Designing a Standardized Process Flow for Regulatory R&D Service Center: A Design for Lean Six Sigma DMADV Case Study

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Abstract — *Lean Six Sigma has great impact in the removal of non-value-adding activities and improving business performance. It does so by applying tools and techniques to eliminate waste, and focus on implementing strategies to efficiently identify areas of opportunity and improve them. This research studies the effects of applying Lean and Six Sigma DMADV methodology for the improvement of an R&D service center functional process flow and performance. The methodology is applied to identify variability in the process flow, measure and analyze them with quality techniques and tools, and design remedies to improve turnaround time. The results provide key inputs to focus on for future studies relating to Lean Six Sigma execution.*

Key Terms — *DMADV, Lean Six Sigma, Process Improvement, Service Center.*

INTRODUCTION

Problem Statement

Many projects are initiated in the research and development (R&D) of new products, as well as in the process of updating the necessary information of old products and their components. To deliver quality projects and continue improving the performance and the efficiency of workflow times, it is imperative to establish an efficient process flow work, as well as appropriate timelines for completing the tasks that govern the whole process. However, in the current functional role of the R&D area, an effective process flow and workflow timelines are lacking standardization and have made the scheduling, monitoring, and completion of activities significantly inconsistent and has resulted in delayed project delivery, human resource overload, and errors that have led to re-work. The consequences for the overall business can lead to bad reputation of the service, which is something many industries work very hard to avoid.

Research Description

This research provides a clear foundation of the Design for Six Sigma (DFSS) DMADV methodology and how it can be applied for continuous improvement efforts in an industry, as well as to identify what areas or tasks are most important to measure and improve process workflow in a case study of an R&D service center. This project also serves to improve an R&D service center functional process flow by applying the Lean Six Sigma methodology to analyze the ongoing input and output of functional projects. The focus will be directed to the application on key techniques of the methodology that are useful to measure, and analyze the most important factors or key performance variables that affect the workflow, and on identifying and eliminating non-value-adding activities, or waste, to improve the flow of work in the current functional process.

Research Objectives

- Describe academic findings in QC process flow improvement applying DMADV.
- Develop an understanding of Six Sigma DMAIC and DMADV methodology applications for functional process flow.
- Apply DMADV methodology to identify current process workflow states and forms of waste.
- Develop and verify a design that efficiently standardizes process flow and reduces output turnaround time at least 10%.

Research Contributions

This research contributes to the knowledge of Lean & Six Sigma practices and methodologies by studying the effects of its application in the creation of standardized work processes. It provides further data on the impact of these methodologies on process improvement and the reduction of waste in R&D service center process flow.

LITERATURE REVIEW

Lean Thinking

Quality control is a sub-system of quality management (quality management [QM]). The results of testing, monitoring, and inspection are managed as a basis for quality assurance (QA). They are used as a basis for product release to the market or quality improvement (QI) [1]. In many companies this focus is guided through a lean thinking vision that has the purpose of reducing costs and variation, and improving cycle times in the delivery of results; in other words, reducing or eliminating non-value-added activities to improve processes. For this reason, it is important to understand what is of most value in a process, always in the eyes of the customer, and focus on improving them to reduce variability in the results. To create value and eliminate waste, or *muda*, "specifying value accurately is the critical first step in lean thinking" [2]. With this in mind, a start in identifying the best practices in a process is to understand which are the necessary steps in a process and distinguish them from those steps in the process that can be improved, modified, or removed. Toyota executive Taichi Ohno, who was described in [2] to be the most ferocious foe of waste in human history, identified the first seven types of *muda* (figure 1).

A powerful antidote to *muda* is lean thinking [2]. Lean thinking provides a way to specify value, line up value-creating actions in the best sequence, conduct these activities without interruption whenever someone requests them, and perform them more and more effectively. In other words, lean provides a way to do more with less [2], which is in many ways easier said than done, but will nevertheless be challenged.

Figure 1
Seven Types of Waste

Techniques for Lean Management

Many techniques have been used to improve processes by identifying sources of waste, as well as the most value-adding activities. A practical way to understand value in a process is by developing a value stream map. Very few people see the process from end to end, unless they are working on a Lean Six Sigma improvement team, much less have accountability for the entire value stream [3]. The value stream is "the set of all specific actions required to bring a specific product through the three critical management tasks of any business" [2]. These three tasks are problem-solving, information management, and transformation. However, to identify the entire value stream for the actions, in the purpose of this project for improving R&D process flow, it will certainly expose an enormous, indeed staggering amount of *muda* [2].

