



Applying Lean Tools and Techniques in Pharmaceutical Environments

Abstract:

Due to its origin, lean has mostly been widely applied to manufacturing focused companies, especially in automotive and aerospace industries. With some pre-planning and industry-specific considerations, these same tools and concepts can also be applied in other businesses as well. In this article, we present some guidelines for a successful implementation of lean tools and techniques in life science industry.

The overall objective of any lean initiative is to identify and eliminate waste ("muda"). Waste comes in many forms: 1. unnecessary human motion, 2. conveyance of product, 3. over-production, 4. inventory, 5. space, 6. over-processing, 7. waiting and 8. improper-utilization of talent. Common lean tools and general guidelines are presented below for successfully identifying each of these wastes in a life-science environment. Although strict regulatory issues often cause delays and make it more difficult to implement changes for pharmaceutical companies, these lean concepts and tools have been applied successfully in numerous organizations.

Unnecessary Human Motion

The single most useful tool for identifying and eliminating (as much as we can) this type of waste is what we refer to as a "spaghetti diagram". This technique involves following a specific person for a minimum of 30 minutes to a maximum of two hours. To ensure proper results, first explain to the group (whether it be production, lab, etc.) what is being done and why. Secondly, explain clearly to the person(s) being followed that we are evaluating our processes and the layout, not the individual(s). The path taken by the individual(s) should be clearly marked on a layout. The results should be shared for accuracy and buy-in.

As you conduct the spaghetti diagram, strictly adhere to the following guidelines:

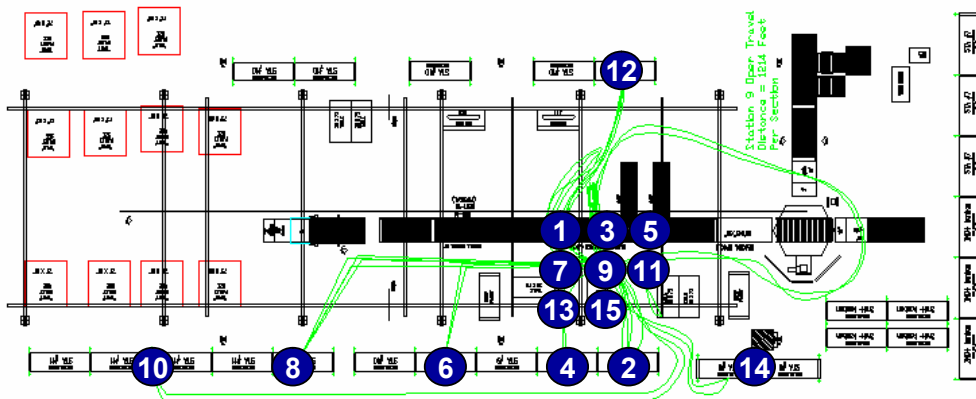
- Note the date, time and the process being evaluated, but not the name of the individual
- Explain to the group what's being done and ask for a volunteer
- Trace the actual paths taken
- Note any stops with sequential numbers and mark the time for each stop
- Note any non-comfort motions - such as reaching too high/low, turning or twisting, etc.

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- Mark any inherent interruptions in the path - such as going from one clean room to another that requires gowning down and up
 - Note the stated cleanliness of each clean room, if applicable. Verify each classification against the SOP and FDA requirements.
 - Note why certain trips are being made - such as getting necessary supplies, getting required signatures before it can be released to the next step, etc.
-
- Ask questions and seek suggestions from the group - the best ideas often come from those who live the process!

An example of what a spaghetti diagram looks like is shown below:



Total Distance Traveled by Operator per set up = 1214 feet

Conveyance of Product

Process walk is a tool that is essential for identifying and eventually minimizing this waste. Whereas “unnecessary human motion” focuses on required movement by people in a specific function or process, this waste emphasizes the movement of a major ingredient across all processes (from incoming quality inspection through compounding, filling, etc. - until it is packaged into a finished good ready for shipment).

