AC 2003-1163: LEAN MANUFACTURING TECHNIQUES REDUCE LEAD TIME FOR IMPLANT PRODUCTION

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Introduction

The industry project described here was completed as a part of a graduate student's work in the Master's Degree program in the School of Technology at Purdue University. The project was done at an orthopaedic implant (prosthesis) manufacturing plant in Indiana and deals with the implementation of lean manufacturing strategies for improved productivity. The prosthesis is used in human joint replacement surgery. Degeneration of the bone cartilage from physical damage or arthritis makes the joint stiff and painful. Bone cartilage and damaged bone ends are replaced with metal and plastic components to restore movement and function to the joint. The number of joint replacement surgeries was expected to increase 11-12% by 2002 (Pharmaceutical and Healthcare Industry Quarterly Review, 2000). To meet the increased market demand, the implant manufacturer needed to increase its production capacity. The Lean manufacturing process uses fewer resources compared to the traditional manufacturing process to manufacture the same products (Rao, 1999). It eliminates waste, reduces lead time, increases product quality, reduces cost of materials, develops the workforce, and implements continuous improvement process (Hall, 1987).

This study examined the relationship between the current global shoulder humeral head (Figure 1) manufacturing process and improvements implemented by lean manufacturing techniques. The humeral head is one of the three components for total shoulder joint replacement. This paper describes the evaluation and implementation of the lean manufacturing strategy that reduced the production lead time for manufacturing of the humeral head. The objectives of the project were to reduce lead time, Work-In-Process (WIP) inventory, and improve material flow, thus improving the productivity.

Implant production and lean manufacturing strategies

The three components (humeral head, humeral body and glenoid) are produced independently of one another. The plant layout is organized with manufacturing operations grouped by process type, not by product types. For example, the humeral head is produced using equipment located in many different areas of the manufacturing facility (Figure 2). Layouts that follow this structure are classified as birdcage layouts by Toyota. Birdcage layouts do not facilitate efficient workflow or balanced work loads, but instead increase WIP inventory and lead times (Monden, 1993). The process grouping requires the product to travel from one location to another location so that specific operations can be performed. The product will move to each of these locations and be placed in WIP inventory. The product will wait in each WIP location until the daily production schedule releases the order for processing. The process grouping of the facility has one WIP location at each operation. Many operations have two WIP locations, one for incoming and one for outgoing work. Figure 3 shows the complexity of the workflow at its current-state in the production of shoulder heads. The variables associated with implant manufacturing efficiencies are lead time, amount of waste materials, rework on finished products, and WIP inventory.

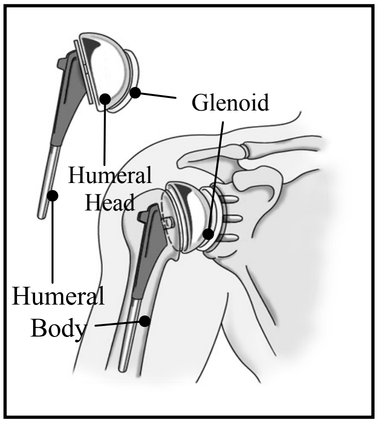

Figure 1. Shoulder implant showing humeral head, body, and glenoid implant.

