Applicability of Lean Concepts in Reducing Change Over Time to Increase Production Capacity

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Abstract *— At this very competitive environment, companies need to do more with less. One way to do this is to maximize the use of the facilities that are already in use instead of building new ones or expanding existing ones. This project applied some of the Lean concepts and tools to reduce change over time for a key equipment during a pharmaceutical manufacturing process, without negatively impacting quality, health, safety or environmental compliance. The main Lean concepts used include: eliminating non-value activities, reducing the time required for business value-added activities and scheduling activities in the most efficient sequence. The Lean tools used include: Cause and Effect Diagram, Brainstorming, Single Minute Exchange of Dies, 5S, Poka Yoke, Standard Work and Risk Analysis. The implemented actions achieved a reduced average change over time (from 19 to 12 hours, for a 37% reduction). With the reduction of the change over time, additional manufacturing can take place within the same time period, and thus, the demand increase can be addressed with no significant investment.*

Key Terms *— Change Over, Increase Production Capacity, Lean, Pharmaceutical Manufacturing Challenges.*

RESEARCH GOAL AND BACKGROUND

Manufacturing industries need to be as cost effective as possible while assuring total quality of their products; this applies specially to pharmaceutical companies which are highly regulated. One of the deliverables by which performance is measured (due to its relevance to cost, revenue and capacity) is cycle time. Within the cycle time, there are different activities which take place, one of them being the changeover.

Pharmaceutical Company ABC's Product X is manufactured by the Blue Manufacturing Process. The process runs 24 hours/7 days a week with 8 hr. shifts. Equipment A (used for Phase A of the overall process) has 2 operators assigned. The change over time for Equipment A represents 28% of the Blue Manufacturing process' total lead time and includes all the activities required to prepare the equipment to run the next production lot (it is not part of the manufacturing process per se). It starts as soon as the last of the previous product has been discharged and ends as the next product's ingredients are loaded into the equipment. Activities included in this part of the process typically include 'scags' (wasted product) collection, reconciliation and disposition, equipment dismantling, equipment cleaning, equipment installation, equipment preparation (for example, reaching a specific temperature), test runs, and documentation and approvals, among others. As with all other activities, the elements of changeover can be completed in series, in parallel or a combination. The ideal changeover is the one that takes less time overall and limits to the necessary activities. Changeover has to be done right every time for different reasons, among them (listed in no particular order):

- For the manufacturing process to run smoothly, the equipment needs to be installed correctly.
- For the product to comply with the validated, and registered, process all start-up conditions need to be met (for example, temperature and spray pressure and duration). This is part of the manufacturer's guarantee that the product meets all specifications for example for potency and effectiveness. Consistency in the

changeover process adds to the reproducibility of the overall manufacturing process.

- Cleaning is a very important aspect of changeover as this assures there is no cross-contamination (if different products are manufactured in the same equipment), materials used for the same product but for different lots are not mixed, and the equipment is cleaned as indicated in the validation exercise. There are specific regulatory considerations inspected by the FDA when assessing the compliance of a given manufacturing process.

By definition, the time dedicated to change over is considered waste as no value is added to the product and the customer is not willing to pay for it. This is the reason special attention needs to be afforded to the changeover activities as a reduction in changeover results in total cycle time reduction and thus reduced cost and increased manufacturing capacity.

The Pharmaceutical Industry is highly regulated by the government and its regulatory agencies, for example the Food and Drug Administration (FDA), the Occupational Health and Safety Administration (OSHA), the Environmental Protection Agency (EPA) and the Drug Enforcement Agency (DEA). In addition, other regulations and requirements may apply depending on the international markets the industry serves.

To protect the patients' health, much care has to be taken by the pharmaceutical company to comply with the FDA's strict requirements. This includes not only the practices followed to manufacture a given product, but also the activities to dispense the ingredients, changeover and all the related documentation, to name some of the activities.

