

# ***High Volume Manufacturing Process Transfer***

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**Abstract** — *Transferring a high volume manufacturing product line requires a detail level of information and analysis which could result in either success or failure. Knowledge of the process and product is critical when new technology for the manufacturing process is required. In addition, forecast of a product, especially in high volume product lines, plays a decisive factor determining the moment of equipment investment. Automation has an important role in this environment by maintaining a competitive market as well as higher quality with a stable and robust process. Not only quantity but also quality is a key factor in the medical device and pharmaceutical industries. Company's reputations are based on the manufacturing culture which is reflected by the customer. At the end of the day, what is important is what the customer thinks about the product in his hands and not where it was made. It must be manufactured under the regulations and manufacturing standards that he trusts.*

**Key Terms** — *Proper Approach, Clear Analysis, Accurate Forecast, Detailed Implementation And Contingency Plan.*

## **BACKGROUND OF THE PROBLEM**

Acme Company has decided to transfer all manufacturing operations to Puerto Rico from their Headquarters facility in the West Coast of United States.

## **PROBLEM STATEMENT**

The initial goal was to increase final inventory to a minimum of 3 months, to be able to transfer all the equipment/operations at the same time. After one year, this goal was not reached. At the same time that the operation is transferred to the Puerto

Rico facility, it also needs to be capable to supply an increasing demand. The current equipment has reached almost 85% of their maximum capacity and can not meet customer demand in the near future. Since the transfer was announced in the current manufacturing facility, the most knowledgeable and capable employees left the company. In order to maintain the production line in operation, a complete team of personnel from operators to management level were hired in Puerto Rico and temporarily transferred to the facility in the east coast to support the operation and to be trained and transfer the product at the same time.

## **SIGNIFICANCE OF STUDY**

Since sales are continually increasing, and the machines have a fixed capacity, a study needs to be conducted in order to transfer the operation and at the same time be able to supply the increasing demand. In addition, a detailed phase-in / phase-out conversion transfer has to be clear so no back orders will occur during the transfer. A Build Plan and production schedule must be aligned with the market forecast since transferring manufacturing facilities requires a synchronized market demand supply plan.

## **PRODUCT DESCRIPTION**

The product transfer consists of two medical device assemblies whose difference is their fill capacity. (For this article, these products will be called A & B).

Sales mix ratio are about 50% / 50% for product A and B. Sales are expected to be at fifty million units per year for Fiscal Year 2013. The current equipment's capacity is approximated 35

million units per year. This means the current production is at maximum capacity.

The goal is to increase capacity to one million units per week which would cover at least up to Fiscal Year 2013. It's also expected that the sales will be stabilized by Fiscal Year 2013 with a minimum incremental sales due to a similar product will be launched to the market and eventually balance the market sales between both products.

Each product uses a total of eight components. Six of them are common and the other two are different from each other. In addition, one of the common components is used twice on each assembly.

- The current equipment process is:
- Two sub-assembly automated machines produce common sub-assemblies for both products.
  - Two automated final assembly machines. One of them can only produce assembly A while second machine can produce both assemblies (A & B).
  - One packaging line composed of a 3 different systems; loader, primary packaging and secondary packaging. This packaging line has the capability to pack both assemblies.

### ANALYSIS AND ASSESSMENT

A forecast needs to be established in order to perform an accurate analysis.

Suppliers' capacities also need to be taken in consideration to order to have the same leverage thru the supply chain flow (supplier-manufacturing-sales). Additional resources are needed to maintain the operation at the current manufacturing facility in the west coast. Capacity analysis per equipment also needs to be defined to determine the maximum production and define new equipment if necessary. An action plan and or a new strategy need to be established in order to achieve and complete company's goal. And last but not least important, budget requirements needs to be determined.

### ANALYSIS RESULTS

Chart 1 below shows the forecast from Fiscal Year 2005 to Fiscal Year 2013, actual sales and machine capacity.

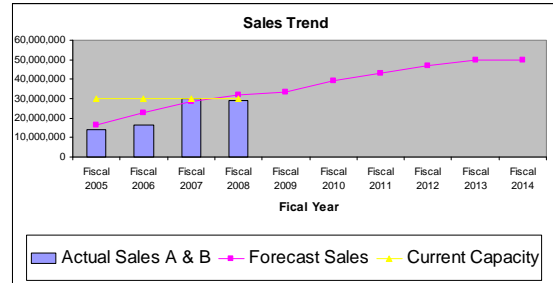


Chart 1  
Sales Trend, Actual Capacity

As noted in Chart 1, actual sales already get to the machine capacity during Fiscal Year 2008. Machine capacity refers to what the production line can produce per week.

