

Control Licenses Area Optimization

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Abstract — *When working in a company that contains processes regulated by state and federal agencies, any task performed by staff is critical. Especially when the company supplies products that are consumed by people. A controlled License staff member wants to improve the process of his daily task. Kaizen is a Japanese business philosophy of continuous improvement. This philosophy will provide tools for this area to achieve their goals. In this implementation process, the subject matter expert team will review all the tasks that they perform. Kaizen's philosophy will guide the person to find the areas with the need to improve. There is always a need to improve in any task, the member just needs to be open minded to have new improved ideas to be implemented in the area. The result of the use of the Kaizen Lean Methodology will help the area and as an output the area will have several ideas to implement. The most important result is to determine control for not discontinuing the improvement established.*

Key Terms: *Control Area, Filing Cabinets, Improvement, License.*

INTRODUCTION

The Company distributor of Medical Devices and Drugs of Puerto Rico's Controlled area must make sure that customers are properly authorized by federal and state regulatory agencies prior to shipping a product. Presently, there is an established process in which various associates from the controlled area conduct a license verification to make sure it is current and valid.

Control area associates do not perform a specific task; they share the same role thus, perform the same functions. The method of transferring information from one shift to another must be

improved in order to provide continuity and allow for a smooth transition between shifts.

Each function must be accompanied by a delineated process (Job Aid) to allow for the improvement of procedures and the continued operations. The area will benefit from a flowchart that will improve the process of "SHIP TO" creation. Forms 1 and 2 contain multiple blocks that are not used or not needed. Standard Operating Procedure does not reflect the actual duties of the work's activities and processes.

Research Objectives

- Identify and review the process and task that a member of the controlled area needs to accomplish. When the analysis and discussion are finished the team will be able to offer recommendation or ideas that could be implemented in this work area.
- Improve the customer services and a faster and better performance without losing quality. (Since a simply wrong address could affect other departments or any other wrong information entered can determine that this client is not properly authorized, most of the improvements that the area implements should have this objective)
- Evaluate ideas or tools to help the team member to not forget to verify any step of the process.
- Provide alternatives from the office supplies market to improve the filling area.

Research Contributions

This research should:

- Improve Business Processes and Sustain Quality Improvement.

- Evaluate electronic ideas and system for the process to be more efficient and precise.
- Improve processes and the quality of deliverables to the customers.
- Better understand the steps need to be taken to fix a process and reduce wastes.
- Conduct a review of current processes, with the result from the analysis be able to take corrective measures.

BACKGROUND INFORMATION

In Puerto Rico to sell any type of prescription or non-prescription drugs, the vendor must have the necessary permits and even more if these medications are controlled. A prescription drug is a pharmaceutical drug that legally requires a medical prescription to be dispensed. In contrast, over-the-counter drugs can be obtained without a prescription. A controlled substance is generally a drug or chemical whose manufacture, possession, or use is regulated by a government, such as illicitly used drugs or prescription medications that are designated by law.

The Department of Health of Puerto Rico (Departamento de Salud de Puerto Rico in Spanish) is a Cabinet-level government agency and one of its responsibilities is to oversee and protect public health in any service, business or activity. A pharmacy must request the license through the local and regional offices of this agency. These licenses will need to be renewed every 3 years. Another agency that provides other type of license is the federal DEA and the Office of Controlled Substances. It transfers the Division for the Control of Drugs and Narcotics, attached to the Administration of Mental Health and Addiction Services (ASSMCA by its acronym in Spanish) to the Office of Investigations of the Department of Health, now Office of Controlled Substances [1].

Once the client (pharmacy or hospital) is properly authorized by the agencies mentioned before, the client can request the services of supplies of the products with the company Cardinal Health. The pharmacy or hospital contacts the sales

or credit area of the Cardinal company requesting services. Once the credit area creates the account of that new client, the controlled area will receive the information and the record number of the new client along with the required documentation.

All licenses have an expiration date and each agency has a different stipulation. Every time the client renews or updates any address with these agencies, they must notify by sending the new license to the Controlled Area of Company by email or fax. When the staff received these licenses, the staff must update the record of the client. If all the information is correct, they will release the held orders on the system. If the information is incorrect the staff member cannot update the records.

