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Cellular manufacturing-throughput reduction in a pharma company

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Abstract
Continuous improvement in pharmaceutical industry is paramount in order to improve the product quality, increase productivity and reduce the cost of drug product. Lean manufacturing has been successfully implemented in various industry including pharmaceutical industry with an objective to deliver customer satisfaction and improve profitability. This paper discusses that focus on eliminating the waste and change in manufacturing layout from conventional type to unicellular type could reduce the total throughput time of drug product batch from 17 days to less than 2 days. This change brings significant benefits to the manufacturer in terms of improved quality, reduction in manpower, reduced manufacturing space, increased production efficiency, enhanced ownership of employee and increased profits.

Keywords: Lean, pharmaceuticals, cellular manufacturing, through put time

1. Introduction
This paper discusses a lean journey by a pharma company resulting into reduction in the throughput time of manufacturing process for drug product. There are many definitions of Lean as lean is an on-going process and philosophy with continuously development. Its utility and application differs from one organization to another organization and one type of industry to another.
Referring to various literatures, it is clear that lean has evolved over a period of time. Lean concept was first discussed in the Toyota Production System (TPS). Quite often, It has been named as World Class Manufacturing (WCM), Continuous Flow Manufacturing, Stock-less production, Lean Sigma and Agile Manufacturing to mention just a few. Lean manufacturing depend mainly on workplace and work flow in the organization. It is starting point for organization to take fresh look at their existing manufacturing flow and process in order to improve the process, to reduce the cost without affecting the quality of the end product [1].

2. Review of Related Study on Lean Manufacturing
An attempt to find the degree of lean implementation in India and the different lean manufacturing practices in automotive industry and other industries in India. Six operational metrics were studied to check the improvement in the employee productivity, first pass correct output and manufacturing lead time reduction [2].
Lean manufacturing has been adopted by all types of manufacturing systems e.g. product layout, process layout, fixed layout; batch production to mass productions; discrete production to continuous production; labour intensive industry to technology driven industries, construction industry to assembly industry, medical healthcare industry to communication industry [3].
In all lean production applications, supervisors have different roles while working with remanufacturing cells than as compare to their traditional job role at work. They need to work with standards which require each component's remanufacturing sequence to be rigidly adhered without any deviation. Supervisor's would be forward thinking, proactive and would look forward to improve their work stations [4].
New manufacturing paradigm called "Fit" manufacture with an aim to provide a "Total manufacturing" solution to the problems encountered in the volatile and complex manufacturing environment. "Fit" integrates key business area such as design, manufacture,

sales, marketing, finance etc. "Fit" develops a company's capacity to meet customer demands, break into new markets, ensure company's technological and strategic infrastructure [5].

Incorporation of six sigma and lean approach in to new product development process while designing new products that could be more reliable for low cost manufacturing and reaching zero faulty products by design. The approach adopted was focused on reducing the risk priority number (RPN) while reducing the opportunity of failure occurrence thus increasing product reliability [6].

3. Purpose of Lean

The purpose of lean is mainly to:

- Deliver Customer Satisfaction
- Improve profitability

Every manufacturing process may have steps which add value and may not add value to the product. It is vital that in the every activity as a part of the process in the manufacturing area shall add value to the product for which end user / customer is willing to pay. The first question should always be "WHY?" this process, while reviewing the manufacturing process. If the purpose of performing the process is not understood and principles of the lean manufacturing applied, then there is high possibility that a wasteful process is made more efficient. The end result of the lean manufacturing may be to do something better for the manufacturing process [7].

3.1 Deliver Customer Satisfaction

Customer satisfaction comes down to just three main areas –

- Quality
- Cost
- Delivery

Out of these three, which is the most important to satisfy the customer would depend on the end product manufactured by the organization; hence understanding the customer needs is vital. In majority products, the customer is satisfied with the best quality product which is delivered in time at the right price.

Lean tools like "Poka Yoke" and "Kaizen" are focused to ensure that product quality is perfect. Lean tool like "Just in Time" improves the delivery time to customer. Another tool "5S" helps to standardize the process activities and keep manufacturing machines reliable through Total Productive Maintenance (TPM).

Cost of the product can be reduced by eliminating all non-value adding steps though the objective of lean implementation is not to reduce the cost.

