Optimization of Chemical Manufacturing Process Area

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Abstract ***—*** *"Industry X" does not have a detailed and effective plan for chemical weighing process which considers optimal number of operators and shifts necessary to accomplish the desired production. The products process flow has inefficiencies due to non value added task and the absence of standardization in this area. The material flow was analyzed using with a Kaizen to decrease the material time period which is 306 feet's from since it leaves the warehouse until it is dispensed. A time measurement studies were performed in order to determine the best time standards for the process. To improve the weighing process, several layouts were analyzed to identify the most effective alternative to reduce the transportation distance in a 42%. Also to improve the documentation area it is proposed to document the required data in the System Application & Products (SAP) system and the electronic batch record with a logbook restructuration to reduce the documentation amount above 50%. Using the proposed layout and documentation alternatives which comply with the industry standards and the production forecast, a shift of 4 satisfy the demand.*

Key Terms *— chemical weighing, dispensing process, Kaizen, SAP system.*

OBJECTIVES

In this research there be comparing the actual product dispensing logistic in "industry x" in order to identify improvements in the areas. Dispensing distance, time studies for weighing process, documentation process and personnel required for the product cycle time were evaluated in order to suggest alternatives that will guarantee a better plan in terms of time and money meeting the production demand.

INTRODUCTION

The chemical weighing area is essential in the drug manufacturing industry. The location and time spent in this area are of important impact when calculating the manufacturing process logistic. Most industries generate strategies which facilitate and save time in ingredients / chemicals weighing and required documentation in order to be more efficient in terms of productivity [2].

Maintaining the anonymity of the industry in which I base this research work, and to avoid conflicts of interest I will refer to it as "Industry X". In industry X the chemicals weighing area was in the warehouse area and as part of the process improvements in order to save time and money in the productivity of drug, was determined to transfer to the chemical weighing area into the manufacturing room. As part of the transfer, it was decided to conduct an intensive study in the area of chemical weighing to guarantee that this new workstation does not cause problems in productivity and / or mishandling tasks performed by resources. Currently the area of chemical weighing operates with 6 operators which are supervised. The process is completely manual and consists of identify the exact quantities of the different types of materials which contain the products on the calibrated scales.

INDUSTRY X

The "industry X" has specialized since 2006 in the production of oral products. It has a staff of approximately 315 employees and generates annual revenues of approximately $23,200,000.

MATERIALS CLASSIFICATION

Materials that are directly involved as part of this research are classified into: active, inactive and dyes. Given its classification, each class must be considered and analyzed individually although the impact is the same in the production area. Not only have the materials played an important role in the study, but the gowning to be used when each class be handled.

In the case of active, these materials are dispensed into a specific area, which is intended for oral use drugs. Considering that in the area working with hormones, for safety reasons any person perform the relevant tasks needs to be trained and must use the necessary equipment that will supply oxygen and avoid inhaling particles that could affect health.

Inactive chemicals and dyes are handled similarly within the production area. The gowning to be used to manage them does not require a supplier of oxygen, but it is required to use eye and respiratory protection to prevent external contaminants or affect our own body material or vice versa.

KAIZEN

Kaizen is used most often to describe a process of quick change or improvement in an organization through utilization of an event. The leader, or, facilitator, of a Kaizen event should be considered very skillful in the arts of influence and communication. This person will be responsible for driving the event, and all related objectives through the course of the process. Kaizen is considered a part of Lean that focuses primarily on improving productivity and reducing cycle times [1].

Critical elements of a Kaizen event:

- Identifying if Kaizen is the right tool
- Tool selection
- Team selection
- Value-Stream Map (VSM)
- Follow-up

To ensure a Kaizen is the correct tool to use for an existing problem, some basic questions need to be asked first.

- Is the problem related to cycle time or productivity?
- With a small team of people, can the problem be fixed within a few days?
- Is the problem obvious and well recognized by many people?
- Is the process repeatable with easily understood performance measures?

What a Kaizen can do

- Feeds on the enthusiasm and emotion of everyone involved and promotes thorough investigation and resolution
- Helps keep costs down by using existing resources
- Allows process users a chance to see the inner workings
- Helps create ownership and empowerment
- Improves job satisfaction

Kaizen events have the power to change the direction and focus of any organization. As a part of a lean transformation, they are used to improve the lives and working conditions for employees through incremental changes over time, effectively changing culture and attitudes in the process [1].