An opportunity that we can focus on when evaluating the value stream is the appearance of bottlenecks in the processes. In [4], their Lean Management approach included a value stream map to eliminate sources of *muda* such as inappropriate processes-unnecessary processing or procedures, overproduction, rework, inventory, and work in process (WIP), material transportation and handling reduction. Their value stream map was resourceful when identifying and removing bottlenecks in the process which allowed for reduction in cycle times, according to the goal of making continuous flow;

and reduction of space, according to the goals of reducing the walkthrough of the product and to achieve efficiency in the use of space. So, in terms of standardizing process flow, the identification of possible bottlenecks in the process is essential to remove process obstacles, maintain continuous flow, and improve value-adding tasks.

5S is a quality tool derived from five Japanese terms (table 1). These words form the pillars to create a workplace suited for visual control and lean production [5].

Table 1
5S Definitions

Japanese	Translated	English	Definition
Seiri	organize	sort	Eliminate whatever is not needed by separating needed tools, parts, and instructions from unneeded materials.
Seiton	orderliness	set in order	Organize whatever remains by neatly arranging and identifying parts and tools for ease of use.
Seiso	cleanliness	shine	Clean the work area by conducting a cleanup campaign.
Seiketsu	standardize	standardize	Schedule regular cleaning and maintenance by conducting *seiri*, *seiton*, and *seiso* daily.
Shitsuke	discipline	sustain	Make 5S a way of life by forming the habit of always following the first four S's.

The American Society for Quality (ASQ) expresses that these pillars are simple to learn and important to implement, and will have great benefits that include but are not limited to lower defect rates, reduced costs, increased production agility and flexibility, improved employee morale, and enhanced enterprise image to customers, suppliers, employees, and management [5].

Some additional quality management tools that also help with efficient building of strategies for collecting and compiling information that leads to knowledge are flow charts, brainstorming, cause-and-effect diagrams, and check sheets. The knowledge that can be obtained from the application of these tools will improve the odds of making better decisions [6].

Lean Six Sigma Focus

The Six Sigma approach is a collection of managerial and statistical concepts and techniques that focus on reducing variation in processes and preventing deficiencies in product [6]. The father of Six Sigma, the late Bill Smith, crafted the original statistics and formulas that were the beginning of the Six Sigma culture. The term *Six Sigma* originated as a quality initiative to reduce defects, and much discussion around Six Sigma now includes the word *quality* [6]. The foundation for maintaining a focus on improvement is the infrastructure itself, which includes formalizing a process for nominating and selecting projects, forming improvement teams, and providing the training and support for the teams [6]. This would make the identification of key process input variables (KPIV) more focused and structured. When KPIV is controlled, the amount of variability in arrival time can be reduced [6]. In other words, by controlling the KPIVs, we can also reduce variation in the outputs or key process output variables (KPOVs).

The objectives of applying a Six Sigma approach are to finding the causes of defects or variability and developing remedies to prevent future defects [6]. These are done in five stages, which together form the acronym DMAIC [7]:

- **Define:** Identify potential projects, select and define a project, set up the project team, create project charter.
- **Measure**. Document the process and measure the current process capability.
- **Analyze:** Collect and analyze data to determine the critical process variables.
- **Improve:** Conduct formal experiments, if necessary, to focus on the most important process variables and determine the process settings to optimize product results.
- **Control:** Measure the new process capability, document the improved process, and institute controls to maintain the gains.

When the current product/process exists and has been optimized, but still doesn't meet customer and/or business needs, then a DMADV approach is appropriate, instead of the DMAIC approach, or when a product or process is not in existence, and one needs to be developed. The major difference between DMAIC and DMADV lies generally in the last two phases, in which the Improve phase is replaced with Design, and the Control phase is replaced by Verify. In the Design phase, the objectives are to design the details needed to meet customer needs; the Verify phase has the objective of verifying the design performance and its ability to meet customer needs [6].