3.2 Improve Profitability

If business does not make money, it cannot exist. If any organization makes more profit, all the involved people like employees, managers, would be happy as they would be getting wages to their satisfaction and live their lives better. Reduction in cost of product is by-product of lean manufacturing. If the cost is reduced with implementation of lean without affecting the product quality, the end user (customer) would be happy because the prices are reasonable and the product quality is good. The vendors or suppliers would be happy as they would be getting consistent order to supply the materials and receiving a reasonable price. And finally the owners would be happy as they are making a profit which is the very purpose of running business.

Following is the traditional view of profit where we base our selling price on our costs plus our profit;

Selling Price = Profit + Costs

However as Taicii Ohno who was the main architect of the Toyota Production system claims that if the customer recognizes the product or service to have a specific value they will only pay accordingly. If we increase the prices because cost has increased but the perceived value of the product remains unchanged then the customers will stop buying as the selling price exceeds the value that they perceive.

So Taichii Ohno and Toyota look at profit and costs in the following way:

Profit = Selling Price – Costs

The selling price is the price that is fixed by what the customer is keen to pay for the perceived value of the end product; therefore the profit will depend on how you can reduce the manufacturing cost. As reduction in cost of product is by-product of lean manufacturing thus organization can make a profit without manipulating the selling price to create a profit [7].

4. Improving Manufacturing Practices Through Lean Implementation

Lean manufacturing is a systematic method for waste minimization ("Muda") within a manufacturing system without sacrificing productivity and product quality. Lean also takes into account waste created through overburden ("Muri") and waste created through unevenness in workloads ("Mura").

Following are the main goals of Lean manufacturing –

(1) Reducing waste,
(2) Implementing efficiency-promoting practices, and
(3) Continuously improving manufacturing operations.

Initially these tasks may seem discouraging for a manufacturer when the improvement program is taken up, however there are many solid steps that shall be taken to shift the culture in the organization before taking up these concepts. For many companies, to increase efficiency and to reduce waste is a commitment and a willingness to continue trying new and creative ideas to strive for the best.

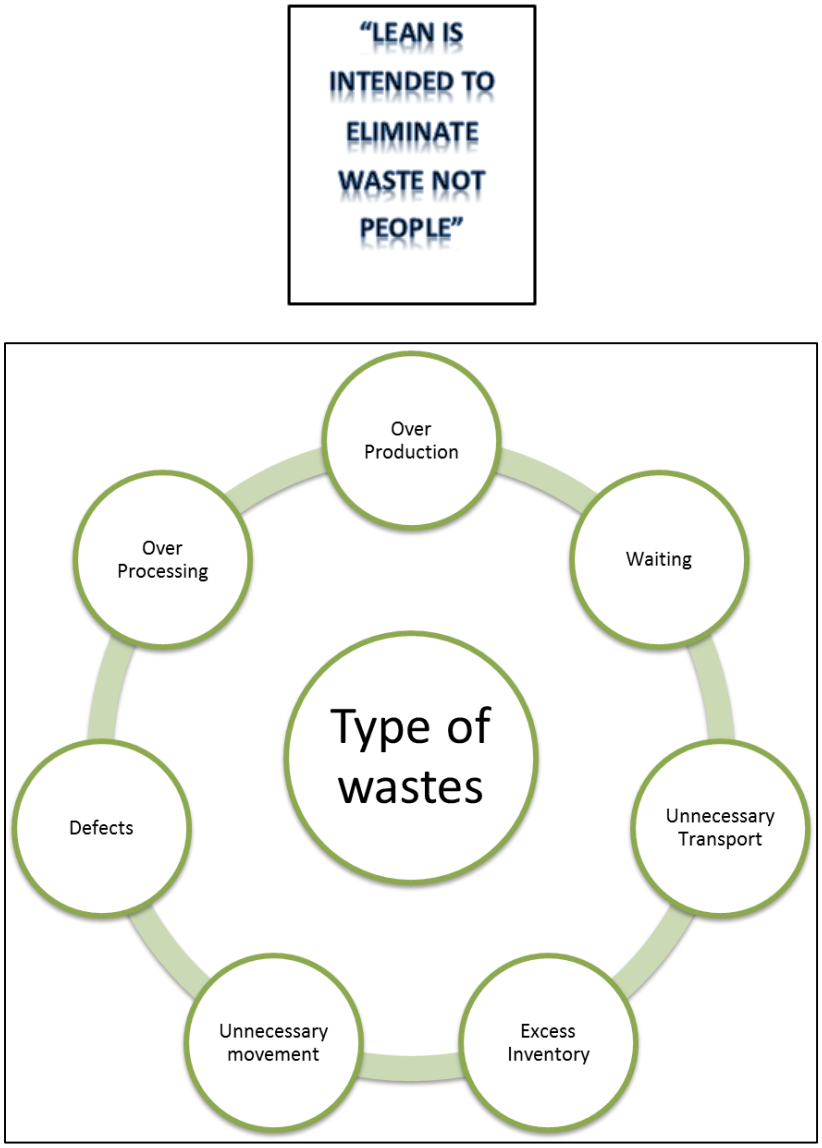
If one is able to simplify the manufacturing tasks and process workflow in the organization, take steps to eliminate the errors, and listen to employees on the manufacturing floor, the company will begin to get reduced waste, enhanced employee morale and training, better efficiency, and a greater ability to manufacture products within stipulated timeline.