DMAIC METHODOLOGY

DMAIC is a structured problem-solving methodology widely used in business. This methodology has five phases to lead a team logically from defining a problem through implementing solutions linked to underlying causes and establishing best practices to make sure the solutions stay in place.

- **Define:** In the Define phase, the focus is to define the problem statement, scope, goals, impact, team members and the schedule to create the project charter. The project charter generally includes a problem statement, project objective and goals, project scope, risks and/or challenges, project timeline (including milestones) and the project team. Some key steps for this phase are; review project charter, validate problem statement and goals and create/validate process map and scope.
- **Measure:** In the Measure phase, the focus is to understand the current state of the process and collect reliable data on the process speed, quality, and costs that will be used to expose the underlying causes of problems. Some key points in the measure phase are to identify the outputs, inputs and process variables relevant to your project and create a data analysis plan.

- **Analyze:** In the Analyze phase, the focus is to identify how factors affect process' output. Also, to pinpoint and verify causes affecting the key input and output variables tied to project goals. Some deliverable in this phase should be documentation of potential causes considered in your analysis, data charts and other analyses that show the link between the targeted input, process variables and critical output and calculation of process cycle efficiency.
- **Improve:** In the Improve phase, the focus is to modify the factors to improve process outputs. Improvement options arise from the data analysis. The purpose of this phase is to learn from pilots of the selected solutions and execute full scale implementation. Some key in this phase should be to develop a potential solution, evaluate, select, optimize best solutions and develop and execute full scale implementation plan.
- **Control:** In the Control phase, the focus is to establish mechanisms to prevent the recurrence of an issue and sustain measures implemented. As well, to complete project work and hand off improved process to process owner, with procedures for maintaining the gains. Some deliverables before and after data on process metric, a system for monitoring the implemented solution along with specific metric to be used for regular process auditing. On this phase monitor implementation use observation, integration, and data collection and charting; make additional improvements as appropriate. [2]

RESULTS AND DISCUSSION

The entire description of this document is based on the performance on the kaizen of the Control Area that executes the tasks described. When the staff member of the area is using the forms to document the task performed, they must cross a line on tree duplicated sections that forms

number 1 and 2 have. This form needs to be update as the actual process is establish at this moment.

One focus is the filing section. Now, any wrong accommodation of a file folder will affect the perform in a way that the staff members will need to get together to try to find that missing file folder. Time is money for any company, in the DMAIC philosophy a situation like this is named waste. A simple OUT flag that marks a red flag on the filing cabinet should resolve the problem. When the staff member returns the folder, they will see this flag and return the folder to an empty space [3]. Following are the results by phase.

Define

At this stage a team was formed, and on each meeting, was creating and analyzing the processes that are executed in the area using the DMAIC Methodology. The problem and deliverables were identified and documented on the project charter. The scope of the project was determined and validated. The project charter draft was discussed with the sponsor getting answer and questions. Adjustment to the scope and timing was performed. A communication plan and schedule based on the agenda of each one was created. Various meetings were conducted to make brainstorming of the task that needed to be performed in the scope area. Every day a summary of this brainstorming was prepared. Figure 1 and Figure 2 are the project charter created with the team member during the Kaizen/Optimization.

Problem Statement - Is/ Is Not

The Is/ Is Not tool presented in Table 1 was used to define the problem and guide to the root cause of the problem. Figure 3 illustrate the SIPOC created during the part of Define with all the Kaizen members involve.

Measure

Walk downs were performed to review workflow and ensure no activities needed to be added or removed. In this phase the standard procedure of the operation was discussed and

during the discussion a process map of the current process was created.


