

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.*

Key Terms — *DMAIC, Employee Satisfaction, Ethic & Compliance Program, Human Error.*

PROBLEM STATEMENT

This project is 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, in some way this could even affect the quality of the service since one aspect of quality is to achieve the shipping date with a product in compliance with high quality. The purpose of this project is to develop a program according the necessity of the company. The highlights of the company are that they were bought by the actual company, on 2014, under a consent decree by FDA and some of the employees were employees of the previous company so they resist to a change of culture, the employees in some cases don't face consequences for their misconduct so they

keep misconducting, they show no importance to comply with the company expectations, they are unmotivated and do not show respect for the management, they do not show any effort to exceed the expectations, they are just “working”.

This project matter because research 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]. 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.

Research Description

This research is meant to design the proper Ethics and Compliance Program for a small company with less than three hundred employees. It is important that employees have a Code of Values to guide them to a healthy work environment that results in process and product of high quality.

RESEARCH OBJECTIVES

The research objectives are the following:

- 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.
- The establishment of a zero tolerance culture to any kind of retaliation on all the reports.
- 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.

RESEARCH CONTRIBUTIONS

The company will have an Ethic and Compliance Program viable to a population of less than 300 employees, supporting the employees and their work environment to achieve employee satisfaction and retention that can positively affect the quality of our performance as a company. Once the company has the program, the company will have employees satisfied and proud of their job working towards the high quality on their processes and products, achieving a decrease in the amount of deviations caused by human errors. The company will have a healthy work environment full of values and respect between the employees at all levels. A Code of Conduct that will assure zero tolerance to retaliation and consequences to any misconduct will be achieved. The employees will care for the goals, mission and vision of the company and will work with effort to comply with the expectations of their leaders and customers to deliver a product of quality without any delay and a decrease in deviations due to human error.

LITERATURE REVIEW

To understand this project is necessary to understand what compliance is. Compliance [2] means knowing and following the relevant laws,

rules, principles, and standards and procedures. To achieve this compliance in a company is necessary to have a program that can remind constantly to the people that they should be committed in acting in compliance and encourage ethical conduct. For this, it is pertinent to begins assuring a clear understanding of the standards and procedure in every employee, standardizing behavior. The Compliance and Ethics Program must have seven fundamental elements: internal monitoring and auditing, implementation of compliance and practice standards, designation of a compliance officer, appropriate response to detected offenses with proper corrective actions, and the enforcing of disciplinary standards through well-publicized guidelines [3]. It is important to start with the Board and upper management since they are role models for the company and they set the Tone at the Top. To have the proper Tone at the Top it is necessary to train board members and upper management in ethics and compliance issues [4]. In addition, training must be provided to all the employees in the company, training related to employment law like sexual harassment, workplace harassment and ethical practices [4]. When this learning achieves the level that it can be called culture, employees should begin to behave and work in compliance and can be aware of what is not in compliance. To obtain a notification from the employees that notices something not in compliance or unethical, the program must assure zero tolerance to retaliation, anonymity and confidentiality through a hotline. This way, employees do not hesitate to report misconduct. In some companies, is more effective the use of a helpline to give advice and assistance to the caller [4]. Every report should be managed, never ignored, and impose the pertinent consequences, no matter the level of the employee misconducting. This task belongs to the designated compliance officer, this person should have access and the authority to review all documents and other information that is relevant to compliance activities, also have direct access to the company’s governing body, the CEO, all other senior management and legal counsel [3]. This individual should evaluate the

effectiveness of the program, monitoring and auditing it to detect criminal conduct and to assess the risk of criminal conduct to take the appropriate steps to reduce the risk or occurrence [5]. To monitor this program, a continuous education about the values and culture, standards and procedures must be in place; this must be part of an Annual Compliance Report.

To maintain employees engaged with the compliance and ethics program, performance incentives could be considered [5], especially when the implementation of this kind of program represent a change of culture to which some individuals may show resistance. It is a good idea to focus on individuality rather than of the compliance program itself, this way produce benefits such as the better employee productivity and also morale, satisfaction, higher profits, and stronger reputation among customers, investors, and other third parties [2].

