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## A CASE STUDY ON LEAN SIX SIGMA FOR REDUCTION IN CHANGEOVER TIME OF DRY GRANULATION AREA IN LEADING PHARMACEUTICAL COMPANY

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**ABSTRACT**

Company XYZ is facing potential drop in throughput of roll compactor batches due to high changeover time for utilization of dry granulation area. To resolve this problem company has targeted 20% reduction in changeover time. Reduction in changeover will leads to the availability of machinery for longer period result in a production improvement. To implement this project following activities are carried out in company. Time motion study of the casual & operator involve in cleaning, analysis of changeover time & drawn of I-MR chart with reference to 3 sigma level of the process, implementation of engineering controls, implementation of 4S and 5S principle. On implementation of these changes in pilot study 43% reduction in changeover time has been achieved.

**Keywords:** Roll compactor, antibiotics, dry granulation, Changeover time, Lean Six Sigma, 4s, 5s

**INTRODUCTION**

Today pharmaceutical company's main aim is to provide cheap and good medicines for public health care. In order to meet all requirements and respond to the challenges companies are struggling to find ways to reduce internal costs and cycle times by providing high quality services to users, through innovative design and efficient response to the unexpected increase in demand for certain products. Implement of six sigma or lean six sigma concept in order to reduce their operational costs and ensure great service to their clients<sup>[1]</sup>. Lean is a management philosophy derived from the Toyota Production System (TPS) in the 1990s. The focus of Lean is to reduce / eliminate wastes across the supply chains so as to deliver maximum customer value. Initiatives like – Six-Sigma, Kaizen, QC Circles and 5S etc are proven to be helping companies eliminate waste and hence are considered as Lean Initiatives<sup>[2]</sup>. Six Sigma is a term used in statistics to represent standard deviation, an indicator of the degree of variation in a set of measurements or a process. It works on the three element i.e. process improvement, process design/re-design and process management<sup>[3]</sup>. For security and confidential matter company name has not been disclosed. Company XYZ is engaged in the production of two antibiotics. Roll compactor is the machine used for dry granulation of antibiotics tablets. Dry granulation is a process in which powder particles are made to adhere to each other without adding liquid and applying force, resulting in larger, multi-particle entities, so called granules. Completion of one batch and starts the production of second batch need some time. The time required to start a new batch is called change over time. In another words changeover is the process of converting a line or machine from running one product to another. In a company production plant, change over time for dry granulation is recorded very high.

Manufacturing companies producing high volumes of different kind of products have in the past been forced to produce large lot sizes in order to minimize equipment downtime. With today's modern technology available and increased customer demand for products to be available on request, ensuring that various different products are available requires smaller lot sizes and less downtime of equipment. This means performing a quick changeover. A quick changeover can be described as the technique of reducing the amount of time to change a process from one specific type of product to another. So the aim of the study is to reduce the dry granulation changeover time by 20%.

**MATERIALS AND METHODS**

This paper will be organized into the phases of the DMAIC (Define-Measure-Analyze-Improve-Control) problem solving methodology. The purpose of each phase is described here: <sup>[4]</sup>.

- 1) Define: The purpose of the Define phase is to delineate the business problem and scope the project and process to be improved.
- 2) Measure: The purpose of the Measure phase is to understand and document the current state of the processes to be improved, collect the detailed, baseline the current state, and validate the measurement system.
- 3) Analyze: The purpose of the Analyze phase is to analyze the data collected related to the Process and identify the root causes of the process problems, and to develop the capability of the process.
- 4) Improve: The purpose of the Improve phase is to identify improvement recommendations, design the future state, implement pilot projects, train and document the new processes.
- 5) Control: The purpose of the Control phase is to measure the results of the pilot projects, and manage the change on a broader scale; report scorecard data and the control plan, identify

replication opportunities and develop future plans for improvement.