Supplier capacities were verified and no new equipment is required to get to the goal of one million per week. Supplier's capacities are as follows:

Table 1  
Supplier's Capacity

Supplier	Component	Goal	Actual	Balance	Part Common / Individual
ACME 1	NE	1,000,000	1,040,000	+40,000	C
ACME 2	TG	1,000,000	1,432,000	+432,000	C
ACME 3	SE	1,000,000	1,400,000	+400,000	C
ACME 4	ST	1,000,000	1,600,000	+600,000	C
ACME 5	SC	1,000,000	1,600,000	+600,000	C
ACME 6	OR	2,000,000	2,400,000	+400,000	C
ACME 7	PLA	500,000	555,000	+5,000	I
ACME 8	BAA	500,000	744,000	+244,000	I
ACME 9	PLB	500,000	700,000	+250,000	I
ACME 10	BAB	500,000	700,000	+250,000	I

Both assemblies share several components, these common units required one million per week capacity. The unique parts require 1/2 million per week. Since most of the highest experienced personnel left the company, it was also required to

hire and train technical and engineering personnel to keep the operation running.

A total of five machines were in production, two of them for subassembly level other two for final assembly and one for packaging line. The packaging line uses an integrated robot loading system to feed the parts. Personnel for the entire production line were divided as follows; five Technicians and three Engineers. Engineering support was available during 1<sup>st</sup> shift only. The machine ran two shifts, ten hours each.

These technical personnel were balanced between all machines which represent about 0.8 technicians per machine and ½ an engineer per machine.

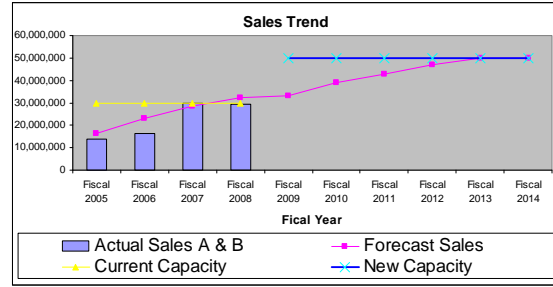
Table 2 shows current machine capacity and the Fiscal Year 2013 goal.

**Table 2  
Machine Capacities**

Line	Goal	Currently	New equipment required Y / N
Machine 1 Sub - Assy.	1,000,000	630,000	Y
Machine 2 Sub - Assy.	1,000,000	700,000	Y
Machine 3 Assy.	500,000	250,000	Y
Machine 4 Assy.	500,000	250,000	Y
Machine 5 Packing Line	1,000,000	700,000	Y

Based on current equipment capacity, new equipment was required to meet sales for at least the next five Fiscal Years (Fiscal Year 2013).

With the new capacity, the company will be capable to supply the demand at least for the next five Fiscal Years. Chart 2 reflects need for capacity based on sales forecast, current and new machine capacity.



**Chart 2  
Sales Trend, New Capacity**

Fiscal Year 2014 was added to reflect the stabilization in sales further the Fiscal Year 2013.

All new equipment will be installed at the new facility in Puerto Rico. This added capacity in parallel with the current capacity in the west coast facility ensured the program's requirements were met. Table 3 shows the new machine's combined capacities. The new capacity requirements will be in accordance with the analysis reported in Chart 2, one million units per week.

Complete assembly and packaging process must meet or exceed that number.

**Table 3  
New Machine Capacities**

Line	Currently	New Machine	New Combined Capacity	Goal
Machine 1 Sub - Assy.	600,000	-----	1,600,00	1,000,000
Machine 1 new Sub - Assy.	-----	1,000,000 (new design)		
Machine 5 new Packaging Line	700,000	-----	1,400,000	1,000,000
Machine 2 new Sub - Assy.	-----	700,000 (duplicate)		
Machine 3 Assy. A	250,000	-----	obsolete	-----
Machine 4 Assy. A or B	250,000	-----	1,250,000	1,000,000
Machine 4 new Packing Line	-----	1,000,000		
Machine 5 Packaging Line	700,000	-----	1,700,000	1,000,000
Machine 5 new Packaging Line	-----	1,000,000		

- Machine 1 will be kept as a back up. This machine is capable to produce both sub-assemblies. A new design machine was developed with 50% more capacity.
- For Machine 2, it was decided to duplicate the current machine due to the complexity and the proven reliability of the current equipment. This is still a benefit since both machines can now be used at the same time with fewer personnel and less machine time.
- Machine 3 is the one that can only produce one type of the products. This machine was taken out of service (obsolete).
- Machine 4 will be kept as a back up. This machine is capable to produce both products. A new designed machine 4 is capable of four times capacity with improved quality and new vision and self testing in the process.
- A new machine 5 (Packaging Line) was built. It's capable to run 50% more parts with fewer personnel and less machine time allowing to perform any maintenance during the off time period as well for the Machine 2. The current machine 5 will be used as a backup.