SAP SYSTEM

SAP is the world's largest provider of Enterprise Resource Planning solutions in the world. An ERP system is a business support system that maintains in a single database the data needed for a variety of business functions such as Manufacturing, Supply Chain Management, Financials, Projects, Human Resources and Customer Relationship Management [4].

SAP focuses on six industry sectors - process industries, discrete industries, consumer industries, service industries, financial services, and public services.

An ERP system is based on a common database and a modular software design which allow to store and retrieve information in real-time. The information should be reliable, accessible, and easily shared. The modular software design should mean a business can select the modules they need, mix and match modules from different vendors, and add new modules of their own to improve business performance [4].

In pharmaceuticals and medical devices industry it became very usable and effective during the manufacturing process at the moment of record data and makes it traceable. Also the human errors are reducing guaranteeing the desire quality in the finish product [2].

METHODOLOGY

With the purpose of calculate the work and required shifts to meet the products demand; it was started measuring current standards times of the dispensing process for all products. Given to the importance of manufactured products and its huge impact, the level of reliability for this study is 95% according to the standards of the area.

As a preliminary step, a sample of 30 data of each element was taken to calculate the N (sample) required to comply with an error of no more than 5%. The following table shows the average time (sec) and standard deviation obtained from the thirteen tasks involved in dispensing the product.

Table 1
Data of the Elements Involved in the Chemical Weighing Process.

Task	Time	St. Dev.
Material Request (SAP)	155.76	11.36
Material dispatch	452.26	38.45
Paletting preparation	42.45	7.08
Material Bin preparation	66.54	10.20
Scales preparation	20.34	3.91
Weigh in the material	33.45	3.84
Weight the dyes	152.01	16.79
Print and Apply Label	46.97	7.98
Manually label	129.18	17.12
Batch Record Verification	33.29	6.35
Record data manually in a document	65.07	8.30
Return material excess	42.92	8.17
Deduct the material excess (SAP)	91.94	11.96

After analyzed the data, it was found that the process was not standard and also it was found a lack of time management by the operators who works in the production area. These deficiencies caused that the variability of the data be very high and had no consistency in the normal distribution graph generated, see Figure 1. The graph was performed using MINITAB, and with "individual distribution identification" function.

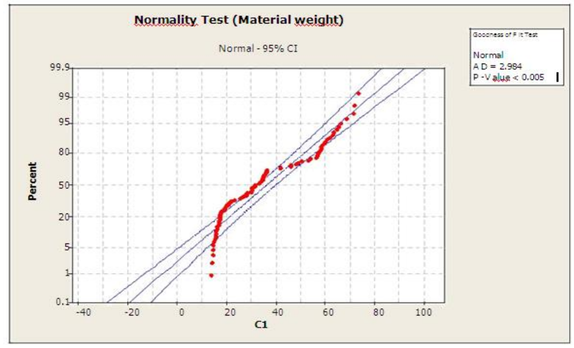

Figure 1
Normal Distribution Chart According the Task Described in Table 1.

After noticed that the standard deviation was too high and the P value, confidence interval was less than 005, it was determined that the process did not follow the normal distribution behavior. In the attempt to find solutions to the problem that the normal distribution chart (Figure 1) was not found as expected it was determined to proceed to standardize the process before making a second process analysis to guarantee that deficiencies will not be repeated. For this it was requested that all operators be qualified to work in the area at the moment of the time measures to reduce additional variants that may affect the data analysis, considering that unqualified operator only consume hours without be productive.

Also in this first analysis, it was identified that during the materials weighing process there is no consistency using the same mass unit, making inconsistent the process and being this another reason to obtained undesired data behavior of Table 1 data.

After verify the data in Table 1 and generate the graph show in Figure 1, it was decided that data grouping was required. Data was pooled according the material weight similarity and divide it into three categories.

Table 2
Materials Data According to Weight

Material weight process	Time	St. Dev.
Heavy weight	17.50	2.31
Regular weight	32.27	4.06
Light weight	58.82	7.86

Once the process were standardize and the data was pooled as established, it was repeated the data analysis but this time only considering the weighing process, which is where the time variation was noticed. Refer to Figure 2.