**Define:** The Pharmaceutical company manager and team identified the problem of high changeover time in dry granulation process of antibiotic tablets in roll compactor machine. This committee reviews and identifies where there is potential opportunity for reducing the change over time. The productions of antibiotics are the routine process of company where roll compactor is the machine used to dry the tablets granule in the absence of water. Changing of one batch and starting of another batch of antibiotics required some time called changeover time. After reviewing company come to know that change over time is very high. The following steps were executed in the Define Phase: <sup>[5]</sup>

1. Develop project charter
2. Select team and launch the project (Table 1)
3. Create project plan/schedule (Table 1)

**Develop project charter:** The team developed the project charter that is shown in table 1. The project charter scopes the project in defining the processes to be improved. It identifies the problem of the process, and the project goal.

**Measure:** In this stage change over process was monitored and calculated total time required in compactor was 490 min (8.50 hrs). Figure 1 shows the time required in each process under roll compactor. To check the process stability I-MR chart was drawn as shown in figure 2. Average roll compactor changeover time at 3 sigma level was found to be 628 min. Graph shows roll compactor changeover process is stable (no special causes identified) with higher average changeover time & higher variation. To illustrate the project schedule Gantt chart was prepared. To identify potential factors causing an overall effect of the process brain storming was done using Ishikawa diagram (fishbone diagram) as shown in Figure 3 and found out the possible opportunities to work on and will be implemented reduces the time as shown in table 2.

**Analyze :** In this phase factors that need improvements are analyzed. The process problems and their root causes are identified. The following activities were performed for the analyze phase to identify and validate the root causes and to assess whether the process is currently capable of meeting the desired specifications. In this phase Lean 4-step setup reduction workshop was conducted. In the workshop following activities were carried out:

- Time motion study of Type-B changeover activity completed to map each micro level activity through I-MR chart
- Evaluated the As-Is occupancy of operator and casual shown in table 3.
- Brainstormed to move internal activities to external and streamline internal activities as shown in figure 4.
- Prepared list of actions that need to be incorporated for pilot trial to reduce changeover time.

**Improve:** Four step reduction strategies were used to differentiate internal and external events to systematically reduce variation and eliminate defects. All activities during changeover were mapped as either Internal or External.

**Step 1:** In first step all setup were documented and separate events into internal or external. Based on this analysis, results show total change over time: 530min, Internal activity time: 435min, External activity time: 80 min as shown in figure 5.

**Step 2:** Internal activities are converted to external activities basis of workshop discussions and ideas as shown in figure 6. Major activities converted from internal to external are mechanical sifter dismantling and cleaning, search time for tools for cleaning accessory, potable equipment send to washing area for cleaning.

**Step 3:** Streamline internal events by brainstorming and preparing fishbone diagram. Job balancing was done between operator and casual to reduce changeover time as shown in figure 7.

**Control:** Future performances of the process are considered under control phase. On implementation of all possible tools, results finally achieved 43% reduction in changeover time for changeover during pilot project shown in figure 8.

**Major Improvements (within cleaning SOP guidelines)**

- Implemented 5S to eliminate the search time for tools required for dismantling, cleaning accessories like silicon tubes, gum boots
- Drying time of Blender and Roll compactor parts reduced by 20% through additional compressed air line and parallelly employing 2 casuals to dry blender body & parts using both compressed air & lint-free cloth.
- Mechanical sifter, Oscillating granulator ,SS Accessory items dismantling, cleaning activity converted from internal to external setup
- Cleaning with potable water and purified water optimized by using silicon hose pipe with water get gun with higher water flow rate

**Key Next Steps:**

Standardize the cleaning procedure and establish visual controls and develop control plan to ensure sustenance.

