



ETHICS AND COMPLIANCE PROGRAM IMPLEMENTATION TO DECREASE HUMAN ERROR DEVIATIONS AND INCREASE EMPLOYEE SATISFACTION

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ABSTRACT

This project achieved to increase the employee satisfaction and decreased the amount of deviations caused by human errors through the implementation of an Ethics and Compliance Program, with a Code of Values and supportive initiatives like recognitions and awards, etc. this project was executed in a small pharmaceutical company, under consent decree by FDA, and acquired by a new company in 2014, 4 years ago. As a by-pass achievement, the production schedule, which usually missed a significant amount of lots to complete in monthly plans due to short count of personnel, with this project they achieved to decrease this amount. This project was designed following the DMAIC tool from Lean Six Sigma application.

INTRODUCTION

Performed in a small pharmaceutical company that lack of an Ethics and Compliance Program that states as a rule a conduct code, this have affected the quality, production and have created a hostile environment. Unhappy employees could show resistance to achieve the expectations of company. Researches has shown that management practices relate to employee satisfaction, which also impacts customer satisfaction. When employees are satisfied with their treatment, given the right tools to do the job, and supported by management; customers are more likely to have higher perceptions of quality and will continue to do business with the company, employees' works with quality [1].

PROBLEM

In this case, there is an increase of deviations due to human errors with an actual of 23 that we want to decrease by 16 to achieve last year's standard of 7. We also wants to increase employees satisfaction from the actual 2= "strongly dissatisfied" to 4= "somewhat satisfied" recovering the decreased gap of two levels. We want to achieve this goal starting the first quarter of year 2018. If we continue with the actual trend the company can face serious losses on money due to bad quality, bad performance and in the worst case, the FDA can punish this behavior not releasing the company from the actual consent decree.

OBJECTIVES

- The implementation of an Ethics & Compliance Program for a small company of less than 300 employees with a high confidentiality and anonymity hotline to deal with any issue reported.
- Decrease the number of lots missed due to short count of personnel on the proposed production schedule.
- The creation and inculcation of a code of values to have a high standard conduct between all the employees.
- Decrease the amount of deviations with Human error as the root cause from 23 to 7 per quarter.
- Increase employee satisfaction from two= "somewhat dissatisfied" to 4= "somewhat satisfied" to achieve a major employee retention and less turnover.

METHODOLOGY

The Lean Six Sigma Methodology, Define, Measure, Analyze, Improve and Control (DMAIC) Process was applied with others techniques like Voice of Customer, Data Collection Plan, Charts, Graphs, Fishbone, Benefit & Effort Matrix, and Control Plan. DMAIC guide us to Define the problem, Measure the relevant data, Analyze it to take decisions, Improve and implement new process, and Control and keep the new process to assure is effective.

RESULTS AND DISCUSSION

Define

The company designated the head of the Human Resources department as the responsible of this new Ethic & Compliance Program. To define the reason of the decreased employee satisfaction, we apply the voice of customer matrix as in Figures 1 and 2, the employee works for the company and the company works for the employee.

VOC Matrix	
Supplier:	Customer:
Company/Management	Employee
	<ul style="list-style-type: none"> Wants to be recognized for their efforts. Wants better trainings, better SOP with clear instructions. Wants to have all the materials needed to complete the job. Wants to be listened, their opinion considered. Wants better tracking of their progress. Needs to feel confidence and trust their direct management. Needs a confident method to report issues without retaliation.
VOC Matrix	
Supplier:	Customer:
Employee	Company/Management
	<ul style="list-style-type: none"> No absenteeism. Perform in compliance lowering deviations due to human error. Productivity Good Documentation Practices Good Manufacturing Practices following Standard Operations Procedures Perform with safety