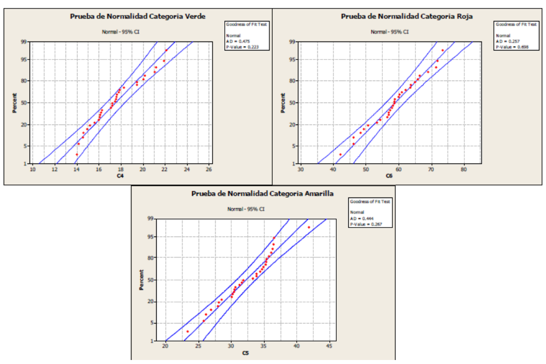

Figure 2
Materials Normal Distribution According Weight Similitude

As we can see once the data segregation was performed, the data it's in accordance the normal distribution behavior. With this behavior it is meet the established confidence level of 95% and it may proceed with the research plan.

As part of the optimization process, an analysis of all manufactured products in Industry X (15 products), demand (lots) and the time it takes to meet the demand was performed.

Table 3
Standard Time According Products Demand

Product	Demand (lots)	Hours	Standard time (hr)
1	1.00	7.2	7.2
2	1.00	11.0	11.0
3	2.00	20.5	10.2
4	5.00	35.9	7.2
5	1.00	5.0	5.0
6	2.00	11.4	5.7
7	3.00	14.0	4.7
8	1.00	13.6	13.6
9	2.00	37.2	18.6
10	8.00	72.1	9.0
11	43.00	422.9	9.8
12	8.00	46.9	5.9
13	112.00	553.8	4.9
14	61.00	481.0	7.9
15	35.00	137.0	3.9

As part of the process improvements, the operator's efficiency was analyzed. It was calculated time it takes to an operator perform all the daily tasks and responsibilities. With that analysis the annual hour's consumption was performed.

Table 4
Analysis Based on Two Operators

Task	Hours per year
Dispense the material	1870
Cleaning activities	93.6
Production hours	1971.2
1 shift hours	2080
Breaks time	130
Gowning time	130
Special gowning time	50
Avaiable hours	1770

Table 5
Analysis Based on Four Operators

Task	Hours per year
Dispense the material	1444
Cleaning activities	101.2
Production hours	1545.2
1 shift hours	2080
Breaks time	130
Gowning time	130
Special gowning time	50
Avaiable hours	1770

After obtaining the standard time for each product, and the total hours consumed by one year, the next task is to identify wastes that help to reduce the cycle time and allow us to have more time available for effective production

The first area of opportunity identified was in the facilities deployment due that currently each material travels a total distance of 306' feet per each material bin used.

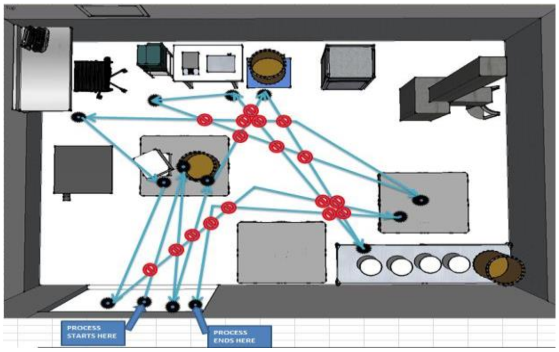

Figure 3
Actual Layout of Weight Room in Industry X

Other identified deficiency was the amount of intersections during the chemical weighing process. As shown in Figure 3, the red spots are considered not desired intersections and the flow of materials currently represents 17 intersections.

To improve the layout shown in Figure 3, it was used the Computerized Relationship layout planning, CORELAP, in order to maximize the proximity between stations which are more related to each other and to avoid intercession, which are undesirable during production time.

The inputs used for the CORELAP algorithm were: Qualitative relationships Diagram, Quantitative relationships Diagram and Mixed relationships Diagram [3].