An ethics and compliance program can bring benefits in areas such as hiring and retaining top quality employees and a decrease in turnover due to low satisfied employees. Employees are very sensitive to business ethics, they are aware of their organization's culture and pay attention to the tone set from the top and around them, and this is why unethical behavior has a strong effect on employee's morale and distracts them from the company's business [2]. An unmotivated employee could be harm to the company, lowering their own ethics towards his job, and damaging economically the company causing significant loss of money. Employees with this attitude can propagate it to other employees if they aren't handled, for example, when a rise in deviations due to human errors, and low productivity can be related to unhappiness of the employees at the workplace.

METHODOLOGY

Every Ethics & Compliance Program is unique for each company. To design the ideal one for this company in this research we must evaluate the necessities of the company, what they need to achieve and seems like they are behind in those

goals. First of all, the company needs a designated head of the E&C Program with the preparation and expertise in this field. The major thread is the high density in deviations opened due to human errors; this is affecting highly the production schedule and causing wasted money. The learning system is doing their part to assure retraining, but is easy to identify a negative attitude from the employees. This is how we start defining an Ethics & Compliance program in this company, employees' attitude towards their jobs need guidance and attention, teach them the importance of what they are doing. Since employees in that company feels a "bad work environment", to change this negative culture with the Ethics & Compliance Program is suggested to implement a nice incentive program for the compliance and ethics behavior promoted in the E&C Program, personnel that behave according the new proposed culture should be rewarded. This way adherence to the expected behavior and compliance with quality is achieved.

To align the culture to the E&C Program a code of values is created according to the deficiencies of the actual culture. To identify this deficiencies properly, we perform an anonymous survey with questions about the actual culture, the attitude, the feeling regarding the upper management, retaliation, confidence in report some misbehaving, ethics, compliance and satisfaction with the company. This gives us a real image of the actual culture and the areas to improve in this field. Also an analysis of the trends of the deviations per category on the human errors root cause should be done to identify what behavior should be modified that affects directly the product of the company.

Once the code of values is established and inculcated in the population, a system of high confidentiality to report any behavior against the code of values must be created. The hotline must be confidential and anonymous to promote more confidence in the program and motivate the personnel to report any unethical behavior and noncompliance acts, and/or behaviors that affects the code of values or affects other employees to not act by the code of values. Every report should be

managed, analyzed, investigated and corrected with confidentiality by the head of the E&C Program. The standard of disciplinary actions like written warnings, unpaid suspensions, and termination of employment should be established to deal properly with every report investigated. The reports should be classified by category for the annual report; also a file will be created for every person reported no matter the outcome of the investigation. This is to keep a track of the trending of reports. To keep this part of the program running is necessary to have a zero tolerance to retaliation culture that applies to all levels in the company. This is to minimize the tense environment due to unofficial comments. Also all levels of management should be trained on how to deal with reports and situations that requires confidentiality.

Is expected that the population begins to feel proud of their jobs and the company, with a set mind in quality and customers satisfaction, and become more productive. The impact on the population behavior can be measured with the increase in productivity and the reduction on deviations and quality issues. Periodically a survey must be performed to measure the changes in this execution, it should be the same survey or a modified one generated as a “son” of the first one to keep the standard. A close evaluation of the trend on how often the production schedule is achieved must be performed to evaluate the program toward the productivity impact. This must be a joint task with production, since we need an honest evaluation of the production schedule, if it is humanly possible to achieve without overtime. This will help to motivate the personnel to execute according some performance expectancies in productivity and avoid the waste of time and money due to overtime. Production managers should show trust in their employees and motivate them to achieve the production goal in the established work days, this is part of the new culture.

Another way to prove efficiency of this program is to keep track and analyze the trend in quality issues, is expected to see a reduction in the quantity of deviations related to quality and human errors.

Every time an increase is identified in the trend, the situation should be analyzed carefully to avoid any fail in the program and manage it on time.