Figure 1: VOC Matrix: Employee as Customer

Figure 2: VOC Matrix: Company/Management as Customer

Measure, and Analyze

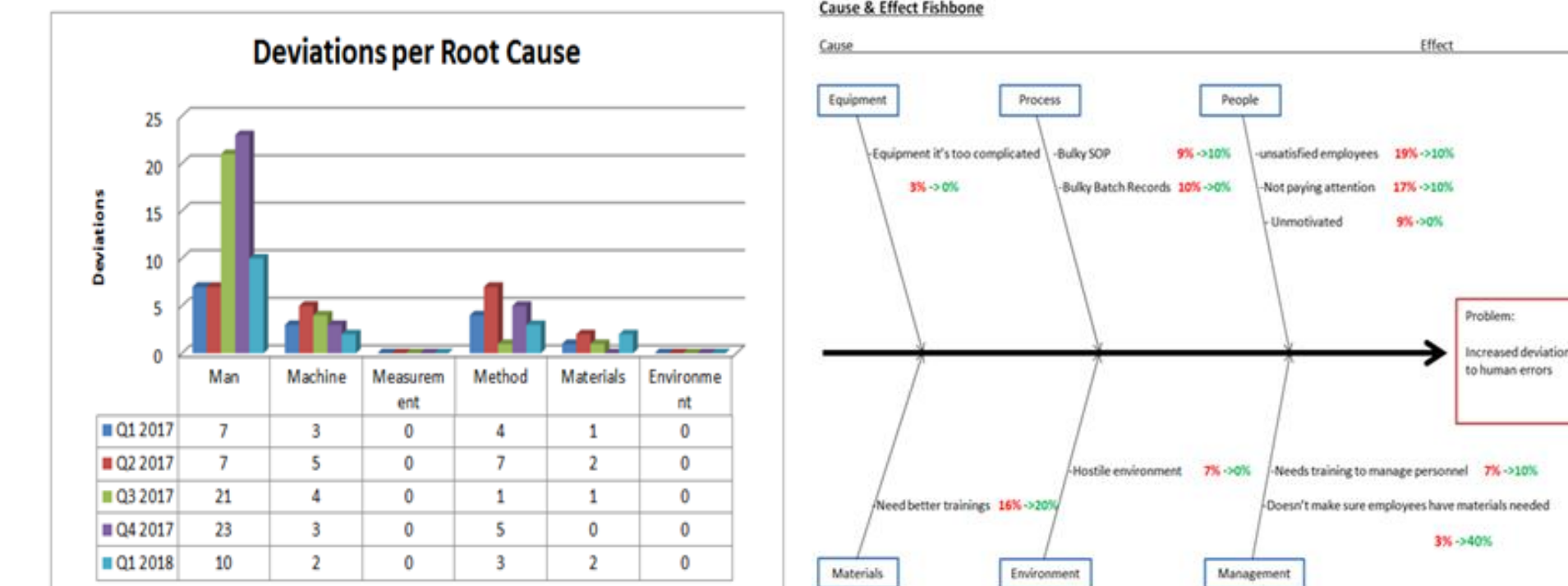
Deviations with Human Error as Root Cause To Measure the deviations, each one of the 58 deviations due to human error is closed with an investigation where the employee is interviewed to understand why the task was performed in a wrong way. The result is analyzed as the highest percent was caused by employee with low satisfaction (19%), followed by not paying attention (17%), and need better trainings (16%). **Employee Satisfaction** A survey to know about the employee satisfaction was performed to a sample of 140 employees from the departments of manufacturing, laboratory, engineering, supply chain and quality, departments in risk or with deviations due to human errors. The survey was performed through Gallup, a site dedicated to satisfaction surveys. The answers were evaluated with Likert Scale, 5 to Strongly satisfied, 1 to Strongly dissatisfied. The areas with very low satisfaction were: materials and equipment available, employees opinion counts, talks about personal progress, satisfaction with the company as a place to work. **Lots missed due to short count of personnel on the proposed production schedule** The production schedule was evaluated comparing the proposed schedule versus the actual schedule monthly. Also, we evaluated the reasons to the delays between workforce, materials, equipment, process, and schedule changes, the top reason to not meet the proposed schedule monthly is the short count of personnel, followed by deviations. Absenteeism is very common in employees with low morale, unsatisfied, unmotivated, and/ or uncommitted with the company.