In addition, this machine has the capacity not only to pack this product but also can pack any other product that could be transferred in the future to the Puerto Rico facility. The only need would be to exchange the forming and sealing mold since the frame of the machine is similar for any of packaging of this type.

In addition to increasing the new capacity, existent equipment can be integrated to cover any additional demand required beyond Fiscal Year 2013.

During this new machine acquisition, not only capacities were considered but all past and present quality issues either product itself and/or the interaction of the machine with the assembly were also considered during the equipment design.

Also, new inspections were implemented into the new equipment to prevent any defect issue that the customer could receive.

Now, not only the production line will have the capacity to cover the next five Fiscal Years, in

addition, will have a better quality product for the customers providing a quality level exceeding Six Sigma.

With this new capacity, the manufacturing site will be capable to meet market demand at a lower cost since new equipment will be capable to produce a higher quantity with fewer personnel.

Budgetary net present value analysis was not a restriction since these acquisitions were justified based on increasing sales demand and the fact that the current equipment reached the 85% capacity. However, most of the new equipment was paid back within two years or less. Based on industry typical practice and text books investigations, it's recommended to have at least a 17% additional capacity from the current or projected demand. This "extra" capacity is called as "capacity cushion". This capacity cushion will allow the company to absorb and meet any fluctuation on market demand. Once pass the 85% "83%" to be specific, company should invest in additional capacity in order to keep up with the market and not get caught with the famous and not welcome word "backorder".

After machine acquisition, implementation and integration to production of the new equipment at the new facility in Puerto Rico will be starting as they arrive to the facility.

Power law unit model type formula was used to determine the learning effect in order to have the new line completely capable to sustain at least the current sales.

Since it's an automated process, learning curve results with least curve change. Slope of 96 was used given that it's an automated process with some operator interaction.

Equation (1) Underlying Power Law formula was used to calculate the learning curve.

$$y = ax^b \quad (1)$$

Where "y" is the power law value, "a" is the theoretical labor hours required to build the first unit produced, "x" always represents the number (count) of an item in the production sequence (unit

#1, #2, #3, etc) and “b” is called the natural slope which represent the rate of learning.

On Table 4 shows the values obtained from the calculation of the power law formula, from 100,000 units to 850,000 units.

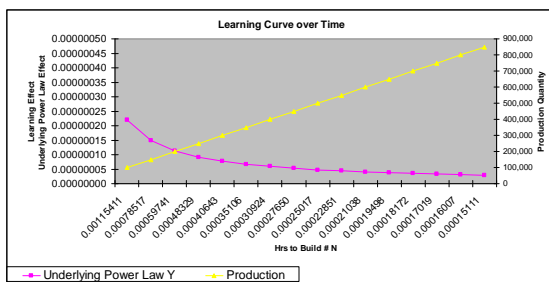
**Table 4**  
**Power Law Data Results**

Underlying Power Law Y	Production
0.00000022	100,000
0.00000015	150,000
0.00000011	200,000
0.00000009	250,000
0.00000008	300,000
0.00000007	350,000
0.00000006	400,000
0.00000005	450,000
0.00000005	500,000
0.00000004	550,000
0.00000004	600,000
0.00000004	650,000
0.00000003	700,000
0.00000003	750,000
0.00000003	800,000
0.00000003	850,000

Equation (2) represents the Unit model Formula used to plot the graph on Chart 3.

$$H_n = H_1 n^b \quad (2)$$

Hours to build unit #n =  $H_n$  =  $H_1$   $n^b$ 
Hours to build unit #1  $H_1$   $n^b$ 
Unit number  $n$   $n^b$ 
Natural slope  $b$



**Chart 3**  
**Learning Curve over Time**

### IMPLEMENTATION PHASE

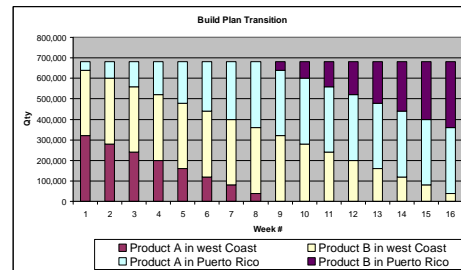
In order to have a smooth transition and not affect any of the product lines, an implementation

strategy was developed such that there would be no impact to customer orders. Certain inventories were allocated for some countries that have not yet approved the new manufacturing facility.