A proven philosophy to achieve the ideal changeover, in terms of efficiency, is Lean. Lean was originally introduced by Henry Ford and later formally developed by the Japanese, specifically the Toyota Company after World War II. Within Toyota, Sakichi Toyoda, Kiichiro Toyoda, Taichi Toyoda and Shigeo Shingo were instrumental in developing the Lean Principles.

The Lean Focus can be described as the continuous creation of value and elimination of waste driven by customer satisfaction. Lean is a strategy, philosophy, process and leadership approach for operating in a superior way. Lean thinking is lean because it provides a way to do more and more with less and less – less human effort, less equipment, less time and less space – while coming closer and closer to providing customers (internal or external) with exactly what they want. Results include:

- Reduced cycle times.
- Increased quality.
- Reduced costs and inventory.
- Increased capacity potential.
- Improved customer service.
- High levels of worker involvement, ownership and commitment.
- Improved financial returns.

Lean Implementation has five main steps [3]:

1. Specify value: from the customers' perspective and express value in terms of a specific product. It is created by the manufacturer but defined by the customer. In short, an activity adds value if it changes the shape or form of the process or product, the customer cares about it (and is willing to pay for it) and it is done right the first time.

2. Map the value stream: map all the steps that bring a product or service to a customer. When mapping the process, activities can be classified as one of three types: value add (as previously described), business value add (the customer is not willing to pay for it but it is required from the business perspective) and non-value add (waste). Waste is defined as any human activity which absorbs resources but creates no value [2]. Waste can be broken down into eight categories: Defects, Overproduction, Waiting, Non-utilized talent, Transportation, Inventory, Motion and Extra Processing.

3. Create flow: continuous movement if products, services and information from end to end through the process.

4. Pull: nothing is done by the upstream process until the downstream customer signals the need.

5. Pursue perfection: continuous pursuit of improvements so that wastes are completely eliminated and all activities create value for the customer.

When applying Lean concepts to a changeover in order to reduce the time required and increase manufacturing capacity, the waste elimination and flow creation are especially important. As mentioned earlier, there are three types of activities (defined by value): value added – the proportion of these should be increased; business value added – these should be reduced as much as possible and transformed to be more efficient; and non-value added (or waste) which should be eliminated. To eliminate waste, it is important to be able to recognize it.

RESEARCH METHODOLOGY

The company decided to implement Lean Concepts and Tools to achieve the required results in change over time. The methodology followed was the following:

1. Creation of a team composed of Operations, Process Engineering, Technical Services, Industrial Engineering and a Black Belt and completion of a project following the Define-Measure-Analyze-Improve-Control (DMAIC) method. Operators, Supervisors and other functional areas were consulted and involved during the entire project duration.

2. A detailed process map of the changeover process was developed, including multiple changeover observations, time studies (with stopwatch), operators and supervisors interviews, process data and documentation review.

3. The value added, business value-added and non-value added-activities (waste) were identified.

4. The efficiency of the value added activities was increased; the business value-added activities were minimized, simplified and/or improved (efficiency) and the non-value added activities were eliminated as much as possible. Following are some of the tools used to address the value added and business value-added activities:

5S – The purpose of 5S is to create and maintain an organized, clean, safe and high-performance workplace [1]. It consists of five steps (Figure 1 illustrates visually the sequence of the 5 steps):

- Sort: eliminate the unneeded items.
- Set in Order: Keep the needed items in the correct place to allow for easy and immediate retrieval; this also helps to easily identify when an item is missing.
- Shine: clean the area.
- Standardize.
- Sustain: provide the means to be able to sustain the first 3 Ss as designed.

Figure 1
5S Steps

Poka Yoke – Is the Japanese term for "mistake proofing".

Standard Work – Provide clear instructions on how to perform the activities, including the order and combination (by resource) to complete them.

5. Once the necessary minimum activities were identified (and addressed as indicated above), the team proceeded to arrange them in the best order and combination (per operator) possible to reduce the changeover time. This was done applying some of the Single Minute Exchange of Dies (SMEDs) concepts and taking into consideration the earliest and latest possible starts for each activity based on processing times and product life cycle.