To create a process walk, consider the following guidelines:

- Walk at a brisk pace - this is intended to be a rough estimate
- Walk the entire process either:
 - o From shipping to receiving (recommended approach) or
 - o Receiving to shipping

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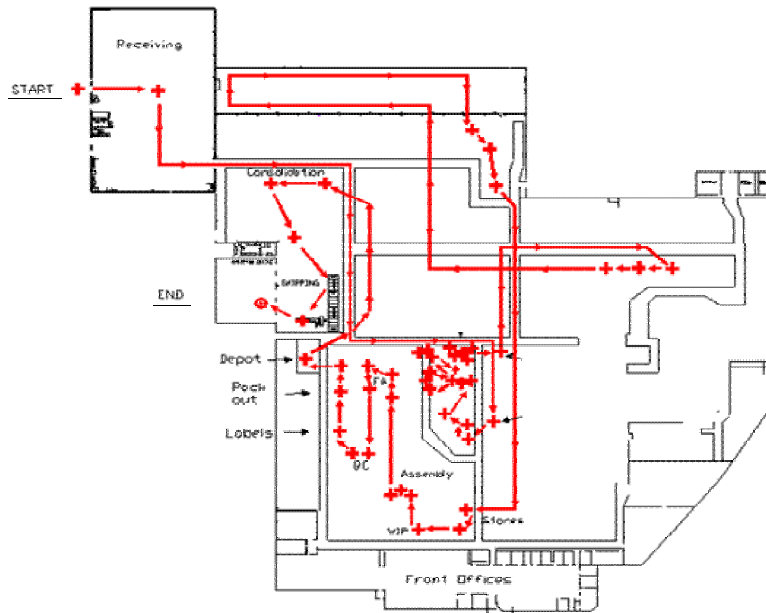
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- Ask (constantly) the people who do the work:
 - Where does this part/ingredient come from?
 - Where does it go to after you are done?
 - What's the frequency/method of conveyance?
- Have five people perform this task simultaneously - one or at most two people should be familiar with the process
 - Scribe: interviews and documents the process

 - Map maker: traces the actual physical movement on a plant layout
 - Pacer: measures the distance traveled to each stop
 - Counter 1: assists the map maker on noting the frequency of material handling occurrences
 - Counter 2: counts inventory at each location (use consistent unit of measurement)
- Note the stated cleanliness of each clean room, consistent with spaghetti diagram
- Note any preparation time/requirement moving from one location to another, if applicable
- Mark each occurrence of material handling with a cross on the layout

An example of a process walk is shown below:



+ Touch Point (47 total)
Over 3000 ft traveled
(equivalent to four laps around production)

Over-Production

Over-production is best avoided by instituting the right metric. This often requires a different management philosophy. We often encounter instances where higher production is regarded as a good event to be celebrated. Higher production on its own means very little -

instead an organization should take pride in higher demand/sales and their ability to meet the higher demand. Simply put, through the eyes of lean, too much production (in excess of sales) is just as bad as under production. To enforce this mentality, consider introducing Schedule Adherence metric:

$$\text{Schedule adherence} = \frac{[\text{total plan} - \text{sum of deviations}]}{[\text{total plan}]}$$

This is best explained by an example.

	plan	actual	deviation
A	500	500	0
B	300	400	100
C	100	300	200
D	200	100	100
	<u>1100</u>		<u>400</u>

➔ **64%**

Promotes production of right SKUs in the right quantities at the right time.

Assigns full penalty for under-production and partial penalty for over-production.

100% schedule adherence is achieved only when the planned quantity has been produced for each and every SKU. The essence of lean requires us to match our production to the actual demand - i.e. to produce only what is needed at the time it is needed.

Inventory

In the pharmaceutical world, the raw ingredients and components used are relatively inexpensive compared to the prices charged for the final product. Thus, missing a potential sale as a result of not having enough inventory is far more detrimental to the business as compared to carrying excess inventory. In this sense, inventory is not as bad of a thing in the life science industry as it is in other traditional manufacturing industries. Nevertheless, we must consider the opportunity costs indirectly involved with inventory. There are tremendous amounts of resources (both human and equipment) spent in converting raw ingredients to the final product. Ironically, excess inventory does not guarantee higher customer service levels. We often find excess inventory and poor customer service levels go hand in hand. This of course is a result of having too much of certain things and not enough of others (the classic case of mix issue). This is an inevitable consequence of misusing time and resources. In attempt to improve both inventory and customer service levels, first review the potential sources - inventory is a waste that results from:

- A long-term, systematic problem with an organization's scheduling process/system - an organization may execute perfectly to a plan (i.e. 100% schedule adherence), but the plan may not correlate well with actual demand
- Variations and/or uncertainties throughout the system such as:
 - Lead times of ingredients, raw material, components, etc.
 - Quality levels of ingredients, raw material, components, etc.