The new manufacturing site will start only with the one of the two products. This line will be running parallel with the current facility for a predetermined time. The new production line will increase as personnel gain confidence and get adjusted to the equipment. At the same time, the current manufacturing facility will be decreasing their production line in balance with the new facility output. Upon completion of the first product, the second product will be starting at the new facility. As the new facility’s production increases the current facility will be decreasing until full shut down. This was called adaptation phase.

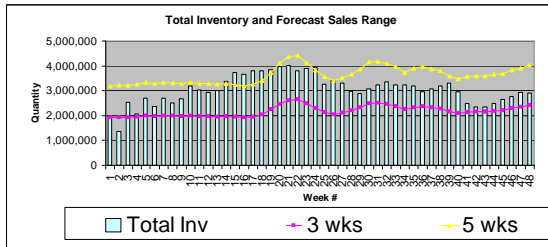
During this process our suppliers had a transition phase as well. Instead of delivering the raw materials to the current facility, they had to split the deliveries as the new facility increased output. Chart 4 present the ramp down/ramp up of both facilities.

Planning and purchasing at the new manufacturing site kept a synchronized wave of material in such way that at any time neither actual nor new manufacturing sites ran out of parts at any moment.



**Chart 4**  
**Build Plan Transition**

Chart 5 represents the relation of the sales vs. actual inventory range. Target inventory is 4 wks with a range of plus minus one week. Since sales vary per week, dynamic inventory is required to maintain it with in the company’s target (4 weeks).



**Chart 5**  
**Inventory and Sales Forecast**

Chart 5 provides a complete view of inventories and sales relation. As you can see at the end of the chart shows a low number of inventories. Reason for this is due to the proximity of the end of the Fiscal Year.

The goal is that manufacturing stays in between the three and five weeks of inventory based on sales. This curve also tells you that the sales are not steady across the time. Fluctuations respond more due to seasonal sales by automatic replenishing or quarter sales cycle, etc.

In order to minimize change over, Chart 6 will show an example of the production mix in the manufacturing line.

**Table 6**  
**Manufacturing Line Flow**

Traditional Manufacturing Plan, Multiple Flows								
Week No.	1	2	3	4	5	6	7	8
Product A	345,600	345,600	345,600	345,600	345,600	345,600	172,800	345,600
Product B	345,600	518,400	518,400	518,400	518,400	518,400	604,800	604,800
Changes	2	2	2	2	2	2	2	2

Maximized Manufacturing Plan, Single Flow								
Week No.	1	2	3	4	5	6	7	8
Product A	345,600	345,600	345,600	345,600	345,600	345,600	172,800	345,600
Product B	345,600	518,400	518,400	518,400	518,400	518,400	604,800	604,800
Changes	1	1	1	1	1	1	1	1

## CONCLUSIONS

After completing the implementation of this project the following items were learned:

- Perform a detail analysis from the beginning including sales forecast and possible show stoppers such as delays on new machine construction, contingency plans in resources and more realistic learning curve as well as review the forecast projection.

- New equipment acquisition, especially when is a complete new design, might represent a huge impact in the success or failure of the implementation / transfer plan of a particular manufacturing line.
- As many people know, team work represents a vital role in any implementation and or technology transfer. Meeting often across facilities.
- Never Assume. Assumptions can take you in a wrong direction causing a loss of time and effort.

## RECOMMENDATIONS

- Delays on the process of new equipment acquisition must be taken in consideration despite the urgency of the implementation since this unexpected delay can even cost much more at the end of the process due to budgetary distribution, expected product cost reduction between plants, etc.
- During the design of new equipment is very important to look back and see what type of defects does the product has and in what manner the new equipment design prevent defects that could get to the end users.
- In addition, what kind of product defects does the current machine produce and how can the new machine improve defects by either automatic inspections or testing as the machine assembles the product.
- Communication between both facilities represents also a key factor during document exchange, issues with parts, technical and engineering support. Clear and effective communication based on detailed process plan can literally prevent disasters during any product transfer.
- Having adequate personnel is also an important factor to consider at the moment of the personnel integration to the team. In this team you must feel ownership for the production line.

- Contingency plan must also be considered based on the level of risk taken from the initial personnel communication about the product being transferred to final implementation process.
- A better sales forecast would prevent on equipment out of capacity situation and preparation of earlier plan to cover these sales and at the same time transfer the product line. In addition, since initial goal was to build certain inventory and not having that forecast vision it represented and huge delay by just trying to build some inventory that never could be reached. Instead of plan to cover the sales demand by acquiring new equipments that would eventually used to support the transfer.

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