Lean Six Sigma is the synthesizing agent of business performance improvement that, like an alloy, is the unification of proven tools, methodologies, and concepts, which forms a unique approach to deliver rapid and sustainable cost reduction [3]. A study [8] that focused on the Lean Six Sigma practices to reduce the defects, the waiting time, the motion, and the overproduction provided some recommendations that emphasized on practical activities that are part of the manufacturing process to achieve good quality of product based on results of available study. As detailed in their results, and based on a multiple regression analysis, the study embraces the alternative hypothesis where it explains that Lean Six Sigma elements influenced the consistency of the goods, with the exception of motion and waiting time variables from the point of view of the respondent [8]. Also, that the manufacturing process has a positive moderating impact on the relationship between the Six-Sigma lean variable and the overall quality of the product [8]. The application of Lean Six Sigma helps in increasing effectiveness of the productive processes in the companies, and helps reduce the cost and continue to improve the products, to avoid the occurrence of the productive errors, reducing waiting time and delivery times, offering to distinguish product at a relevant and competing price, achieving profits leading at the end to customers' satisfaction [8]. A case study [9] describes four steps in the Design phase of DMADV. These are constructing a detailed design, converting CTQs into Critical to Process elements (CTPs), estimating the capabilities of the CTPs in the design, and preparing a verification plan [9]. In its Verify phase, [9] mentions that it "includes facilitating the buy-in of process owners, designing a control and transition plan, and concluding the DMADV project.

METHODOLOGY

A pilot study will be executed within the R&D area of a Pharmaceutical Service Center using the Lean Six Sigma approach, which should identify the opportunities for improvements in the delivery of outputs, and to design a standardized work instruction based on the findings that will lead to more efficient processes and reduction of waste.

Define Phase

In the Define phase, a project plan and Gantt chart will be developed. Within the objectives to standardize processes and reduce variability in timelines, a clear problem statement is described. This problem statement will serve as a focus point to where the project will be heading. Historical data of the events occurring, current cycle times of output delivery, takt, and current process flows will be assessed to have a clear visualization of the process KPIVs. The events that will be measured will be described, including the possible reasons that are causing deficiencies in them.

The project plan will include key stakeholders, those that support the process, as well as those that will be affected by it. Management will be informed to transparently communicate project goals, business benefits, as well as to obtain approval. A team of specialists will be assembled to support the project, and these will be assessed for knowledge in key areas, as well as instructed of the objectives to be obtained. A clear communication plan is key to improve chances of applying the activities of the project. The team members' roles, and amount of time needed to apply strategic activities will be addressed and defined.

Measure Phase

For the Measure phase, several lean and quality techniques will be applied to address process definition, process performance, and quantification of variability. Potential KPIVs will be identified using several basic analysis tools like brainstorming, voice of the customer, data collection, process flow charts, flow diagrams, value stream mapping, and cause-and-effect diagrams that will provide necessary information related to the KPIVs as well as identifying the key process output variables (KPOVs). After these variables are identified and theories for sampling are arranged and prioritized, they will be assessed for accuracy and representativeness. Collection and measurements of possible errors in the current process will be identified, and analyzed to evaluate if capability of the designed/desired state can be achieved with available resources.

Analyze Phase

For the Analyze phase, a process dissection will be used to determine the events of the sequence of steps in the process and make assessments at intermediate steps to identify deficiencies. A study of worker methods will be evaluated to identify inconsistencies of worker process flow that are inefficient and thus communicated for improvement opportunities. Various opportunities for design implementation will be identified following the analysis of data obtained.

Design Phase

After evaluating the different designs for functionality and effectiveness, the one that meets the expected criteria defined in the Analyze phase will be selected. The proposed design will be detailed including the critical process elements, controls for deviations. Remedies will be considered in the process flow design for contingencies, and the performance will be evaluated for compliance to requirements. Lean techniques will be taken into consideration by evaluating the value stream map desired state to ensure efficiency in the process and focusing on value added activities in the process. The proposed design will be discussed with the team for training purposes and preparation for pilot design implementation.

Verify Phase

The design will be implemented, and remedial controls will be developed and measured for quality and efficiency. Engagement efforts will be made with the process owners to validate the design. Feedback will be fundamental to confirm process owner understanding of the proposed design. A monitoring plan as well as a response plan will be established to verify and validate if proposed design can consistently meet the desired requirements. To complete this phase, the design will be transitioned over to be further developed into an official standardized process that meets capability needs.