This program must have the full support of the board and upper management. The budgeted to complete this project which includes a program for the anonymous surveys, trainings for the whole company, materials to do some promo of the program, the establishment of a hotline/helpline, and supportive programs. This could be estimated in \$330,000 or less for the first year, expecting a decrease with the acceptance of the new culture. The budget can be justified with the savings when the production schedule is achieved on time, the production time is maximized, overtime eliminated and reduction in deviations and quality issues that needs expensive investigations. The duration of this project will mostly depend on the resistance to the change of culture. It can be implemented in 3 months, the monitoring of the program must remain in place to prove the program is effective; is expected to see remarkable improvement quarter by quarter. The method to develop this project will be the Lean Six Sigma method's DMAIC. This method 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. In each step some other methods very common in Lean Six Sigma will be taken in consideration like the Voice of Customer, Data Collection Plan, Charts, Graphs, Fishbone, Benefit & Effort Matrix, and Control Plan.

RESULTS AND DISCUSSION

The company has designated the head of the Human Resources department as the responsible of this new Ethic & Compliance Program, as well as a team supporting the initiative.

Following the Lean Six Sigma method, DMAIC we designed the steps of the project to achieve the objectives of the project.

Define Phase

To define the problem we identify the possible root causes for the problem stated in the problem statement section, to decrease of deviations due to human errors and increase employees satisfaction from the actual, we want to achieve this goal starting the first quarter of year 2018.

To define the reason of the decreased employee satisfaction, we apply the voice of customer matrix. For this purpose “customer” will be defined as the employees of the company, taking in consideration the term “internal customers”. The base for the Japanese method, the company-wide quality control (CWQC) by Dr. Kaoru Ishikawa states that there must be acknowledgement that the worker contributes to the success of the company through suggestions, creativity, and ideas. The upper part of Figure 1 is the Voice of Customer for the employee as the customer, and the lower part is the Voice of Customer for the Company/Management as a customer from the employees as suppliers. This is a two-ways street, the employee works for the company and the company works for the employee.

VOC Matrix	Customer : Employee
Supplier: • Company/Management	<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	Customer : Company/ Management
Supplier: • Employee	<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 Operation Procedures • Perform with safety

Figure 1
VOC Matrix

Measure Phase

To organize the measure of the data we have a Data Collection Plan (Table 1). Each one of the 58 deviations due to human error is closed with an investigation, as part of it the employee is interviewed to understand why the task was performed in a wrong way. The result is analyzed in the next section.

Table1
Data Collection Plan

Data Collection Plan						
Performance Measure	Operational Definition	Data Source & Location	Sample Size	When the data will be collected?	How the data will be collected?	Other Data that should be collected at the same time?
Employee reason to Deviate	The reason why the employee thinks failed and had a deviation for human error	The report/ investigation on each deviation by human error. Trackwise system.	Total amount of deviations due to human errors 58 from January 2017 to December 2017	Measure Stage	Query on Trackwise by root cause: human error, period of time 01/01/2017 to 12/31/2017. Then compare to 1 st quarter after implementation.	
Employee Satisfaction	Employees' satisfaction with the company	Survey. Company Site.	140 employees	Measure stage. Control Stage.	Gallup electronic Survey Quarterly the 1 st year from implementation, next 2 years twice yearly. This could change upon results.	
Production schedule	Proposed schedule vs. achieved schedule	Supply Chain metrics	Monthly schedule Jan17-Dec17	Analyze stage	Supply chain schedule missed or delayed.	Percent of the delays due to personnel.

The 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 thirteen questions were standards provided by Gallup: 1. How satisfied are you with your company as a place to work? 2. I know what is expected of me at work 3. I have the materials and equipment I need to do my work right. 4. At work, I have the opportunity to do what I do best every day. 5. In the last seven days, I have received recognition or praise for doing good work. 6. My supervisor, or someone at work, seems to care about me as a person. 7. There is someone at work who encourages my development 8. At work, my opinions seem to count. 9. The mission or purpose of my company makes me feel my job is important. 10. My coworkers are committed to doing quality work. 11. I have a best friend at work. 12. In the last six months, someone at work has talked to me about my progress. 13. This last year, I have had opportunities at work to learn and grow.