Project Type	<input type="checkbox"/> Black Belt <input type="checkbox"/> Green Belt <input checked="" type="checkbox"/> Kaizen <input type="checkbox"/> JDI <input type="checkbox"/> Workshop
Project Title	Controlled Licenses Area Optimization
Business Location	Pharma Segment
Sponsor	Rafael Nieves Date 8/2019
PROJECT DESCRIPTION	
Problem/Opportunity Statement	<p>The Cardinal Health Puerto Rico's Controlled area must make sure that customers are properly authorized by federal and state regulatory agencies prior to shipping a product. Presently, there is an established process in which various associates, from the controlled area, conduct a license verification to make sure it is current and valid.</p> <p>Control area associates do not perform a specific task; they share the same role thus, perform the same functions. The method of transferring information from one shift to another must be improved in order to provide continuity and allow for a smooth transition between shifts.</p> <p>Each function must be accompanied by a delineated process to allow for the improvement of procedures and the continued operations. The area will benefit from a flowchart that will improve the process of "SHIP TO" creation. Forms 1 and 2 contain multiple blocks that are not used or not needed.</p> <ul style="list-style-type: none"> • Improvement to filing container: <ul style="list-style-type: none"> o Drawers at over capacity o Labels are too small o File folders do not have color coding o Filing system is not adequate for storage of folders
	
Project Goals and Objectives	<ol style="list-style-type: none"> 1. Establish a flow process for each type of transaction to be entered on ERP 2. Make better use of technology to store information that can be quickly accessed and eliminates the stove-piping of information 3. Implement a new filing system 4. Improve filing cabinet 5. Improve File folders <ul style="list-style-type: none"> a. Color code b. More partitions 6. Create flowchart for each process 7. Update forms 1 and 2 8. Obtain a scanner

Figure 1
Project Charter, First Page

	Metric	Baseline	Goal	Notes
Think SMART: Specific, Measurable, Achievable, Realistic, and Time Based				New metric (Quality)
				As applicable
				As applicable
				Metric related to potential unintended consequences /risk
Business Impact (Safety, Quality, Delivery, Cost, Strategy)	Not applicable for now			
Scope	Controlled Licenses Area			
Team Members	Project Leader: Rafael Nieves Support Team: Iris Garcia, Elizabeth Santiago, Maria Trinidad			
Comments	Not applicable			

Figure 2
Project Charter, Second Page

In Figure 4 a process map shows the steps of a work activity to be performed by type of licenses.

After creating, verifying and examining detailed process maps created in the Measure phase, the team will be able to list concerns or pain points within the process (see Figure 5). This allows the team to take advantage of the collective

understanding of process participants. Then, the team can determine the value of each step: Total of step 13, Total pain 43.

Table 1
Is/ Is Not

	Is	Is Not
What	License process performed in the controlled substance area	Ship to creation performed in the controlled substance area
Where	Controlled substance area in the Distributor Company, Guaynabo Distribution Center	Any other department within Distributor Company
When	Actually	N/A
Extent	New licenses creation, licenses up-date	New accounts set up

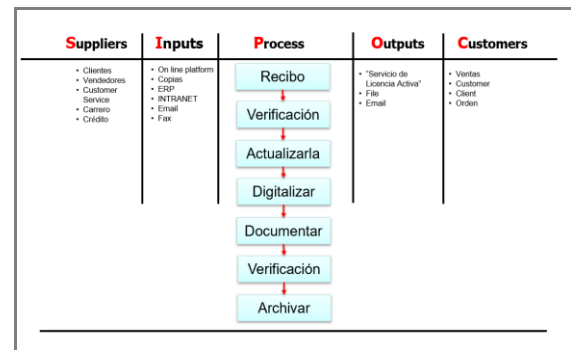


Figure 3
SIPOC

Analyze

In this phase the team decided to use TRIMWOOD as one of the tools to analyze the tasks (see Figure 6). The seven wastes are Transportation, Inventory, Motion, Waiting, Overproduction, Over processing and Defects. They are often referred to by the acronym "TIMWOOD". The 8th waste of non-utilized talent or skills of workers "Resources" was later introduced in the 1990s when the Toyota Production System was adopted in the Western world. As a result, the 8 wastes are commonly referred to as 'TRIMWOOD'