## DISCUSSION

There were no articles specifically addressing applying Lean Six Sigma to reduce changeover time in pharmaceutical company. There is still a great need to fill the gap of case studies and research articles applying Lean Six Sigma to healthcare. There is tremendous potential to apply this data oriented approach to healthcare to streamline operations, enhance customer satisfaction and ensure positive healthcare outcomes. As a methodology for improving both factory output and quality, Lean Six Sigma has gained widespread popularity. The approach, which aims to help companies create leaner manufacturing operations and boost product quality to no more than 3.4 defects per million opportunities, has delivered significant improvements and cost savings at number of leading companies. This study results shows the reduction of change over time in roll compactor used for the dry granulation of antibiotic tablets by using six sigma and lean concept together. Our results substantiate with the case study conducted in Orthopedic and neurological spine surgery division, Memorial Hermann Southwest Hospital in Houston, Texas, U.S.A., Researchers implement six sigma strategy to reduce turn over time required to prepare the operating room between cases and found the baseline turnover of 24 minutes to 20 to 21 minutes. More importantly the number of defects (turnovers exceeding 25 minutes) has dropped from 40 percent to 21 percent <sup>[6]</sup>. With the implementation of 5s lean tool along with six sigma, company got gain in the reduction of high change over time. In India Dr. Reddy's, Granules India Ltd in Hyderabad, Divis Laboratories Ltd in vishakhapatnam, Aurobindo Pharma Ltd and Natco in kothur all these company implemented 5s tool to increase the productivity and gain high turnover in a year <sup>[7]</sup>. Khamis et al.,<sup>[8]</sup> discussed a case study of two manufacturing companies and shows by implementing lean 5s tool there is increase in the production of xyz material. In this study by preparing the gantth chart and job balancing each employee give almost equal hours to work like wise a case study done by Priyadarshini <sup>[9]</sup> shows by implementing six sigma and keenly observe the job distribution among employees result so obtained are magnitude of work was reduced in the overutilized teams, the utilization metric started to trend down, going from 240 percent to below 90 percent. Fish bone diagram was drawn in this study to find out the loopholes of the current working process and found job distribution among employees is not even. Bose in 2012<sup>[10]</sup> conducted a case study in James hospital and using fishbone diagram to evaluate supply Chain and Business Process.

**CONCLUSION**

This case study demonstrates the applicability and appropriateness of lean six sigma to company support processes, such as management, distribution, replenishment, usage and control of changeover time. This particular company has been extremely successful applying Six Sigma tools in production processes to improve throughput, save time, equal distribution of work, improve revenue, improve quality and help to ensure benefit of the

company. On implementing this pilot study on large scale it will help in large production of antibiotics in shorter time which leads to the economical benefit to the company.

**ACKNOWLEDGEMENT**

I would like to thank the entire team of company which directly and indirectly involved in this project.

<p><u>Problem Statement</u></p> <p>&gt; Potential drop in throughput of roll compactor batches due to higher changeover time for utilization of dry granulation area.</p>	<p><u>Goal Statement</u></p> <p>&gt; 20% Reduction in changeover of dry granulation area.</p>
<p><u>Business Case</u></p> <p>&gt; Reduced changeover time will allow higher available time for production.</p>	<p><u>Scope</u></p> <p>&gt; All equipment in process area required for dry granulation manufacturing.</p>
<p><u>Schedule</u></p> <p>Define : 05.03.14                  Measure: 18.04.14                  Analyze :25.04.14                  Improve : 30.04.14                  Control : 30.04.14</p>	<p><u>Team</u></p> <ul style="list-style-type: none"> <li>- Akhilesh Solanki(Oral Process Area)</li> <li>- Vinay Rana (Oral Process Area)</li> <li>- Ajit Mohanta(Oral Process Area)</li> <li>- Pankaj Pandey(Oral Process Area)</li> <li>- Vaidehi Gautam(Oral Process Area)</li> <li>- Balram Raghuwansi(Oral Process Area)</li> <li>- Kunal Rai(QA)</li> <li>- Mohd Ahsan Khan(Validation)</li> <li>- Zeba khan (Data analysis)</li> </ul>

Table 1: Project charter

Figure 1:

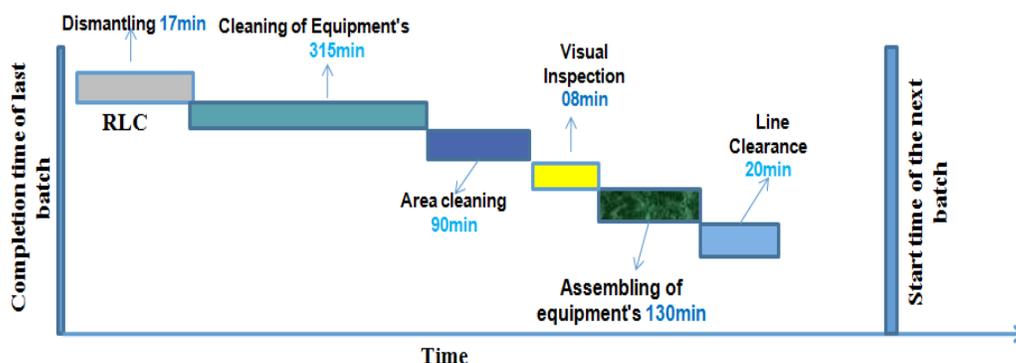


Figure 1: Flow diagram of changeover of roll compactor

Table 2: Opportunities need to be identified and implemented

AREA	OPPORTUNITIES	STATUS	BENEFITS	REMARKS
Granulation-2	Water jet cleaner to be used for dry granulation area in Type-B cleaning.	To be implement.	Approx. 40 min. saving	PRS raised
Granulation-2	Blender dismantling can be done during transferring of IPC to quarantine area from 3 <sup>rd</sup> casual.	To be implement.	Approx. 10min. Saving	-
Granulation-2	Campaign cleaning to be instead from 72hrs to 168hrs.	To be implement.	Change over time save	Change Control to be raised.
Granulation-2	SS box to be fitted on electrical panel box.	To be implement.	Time saving( Approx. 05 to 10min)	To be discuss with Engg.
Granulation-2	Two hose pipe to be used for cleaning activity 01 for potable water and 01 for purified water.	To be implement.	Approx. 30min. Saving	Hose pipe to be arrange.
AREA	OPPORTUNITIES	STATUS	BENEFITS	REMARKS
Granulation-2	In case dry cleaning or dedusting of parts to be used only vacuum cleaner.	To be implement.	Approx. 45min. Saving	PRS to be raised.
Granulation-2	Cleaning of HPL & stair case instead of water cleaning only wet mopping as well as dry with lint free cloth to be implemented	To be implement.	Approx. 15 min. Saving	-
Granulation-2	Arrangement of cleaning accessories before starting the cleaning activity.	To be implement.	Approx. 10 min. saving.	-
Granulation-2	During cleaning of the equipment intermittently cleaning of the area (wall, fall ceiling) to be carried out.	To be implement	Approx. 30 min. saving	-
Granulation-2	Pre intimation during starting of cleaning to be given for hot potable water(50°C to 60°C) temp. maintaining.	To be implement	Time saving approx. 25 min	Automatic set point (Eurotherm) to be provided.
Granulation-2	Potable equipment's to be send in washing area for cleaning.	To be implement.	Approx. 70min. Saving	-
Granulation-2	Manpower to be trained for this area.	To be implement.	Time saving	-

Table 3: Changeover time reduction in cleaning of dry granulation area equipments

	Baseline (As-Is) Average of Jan'14 batches	Baseline (As-Is) Time motion study of TTZUS	Target (To-Be) 20% Reduction
RLC Cleaning (min)	10.5hrs.	315	252
Area Cleaning (min)		90	72
Parts Assembling(min)		90	72
Line Clearance (min)		20	16
Total Changeover (min)	630	530	412
Manpower	1 Operator + 3 casuals	1 Operator + 3 casuals	1 Operator + 3 casuals

Table 3: Changeover time reduction in cleaning of dry granulation area equipments