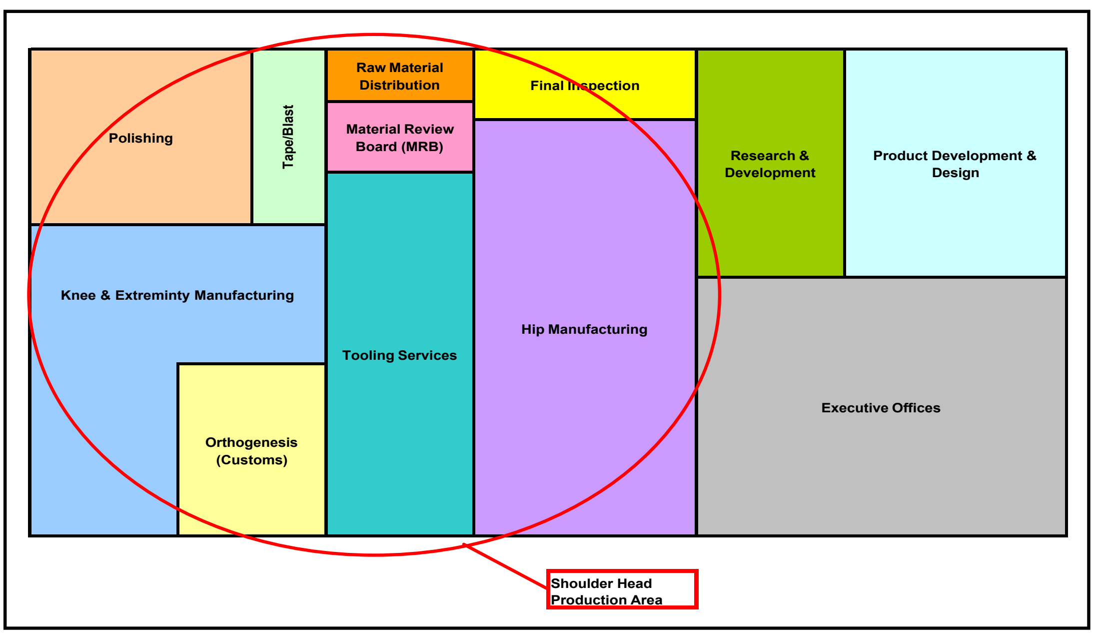

Figure 2. Block diagram showing overall plant layout grouping.

Existing lead time for humeral head production was at least 18 days. In the year 2000, the number of humeral heads produced was 13,877. The annual material waste or scrap cost (3.3% scrap) was $97,000; and $61,000 was spent on rework (16% rework), which also increases WIP inventory. The goal of this project was to reduce the lead time to 10 days or less through implementation of lean manufacturing techniques. Lean manufacturing strategies implement practices that include reduction of inventory, WIP, and the amount of waste during the production process (Jusko, 2000). The elimination of non-value activities is the goal of lean manufacturing.