The process owner has to understand the Value Stream in order to add value to manufacturing process right from raw materials through to the finished product. The objective shall be to add value in the manufacturing process and avoiding the non-value adding steps (i.e. waste) that can be removed from the manufacturing processes.

4.1 Elimination of Waste

The most critical principles of lean manufacturing are the removal of waste which is also known as "Muda". Following are the 7 basic types of wastes observed in manufacturing (Figure-1) [8]:

1. Over Production
2. Waste of Unnecessary Motion
3. Waste of Inventory
4. Production of Defects
5. Waste of Waiting
6. Waste of Transportation
7. Waste of Over-processing



Source: Authors, based on literature

Fig 1: Types of Wastes

5. Cellular Manufacturing

Cellular Manufacturing is a key element of lean manufacturing management and powerful tool into the battle of waste reduction.

5.1 Definition

Cellular manufacturing is a process of manufacturing which is a subsection of just-in-time manufacturing and lean manufacturing encompassing group technology. The goal of cellular manufacturing is to move as quickly as possible, make a wide variety of similar products, while making as little waste as possible. Cellular manufacturing involves the use of multiple "cells" in an assembly line fashion. Each of these cells is composed of one or multiple different machines which accomplish a certain task. The product moves from one cell to the next, each station completing part of the manufacturing process. Often the cells are arranged in a "U-shape" design because this allows for the overseer to move less and have the ability to more readily watch over the entire process [9].

A cell can be defined as an amalgamation of people, equipment and manufacturing stations organized in the order of process flow to manufacture the production unit. Cell manufacturing is generally arranged in either C or U shape in order to monitor the incoming material and finished product produced. Cellular manufacturing units are handled by cross trained people who bring flexibility and used for manufacturing of the product which follows the same process flow or from the same family of products.

Cellular manufacturing also demands for the same process to be followed each time a certain part is produced. Potential errors are reduced by this increased repetition and training of the operator is made simpler. Perhaps, most important to the Lean manufacturing process, repetition makes it easier to make change in the process and track whether these changes have a positive effect on the overall effectiveness of the process. Cellular manufacturing is one of the most effective tools for the positive outcomes that can result from implementing Lean practices.

5.2 Cellular Manufacturing in Pharma Industry

If pharma industry involved in manufacturing of the final drug product, the cellular manufacturing can reduce the wastes significantly which can be understood from below case study. Any pharmaceutical plant manufacturing Tablet dosage form would involve following manufacturing stages and respective minimum equipment (Table-1)

Table 1: Tablet Manufacturing Stages

Manufacturing Stage	Equipment
Dispensing / Pharmacy	Laminar Air flow station Weighing balance
Granulation	Rapid Mixer Granulator Fluid Bed Dryer Sifter Milling equipment Blender
QC Analysis – In process sample testing	High Performance Liquid Chromatogram (HPLC) Weighing Balance Water by Karl Fischer (KF)
Compression	Compression Machine Metal Detector
Coating	Coating machine
Packaging	Packaging line