	A	B	C	D	E	F	G	H	I
A		a	u	u	u	i	u	i	i
B			a	e	u	e	e	i	u
C				e	i	a	e	o	u
D					u	i	u	u	o
E						u	u	o	u
F							e	i	u
G								o	u
H									o
I									

Figure 4
Qualitative Relationships Diagram

	A	B	C	D	E	F	G	H	I
A		o	u	u	u	e	o	e	u
B			i	u	i	u	o	a	u
C				i	u	i	o	u	u
D					i	i	u	u	u
E						i	u	a	u
F							a	u	u
G								u	u
H									u
I									

Figure 5
Quantitative Relationships Diagram

	A	B	C	D	E	F	G	H	I
A		I	U	U	U	E	O	E	O
B			E	O	I	O	I	A	U
C				E	O	E	I	O	U
D					I	I	U	U	O
E						I	U	A	U
F							A	O	U
G								O	U
H									O
I									

Figure 6
Mixed Relationships Diagram

Table 6
Qualitative Elements Legend

Qualitative elements	
a	Absolutely neccesary
e	Very important importante
i	important
o	ordinary
u	No important
x	Not desire

Table 7
Quantitative Elements Legend

Cuantitative elementss	
A	Materials
B	Weighning station
C	Printer
D	Complete pallet
E	Empty Bins
F	Documentation station
G	Board
H	Trash cans
I	Inverter dron

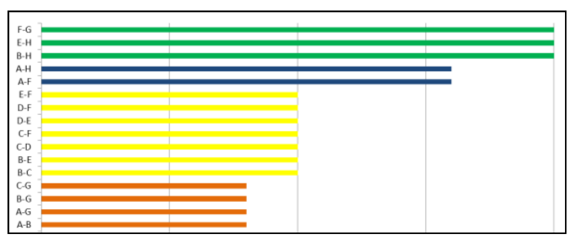

Figure 7
Flow Matrix Relationship with Qualitative Matrix

Pareto chart shows the intensity in terms of priority between the relationship and the transportation process of the elements.

Another area of opportunity identified to reduce the cycle time weighing of chemicals was in the documentation process. By achieving a time reduction in the documentation process, the operator will have more time to assist in the weighing process and make more effective the manufacturing process.

As part of obtaining effective ideas regarding the deficiencies, a Kaizen event was conducted.

Table 8
Time Expended in Documentation Activities

Documentation Task	Time (sec) per material
Enter the material information	87
Reconciliation Form	90
Logbook	144
Board	43
Batch Record	82

The time performing documentation activities for each product is about 1.44 hours.

RESULTS

Once completed the entire analysis process and evaluation of all the data as part of the investigation, which was described in methodology section were able to obtain the expected results and noticed the positive impact on the industry X in case that all the alternatives that will be suggested be incorporated.

Concerning the arrangement of stations in the weighing room, once used CORELAP algorithm inputs, it was noticed that with a modification to the actual room layout, intercessions will be reduced in the process flow something that is very positive given the time and money that would save.

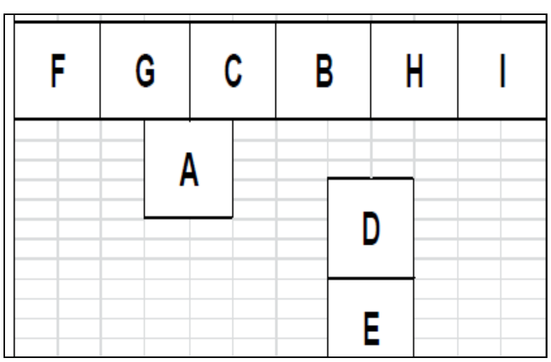

Figure 7
Station Locations According Actual Layout

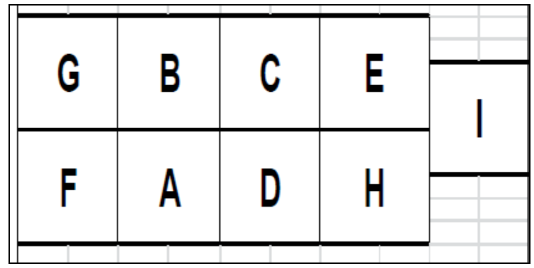

Figure 8
Station Locations According Suggested Layout

The algorithm calculates a TR, right location function for each layout option. A higher the TR means that is the best layout option in terms of amount of material and proximity of stations required [3].

Based on the layout and the analysis performed with the actual layout the TR=15, in other hand the suggested layout represent a TR=23.