RESULTS AND DISCUSSION

Define Phase

The results obtained in the Define phase relate directly to the definition of what the project would entail, and a startup to the identification of the problems in the process of delivering the outputs. A project charter and Gantt chart was developed to structure the project, as well as to identify the key stakeholders.

The project charter (table 2) was essential to maintain a visual understanding of the different areas of the project, as well as to establish a clear communication plan with stakeholders that will be supporting the project. The Gantt chart (table 3) was also essential to establish appropriate timelines according to the activities that were going to be executed and to maintain control of the tasks.

To address the areas of opportunity stated in the problem statement, as well as to complete the project charter and establish appropriate timeframes, brainstorming sessions were executed with the work groups, focused principally in identifying which were the steps in the current process, thus a process flow diagram (figure 2) was created.

Table 2

Project Charter

Project Name	***Design Project***	**Start Date**	*08-26-22*
Project Manager/Owner	*Jonathan M. Molina Cordero*	**Scheduled Completion**	*10-26-22*

Project Charter

Purpose	To design a standardized process for initiating and completing customer request projects.
Scope	This project will apply to all requests made by country/market, and all the specialists that are involved in the acquisition and delivery of regulatory information.
Objectives	• Define and evaluate current state • Design future proposed state • Standardize process steps • Improve process efficiency, identify hidden waste in the process • Deliver a product that is consistently perceived as great to the customer
Assumptions	• There are SOP's that are not easily accessible or incomplete creating waste. • Some processes are not standardized and creates waste. • Steps are improvised and not consistently done the same way. • Times can be established to ensure a consistent timely delivery. • Assuming the demand is one document set (All labels and artwork) per request
Constraints	• Delivery Time is limited • Limited human resources • High wait times are endured during some steps
Time/Decision Points	• On time delivery. • Identification of critical process steps and control parameters to avoid defects during the process. • Critical points are the "Initial Draft preparation, delivery and wait times". • Project initiation FIFO and according to submission priority.
Measurement Criteria/Quality	• Developing Current flow of the process. • Measuring times during the process steps. • Measuring the wastes during the steps. • Adding controls to monitor differences in times vs quality of product.
Major Risks	• Missing or misinterpreted information • Inconsistent or unknown process verification may cause setbacks or rework. • Uncertain delivery estimates may cause poor customer satisfaction.

Key Stakeholders

Stakeholder	Name
Project Core Team	Jonathan and Team (+4 Specialists)
Subject Matter Expert	SME (+1)

Approvals

Approvers	Virtual Signature	Date
Project Manager	*Jonathan M. Molina*	08-26-22
Sponsor	*Sponsor*	08-30-20

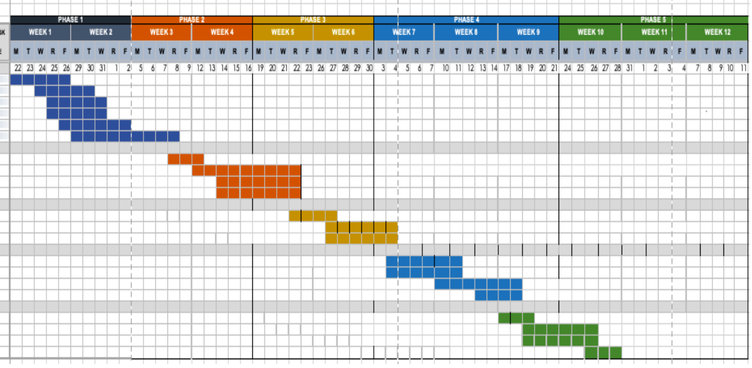
Table 3

Gantt Chart

PROJECT MANAGEMENT PLAN

PROJECT TITLE	LEAN SIX SIGMA RESEARCH PROJECT
PROJECT MANAGER	Jonathan Molina
IMPROVEMENT AREA	Regulatory QC