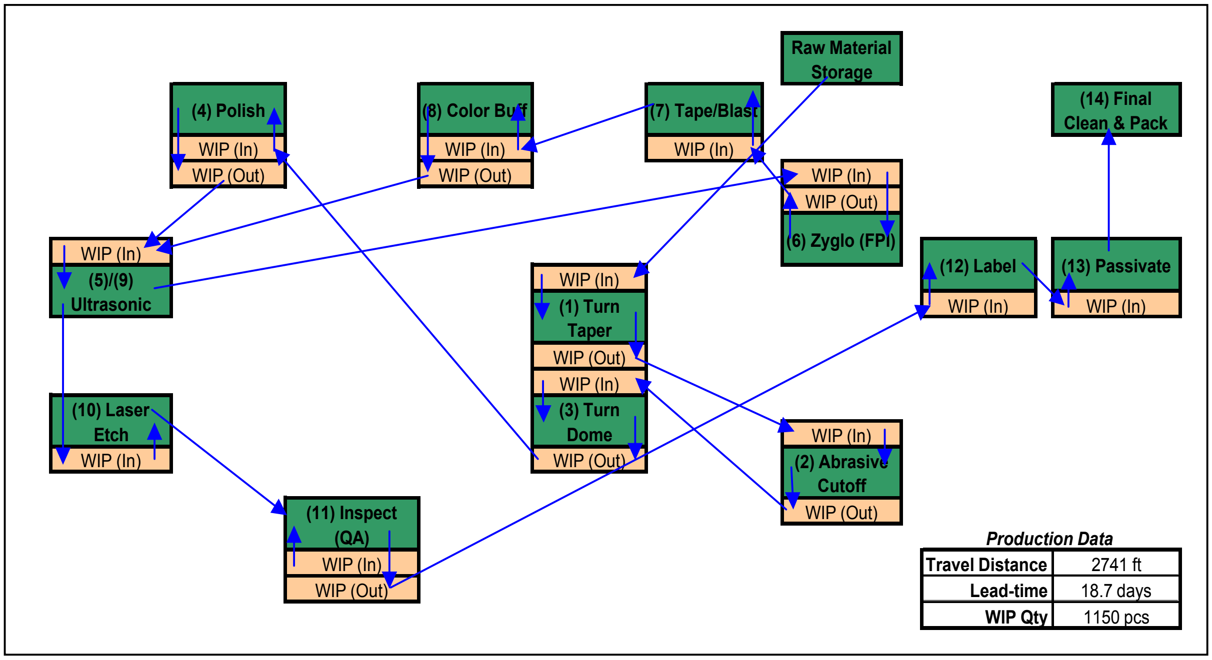

Figure 3. Block diagram showing layout by process type.

Lean Manufacturing

Lean manufacturing is a production philosophy that strives to eliminate waste in all activities within an organization (Kraebber, 2000). The elimination of waste allows a product to flow through the manufacturing process in smaller quantities than that required by the batch-and-queue process. Lean manufacturing incorporates a pull system to move the product through the production process. Products are sent to subsequent operations only when succeeding operations have signaled they need more products. The use of the pull system allows smaller quantities to be produced while eliminating WIP inventory. Taiichi Ohno discovered that it actually cost less to produce products in small lot sizes instead of large batches (Jones, Roos, and Womack, 1990). Small lot sizes reduce the carrying cost for large batch inventory, and non-conforming products were discovered more easily. Lean manufacturing gives the producer the flexibility to produce only the necessary components to meet customer demand.

Lead Time

Lead time is the amount of time required to convert a product from raw material (e.g., casting, bar stock, forging, etc.) to a finished product. Lead time is a productivity metric that is commonly used because the data can be easily tracked or measured. Lead time is the difference between the times recorded as the product is released as a raw material, and when the product is completed (Schonberger, 1986). Tracking of lead time is necessary in the production of components because this is the time the customer will wait to receive a finished product. Reduction in lead time allows the manufacturer to more quickly recover investments in time and material. Lean manufacturing addresses lead time by removing non-value-added steps that create waste in the production cycle (Nyman, 1992).

Value Stream Map

Every value-added and non-value added activity required to bring a product through the production flow from raw material to the customer is called the value stream (Rother and Shook, 1999). The purpose of value stream mapping is to highlight the sources of waste and eliminate them by implementation of a future-state value stream. Documenting the current state of the process is important so that all value-added and non-value-added operations can be visualized. The non-value-added steps in the production of shoulder humeral heads are (a) travel distance, (b) WIP inventory, (c), material waste, (d) rework, and (e) extra inspection operations, which all increase production lead time. Value-added steps in the production of shoulder humeral head include (a) machine, (b) polish, (c) blast, (d) fluorescent penetrant inspection (FPI), (e) etch marking, and (f) cleaning operations. All of the value added steps change fit, form, or function of the product, which are activities the customer is willing to purchase.

The current-state value stream map establishes a baseline of the current process under investigation. Information collected with value stream mapping includes (a) cycle time (C/T), (b) value-added time, (c) lead-time, (d) WIP quantity, (e) changeover time (C/T), (f) average production batch size, (g) number of operators per process, (h) available time, (i) scrap rate (material waste), and (j) rework rate (process yield). The information collected for each process in a value stream should include any information or metric that is considered significant to the process.

Work in Process (WIP)

Work-In-Process (WIP) causes the most non-value-added time during a production process. Mass production techniques group equipment by similar function not by product groups, which create material inventories at each operation. Production facilities that use the mass production strategy have equipment located in all areas of the plant. Plant layouts following this strategy create physical distance between subsequent operations (Figure 3). Storage racks or staging areas are necessary because products flow through the facility in large lot sizes waiting for the next operation. Large lot sizes are necessary to insure that each subsequent operation has enough material to complete the order. The more operations required manufacturing a product, the more non-value added steps necessary in the production cycle.