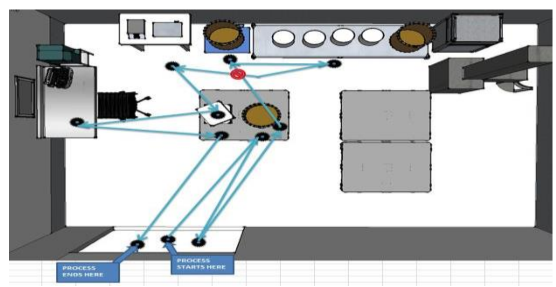

Figure 9
Suggest Layout for the Weight Room in Industry X

This suggested layout only required the relocation of tables and scales, obtaining a positive impact on reducing the production cycle distance transportation by 42%. The reduced distance in time is equivalent to 152' = 37.8 seconds per bin of material.

At the same time it needs to be considering that this suggested layout reduce intersections flow significantly by 94% with only requiring a recalibration of the scales. The total reduction time will be different for each product because it depends on the amount of bins that the material requires.

Similarly, with regard to the analysis of hours consumption and production demand, it can be deduced the following about the number of operators per 8 hours shift of. The current plan of six operators equivalent to a labor cost of $ 199.680 per year. Based on demand 6 operators generate a waste total leisure time of 4.385 hours equivalent to $ 70.160. In this case 35% of the money invested in the X industry work is lost.

The alternative of using two operators is not viable because the hours necessary to meet the demands, 1971 hours, exceed the available hours to be effective in production 1770 hours. This alternative does not allow comply with established metrics.

This alternative is cost effectively paying overtime to the operators because the overtime would cost $ 66.560 versus the total reduction of $ 133.120 per year. What happens is that in order to comply with the expected demand, will make this option inconsistent considering that the demand forecasts suffer many variations throughout the year. It would be a very high risk of only has 2 operators working in the area, if one of the 2 operators is not in the industry for any reason the relatively production would stop.

From these results the option of having four operators is optimal for the industry. With 4 operators the established metrics will be achieved and at the same time 225 will be remain. These hours would not be used for production but are surplus to prevent operator's overtime, any maintenance in the area or daily accident or troubleshooting as part of the process. The labor cost for this alternative is $ 133.120 and the reduction total cost is $ 66.500 per year.

As part of improvements to the documentation process, the Kaizen results were analyzed and it is suggested to eliminate the reconciliation sheet materials and only use the SAP system to document all the material data. Given that is was confirmed that the opportunity to document the excess available in SAP is also is available in the "batch record", and then the reconciliation sheet is redundant.

Another opportunity is in the Logbook document, in which the information of each material with the time and date of the weighing performed is recorded. Likewise, it was confirmed that the batch record capture the same information as the logbook. In this case in order to save time the is not necessary to document this data in the logbook, so the logbook template could be modified to be more effective.

If the recommendations mentioned above be applied there will be a reduction of 50% in the logbook documentation process. Also 90 seconds would be reduced by document the reconciliation sheet that is the time it takes at this moment.

Then the total reduction time is 162 seconds providing 30% more time to the operator to assist in the weighing process or other critical area or task.

The aforementioned reduction rate is defined in the following function:

$$\frac{(\text{Task Time} * \text{mat. qty}) + (\text{Task Time} * \text{bin qty})}{\text{Material Dispensing time}} \quad (1)$$

CONCLUSION

Once be performed the time study and layout analysis in the chemical weighing area, identified deficiencies in the tasks employed and had being established the relevant alternatives and recommendations according to findings, it is conclude that this research was very assertive in making a positive impact for Industry X.

The impact of changing the position of the elements of the weighing room and incorporate the suggested layout causes a reduction of 42% in the transport of materials.

The same applies to the 50% time reduction in documentation activities. If the proposed alternative being applied and the data be recorded in SAP electronic system, which guarantee greater efficiency in the process of chemical weigh when dispensing a product.

It is noteworthy that all these calculations were performed without applying the recommendations established in this research in order to reduce the product cycle time and material distances. It means that if the company decides to implement the recommendations, the process will be faster and without overtime required.

RECOMMENDATIONS

Continuous revisions to the material flow, chemical weighing process, documentation required and dispensing strategy by “Industry X” personnel in order to continuing improving and positive impacting the production efficiency and quality.

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