Improvement

To obtain an overall improvement a Code of Values was designed as part of a program of Ethic & Compliance. The Code of Values is derivate from the points that needed support that we could identified in the analysis of the investigations on the reasons for each deviation due to human error, and the survey for employee satisfaction. The Code of Values also explain roles as employee and management, where to ask questions or report concerns, how to manage and assure confidentiality and data privacy, assure a non-retaliation policy, the investigations and disciplinary actions, the fair competition and anti-trust, anti-bribery and anti-corruption, the competitive intelligence, the false claim act, the conflict of interest and how to avoid it, equal opportunity, workplace harassment and violence, record and information management. With this they also implemented a hotline to report confidentially any violation to this code, or other compliance and ethic concern. Also, implemented a few different programs promoting the employees' engagement, collaboration and retention like Quarterly Town Halls, Monthly Site Performance Review, Monthly Shining Stars Awards, Employee Appreciation Day, Quality Excellence Program, Extended Leadership Team Governance, Focal Groups, and Individual Growth Plans.

RESULTS AND DISCUSSION

Deviations with Human Error as Root Cause During the first quarter of year 2018 a total of ten (10) deviations due to human errors were closed, this is a significant decrease compared with the previous two quarters. The Graph 1 shows the improvement and to analyze it a fishbone (Figure 3) with the percentage of the reasons given by the employee on the investigations for the human errors deviations is presented with the previous score from year 2017 and the new score of the first quarter of year 2018, after implementation of the program and initiatives.