TASK ID	PHASE TASK	TASK OWNER	START DATE	DUE DATE	DURATION IN DAYS	PCT OF TASK COMPLETE
1	Define	Jonathan Molina				
1.1	Define Clear Problem Statement	Jonathan Molina	08/22/22	08/26/22	4	100%
1.2	Identify Key Stakeholders	Jonathan Molina	08/24/22	08/30/22	6	100%
1.3	Define Milestones	Jonathan Molina	08/25/22	08/31/22	6	100%
1.4	Project Plan/Proposal	Jonathan Molina	08/25/22	08/31/22	6	100%
1.5	Project Initiation	Jonathan Molina	08/26/22	09/02/22	7	100%
1.6	Deliver Proposal	Jonathan Molina	08/29/22	09/08/22	10	100%
2	Measure	Jonathan Molina				
2.1	Identify KPOV's	Jonathan Molina	09/08/22	09/12/22	4	0%
2.2	Apply Tools to Measure KPIV's	Jonathan Molina	09/12/22	09/22/22	10	0%
2.3	Identify Data to Organize	Jonathan Molina	09/14/22	09/22/22	8	0%
2.4	Prioritize KPIV's to Analyze	Jonathan Molina	09/14/22	09/22/22	8	0%
3	Analyze	Jonathan Molina				
3.1	Organize and analyze Collected Data	Jonathan Molina	09/22/22	09/27/22	5	0%
3.2	Develop Designs and alternatives	Jonathan Molina	09/27/22	10/04/22	7	0%
3.3	Analyze Designs for Process Capability	Jonathan Molina	09/27/22	10/04/22	7	0%
4	Design	Jonathan Molina				
4.1	Propose Best Design for Improvement	Jonathan Molina	10/04/22	10/11/22	7	0%
4.2	Establish Remedies for Improvement in Design	Jonathan Molina	10/04/22	10/11/22	7	0%
4.3	Implement Remedies for Improvement (WI)	Jonathan Molina	10/10/22	10/18/22	8	0%
4.4	Discussion of Proposed design	Jonathan Molina	10/13/22	10/18/22	5	0%
5	Verify	Jonathan Molina				
5.1	Implement design	Jonathan Molina	10/17/22	10/19/22	2	0%
5.2	Verify Design Controls to sustain remedies	Jonathan Molina	10/19/22	10/26/22	7	0%
5.3	Gain Design Process owner validation	Jonathan Molina	10/19/22	10/26/22	7	0%
5.5	Close out Project and Presentation	Jonathan Molina	10/26/22	10/28/22	2	0%



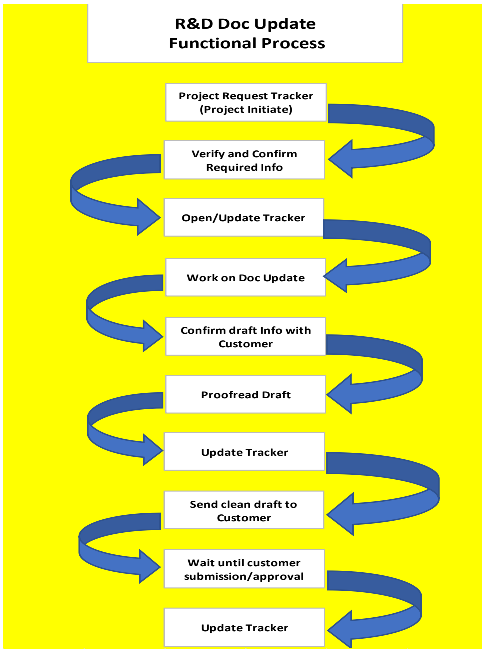


Figure 2
Process Flow Diagram

After executing a process flow diagram, a SIPOC table (table 4) was developed to identify which were KPOVs to focus on, as well as the stakeholders that we can contact in each phase of the R&D project requests.

Table 4
SIPOC Table

S	I	P	O	C
~Country Manager ~MS&T Area ~Label and Launch ~Science ~Proofreading area	~Customer A Requested Information ~Regulaory Information ~Proofreading notes ~MS&T Request	~R&D Functional Process	~International Regulatory Doc Draft ~Artwork Regulatory Approval/ Rejection	~Customer A ~Customer B

Measure Phase

The Measure phase results relate to the steps of the process that was laid out in the Define phase. Historical data was acquired from previous and ongoing requested projects to verify the inconsistencies or differences in the completion times of tasks among the work that was completed, as well as the work that is yet to be completed. The process flow and SIPOC diagram were used as references to acquire more specific details of the critical steps in terms of areas of opportunity. A value stream map of the current state (figure 3) was developed.