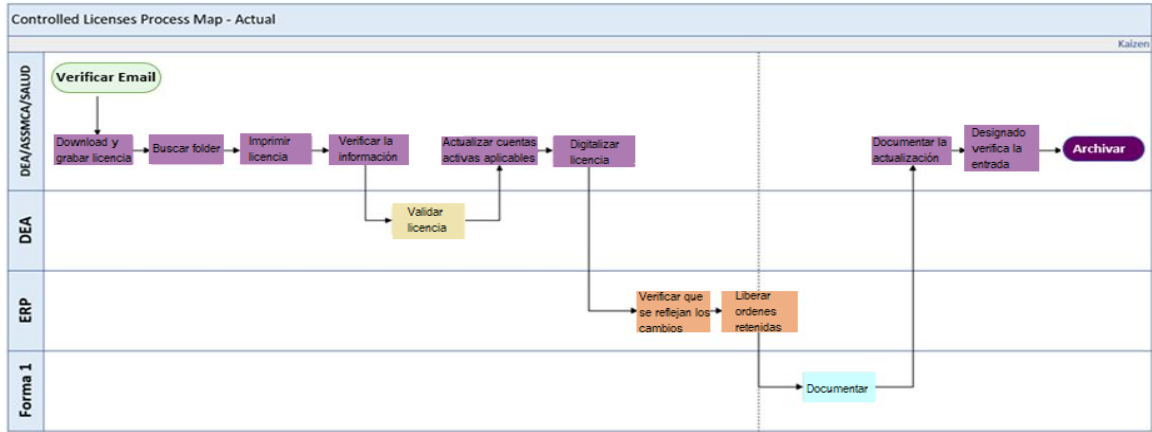


Figure 4
Process Map

Verificar email	Download y Grabar Licencia	Buscar folders	Imprimir licencia	Verificar la información de las licencias (DEA, ASSMCA, SALUD) Alinear Licencias	Validar Licencia DEA	Actualizar todas las cuentas activas relacionadas a esa licencia	Digitalizar Licencia	Ver en ERP que se reflejen los cambios	Ver ordenes retenidas y liberarlas	Documentar cambios en la forma 1 y adjuntar en el folder	Comunicar la actualización de licencia via email	Archivos el folder
Email llegan sin número de cliente	Acumulación de documentos guardados	Documentos "apiñados"	Impresora fuera del area del	Folders no apropiados sin divisiones	No se valida licencia - DEA	No están claras cuales son las	Impresora fuera del area	Uso de multiples pantallas en una	Se nos olvida verificar los	La forma tiene muchos campos que	No hay un formato	Se nos olvida verificar folder
Documentos NO legibles		Algunos fuera de lugar		No estandarización en orden los documentos			No hay evidencia de	Espacio en modulos	No hay consistencia en	Varias cuentas con muchos numeros de	Duplicidad de la misma	Archivos obsoletos
Documentos incorrectos		Condición no ergonomica		Verificación de SOP							Si es fax no hay comunicación	Hay que doblarse
Información duplicada		Documentos obsoletos		No hay evidencia de que se hizo la							No hay comunicación	Apretados
Sin indicaciones		Falta de									Comunicamos	No hay formato
No se sabe cual es la última trabajada												Se pierden los archivos
Falta adiestramiento a todos los involucrados												Mal archivados
No hay guía del proceso												Regla de 24 hrs no se sigue
No SOS												

Figure 5
List of Steps and Their Concerns and Pain

A total of 43 pains was determine with all the member of the Kaizen. When the kaizen is wrap in, those people who perform the task and who have a desire to continuously improve this process flow quicker and more dynamic, are noticed. After the analysis, the result showed that most of the tasks are defects, very few resulted in the other types, and none in the transportation type. Some potential route causes are known, this will help the transition to the next phase creating new ideas to not have these pains/concern in the actual process.

Continuing the brainstorming process, it was decided to create a Fishbone to assist the team in finding out what is the potential root causes for all the 43 an undesirable effect and pains. Figure 7 illustrated the fishbone completed.

Improve

To update the record in the system the user is required to perform a transaction on each license. The Kaizen members noticed that the client, for example pharmacies, are not required to hold license T, for that matter they brought the ERP system expert and as a result of this discussion the pharmacies will not be required to be updated on each license type. A total of 6 updates will be performed in the systems to improve and reduce the number of steps in the process. Figure 8 shows the process that will be edited in the system. The legend in Figure 8 is in Spanish. It means: X is equal to the client can buy without retaining the orders, 0 is equal to permit retain orders the staff will need to evaluate, and Y means the client cannot order the product.