The first question was evaluated with the Likert Scale, 5 to Strongly satisfied, 1 to Strongly dissatisfied. The questions 2 to 13 were evaluated in a Likert scale 5 to Strongly agree, 1 to Strongly Disagree. 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 turnover was evaluated with the metrics from Human Resources department against the total amount of employees on January 1st plus the amount of new hires in the year; these amounts were compared yearly, with the amount for the 1st quarter of 2018.

Analyze Phase

Identifying the possible causes or the root causes from the investigations for each deviation due to human error on 2017, the answers were grouped and assigned percent to each one according frequency, the highest percent was caused by employee with low satisfaction (19%), followed by not paying attention (17%), and need better trainings (16%). The “Decreased employee satisfaction” will be managed as the main root cause to solve in this project since it is the major threat to the company in terms of performance and direct root cause for the increase in the amount of deviations due to human errors. This decision is supported by the results from the survey that measured the employee’s satisfaction that as well hows a low satisfaction in questions related to the same root caused with high percentage.

Gallup provided the summary of the result from the survey to Human Resources department. This department wasn’t in the liberty to share the numbers

but, they provided a list of the questions in order of priority based on the result, starting with the questions with critically lowest satisfaction. The rearranged list of questions based on the results, matched with the causes for human error deviations, looks like this (Table 2).

Analyzing the impact on production schedule, the top reason to not meet the proposed schedule monthly is the short count of personnel, followed by deviations. In this case, the supply chain department does not keep a track of the root cause of the deviations that caused the delay. The schedule proposed take in consideration the vacations scheduled by the employees, following the rule that vacations must be requested a month before the day requested. In this case the short count of personnel refers to employees who were absent due to call in sick, emergencies, or unexcused absents. Absenteeism is very common in employees with low morale, unsatisfied, unmotivated, and/ or uncommitted with the company.

Analyzing the Human Resources metrics for employee retention, we can see in Figure 2 that the rate of turnover has increase over the time. This analysis includes data up to April 2018, where we can see the rate is halfway to reach the same rate for past years. An exit interview was performed to the eighteen employees that leaved the company during the first quarter plus one month of the 2018, fifteen

Table 2
Survey Match Causes of Deviations

Question from Survey	Causes for Deviations due to Human Errors
1. I have the materials and equipment I need to do my work right.	Management - No make sure materials are available
2. At work, my opinions seem to count.	People- Low Satisfaction & no motivation
3. In the last six months, someone at work has talked to me about my progress.	Management - Training for management
4. How satisfied are you with your company as a place to work?	Unsatisfied employees
5. In the last seven days, I have received recognition or praise for doing good work.	Management - Training for management
6. My coworkers are committed to doing quality work.	People- no motivation
7. The mission or purpose of my company makes me feel my job is important.	People- no motivation
8. This last year, I have had opportunities at work to learn and grow.	Materials- Needs better training
9. There is someone at work who encourages my development	Management - Training for management
10. At work, I have the opportunity to do what I do best every day.	People- no motivation
11. I know what is expected of me at work	Management - Training for management
12. My supervisor, or someone at work, seems to care about me as a person.	Management - Training for management
13. I have a best friend at work.	Environment- hostile

focused on how dissatisfied they were with the company management and no growth on their careers, the other three focused on they got a better pay rate on the new job offer and those new workplaces were closer to their residence town. Clearly the company needs a program to achieve higher employee retention and decrease the turnover rates.