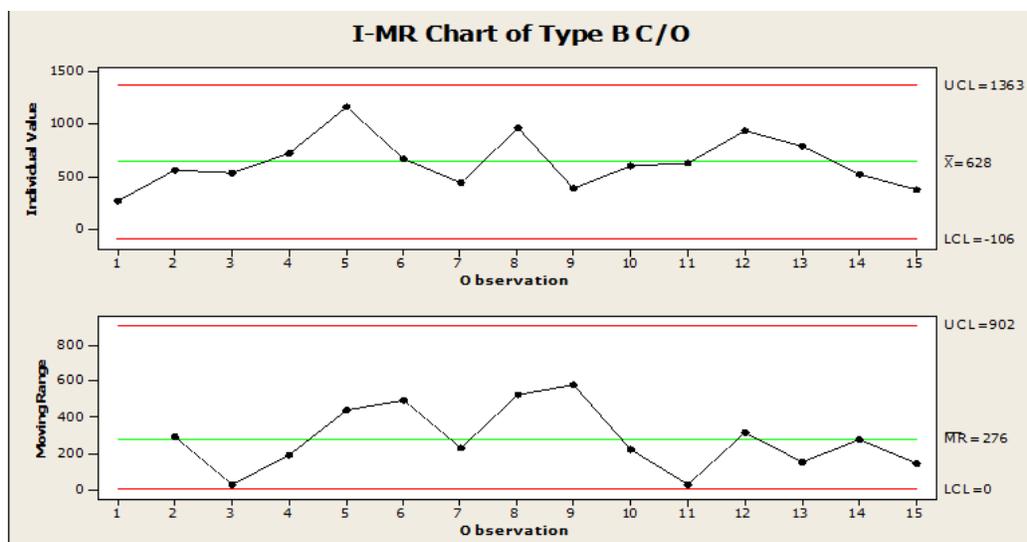


Figure 2: Dry granulation changeover time: I-MR chart to evaluate process stability

Brainstorming and fishbone diagram for identifying causes for high changeover time