	T	R	I	M	W	O	O	D
1					X			
2					X			
3					X			
4						X		
5					X			
6						X		
7		X						
8								X
9								X
10								X
11			X					
12								X
13								X
14								X
15								X
16				X				
17								X
18								X
19								X
20								X
21								X
22								X
23				X				
24								X
25			X					
26								X
27								X
28								X
29							X	
30								X
31								X
32					X			
33								X
34								X
35								X
36								X
37								X
38								X
39								X
40								X
41								X
42								X
43								X

Figure 6
TRIMWOOD

Actual					
Licencia	RX	OTC	Ley 75	Medical	Comentarios
F	X	X	X	X	
B	0	0	0	X	Se le vende sin retener todos los inyectables
RT	0	0	0	X	Se le vende sin retener todos los inyectables
RTB	0	0	0	X	Se le vende sin retener todos los inyectables
T	0	X	0	X	
P	0	X	0	X	
D	0	0	0	X	SOLO SE LE VENDE LEY 75
V	0	0	0	X	
Recomendación					
Licencia	RX	OTC	Ley 75	Medical	Comentarios
F	X	X	X	X	
B	0	0	0	X	Se le vende sin retener todos los inyectables
RT	0	0	0	X	Se le vende sin retener todos los inyectables
RTB	0	0	0	X	Se le vende sin retener todos los inyectables
T	Y	X	Y	X	
P	Y	X	Y	X	
D	Y	Y	0	X	SOLO SE LE VENDE LEY 75
V	0	0	0	X	

Legenda: X=Permitido comprar sin retener
0=Permitido ordenar con retener orden para evaluación
Y=No se permite ordenar

Figure 8
ERP Systems Updated

For Table 2, the team was able to create a list of improvements and make the analysis of what it is priority to be implemented and be able to assign deadlines.

Table 2 was created to have all the pains and the action to eliminated or improvement the pains detailed with deadline and owner to implement the better way to perform the task. Figure 9 illustrate the format to notify the last email worked. This format was created since the folder to receive the emails does not notify the second person what was the last email worked. This will be in a common area where everyone will have access. The staff member who print and save the last email or license should write the information in this format. In this way the staff avoid not knowing what the last email job was.