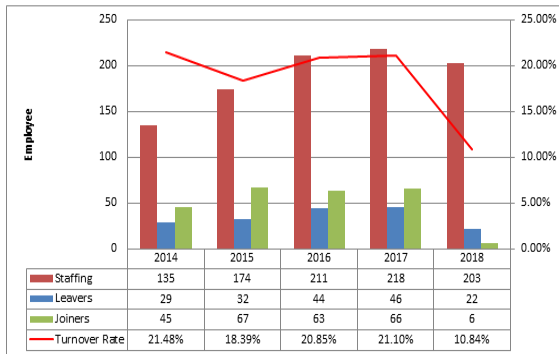


Figure 2
Staffing History

Improvement Phase

To achieve an improvement in every rate mentioned in the previous section, we begin designing a Code of Values 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 includes a detailed list of values and explains how the employee should perform according to them. To support this document, the human resources department made new revisions of the policies and Standard Operating Procedures regarding behavior and norms. The goal with this initiative is to create a new labor environment, making every employee accountable for their actions to raise their morale, pride and consciousness on their daily job, and at the same time implementing a strong system to promote zero retaliation smothering the environment to a non-hostile one.

The Code of Values includes: •Safety, Quality, and then Quantity mind-set •Absolute honesty and

integrity •Trust and Respect to each other: An environment that fosters inclusion, respect, individual responsibility and values diversity. Trust is strengthened through personal initiative and by obtaining quality results quickly. •Customer driven, both internal and external •Reward on merit •Resources allocated based on the expectation of profitable growth •Collaborate, Communicate and Be Accountable: Leaders should seek input and involve key stakeholders in important decisions. While gathering the inputs, strong leaders welcome diverse opinions, conflicting views and open dialogue for serious considerations. They must clearly communicate decisions and rationale openly and in a timely manner. Once the decisions are made, the leader and the team are accountable for the results and the quickly implementation of the decision. Innovative in quality products and service. Policies to hire and retain talented and dedicated people who are focused on the success of the Company. Work in teams: Diverse teams working together generate the best decisions for patients, staff and stockholders. Team structure provides opportunities for the staff to impact the direction of the organization. The company strive to create an environment in which individuals can work to reach their maximum potential and a reward system that recognizes the contributions of those individuals. The company value and respect each and every employee in the organization.

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. The hotline passes the report to Human

Resources head to manage the investigation to every report.

To support the expected conduct from all the employees under this Code of Conduct, the company also implemented a few different programs promoting the employees' engagement, collaboration and retention. To support employee engagement, collaboration and retention, the company implemented:

- The Quarterly Town halls which they conduct off-site town hall meetings with entire site, led by Leadership team and HR where team members are recognized and awarded for contributions.
- Monthly Site Performance Reviews held monthly on site to update site personnel on current happenings within the organization, also team members are recognized and awarded for contributions.
- Monthly Shining Stars Awards - Team members nominate those that have gone "above and beyond" their job responsibilities. Three employees are selected as stars each month and receive a monetary award and recognition.
- New Hire Buddy Program - New Hires are assigned a "buddy" within their department to help acquaint them with the workplace by answering questions, helping them around the facility, etc. making their adaptation friendlier and easier.
- Anniversary Celebration - Annual anniversary celebration held offsite for all employees. Fun, games, and food make for a night of family fun, dedicated to the employees' families.
- Wellness Program - Wellness initiatives implemented monthly through weekly wellness updates, annual biometrics screening, blood drives, bi-annual wellness fair, weight loss initiatives, etc. everything to assure the good health of the employees.
- Employee Appreciation Days - Held throughout the year to recognize employees. Examples include Veteran's Day and International Potluck Day to promote fellowship between all the employees.
- Employee Life Event Recognition- Send employees flowers, etc. in honor of major life events such as births, deaths, illness, etc. to support the employees' in those life events.
- Extended Leadership Team Governance- Monthly meeting with managers and above to communicate HR information, training topics, sharing ideas and successes to achieve the main goal of retaining our employees.
- Focal Groups - Meeting with core groups within each department (ex. Management, Supervisors, Individual contributors) to discuss company and departmental feedback and ideas for improvement.
- Individual Growth Plans- Put in place individual growth plans for employees to ensure cross training and growth within the organization.
- Leadership Training - Conduct formal outsourced training for all employees with direct reports, as well as those in lead roles or identified for potential lead/managerial roles in the future to enhance their leadership skills.
- Talent Management & Succession Planning - Conduct Skills Assessments and identifying High Performers and Critical Roles in order to develop top talent and plan for succession to assure a standardized continuation of the process.
- Policy Revisions- New Revisions to policies to be more "employee friendly" while still benefiting overall welfare of the company.
- Quest Program - To promote ownership of the processes to the employees whom performs them, providing tools to achieve a quality excellence in the performance, process and product.
- Devine exit interviews - Exit interviews to the employees that decide to leave the company to understand why the company lose them, the expectative the company did not meet and the ones that were meet to the purpose on improve those aspect.