The concept behind SMED is to eliminate changeovers - at least reduce the time to a minimum mainly by eliminating unnecessary activities; converting internal activities (that need to

be done while the equipment is down) to external activities (that can be done while the equipment is running); converting serial activities into parallel activities and standardizing as much as possible [4].

6. Final steps included completing a risk analysis to assure the solutions didn't result in a negative impact to quality, health and safety or environmental compliance, revising Standard Operating Procedures, development of Standard Work/Operational Flow Guidelines and offering training.

7. Performance was tracked real time and adjustments were made thru the validation period.

RESEARCH RESULTS AND DISCUSSION

The completion of the project resulted in a decrease of an average of 7 hours (almost an entire shift) for Equipment A's changeover (from 19 hours to 12 hours). Please refer to Figure 2, Equipment A's Change Over Time Before Lean (data includes 50 manufacturing lots prior to implementing the project) and Figure 3, Equipment A's Change Over Time After Lean (data includes 50 manufacturing lots after implementing the project). This contributed significantly to increasing manufacturing capacity as it was one of the major 'bottlenecks', and thus additional demand could be met without major capital investment, additional headcount or impact on quality, safety or environmental compliance levels. The results prove that the methodology and tools employed to address the goal of reducing the changeover time were effective. Statistical analysis of the results confirmed that the improved process was in control with only random variability.

As shown by the data, although the variability and average of the cycle time has been reduced, there is still variability in the process. This variability can be attributed to different causes, among them that the cycle time metric ends when the next lot is ready to start manufacturing – this in itself has variability independent from the normal change over variance since the changeover can be completed but the lot is not ready for starting manufacturing (not related to changeover). The data did prove that, having no 'external factors' influencing the metric, the changeover can be completed in as little as 6 to 9 hours. There are 4 shifts that work this process and there is still some variability on how each shift and individual operator performs his/her assigned tasks during the changeover. Due to other restrictions in the manufacturing process, the variability in the changeover demonstrated after implementing the lean tools doesn't affect the overall manufacturing capacity.

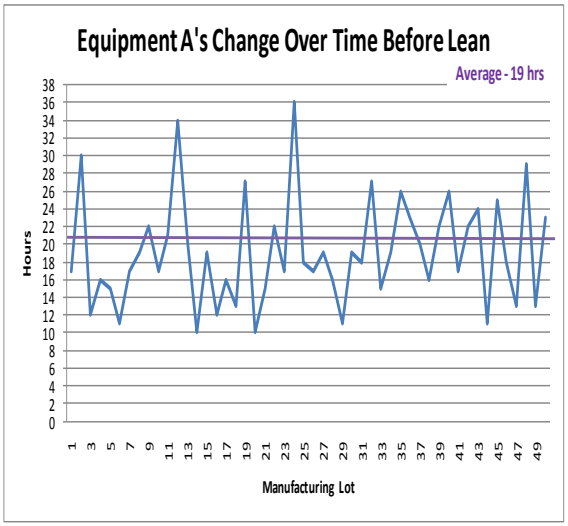

Figure 2
Equipment's A Change Over Time Before Lean

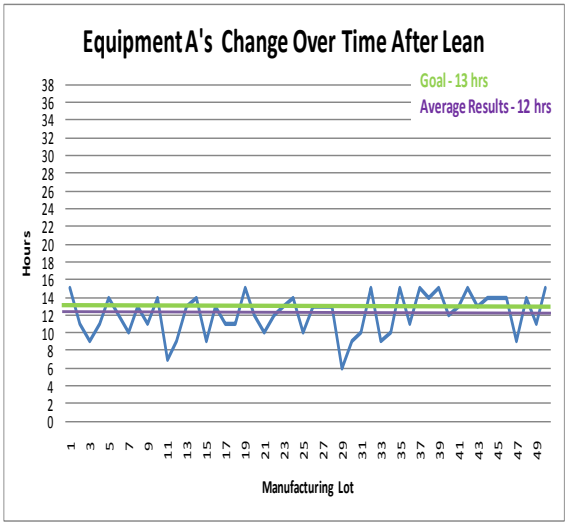

Figure 3
Equipment's A Change Over Time After Lean

As part of any continuous improvement effort, additional activities are needed to further standardize the changeover to minimize, as much as possible, the variability and consistently reduce the change over time to a sustainable level.