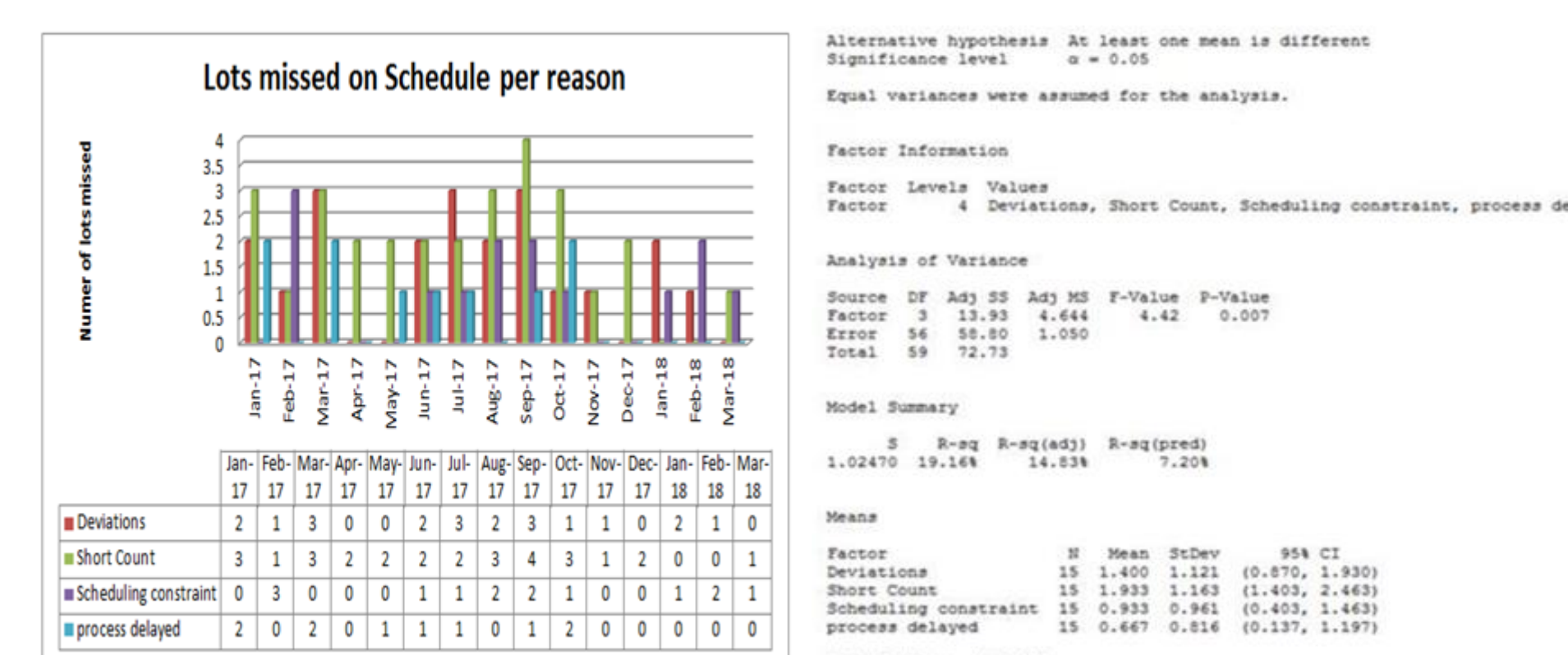


Graph 1: Deviations per Root Cause

Figure 3: Cause & Effect Fishbone

Employee Satisfaction The results on the survey after the implementation of the Code of Values and the Supportive Programs presented a significant improvement on the employee satisfaction with the company in every aspect presented. Even with this improvement, there are three aspects the company must continue working on: Supply materials, "skills and abilities are put to good use", and "is a good place to build your career". From these three aspects, the first two scored an average of two, which is "Somewhat disagree" and the last one scored an average of 3 "Neither agree nor disagree".

Lots missed due to short count of personnel on the proposed production schedule The quantity of lots missed due to short count of personnel has decreased as shown in Graph 2. Even when the quantity of lots missed decreased on Q1 2018, the few lots missed are mostly due to scheduling constraints and deviations. This data was analyzed with an analysis of variation (ANOVA) in the program Minitab® to determine the variation between the reasons to miss lots on the production schedule. The results are shown in Figure 4, where the analysis resulted in a F-Value of 4.42, a p-Value of 0.007 and the highest mean and standard deviation it is for the Short Count reason. The comparison of the means for each reason is analyzed in Graph 3 as part of the analysis in Minitab®. To analyze the difference between the lots missed on schedule, before and after the implementation of the programs the same data was analyzed in Minitab® with a Two Sample T-Test (Figure 5). Assuming the null hypothesis is no change, and the alternate hypothesis is change, according with the p-Value that falls below the alpha of 0.05, the null hypothesis will be rejected, accepting the change on the alternate hypothesis because the variance from 2017 is different from variance 2018. This analysis was also tested on Microsoft Excel® as in Figure 6, that shown a T-Value of 3.36, greater than the T-Critical of 2.16, which also reject the null hypothesis.