- Work in teams: Diverse teams working together generate the best decisions for patients, staff and stockholders. The team structure provides opportunities for the staff to impact the direction of the organization.

After implementing the Code of Values and the initiatives listed, we performed a survey to analyze the impact of this implementation on the employees' morale and satisfaction. The survey that was evaluated with the Likert scales, five points to Strongly Agree to one point strongly disagree, included the following questions: 1. I am happy at work. 2. I would refer my friends or family to work here. 3. My manager supports and encourages me to grow. 4. My pay and compensation are fair. 5. I understand what my role is and what is being asked of me at work. 6. This is a good place to build your career. 7. I feel encouraged and motivated to come up with new and better ways of doing things. 8. The organization has provided adequate resources, materials and equipment to do my job well. 9. My work's mission and purpose gives me the feeling of personal accomplishment. 10. I feel like my skills and abilities are put to good use. 11. Coworkers and teams support and respect each other's. 12. In the last seven days, I have received recognition or praise for doing good work. 13. My supervisor, or someone at work, seems to care about me as a person.

The results on this survey 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".

Along with the improvement in employee satisfaction, another improvement was identified in the amount of deviations due to human errors. Beside a stronger commitment from the employees with the company, the training department has been

changing the method to train employees. This department is working in Cognitive Science based training, to simplify and do employee-friendly standard operating procedures. This initiative has been implemented to trainings in the Laboratories, and that department has shown a decrease in the amount of total deviations. It is expected to be implemented through the whole company on the next three quarters as another tool to decrease the amount of deviation and achieve a performance of excellence. Figure 3 show us the trend on deviations due to human error beginning with the quarter one from year 2017 up to the first quarter of year 2018, the quarter before the implementations.

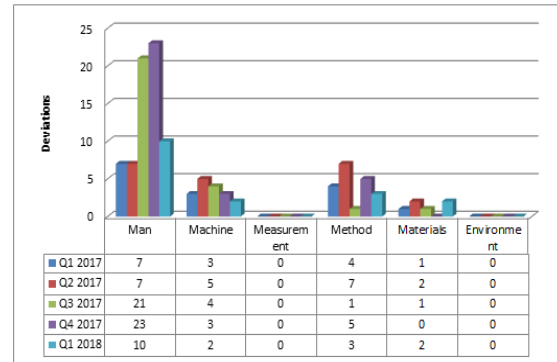


Figure 3
Deviations per Root Cause

During the first quarter of year 2018 a total of ten deviations due to human errors were closed, this is a significant decrease compared with the previous two quarters. This is clearly an improvement. To analyze the improvement, the fishbone with the percentage of the reasons given by the employee on the investigations for the human errors deviations was 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. The reasons for those ten deviations due to human errors in the Q1 2018 are described in Figure 4. In Figure 4 it is shown that the company must continue improving the method on how the management makes sure all the materials needed by their employees are available at the moment.