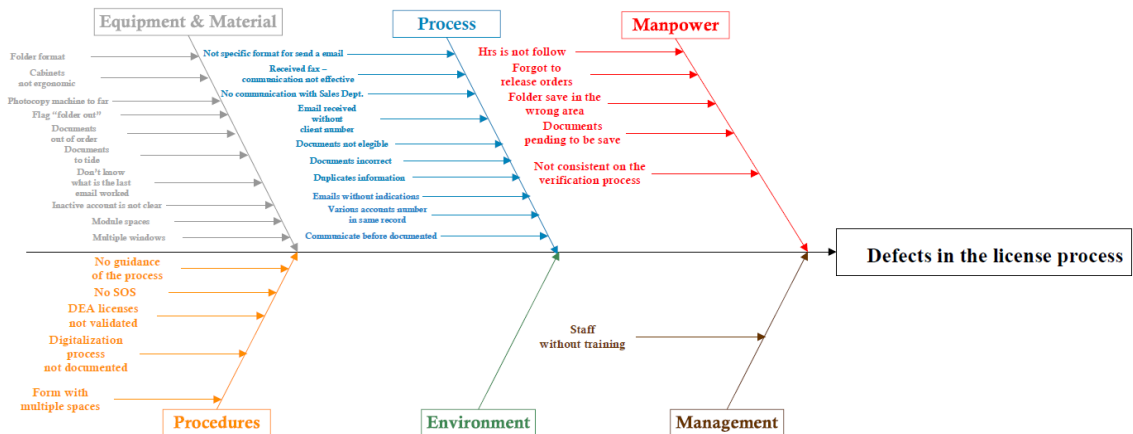


Figure 7
Fishbone

Table 2
Opportunities and Actions

#	Opportunity	Completed (Yes or No)	Responsible / Dead line	Action:
1	Email llegan sin número de cliente	No	Rafael Nieves / 10-31	Presentar situación en GEMBA de "Customer services" – buscando solución Desarrollar comunicado y compartir con todos Departamentos involucrado
2	Documentos NO legibles	No	Rafael Nieves / 10-31	Presentar situación en GEMBA de Customer services – buscando solución Desarrollar comunicado y compartir con todos Departamentos involucrado
3	Documentos incorrectos	No	Rafael Nieves / 10-31	Presentar situación en GEMBA de Customer services – buscando solución Desarrollar comunicado y compartir con todos Departamentos involucrado
4	Información duplicada	No	Rafael Nieves / 10-31	Presentar situación en GEMBA de Customer services – buscando solución Desarrollar comunicado y compartir con todos Departamentos involucrado
5	Sin indicaciones	No	Rafael Nieves / 10-31	Presentar situación en GEMBA de Customer services – buscando solución Desarrollar comunicado y compartir con todos Departamentos involucrado
6	No se sabe cuál es la última trabajada	Si	Iris García / 10-16	Desarrollar una herramienta "visual management"
		No	Rafael Nieves / 10-31	Discutir formato con el equipo
7	Falta adiestramiento a todos los involucrados	No	María Trinidad Elizabeth Santiago / 12-15	Adiestrar al personal de controlado del nuevo proceso y de los acuerdos
8	No hay guía del proceso	Si	Equipo / 10-16	Se sustituye por desarrollar el SOP y crear el SOS
9	No SOS	Si	Iris García / 10-16	Desarrollar SOS

	No	Eli Pizarro / 11-15	Someter a Operacional Excellence	
	No	María/Elizabeth	Adiestrar el equipo	
10	Acumulación de documentos guardados	Si	María Trinidad / 10-16	Se estableció nuevo proceso el cual determina que una vez revisado el cartapacio se archiva inmediatamente
				El área de documentos pendientes de archivar al final del turno todo tiene que estar archivado Se elimino el área de cartapacios pendiente archivar
11	Documentos "apiñados"	Si	María Trinidad e Juan Ramos / 10-16	Se eliminaron los cartapacios inactivos.
12	Cartapacios algunos fuera de lugar	No	María Trinidad Elizabeth Santiago / 10-31	Discutir en GEMBA la situación para disminuir la situación
13	Condición no ergonómica	No	Luis Velázquez / 11-15 Rafael Nieves / 12-31	Realizar evaluación Ergonómica Completar los acuerdos y recomendaciones
14	Documentos obsoletos	Si	María Trinidad e Juan Ramos / 10-16	Se removieron cartapacios de clientes inactivos
15	Falta de indicadores de ubicación de folders	No	María Trinidad e Rafael Nieves / 10-31	Comprar indicador
16	Impresora fuera del área del trabajo	No	Rafael Nieves / 11-15	Evaluar alternativas con la gerencia
17	Folders no apropiados - sin divisiones	Si	Iris García / 10-16	Evaluar las diferentes alternativas en el mercado
		No	María Trinidad e Rafael Nieves / 11-15	Escoger la alternativa más adecuada para la operación.
18	No estandarización en orden los documentos	No	María Trinidad e Rafael Nieves / 11-15	Establecer un proceso para la organización de los documentos en los folders según vayan siendo actualizado.
		Si	Elizabeth Santiago / 11-15	Formas sometidas Pendiente someter SOP
19	Verificación de SOP	No	Elizabeth Santiago / 11-15	
20	No hay evidencia de que se hizo la verificación de la alineación de licencias	Si	Iris García / 10-16	Se añadió para documentar tarea en la forma 1