The actions taken by the project team are described in the next paragraphs.

The entire change over process (for Equipment A) was evaluated (observed) multiple times by the team, challenged and discussed with the operators and supervisors. From this exercise, the actions were classified as value-added, business value added and non-value added and addressed accordingly. Figure 4 shows the breakdown, in percentages of the distribution.

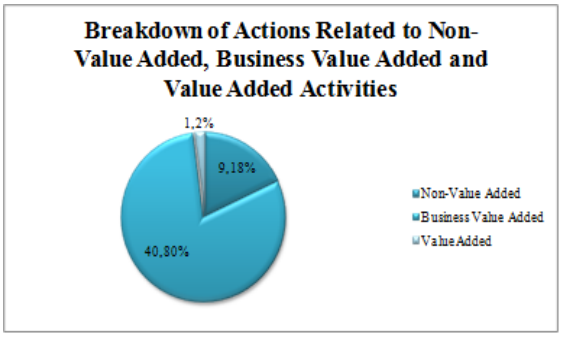

Figure 4
Breakdown of Actions by Type of Value

The breakdown of the improvements is the following:

Non-value Added Activities

Examples of the non-value added activities eliminated include:

- Change over steps not required (for example, equipment dry-run, "flushing").
- Redundant (and not required) verifications and approvals at multiple steps.
- Duplication of efforts [examples: cover transfer points to later exchange for 'connectors'; install temporary piece to later install a filter (available)].
- Looking for equipment/material outside the room.

Business Value-added Activities

Examples of the business-value added activities improved include:

- Documentation and Data Collection
  - Simplified documentation to eliminate redundant instructions (and thus required documentation).
  - Automation of data collection.
  - Divided the manufacturing ticket instructions by floor to avoid having to take the document back and forth.
  - Improved forms to be completed as part of the changeover to facilitated completion and avoid errors or missing information.
- Facilitate Method/Validate Requirements
  - Automation of hose "priming" activity.
  - Validation of cleanliness level required for minor cleanings (by definition less strict than mayor cleanings, minor cleanings were being done at a similar level).
  - Increase water temperature (within safe limits) to facilitate cleaning the equipment.
  - Clean some components of Equipment A 'in-situ' (without removing, transporting, disassembling, cleaning, drying, transporting them back, re-assembling and re-installing them) from Equipment A. This modified cleaning was negotiated and approved by the Quality Unit.
- Equipment Improvements
  - Provided improved auxiliary equipment used to clean the main component of Equipment A (cart with spray nozzles from underneath, longer and improved brushes).
  - Placed calibration equipment on rolling stand so operation can be done

much faster and with only one operator (instead of the current 2).
    - Changed "tri-clamps" for butterfly clamps (it is faster to adjust and doesn't require tools).
    - Provided carts to hold the different equipment parts and use them to transport all the parts at the same time. These same carts were modified to hold in a very visible and accessible way all elements and are moved around the Equipment A (or the room) instead of having the operators move around transporting the parts.
    - Improved tools to clean the different nozzle connections (less effort and time required).
- Availability (Equipment/Materials)
    - Provided auxiliary equipment [carts, stairs, bags, personal protective equipment (PPE), detergent, buckets, color printer] where it is needed (at the area), and organized. This eliminated the need to leave the room multiple times (and change PPE every time) to look for the equipment/material.
    - Assured the tools required during the changeover were always available in the room – for this a cabinet was installed using the 5S concepts.
    - Provided cart to place all the disassembled parts next to Equipment A so no excess traveling was needed (previous to the project each part was transported individually to the sink – and then back).
    - Relocated scale to the adjacent room to weigh 'scags' with limited travel distance.
    - Provided calendar and calculator in room to facilitate calculations to close manufacturing ticket.
- Facilities
    - Marked on the floor where one of the components needs to be placed so that the main component can be installed easier.
    - Provided mirror so employee re-installing the main component of Equipment A can do it without hesitation and thus, in much less time (a hoist is required, and is available).
    - Clearly indicated with perforations and matching bolts where the main component needs to be placed (a specific position/orientation is required). Poka Yoke principles were used.
    - Clearly marked the approved range on the calibration equipment so lecture is fast and error free.
    - Provide access platform for operator and vacuum to easily collect 'scags' from inside Equipment A.