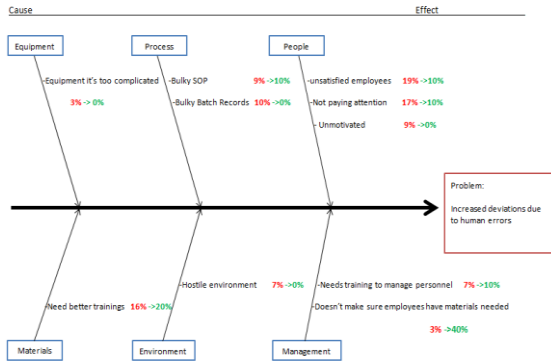


Figure 4
Cause & Effect Fishbone Improved

Continuing analyzing the data measured in the previous section, the quantity of lots missed on the proposed schedule, Figure 5 show us how the quantity of lots missed due to short count of personnel has decreased. Even when the quantity of lots missed decreased on Q1 2018, the few lots missed are mostly due to scheduling constraints and deviations. Important to mention that there is 9 more reasons to get a deviations besides human error, for example Yield Related, Software, Hold Time, Engineering/Facilities, Process Related, Material, Supply chain, Third Party, and Equipment. Since Supply chain department's report does not classify the delay specifying the type of deviation that caused the lot missed the schedule, we cannot assure the "deviation" category is due to human error.

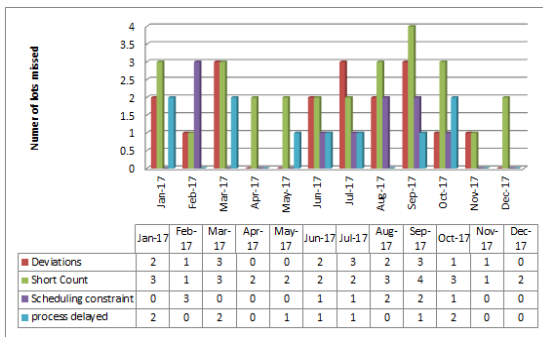


Figure 5
Lots Missed on Schedule per Reason

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 6, 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 the graph (Figure 7) 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 8). 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 9, that shown a T-Value of 3.36, greater than the T-Critical of 2.16, which also reject the null hypothesis.

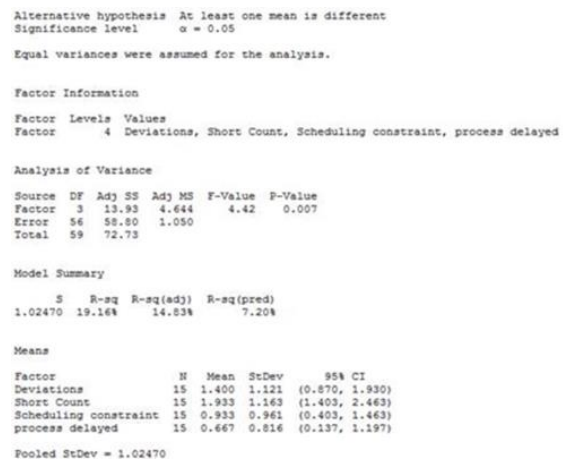


Figure 6
ANOVA by Minitab®

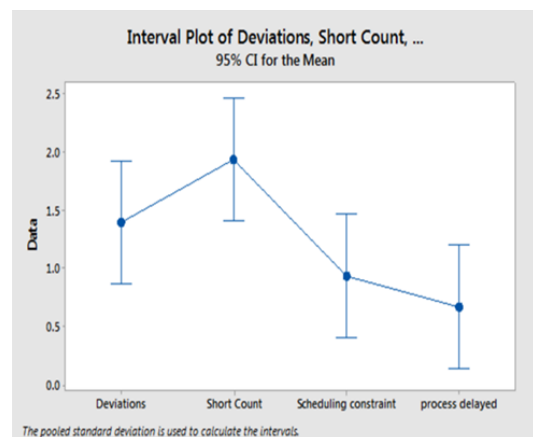


Figure 7
Interval Plot of Means from ANOVA by Minitab®

Two-Sample T-Test and CI: Before, After

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Two-sample T for Before vs After
|
|      N   Mean  StDev  SE Mean
|-----|-----|-----|-----|
| Before 12  5.50  2.68   0.77
| After  3  2.667 0.577  0.33
|
| Difference =  $\mu$  (Before) -  $\mu$  (After)
| Estimate for difference: 2.833
| 95% CI for difference: (0.998, 4.669)
| T-Test of difference = 0 (vs  $\neq$ ): T-Value = 3.36 P-Value = 0.006 DF = 12
    
