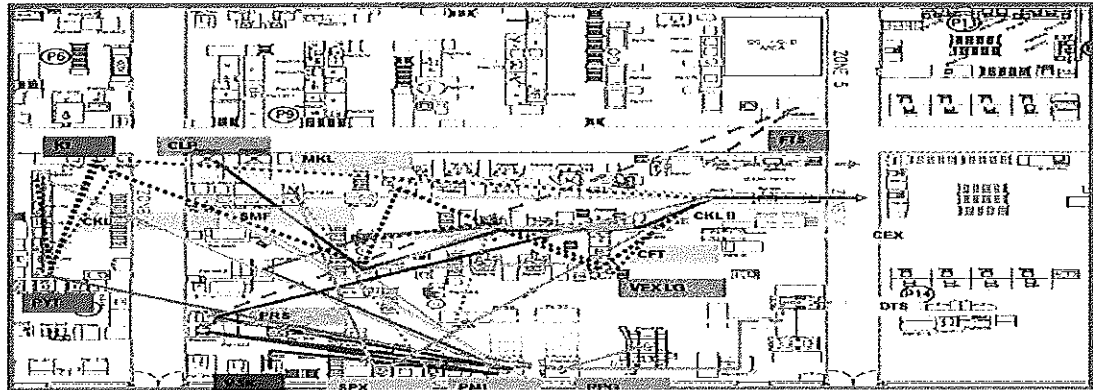


Figure 7  
Proposed Product Family Process Breakdown

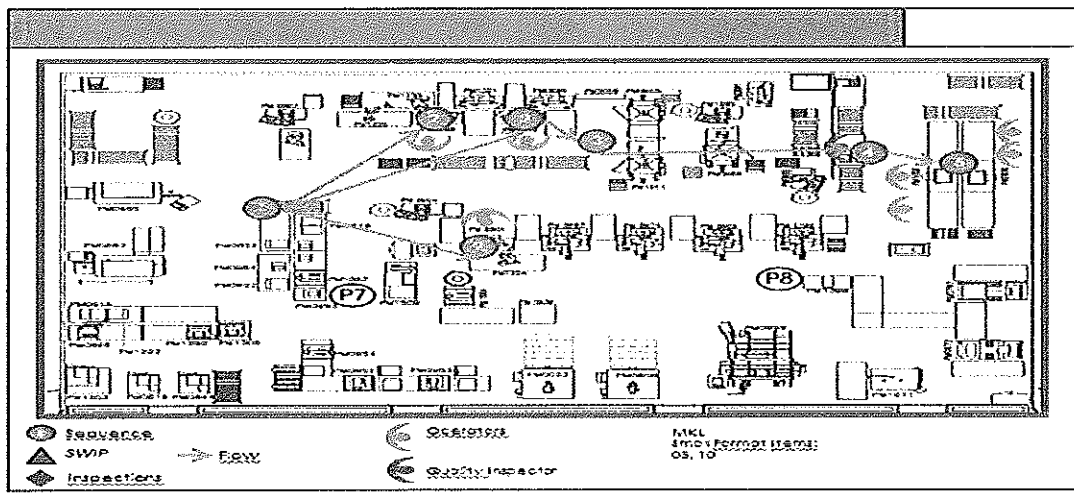


Figure 8  
MKL Small Items Process Layout

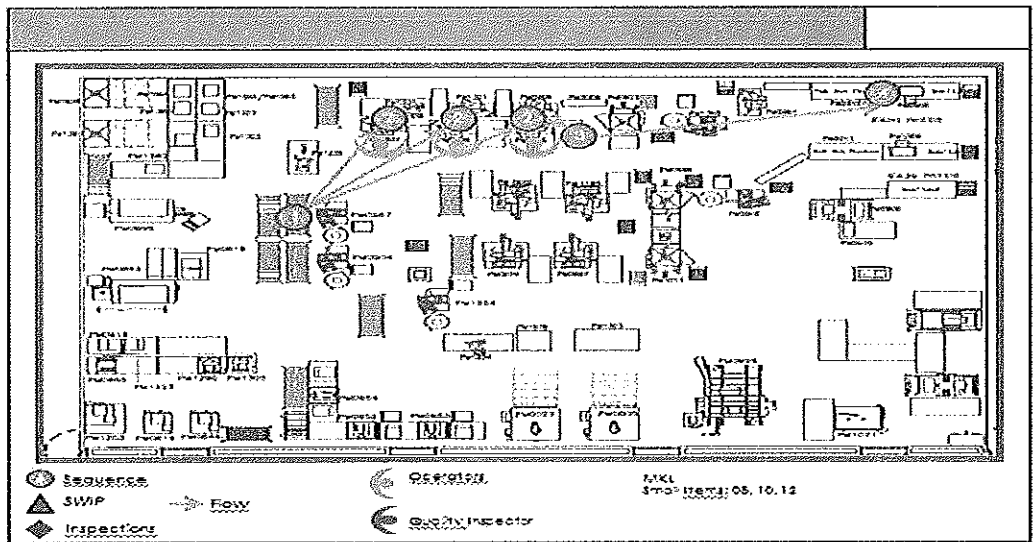


Figure 9  
Future State MKL Small Items Process Layout

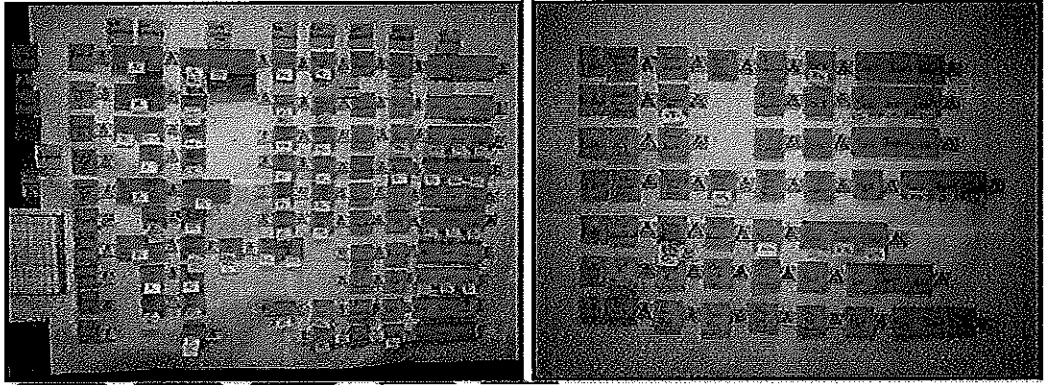


Figure 10  
Current Process VSM

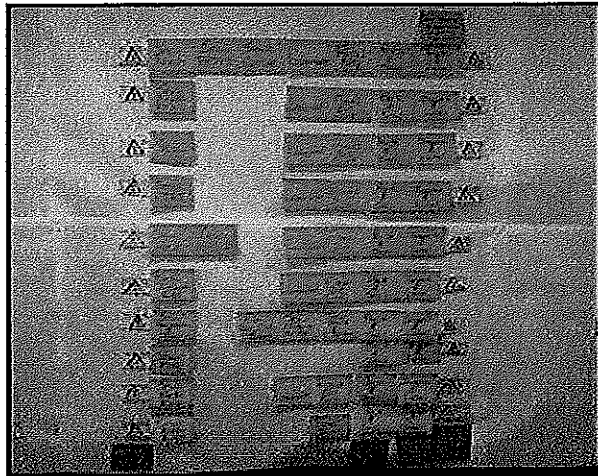


Figure 11  
Future State VSM

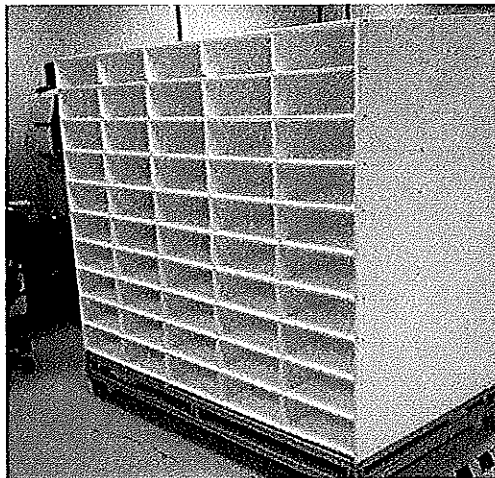


Figure 12  
Kanban Inventory System



## CONCLUSION

The changes proposed were achieved on the three phases as: dividing the BOMs, creating a Kanban Inventory System, Improve the VSM and standardizing the QC Inspections reduce damages and exposure to particle matter due to high manipulation of the units. A kanban was created for the Sub-assemblies and the BOM will call the SA from the kanban to create the End Item. This division facilitated the continuous flow in the manufacturing lines. With the implementation of these changes:

- Area headcount was reduced on 19% (from 37 to 30 operators);
- Packaging and sealing rework was decreased on 10-30% (from 15-40% to 5-10%);
- Weekly production standard deviation was decrease on 68% (from 10.185 to 3.227);
- 10% Reduction of Defects Related to Particulates + Early Defect Detection;
- 50% Reduction WIP;
- Lead Time Reduction (Avg. from 3 to 1 Day);
- Continuous Flow and Reduced Cycle Time Leading to Increased Line Efficiency.

Based on all the benefits that will be obtained is highly recommended the three phases implementation.

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