Value added activity

A value-added activity was improved by replacing the equipment to discharge material into Equipment A to make the process faster (and decrease cleaning requirements/time).

Once all activities that needed to be conducted for the change-over were identified and improved, they were arranged in such an order [either in series or in parallel, following the Single Minute Exchange Dies (SMED) concepts] that the human resources' time and efficiency was maximized.

- Remove actions from "internal" to "external" (SMED concepts)

Following are examples of some of the improvements:

    - Use of a spare (available) main component of Equipment A assured at least a 2 hours reduction in changeover as the cleaning of the used one could be done outside the changeover, at another time when overall lead time would not be impacted.

- Have two sets of hoses pre-installed so when a given step in the process concludes, it only takes 3 minutes to change to the next set (instead of having to clean and dry the hoses and nozzles before connecting again). The used hoses/nozzles are cleaned during a non-critical step of process (out of the changeover time).
- Start cleaning auxiliary rooms during Equipment A's run (not wait until the changeover) and the main room as soon as the 'scags' are removed.
- Charge the ingredients before the changeover is complete (it is done in another floor and doesn't affect quality). This change alone saved at least 30 minutes per changeover.
- Start warming/chilling parts of the system as soon as possible instead of waiting to complete the cleaning (this eliminates the need to wait for the equipment to be ready to run).
- Start running pre-run operations for equipment that will discharge to Equipment A before Equipment A's change over is concluded.

- Economy of Movements

Following are examples of some of the improvements:

- Group tasks in logical sequential order per operator to avoid wasted time (instead of having 2 operators alternate between sequential tasks).
- Logically arrange the disassembled components so it is faster to assemble them back in place.

- Standard Operating Instructions, Including Logical Sequential Order

Following are examples of some of the improvements:

- Provide clear instructions on how to conduct the change over – what to do, when, how and who (standard operating procedures and operational flow guidelines).
- A computer system was developed to keep real time information on status of each of the steps (in addition of providing the standard instructions – including task order – for each operator). The system provides alerts of how much time remains to complete a given task (based on standard times).

CONCLUSIONS

The conclusions for this project can be summarized as follows:

The changeover is a business value-add but it does not add value to the final product as it doesn't transform it in any way. As such, it needs to be as effective and efficient as possible. As changeover time decreases, the manufacturing capacity increases and thus allows for adding value for the company.

With a multi-disciplinary team knowledgeable on the process, good data collection and process observation, a detailed process map can be developed and used to identify value-added, business value-added and non-value-added activities. Once non-value added activities are eliminated, lean and problem solving tools can be very effective in improving the effectiveness and efficiency of the remaining activities.

Some effective tools for problem solving used during this project were brainstorming of ideas, experimenting different options and identifying the cause and effect relationship of particular situations.

Once the opportunities are identified, a series of lean tools can be used to reduce the resource (headcount and time) requirements of a given task. These tools include simple standard operating procedures, visual management, 5S, Poka Yoke and SMED. For this project in particular, the concept of SMED was critical to achieve the goal as remaining (although more effective) tasks were organized in a

way that only the tasks that need to be completed in series are done this way. This helps assure the shortest 'critical path' to the change over.

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