Source: Authors

Any conventional manufacturing unit where multiple products are manufactured would have all above manufacturing area as separate sections. These sections are supervised by individual section-in-charge having expertise of respective area. The Typical layout of the conventional manufacturing unit would look like as shown in Figure-2. In this layout, the responsible section-in-charge completes the manufacturing of product for that stage and pushes the semi-finished product in the Quarantine area where it would be lying for days / weeks waiting for initiation of the next processing stage. Thus, typically after completion of each processing stage (value addition to the product), it would be waiting in the quarantine area for the initiation of the next stage. Also, as can be seen in the Figure-2, the material has to be transported from stage 1 to quarantine to stage 2 to quarantine……until the processing is completed. Completion of one batch of the product would take normally from 15-35 days which can be understood from below table 2

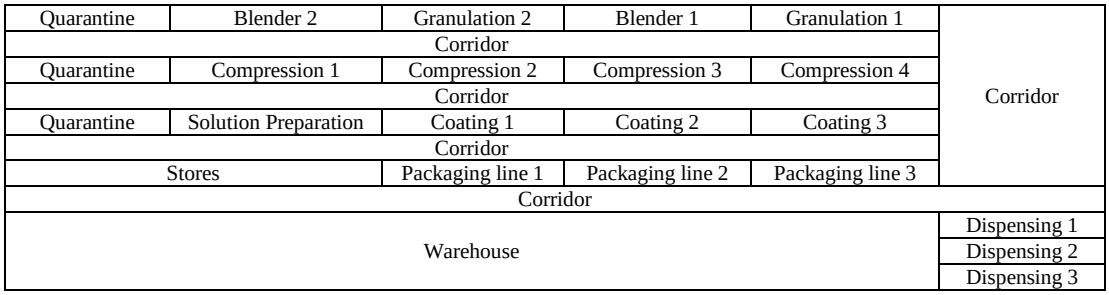


Fig 2: Existing Conventional Layout – Tablet Manufacturing (Source: Authors)

Table 2: Throughput time (Existing Conventional Manufacturing layout)

Manufacturing Stage	Number of hrs / days	Value addition or waste
Dispensing / Pharmacy	8 hrs (1 day)	Value addition
Quarantine*	2 days	Waste
Granulation	16 hrs (1 day)	Value addition
Quarantine*	3 days	Waste (waiting for QC Analysis – In process sample testing)
Compression	16 hrs (1 day)	Value addition
Quarantine*	2 days	Waste
Coating	24 hrs (1 day)	Value addition
Quarantine*	5 days	Waste
Packaging	8 hrs (1 day)	Value addition
Total through Put time	17 days	

Source: Authors
*Estimated on lower side

In the conventional manufacturing system, there would be minimum 10-12 batches of the product either under at processing stage or lying in Quarantine waiting for initiation of next processing stage, thus lot of inventory being handled on the shop floor. In case of any breakdown at particular processing stage (e.g. coating stage), the production at its previous stations would be continued thus creating lot of inventory and over production till the problem in rectified. In case of any quality issue in any of the batch, the product batch would be held in quarantine unattended and the next batches would be pushed to achieve the production targets by the production manager. Sometimes, enough efforts are not made to resolve the quality issue of the batch and it may be rejected if remain unresolved. Total through put time for one batch would be ranging between 15-35 days depending on the production priorities. In any pharma unit with conventional layout, Quality Control lab would be separate away from manufacturing facility. The responsible person would collect the sample and would send to QC lab for testing. The sample would be received in the laboratory and would be taken for analysis until the previously received samples are analysed hence the sample would be waiting for initiation of the analysis.

On the contrary, if this processing is done in the cellular manufacturing cell having U shape layout (Figure-3), there would be significant reduction in the through put time and all the wastes are eliminated from the system. Following are the rules of the U shaped unicellular manufacturing unit –

- The facility shall not have any Quarantine
- The facility shall be supervised by one manager and shall be accountable for all sub stages
- The QC test (in-process) equipment would be in close proximity to the blending area where from the in-process sample is collected for analysis.
- Every stage should have one batch being handled
- The capacity of machines at each processing stage shall

be similar i.e. 8 hrs so that batch processing at each stage is completed within same time and product is pushed to the next processing stage.

- In case of any breakdown at a particular stage, manufacturing of the previous stages to be suspended until the problem is rectified and process is resumed.