Waste

Non-value-added steps in a process are described as waste. The typical approach has been to focus on the manufacturing process, the value-added steps. Many process improvement initiatives fail to focus on the non-value-added activities such as transportation and storage (Conner, 2001). The results of improving value-added steps are minimal when compared to the total lead time. Figure 4 shows the relationship between value-added and non-value-added steps in a typical manufacturing process (Conner, 2001). Reducing value-added activities by 50% would be an improvement of 2.5% to the total lead-time.

A better approach to lead time reduction would be to improve or remove the non-value-added waste from the process. Figure 5 illustrates how a reduction of non-value added activities by 50% would yield a 47.5% reduction in total production lead time (Conner, 2001).

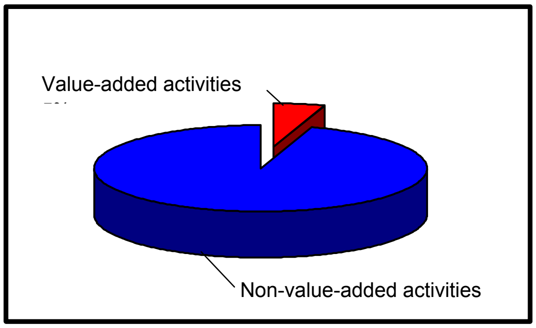

Figure 4. Value added time as a % of lead time

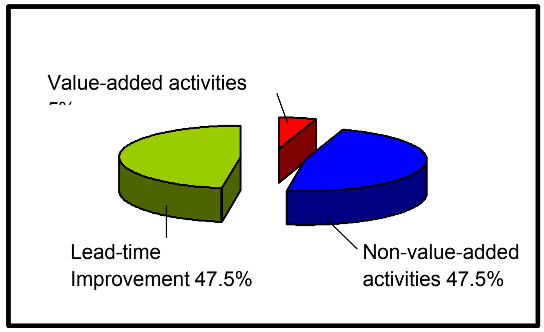

Figure 5. Potential lead time reduction

Applying this philosophy to shoulder head implant production would dramatically impact production lead-time. For example, the current-state value stream map calculated the value added time at 6.21 hours. Production lead-time was calculated to be 18.4 days or 441.6 hours. Cycle time for shoulder head implant production was 447.8 hours. Improving the value added time by 50% for shoulder head implant production would reduce the cycle time by only 3.10 hours. A 50% improvement to non-value added time would achieve a savings of 220.8 hours or 9.2 days for shoulder head implant production time.

Procedures

The objective of this study was to apply lean manufacturing techniques to a production job shop environment to reduce the lead time from the current average to an acceptable average established by customer demand. To accomplish the objective, the following procedure was followed.

The independent variable was identified as the manufacturing process. Dependent variables were lead time, WIP, and material flow. Current-state data was used to establish a baseline for the dependent variables. Lead time was calculated for the global shoulder head part family using production data from January 2001 thru August 2001. The data is historical and was retrieved from the AS-400 system database at the Warsaw, Indiana, plant. Lead time was verified by actual time measurements collected from the production floor. Material flow and WIP data was also collected from the production floor. After the evaluation of the current-state data, changes were implemented using lean principles to reduce lead time, and WIP, and improve material flow. The manufacturing process was allowed to operate for 30 days after the improvements were implemented. Lead time, WIP, and material flow data were again collected for comparison with the baseline data. Value stream mapping was used to establish the manufacturing process baseline.

Lot sizes were reduced, and each production lot was marked with a blue sticker simulating cellular manufacturing and workflow. The blue sticker was a visual sign to process the order before any other orders waiting in WIP inventory. A visual sign was necessary because many of the operations produce other products (e.g., hips, knees, elbows). Reduction of lot sizes from 18 to 10 pieces assisted the simulation of one-piece flow.

<u>Data Collection</u>

The current-state data collection established a baseline that represents the true condition of the production cycle. The production data was collected at random times along the process to achieve a true representation of the current and future production performance. The lead time data was analyzed to get an average lead time for production of global shoulder heads. Global shoulder head component production data from January 1, 2001 through August 31, 2001 was used for the current-state data analysis of lead time and year-to-date sales. The sales data is necessary for the takt time calculation (Table 1). Takt time is defined as the available production time divided by the rate of customer demand.