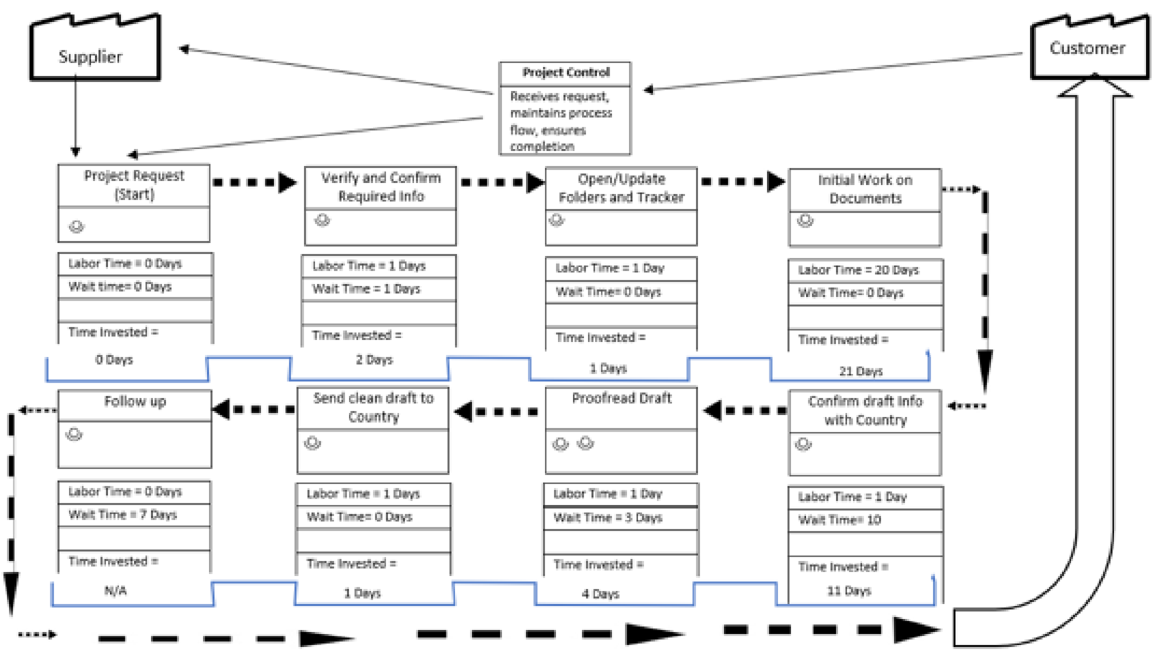


Figure 3
Value Stream Map

The value stream map helped identify which of the steps of the process had the most effect in relation to delivery of the outputs, and which of those had areas that can be improved on by applying lean techniques. It also gave us a visual idea of the time it takes from the initial request of a project to the delivery of the request by the functional process based on estimates that were made from historical data. The data obtained showed that many projects took at least 40 days to completion, although some took even more, and a few were requested with high urgency which were delivered before the 40 days. The step that took the most time was the Initial Work on Documents, with 21 days to completion.

Analyze Phase

After analyzing the historical data and evaluating the flow of the process, considering the current state value stream map, a fishbone diagram (figure 4) was developed. Various areas of opportunity were identified within the critical steps, most relating to the need of a standard way of approaching the regulatory document updates requested by the customers, a lack of knowledge of who are the resources to contact to obtain necessary information, and an improvement in training curriculum that would include an overview of the whole overall process, the specific task steps, and the scope of each task.

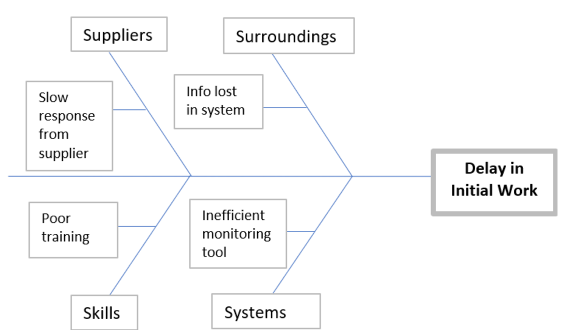


Figure 4
Fishbone Diagram

The value stream map also helped understand where went most of the time that is invested in each process step, to then establish timelines that were imperative to follow during each critical step to better improve time allocation and time management per project. These areas of opportunities were prioritized during voice of customer discussions focusing on a way to bundle these opportunities in the most efficient manner.