In the unicellular manufacturing unit, completion of one batch of the product would take less than 2 days which can be understood from below Table-3

Table 3: Throughput time (New Unicellular Manufacturing layout)

Manufacturing Stage	Number of hrs	Value addition or waste
Dispensing / Pharmacy	8 hrs (Shift 1 – day 1)	Value addition
Granulation	8 hrs (Shift 2 – day 1)	Value addition
Compression	8 hrs (Shift 3 – day 1)	Value addition
Coating	8 hrs (Shift 1 – day 2)	Value addition
Packaging	8 hrs (Shift 1 – day 2)	Value addition
Total through Put time	Less than 2 days	

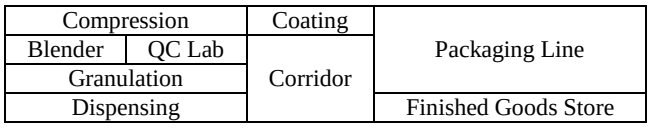


Fig 3: New Unicellular Layout-Tablet Manufacturing (*Source*: Authors)

There is significant reduction in the through put time from 15-35 days to less than 2 days as there is no quarantine on the shop floor and every batch is pushed to next processing stage in 8 hrs time period.

6.3 Benefits Achieved

Following benefits are achieved in the unicellular manufacturing unit model adopted –

1. Better quality-A lot of the activity in a lean environment is targeted towards better finished product quality. Lesser the exposure of the product to the environment, there is reduced chances of deterioration and increased quality of the product. If any quality issues arise for a particular batch, different problem solving techniques are used to identify the root cause of the problem by all responsible persons as a team. From there, as a corrective action mistake proofing is implemented to strengthen the process and to prevent the recurrence. The same product is manufactured in campaign in this kind of manufacturing lay out, thus there is no mix-up and cross contamination and as a result, the quality of the finished product is improved.

2. Enhanced Owner ship-The responsible manager of the unit oversees the entire processing area right from dispensing to packaging (not one particular stage as observed in conventional manufacturing layout) and any irregularities will stand out and will be taken for resolution on priority.

3. Increased consistency and efficiency-Line balancing in the unicellular manufacturing ensure each person is working in the most competent manner. Standard Operating procedure (SOP) ensures that they are doing it correctly by following the same procedure every time. Due to campaign production of the same product, the time required for the cleaning of the machines and area has gone down significantly and this time is utilized for processing of the product. This leads to consistency and increased efficiencies.

4. Reduction in Manpower-In this type of unit, more output is achieved with less manpower. With standardized procedure and increased efficiencies, the ability to do the same kind of activity with less people becomes real and possible.

5. Easy to manage-The production is done in campaign and planning is easy in unicellular manufacturing unit. The clear instructions with standardized work let the operator know what the target is and what they have to do to achieve it. This helps for easier management of the work area for the supervisor / area-in-charge.

6. Reduced Space-As the through put time reduces significantly and there is reduction of finished product and raw material / packaging material inventory. Therefore, the new layout save space on the shop floor. In this new layout, Quarantine rooms are completely eliminated.

7. Organized and safe Work place-Once the material flow is unidirectional and unnecessary components are removed from the manufacturing operation, the shop floor becomes much more organized. Thus the organized work place and environment becomes safe work environment.

8. Increased profits-In cellular manufacturing unit, inventory of both Active drug material, product batches have reduced which has direct positive impact on the finance. Low inventory means less investment and increased profits. In view of reduced through put time, the delivery time is shortened considerably, hence high customer satisfaction and increased profits.

7. Conclusion

Defining Lean in a few sentences is very difficult as Lean encompasses so much. Lean is about creating value in the process, it is about service for the end user, it is about revolution and evolution of manufacturing processes and operating systems, thus to conclude "IT Is A Journey Towards Success".

Lean Manufacturing is widely accepted and used in pharmaceutical industry. In this study, the focus was to eliminate the waste (MUDA) from the shop floor at all the stages of manufacturing including removal of quarantine (storage at Intermediate stages); thus product shall not wait for machine to initiate the manufacturing but the machine shall be waiting for the product at all the stages. As evident from the Table 2 that most of the time wasted during the process was due to storage (quarantine) between 2

manufacturing stages. Simply eliminating this waste has reduced the total through put time from 15-35 days to 2 days.
The Implementation of lean manufacturing / unicellular manufacturing can significantly reduce the total through put time thus faster delivery, reduced inventory, reduced cost and improved production efficiency. Unicellular manufacturing unit is very useful for voluminous product or the products sharing the same train of the equipment. Lean means producing more with less time, less space, less human efforts, less effort, less waiting, low inventory and giving customers what they want**.**
"Lean Organization Means An Organization Without Fat."

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