Graph 2: Lots Missed on Schedule Per Reason

Figure 4: ANOVA

RESULTS AND DISCUSSION

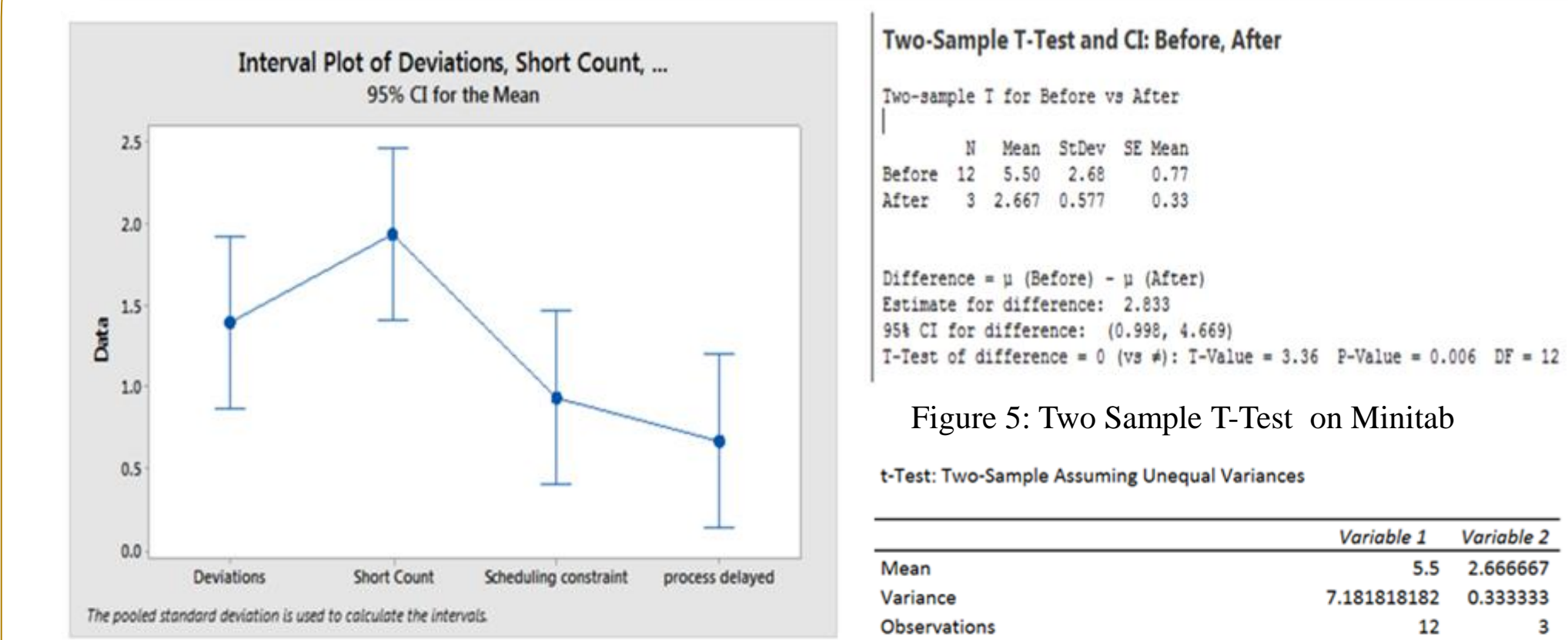


Figure 5: Two Sample T-Test on Minitab

Control

Every control analyzed in the Control Plan (Table 1) must be submitted to the Human Resources department in charge of the Ethics & Compliance Program. Is very important the commitment with this Program, report the data with integrity, and report any out of specification outcome to deal with the promptly the team can. It is necessary to maintain the support to this program. "Employee satisfaction is a key towards greater productivity and quality; this is why they should be surveyed on regular basis. The survey must include job satisfaction, training, pay, advancement fairness, treatment: respect and dignity, and Company's interest in well-being" [2].

Figure 6: Two Sample T-Test on Excel

Control factor	Specifications	Measure Technique	Sample Plan (%)	Sample Frequency	Control Method	Reaction Plan
Deviations due to human errors	7 Deviations per Quarter	Audit	100% human error rate cause deviations	Monthly/Quarterly Report	Metrics in dashboard and share folder	Analyze reasons given in the investigations, Management should decide with HR path to solve.
Code of Values, Policies, and SOP related to conduct and behavior	A maximum of 3 violations in the one over 1 year	Metrics on Reports to include, HR department of questions related	100% Reports	Quarterly/Annually report	Metrics in dashboard and share folder	HR: Analyze, document, update aligned with business needs.
Lots missed on proposed schedule	A total of less than 5 lots missed monthly	Metrics from Supply Chain	100% Proposed schedule	monthly	Metrics in dashboard and share folder	Review the program and all the supportive activities perform different focal groups to get to mass to improve and find the root cause.
Employee satisfaction	higher or equal average of 3.5 questions, Overall average of 3.5 higher	Surveys	Calculated with 95% Confidence and 95% error	Quarterly score 4 or higher, then survey every 6 months	Metrics by HR department in share folder	Review reasons to delay improve for next month.

Table 1: Control Plan

CONCLUSIONS

The problem presented has been solved, the amount of deviations caused by human errors has decreased and the satisfaction of the employee has increased as a consequence of the implementation of an Ethics & Compliance Program with supportive initiatives. We achieved the objectives of this project, especially, decreased the quantity of Deviations caused by human error from 23 deviations quarterly, and increased employee satisfaction from an average of 2 "Somewhat dissatisfied" to 4 "Somewhat satisfied".

FUTURE WORK

Should be a good future research to measure and analyze the improvement on deviations, and production schedule, achieved after a Cognitive Studies Program completes the improvements to trainings and Standard Operating Procedure, and how this program influence in the employees satisfaction. There is also an opportunity to do some focal groups to get the perception of the longtime employees comparing the before and after this program and initiatives, and as a separate division, this same point of view of the employees retained from the previous company.

REFERENCES

- [1] D.Schaaf, & R.Zemke. "The Service Edge", Plume, 1989.
- [2] J.L.Heskett, T.O.Jones, G.W.Loveman, Jr.Sasser, W. E. S., & L.Schlesinger. "Putting the Service-Profit Chain to Work" Harvard Business Review, March-April 1994.