21	No se valida licencia - DEA	No	María Trinidad e Elizabeth Santiago / 10-31	Adiestrar el personal
22	No están claras cuales son las cuentas inactivas	Si	María Trinidad e Juan Ramos / 10-16	Se removieron cartapacios de clientes inactivos hasta 2017
23	Impresora fuera del área del trabajo	Duplicada	Duplicada	No aplica
24	No hay evidencia de que se digitalizo	Si	Iris García /10-16	Se añadió para documentar tarea en la forma 1
25	Uso de múltiples pantallas en una sola pantalla de computadora	No	Luis Velázquez / 11-15	Realizar evaluación Ergonómica
			Rafael Nieves / 12-31	Completar los acuerdos y recomendaciones
26	Espacio en módulos	No	Luis Velázquez / 11-15	Realizar evaluación Ergonómica
			Rafael Nieves / 12-31	Completar los acuerdos y recomendaciones
27	Se nos olvida verificar los retenidos	No	María Trinidad e Elizabeth Santiago / 10-31	Incluir en el "Leader Standard Work"
				Determinar las horas de verificación
28	No hay consistencia en verificar las licencias de botiquín, No hay un ciclo de verificación	No	María Trinidad e Elizabeth Santiago / 10-31	Incluir en el "Leader Standard Work"
				Determinar las horas de verificación
				Someter las nuevas reglas de ordenes retenidas en sistema de acuerdo con sus licencias
29	La forma tiene muchos campos que no se usan	Si	María Trinidad e Elizabeth Santiago / 10-31	Incluir en el "Leader Standard Work"
				Determinar las horas de verificación
30	Varias cuentas con muchos números de cuentas en un solo cartapacio	Si	Iris García / 10-16	Evaluar las diferentes alternativas en el mercado del cartapacio
		No	María Trinidad e Rafael Nieves / 11-15	Escoger la alternativa más adecuada para la operación.
		No	María Trinidad e Elizabeth Santiago / 10-31	Establecer cuál va a hacer la regla de cuándo se va a crear diferentes cartapacios para una misma cuenta
31	No hay un formato específico	No	Rafael Nieves, María	Desarrollar formato y comunicar al equipo

	para enviar la información		Trinidad e Elizabeth Santiago / 11-15	
32	Duplicidad de la misma información	No	Rafael Nieves, María Trinidad e Elizabeth Santiago / 11-15	Desarrollar formato y comunicar al equipo
33	Si es fax no hay comunicación efectiva	No	Rafael Nieves / 11-15	Consulta a IT buscar alternativas
34	No hay comunicación con venta	No	Rafael Nieves, María Trinidad e Elizabeth Santiago / 11-15	Desarrollar formato, conseguir a quien se va a notificar y comunicar al equipo
35	Comunicamos antes de documentar	No	María Trinidad e Elizabeth Santiago / 11-15	Adiestrar en el proceso en los nuevos acuerdos
36	Se nos olvida verificar folder y se archivan NO incompletos	No	María Trinidad e Elizabeth Santiago / 11-15	Adiestrar en el proceso en los nuevos acuerdos
37	Archivos obsoletos	Si	María Trinidad e Juan Ramos / 10-16	Se removieron cartapacios de clientes inactivos hasta 2017
		No	Luis Velázquez / 11-15	Realizar evaluación Ergonómica
38	Hay que doblarse mucho	No	Rafael Nieves / 12-31	Completar los acuerdos y recomendaciones
		Si	Iris García / 10-16	Evaluar las diferentes alternativas en el mercado
39	No hay formato de los folders (muchos tipos)	No	María Trinidad e Rafael Nieves / 11-15	Escoger la alternativa más adecuada para la operación
		Si	Iris García / 10-16	Evaluar las diferentes alternativas en el mercado
40	Se pierden los archivos	No	María Trinidad e Rafael Nieves / 11-15	Escoger la alternativa más adecuada para la operación
		Si	Iris García / 10-16	Evaluar las diferentes alternativas en el mercado
41	Mal archivados	No	María Trinidad Elizabeth Santiago / 10-31	Discutir en GEMBA la situación para disminuir la situación
42	Regla de 24 hrs no se sigue	No	María Trinidad Elizabeth	Adiestrar en el proceso en los nuevos acuerdos

			Santiago / 10-31	
43	Apretados	Si	Iris García / 10-16	Evaluar las diferentes alternativas en el mercado
		No	María Trinidad e Rafael Nieves / 11-15	Escoger la alternativa más adecuada para la operación
44	“Sales Force Tool”	En proceso	Equipo – 10-31	Evaluar posible utilización para manejo del proceso de licencia
45	Uso de formas expiradas conversiones obsoletas	No	María Trinidad Elizabeth Santiago / 10-31	Buscar todas las formas obsoletas y descartarlas
				Incluir en su “leader standard work” verificación mensual de que se usa la forma adecuada

Último email trabajado:

Nombre del cliente: _____

Fecha: _____

Hora: _____

Figure 9
Last Worked Email

Forms 1, 2 and 3 used to document the process (see Figure 10) were improved. These previous forms had duplicate tables that meant that the one who had to document the task would need to obliterate several blank spaces.