Table 1. Takt time calculation

Takt Time

$$\text{Takt Time (TT)} = \frac{\text{Available work time per shift}}{\text{Customer demand rate per shift}}$$

Global Shoulder Humeral Head TT Data

	Available Work Time (minutes):	480
Subtract	- 1st Break	15
	- Lunch	25
	- 2nd Break	15
	- Cleanup	15
	Per Shift	410
	Shifts/day	3
	Total Available Time	1230

Demand (shoulder head)	
2002 Forecast	15000
Monthly	1250
Daily	63
Shifts/day	3
Demand/Shift	21

*Note 20 days/month used to calculate Takt time

$$\text{Takt Time (TT)} = \frac{\text{Available work time per shift}}{\text{Customer demand rate per shift}} = \frac{410}{21} = 19.7 \text{ minutes}$$

The takt time was used to post a visual production goal for each operation of the manufacturing process (i.e., number of pieces required per shift). Future-state data was collected on the same part family in January 2002 after the process improvements had been in place for at least 30 production days. Current-state data was collected for WIP inventory and machine location by collecting WIP quantity and machine location data. The current-state data was collected in the fourth quarter of 2001, and the future state data was collected in the first quarter of 2002.

Data was collected at each processing step from turn taper to final inspection (operation 1 to 11, Figure 3.). Using time observation sheets for each operation, data was collected for lead time. Figure 6 is an example of a time observations sheet used for a turning operation of global shoulder turn dome.

The data was collected over five days so that global head components could be observed at each process. Takt time was calculated using available work time in seconds and historical sales data from January 1, 2001, through August 31, 2001. Lead time was recorded in seconds. WIP inventory was recorded in number of pieces instead of by lots, which historically has been the metric. Material flow was diagramed using a block diagram (Figure 3), which will show where and how far the component travels through the manufacturing cycle.

Findings and discussions

The objective of the project was to reduce lead-time, WIP inventory, and improve material flow. Data was collected before the experiment was performed so that comparisons could be made between traditional (batch) manufacturing methods and lean manufacturing. The current-state data was compiled into a completed value stream map, which shows the lead time and WIP inventory. The current-state value stream map was used to characterize the global shoulder humeral head manufacturing process, as it exists in its current condition. A future state value stream map was completed that facilitates shorter lead times, material flow, and reduced WIP inventory. Lead-time data was compared for percent change (Table 2) between the current and future-state lead times and WIP inventories.

Part Number: 1128-44-010 (16pc order)

Process	Operation		Operation: Turn Dome (Op 30)					Observer: T. Metzinger					Date: 10/27/01	
Step	Element	Obs	1	2	3	4	5	6	7	8	9	10	Task Time	Comments
1	Load	C	00:16	00:15	00:17	00:16	00:15						00:16	Put sleeve on taper and place in collet
		E	00:16	00:15	00:17	00:16	00:15							
2	Turn	C	04:30	03:55	03:57	04:08	04:02						03:51	Turn dome
		E	04:14	03:40	03:40	03:52	03:47							
3	Unload	C	04:41	04:03	04:04	04:20	04:11						00:09	Remove part and sleeve
		E	00:11	00:08	00:07	00:12	00:09							
4	Inspect	C	04:47	04:17	04:27	04:31	04:26						00:14	Check height & profile
		E	00:06	00:14	00:23	00:11	00:15							
5	Store	C	04:58	04:35	04:38	04:41	04:51						00:15	Place cap on taper and put into tub
		E	00:11	00:18	00:11	00:10	00:25							
6		C												
		E												
7		C												
		E												
8		C												
		E												
9		C												
		E												
10		C												
		E												
	Cycle Time>>		04:58	04:35	04:38	04:41	04:51						04:45	<<Average Cycle Time

Change Over (seconds)	
Setup	1080
Fixture Setup	
Product ID	
Find Process	
Check Criteria	
Touch Off Tools	
Run off 1st pc	
Change Rough Insert 8x/16 pcs	440
Change Finish Insert 4x/16 pcs	180
	1700

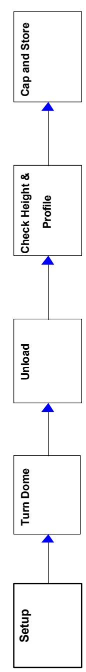

Figure 6. Process observation and determination of cycle time

Improvements to lead-time were recognized as the time was reduced by 44% (Table 2) from 18 days to 10 days (Figure 7). The lead time reduction was achieved but was difficult to sustain when other products began sharing production resources.