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- o Demand peaks and valleys often self-imposed from tradeshows, specials and any other marketing efforts
- o Production capacity and capability due to resource (human and equipment) constraints and availability
- Long set up times and large batch sizes
- Inadequate product rationalization and life cycle management
- Lack of active management and focused effort

Space

For pharmaceutical and other life science companies, space is usually not the most significant form of waste. However, this can be of utmost importance for organizations in a growth mode or those considering bringing in additional product lines. Space can also be critical for warehouse/distribution centers.

This waste is often lessened as a result of reducing other forms of waste such as inventory, better layout (unnecessary human motion and conveyance of product), etc. When claiming space savings, it should be noted that these freed-up space be practical and usable. As an extreme example, a 1000 ft² savings reported is phantom if it is made up of 100 individual spots of 10 ft².

Over-Processing

This term refers to the design as well as the process. The following are key questions to ask in evaluating one's leanness against this particular waste.

- How well do we understand the FDA requirements?
- How accurate is our interpretation of FDA requirements?
- Have we verified our SOPs against the true compliance requirements?
- Have we introduced/instituted a procedure to satisfy a CAPA item that may no longer be applicable?
- Can we definitively explain why we have been doing certain things in certain ways - have we challenged ourselves whether we can satisfy regulatory issues more efficiently?
- Paperwork - are they needed / redundant - can they be simplified / consolidated? For example, an FDA regulation that requires keeping and tracking of all records may not necessitate multiple, redundant manual paper trails.

Waiting

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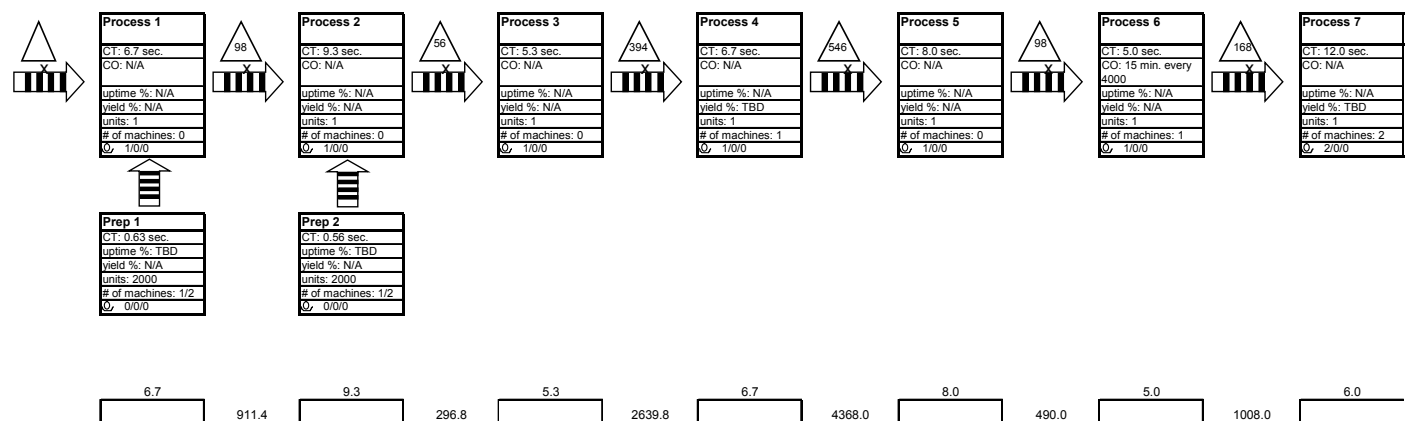


Waiting is an indication of imbalance between the processes and a result of variability in the entire chain. The variability can be inherent in the system due to resource capabilities/constraints - it can also be self-imposed due to large batch sizes and processes in place. Value stream mapping and CT/TT chart (cycle time / takt time) are two very important tools in highlighting this type of waste.