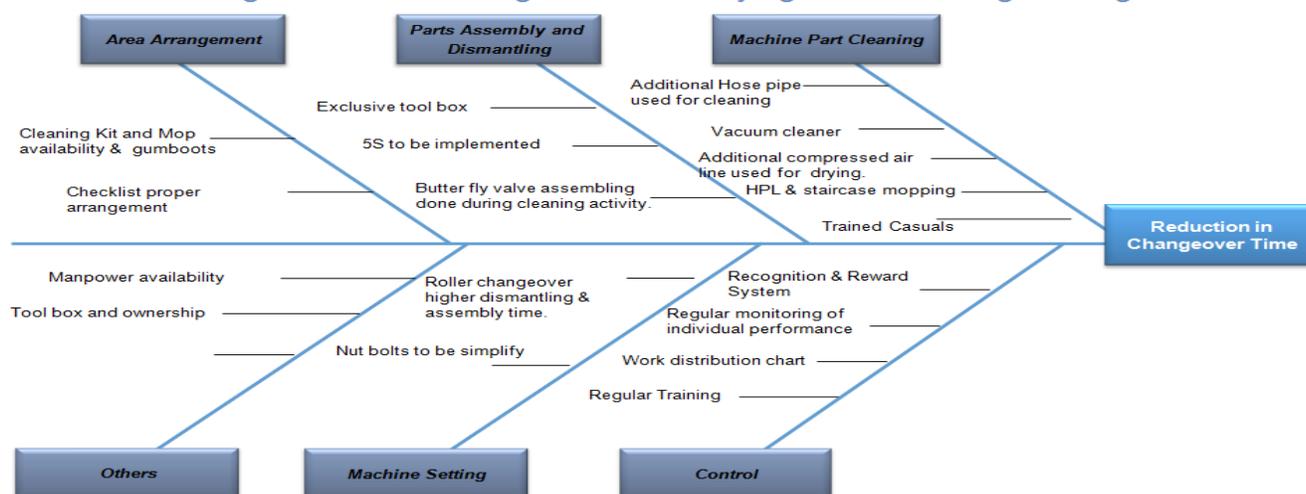


Figure 3: Fishbone diagram for reduction of change over time

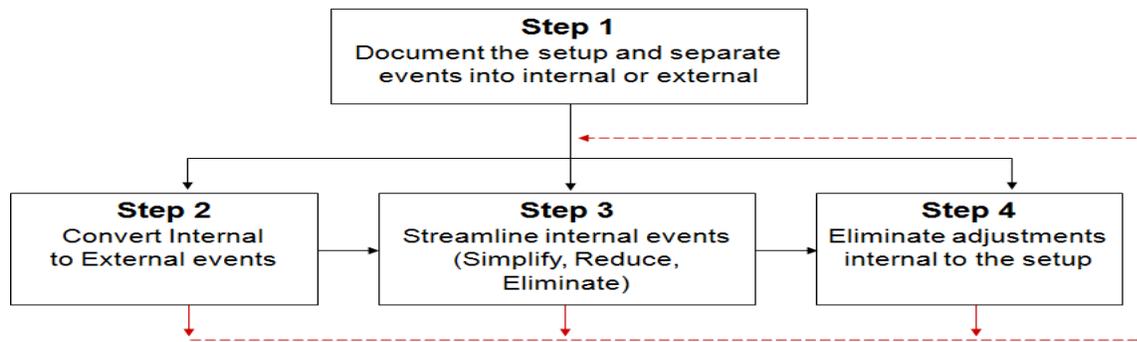


Figure 4: streamline internal and external event using 4 step reduction tool

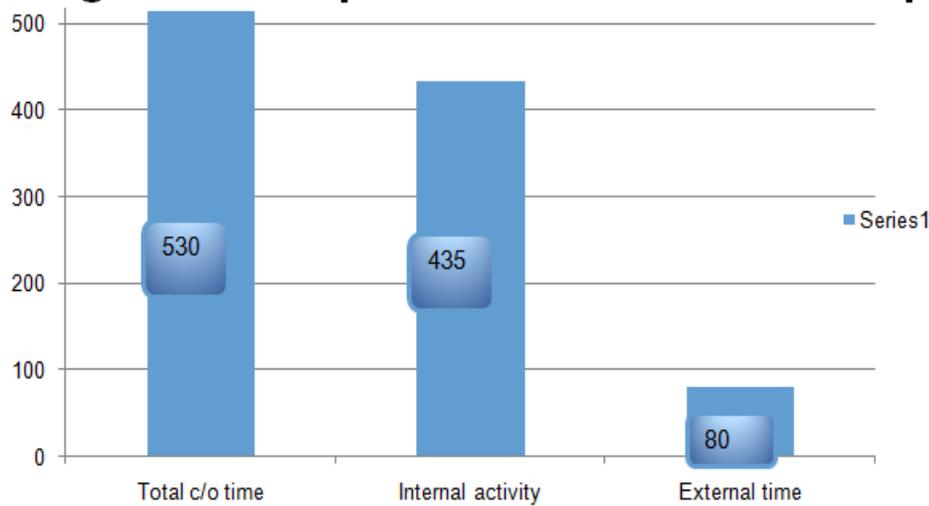


Figure 5: step 1-Document the setup and seperate events into internal and external