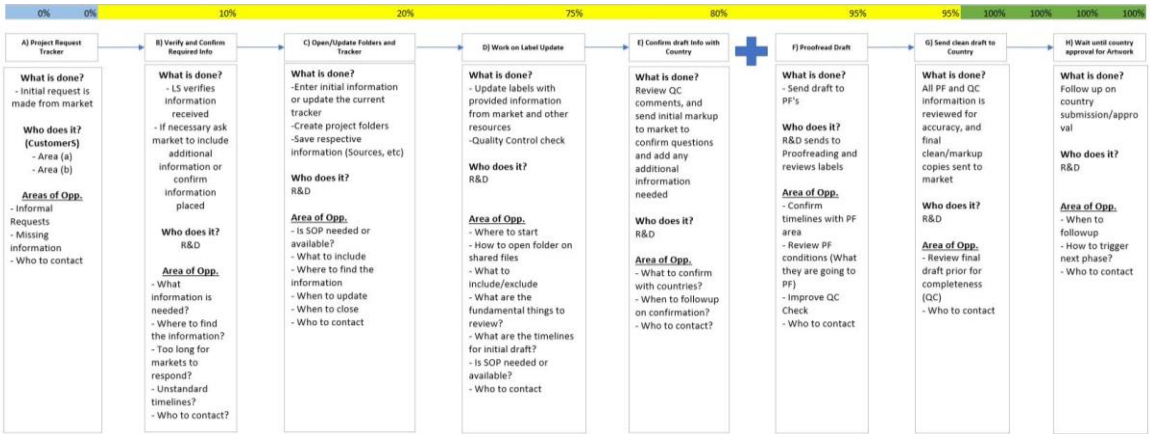
The focus was then turned to the development of several design options for standard work instructions on how to best approach the initiation of the requested project, what visual aids should be included to support the standard procedure, who are the stakeholders or resources to contact to acquire the correct regulatory information, and how to efficiently open, track, and monitor projects. An overview of the functional process (table 5) was created to re-enforce what should be taken into consideration when establishing the critical information that should be included in the standard work instruction.

An opportunity to combine two of the steps was assessed for feasibility (E and F on table 5). It was found that it was an activity that did not necessarily have to wait for the previous activity to be completed, and thus helped in eliminating the bottleneck waste of waiting. This would result in a reduction of the few days that usually takes to start step F, and consequently to the reduction in days for the whole process.

Another opportunity was found when analyzing the essential general R&D folder where old, irrelevant data and folders were being kept along with new and ongoing data. This led to the application of 5S on these folders, where a total of more than 35 folders were found. After sorting the files and setting them in a proper folder, the total main folders were reduced to only six, which made the finding of essential data more efficient, as well as organizing new data more easily and in a user-friendly manner. Most of the irrelevant data was eliminated or stored in specific folders and an overall clean-up the folders was performed. Additionally, a standardized bulk folder was created, with the specific sub-folders to use when opening and saving new projects. This simplified

Table 5

R&D Functional Process Overview



the process, adding consistency in sub-folder naming conventions and saving time in the thinking process when creating new project sub-folders.

Design Phase

After evaluating the results of the Analyze phase, the team focused on reviewing the current value stream flow to convert it into the designed and desired work instruction. This work instruction includes the critical steps of the process, with detailed instructions of what should be done per critical process step, who are the resources responsible for specific information, and will include visual aids to cover most of, if not all, the areas of opportunity that were mentioned in the Analyze phase that directly affect the outputs of the process. These are the following:

- Formal request to initiate new projects
- Standard general process flow of work per project
- Specify the standard information needed to initiate the project
- Specify what are the tools/resources/SOPs to use for specific steps of the processes and where to find them
- Specify what is needed, to know when project is completed
- Specific area stakeholders that will support the process

To mitigate the possibility of misses during the recollection and entering of information when updating the documents, a verification checklist will be developed, standardized, and verified. This checklist will serve as a template to review the critical points of the projects, and for maintaining an accurate tracking of the project status.