The reduction in lead time contributed to a reduction in WIP inventory (Figure 7). The shorter time required to produce finished product reduced WIP requirements. A reduction in WIP inventory of 25% was realized along with the lead-time reduction (Table 2).

		Lead Time & WIP			
		Before		After	
Op#	Operation	WIP (Qty)	LT (days)	WIP (Qty)	LT (days)
10	Turn Taper	141	2.3	64	0.8
20	Abrasive Cutoff	68	1.1	54	0.7
30	Turn Dome	104	1.7	72	0.9
40	Polish	390	6.4	146	0.8
50	Ultrasonic	177	2.9	98	0.9
60	Zyglo (FPI)	61	1.0	42	0.7
70	Tape/Blast	0	0.0	44	0.6
80	Color Buff	38	0.6	62	0.8
90	Ultrasonic	104	1.7	96	0.8
100	Laser Etch	0	0.0	48	0.7
110	Inspect (QA)	0	0.0	34	0.8
120	Label	30	0.5	48	0.8
130	Passivate	37	0.6	18	0.9
140	Final Clean & Pack	0	0.0	0	0.0
	Total:	1150	18.8	826	10.0

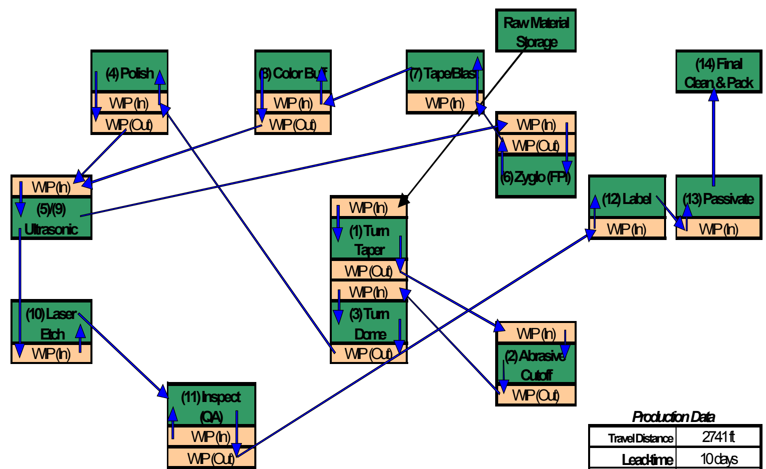

Figure 7. Lead-time and WIP reduction change using blue sticker method.

Table 2. Manufacturing method comparison metrics

	Manufacturing Method			
	Batch	Lean	Difference	% Change
Lead-time (days)	18	10	8	44.4%
WIP Qty (pcs)	1098	826	272	24.8%
Daily Demand (pcs)	61	61	N/A	N/A
Rework Rate	16.0%	14.9%	1.10%	6.9%
Scrap Rate	3.3%	2.1%	1.20%	36.4%
Travel Distance (ft)	2741 ft	2741 ft	N/A	N/A

Material flow did not change for this experiment; therefore travel distance remained at 2741 feet (Table 2). Rework and scrap rates remained relatively unchanged when compared to baseline data.

Visual signals (blue stickers on part tubs) allowed the product to keep moving in the process. The visual signal identified the products so that the operators knew to process the parts as soon as machine time was available. The technique was effective, but the improvement that was achieved was possible only because of paradigm shift on the production floor. The two-day training session taught the operators and supervisors the importance of product flow. A change in culture has been the most difficult obstacle in the implementation of lean manufacturing. Operators have become accustomed to viewing large quantities of product on the production floor. There is a certain amount of security for the operators when large amounts of product are visible. The lack of product created a situation where the operators felt threatened by the lack of work. The change to a lean environment creates numerous opportunities to deal with the human factor and culture change.