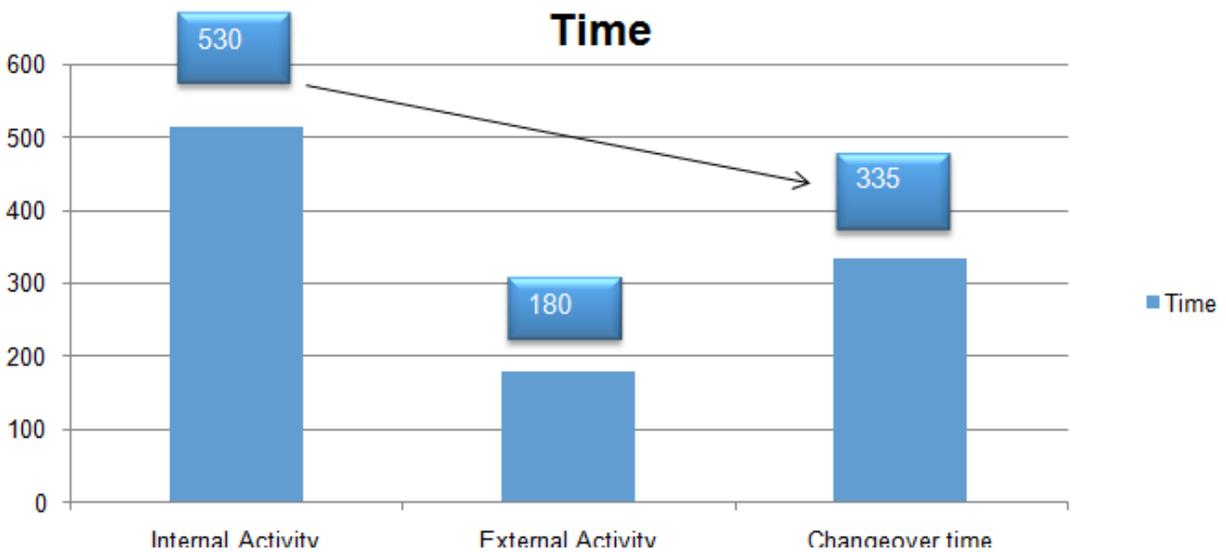


Figure 6: Conversion of internal activities to external activities

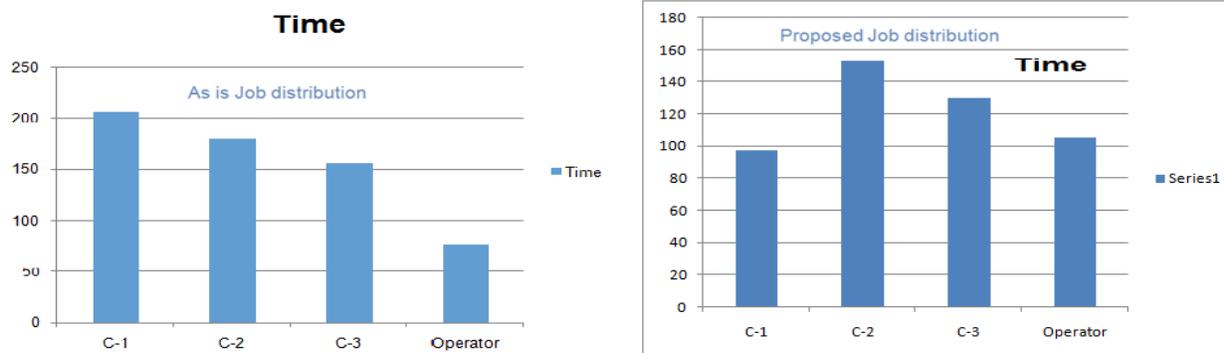


Figure 7: Job balancing between operator and casual to reduce changeover time

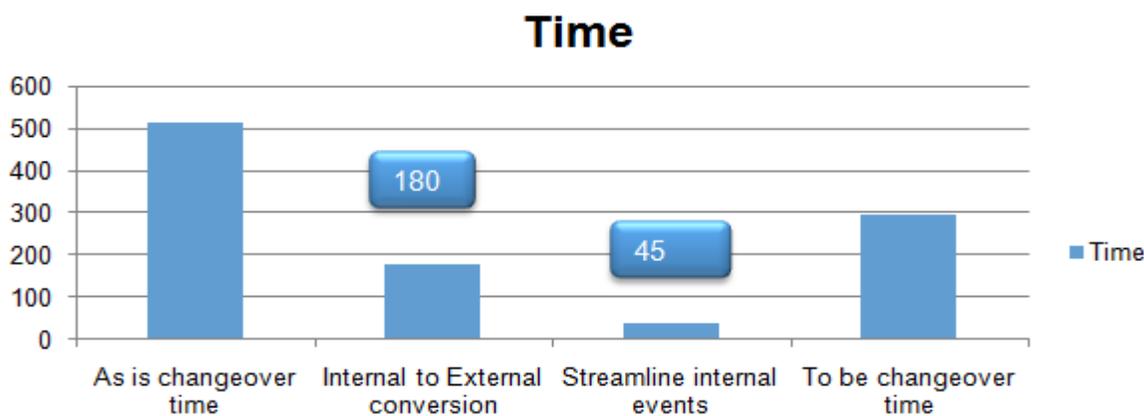


Figure 8: Achieved 43% reduction in changeover time for changeover during pilot

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