Figure 10
Forms 1, 2 and 3

To document the process of digitizing there was no space available in any of the three forms. Therefore, form 1 was modified and included a check box to document this process (see Figure 11). Also figure 11 illustrated a check list that was added to the form to help the user don't forgot to review any step. As part of this phase, three quotes from three different suppliers were sought. These quotes will be evaluated to see if it is feasible to acquire new equipment for the filing area. Figure 12 illustrated the proposed cabinets and folders.

Forma 1 – LOGO Entrada y Verificación de Licencias

Fecha: _____

Número de cuenta: _____

Nombre del Cliente: _____

Nuevo Renovación Cambio Desactivar (ASSMCA/DEA) Digitalizado

Tipo de licencia recibida:

SARAFS Oficina de Investigaciones (ASSMCA) DEA Validación DEA

Otros

Nombre del establecimiento está alineado
 Nombre de la corporación está alineado
 Dirección física está alineado en las tres licencias

Comentarios:

Sección de firmas:

Entrado por:	Firma:	Fecha:
Verificado por:	Firma:	Fecha:

*El proceso de verificación de licencias incluye verificar fecha, numero, nombre, dirección de localización, además, verificar que la información de las licencias concuerden con la dirección de "Ship to" en intranet.
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Figure 11
Form 1 With Digitizing Check Box

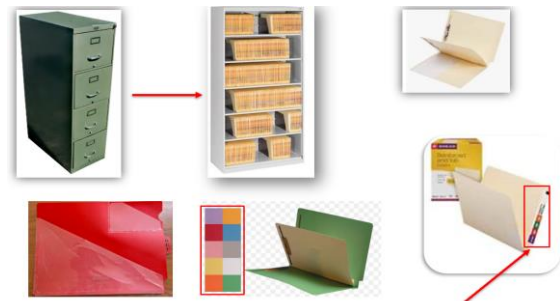


Figure 12
Filing Area Equipment
Control

One of the types of control that are going to be implemented is the standard operating procedure

(SOP) with the new changes. All team members will be trained. It is worth mentioning that several of them were part of the kaizen process. In most of the cases if you don't involve the staff that perform the task in the Kaizen process most of the improvement will not be effective. By involving the staff that executes the task as part of the process of continuous improvement you will have the key of success. Because they are the experts that are running daily, they know what is needed and what is not. In addition to the SOP there is a Standard Observation Sheet (SOS). This SOS (see figure 13) is a visual guide which allows you to see the process step by step and in addition to showing the screens or drawings of what you should do [4].

implementation and present the result of the kaizen to management will help them improve their engagement and presentation skills. When clients buy products in pharmacies they simply go and do not know everything behind the scenes to get it to our hands. Each of the ideas expressed will help the area to do the job better more quickly without losing quality. In this Kaizen about 30 defects was found but in the same way they proposed about 40 ideas for improvement. In these days the environment of constant change, technology helps us a lot to improve our processes. Companies should maximize the use of tools to reinvent processes because if people do not change, we will become extinct.

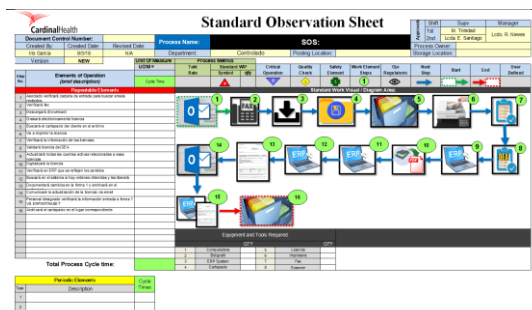


Figure 13
Forms 1, 2 and 3

CONCLUSION

As previously mention in this document, to work in an area that the process is regulated is serious. It is good that these companies keep using methodologies like Lean Sig Sigma which will be beneficial for the company to maintain and improve the quality of the processes. When the company have audits either internal or external, the result will be positive. But the focus should not be just to go well in audits but to do things right from the first time and always improve them. Always involving in the Kaizen or projects those who perform to any task that is determine needs improvement is the only way that the improvement you implement does not fall over. Because putting new and improved processes for them to manage it when you can wrap them up from the beginning. The members of the team should be the most important part of the

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