```

Figure 8

Two Samples T-test: before and after Implementation by Minitab®

t-Test: Two-Sample Assuming Unequal Variances

	Variable 1	Variable 2
Mean	5.5	2.666667
Variance	7.181818182	0.3333333
Observations	12	3
Hypothesized Mean Difference	0	
df	13	
t Stat	3.363505204	
P(T<t) one-tail	0.002543447	
t Critical one-tail	1.770933396	
P(T<t) two-tail	0.005086893	
t Critical two-tail	2.160368656	

Figure 9

Two Samples T-test: before & after Implementation by Excel®

Control Phase

This phase intent to sustain the gains achieved during the Implementation phase. In this project we developed a Control Plan (Table 3) to maintain in place the improvement achieved and promotes the continual improvement on this topic in the company. Every control analyzed must be submitted to the Human Resources department in charge of the Ethics & Compliance Program. It is very important that the person in charge communicate to the management and pertinent teams in case of some observations out of specification detailed in the Control Plan. As well, 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” [6].

CONCLUSION

The problem presented at the Problem Statement section 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. With this project the following objectives were achieved: 1. A successful creation and implementation of an Ethic and Compliance Program, that manage report confidentially, and provides anonymity through a hotline, supported with a series of initiative to increase employee satisfaction, engagement and retention. 2. The program assures to every employee an environment of zero tolerance to retaliation to any person that reports a concern, opening good communication channels. 3. Inculcation of a Code of Values that provide guides of high standard of conduct at the workplace. 4. Decreased the quantity of Deviations caused by human error from 23 deviations to 7 deviations quarterly. 5. Increased employee satisfaction from an average of 2 “Somewhat dissatisfied” to 4 “Somewhat satisfied”.

**Table 3
Control Plan**

Control Factor	Specification	Control Plan			Control Method	Reaction Plan
		Measure Technique	Sample Plan (%)	Sample Frequency		
Deviations due to human errors	7 Deviations per Quarter	Audits	100% human error root cause deviations	Monthly Sample/ 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 SCP related to conduct and behavior	A maximum of 3 violations in the site over 1 year	Metrics on Reports to Hotline, HR department or deviations related.	100% Reports	Quarterly metrics/ Annually report	Metrics in dashboard and share folder	Retrain, Reinforce campaign. Revise to documents yearly to keep updated 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	Analyze reasons to delay, improve for next month
Employee Satisfaction	Higher or equal Average of 3 on 3 questions, Overall average of 4 or higher	Surveys	Calculated with 95% Confidence and 5% error	Quarterly until 4 consecutive Quarters scored 4 or higher, then Every 6 months.	Metrics by HR department in share folder	Reevaluate the program and all the supportive initiatives; perform different focal groups to get ideas to improve and find the root cause.

REFERENCES

[1] D. Schaaf, & R .Zemke. “The Service Edge”, in *Plume*, 1989.

- [2] L. Andreisova, "Building and Maintaining an Effective Compliance Program", in *International Journal of Organizational Leadership*, vol. 5, no. 1, Feb 2016, pp. 24-39.
- [3] S. Bonfield, "Practical Considerations for Maintaining an Effective Compliance Program", in *Journal of Health Care Compliance*, vol. 5, no.4, Jul 2003, pp.14.
- [4] C. Verschoor, "How Good Is Your Ethics and Compliance Program?" in *Strategic Finance*, vol.88, no.10, Apr 2007, pp.19-20.
- [5] J. Scanlan, "Designing a Compliance Program for the Small-to-Medium-Sized Private Company", *Federal Ethics Report*, vol.16, no. 2, 2009, pp. 6-7.
- [6] J. L. Heskett, T. O. Jones, G. W. Loveman, Jr. Sasser, W. E. S., & L. Schlesinger. "Putting the Service-Profit Chain to Work," in *Harvard Business Review*, March-April 1994.