In creating value stream mapping and CT/TT chart:

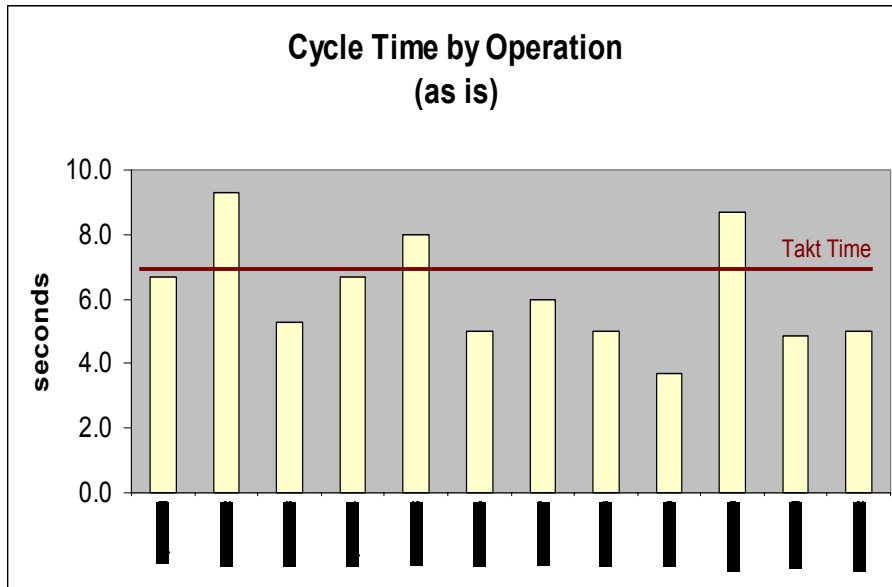
- Measure the cycle time for each step of the production area. Those steps that involve equipment, note the MTTF (mean time to failure) and MTTR (mean time to repair) data.
- For quality and inspection areas, measure the entire lead time
- Note the following for each process in the value stream:
 - Cycle time
 - Scrap level
 - Uptime
 - # or resources
 - Set-up time and frequency
 - Inventory levels
 - Lead time
- In calculating TAKT time, take the total time available and divide by the actual demand. For example, a one eight-hour shift with two fifteen minute breaks has 450 minutes available. If the daily demand is 900 units, then the TAKT time is 0.5 minutes (i.e. we need to produce one unit every 30 seconds to match demand).
- Note the difference between processing time to lead time - lead time includes the waiting (or queuing) time.

Examples of a value stream map and a CT/TT chart are shown below:



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Improper-Utilization of Talent

This is an often overlooked yet all too frequent form of waste. Identification and elimination of this type of waste is especially crucial for life science companies. We often observe well-educated and highly-trained lab technicians spending more than half of their time in filling out menial paperwork and getting ingredients/components. To assess the extent of this waste in your organization, ask the following questions:

- Do we have the right number of supervisors and/or workers?
- How does our number and ratio of supervisors and workers compare with other divisions in the company (i.e. internal benchmark) and other companies (i.e. external benchmark)?
- Do we have clearly defined roles and responsibilities for each position?
- Do we have the right people performing the right tasks?
- Do we have a rigid training program in place?
- Do our people feel challenged?
- Are work procedures accurate, up-to-date and followed? Do we have identical tasks performed differently based on individuals?
- What percentage of time is spent on:
 - Paperwork
 - Getting supplies
 - Rework
 - Chasing information
 - Actual task itself



Conclusion

It should be noted first and foremost that proper application of lean tools and techniques results in true improvements, i.e. identification and reduction of waste(s) within a given set of processes. No compliance requirement should ever be compromised during any lean initiative.

Understanding and being able to see and recognize waste is the first step in the lean journey. In this article, we have presented many of the common tools used to identify each type of waste.

Although it is true that FDA compliance issues make proper application more challenging, the key to success lies in focusing on what we can do despite these inherent constraints. For example, while it may be a daunting task to move an entire lab that's been certified as class 100, it may be relatively easy to organize and relocate supply cabinets closer to their point of use. While it is infeasible to eliminate the FDA tracking requirements, we can make it more efficient by identifying and eliminating unnecessary and redundant ones. With proper understanding and adaptation, lean tools and concepts can and will work wonders in any environment.

About Tefen

Tefen is a publicly traded, international operations consulting firm with seven offices in United States, Europe and Israel. The firm has over twenty years of experience in improving the overall operational effectiveness of Fortune 500 clients around the world. Tefen designs and implements solutions that enhance operational performance throughout an organization. The main areas of focus include operational excellence, manufacturing, quality, customer service, research and development, and supply chain management. All of Tefen's support programs are ISO 9001 and TCS (Total Customer Satisfaction) certified. Our hands-on approach has achieved success in delivering quantifiable and value-driven results. The company has remained profitable since its inception and currently employs over 250 professionals worldwide, 40 of whom are certified Six Sigma Black Belts.

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