Verify Phase

In the Verify phase, the standard process design was introduced to the team for verification of the feasibility. Training sessions were scheduled to detail the steps in the process, and to ensure understanding of the whole process, as well as the importance of following the standard steps and what they entail. As part of the verification of the standard process, the checklist was tested to monitor the progress of the project and to verify if indeed the critical steps are completed. The checklist was also included in the training and the timelines were discussed for each of the steps to effectively monitor the process. These timelines were established taking into consideration the historical data that pointed to what could be possible if project steps were standardized, understood, and monitored effectively and efficiently. The establishing of standard timelines for completion, even though project requests may vary in their complexity, is meant to reduce the turnaround time of the whole process, from initiation to completion, by at least 25%. By reducing the standard from 40 days to completion to 30 days to completion by following the established timelines, the process delivery or turnaround time will see a reduction of 25%. This would be even more considering previous projects that have been known to take more than 40 days to completion.

Conclusions

After seeing the results of this research study, we can say that the Lean Six methodology proved to be very useful for the improvement efforts of the process. The structured methodology, as well as the quality and lean tools and techniques that were used, had a great effect on the identification of the areas of opportunity. It also gave us a better understanding of the strengths of having a lean mentality, which focuses on reducing waste, and manifested itself in the reduction of waste and making room for innovative ways of thinking and working. The analysis of data led to a design that improved the flow of the process by establishing a standard process that can be efficiently executed, monitored, and measured to continue improving the performance in the delivery of projects and with high quality.

Some of the limitations of the research, that should be taken into consideration in future studies, was the lack of concrete historical data. If more specific numerical data of the exact times the tasks take to complete, as well as the times of delayed deliveries, were available, it would improve the odds of evaluating the data with statistical tools in the Measure and Analyze phases. In all the phases, it is crucial to acquire the information needed for the next phase. However, one of the points that we found most crucial in the decision-making process was the definition of the data to be measured, as well as the organization of this data into hierarchies of importance. Having a good understanding of what exactly to measure makes a great difference when obtaining relevant data to then analyze. Even so, each phase is a predecessor to the next and the appropriate efforts performed in each phase determines the success of the next.

The research also proved to accept the fact that Lean Six Sigma can be implemented in any industry that aspires to a structured and efficient way to make better decisions. It provides a guide for collecting and analyzing data of a process to reduce variability and improve performance efficiency. Its use in the service sector should be greatly emphasized so more resources and knowledge can be gathered that would result in new innovative ways of thinking and making decisions.

References

[1] A. Darmawan, R. Hanafi, and A. Asqarye, "Reducing variability in process and the risk of product defects: A case study in SMEs," in *IOP Conference Series: Materials Science and Engineering*, 2020 [Online]. Available: iopscience.iop.org/article/10.1088/1757-899X/885/1/012055/pdf.

[2] J. P. Womack and D. T. Jones, *Lean Thinking: Banish Waste and Create Wealth in Your Corporation*, New York: Simon & Schuster, 1996.

[3] M. O. George, *The Lean Six Sigma Guide to Doing More with Less: Cut Costs, Reduce Waste, and Lower Your Overhead*, Hoboken: Wiley, 2010.

[4] M. E. Nenni, L. Giustiniano, and L. Pirolo “Improvement of manufacturing operations through a lean management approach: A case study in the pharmaceutical industry”. *International Journal of Engineering Business Management*, vol 6., Jan. 2014 [Online]. Available: doi.org/10.5772/59027.

[5] ASQ, "What are the five S's (5S) of lean." Accessed Feb. 6, 2023 [Online]. Available: asq.org/quality-resources/lean/five-s-tutorial.

[6] F. W. Breyfogle III, *Implementing Six Sigma: Smarter Solutions Using Statistical Methods*, Hoboken: Wiley, 2003.

[7] F. M. Gryna, R. C. Chua, J. Defeo, *Juran's Planning and Analysis for Enterprise Quality*, Boston: McGraw-Hill, 2007.

[8] M. M. Omoush, "Lean Six Sigma effect on the quality of the products in Jordanian food companies: The moderating role of the manufacturing process," *International Review of Management and Marketing*, vol. 10, no. 6, pp. 1-12 [Online]. Available: doi.org/10.32479/irmm.10680.

[9] J. A. Johnson and H. Gitlow, "Designing new housing at the University of Miami: A “Six Sigma” DMADV/DFSS case study," *Quality Engineering*, vol. 18, no. 3, pp. 299–323 [Online]. Available: doi.org/10.1080/08982110600719399.