The use of blue stickers did assist in the reduction of lead time for humeral head production, but processes that produced other products were forced to prioritize work by this system. Other product lines (e.g., hip stems) are using the same marking method to help facilitate lean manufacturing. As different products arrive at these processes, the operator is forced to choose which product to produce first. The blue stickers help demonstrate the positive impact of improved product flow, but this method will not sustain these improvements as other products implement lean manufacturing.

Lot size reduction was advantageous in reducing WIP inventory levels by 25%. WIP inventory reduction was not as dramatic as the 44% lead time reduction. The difference was due to the lot size constraint related to the production of medical devices. Medical devices are required to maintain a device history, which archives all design and production information required to produce the implant. If true single piece flow were used in implant production, some of the cost benefit would be lost because of the extra resources required to maintain the device history record. Reduced lead time also had a positive impact on WIP inventory levels because the shorter production time reduced the inventory levels required to support shoulder head implant production.

The physical location of the equipment did not change for this study. Equipment moves were not allowed within the facility because other changes where taking place on the production floor. A two-day lean manufacturing session was given to operators, supervisors, and production planners as an overview of lean manufacturing. Floor operators were trained on lean concepts and how product flow would impact each operation The session focused on product flow and waste elimination and was used to help shift the paradigm of batch processing to lean manufacturing.

The closeness of the operations does not allow large quantities of defective product to accumulate before the next operations are performed. The constraint of not having the ability to move the operations into a cellular structure limited the effectiveness of the project.

Summary and Conclusions

Reduction of lead time from 18 days to 10days was accomplished by reducing the amount of WIP inventory located between manufacturing operations used for shoulder head production. Decreasing the WIP inventory quantity improved process flow and facilitated smaller lot quantities. Understanding the process and steps utilized for shoulder head production assisted with the implementation of lean manufacturing to reduce lead time. Through the use of value stream mapping, non-value-added and value-added activities were identified. The process characterization that was accomplished with value stream mapping assisted in reducing lead time by graphically highlighting areas of WIP inventory. The reduction in WIP inventory was not as dramatic as the change in lead time, but it was still significant. However, reduction of WIP inventory allowed processes that share resources with humeral head products to improve the throughput of these other products. Reducing the capacity constraints on these processes allowed more products to flow through the facility, which improved productivity. The reduction of lead time demonstrated the advantages of lean manufacturing when compared to batch-and-queue processing.

References

Conner, G. (2001). Lean manufacturing for the small shop. Dearborn, MI: Society of Manufacturing Engineers.

Hall, R.W. (1987). Attaining manufacturing excellence: Just in time total quality total people empowerment. Homewood, IL: Dow Jones-Irwin.

Jones, D.T., Roos, D., & Womack, J.P. (1990). The machine that changed the world. New York, NY: Simon & Schuster.

Jusko, J. (2000). Paths of progress. Industry Week, 249, 24-31.

Kraebber, H.W. (2000). Workforce education and development: The key to competitive manufacturing. International Journal of Agile Manufacturing, 3, 45-52.

Monden, Y. (1993). Toyota Production System (2nd ed.). Norcoss, GA: Institute of Industrial Engineers.

Nyman, L.E. (1992). Making manufacturing cells work. New York, NY: McGraw Hill.

Pharmaceutical and healthcare industry quarterly review (2000). San Francisco, CA: Bio-News. Retrieved July 4, 2001, from the World Wide Web: http://www.bioportfolio.com/deloitte/00quarter1.htm

Rao, K.A. (1999) Lean manufacturing. Monthly Labor Review, 122, 50-51.

Rother, M., & Shook, J. (1999). Learning to see: Value stream mapping to add value and eliminate muda. Brookline, MA: The Lean Enterprise Institute.

Schonberger, R.J. (1986). World class manufacturing: The lessons of simplicity applied. New York, NY: Macmillan Publishing.

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