Validation and Project Process Improvement Using DMAIC Methodology

Lisbeika Morales-Ramos
Master in Manufacturing Competitiveness
Jose A. Morales, Ph.D.
Industrial and Systems Engineering Department
Polytechnic University of Puerto Rico

Abstract — Lean Six Sigma Methodology impacts positively the efficiency, customer satisfaction and quality for manufacturing and systematics process. This article provides a successful example of how the Sig Sigma methodology can improve the lead time associated to project/validation documents in the LMR company by 15%. In addition to the reduction in the lead time, a cost saving of one million was identify. This was achieved by the elimination of non-value-added activities, creation of approval matrix and development a system for the execution of minimum changes and First Articles Inspections avoiding the protocol generation. As consequence of this streamline process, the company have a capacity incrementation to absorb more projects that will contributed in the continuous improved in product quality and customer services.

Key Terms — *DMAIC, Lead Time, Value Stream Map.*

INTRODUCTION

During the last two decades a recognized and valuated medical device company was highlighted as an example of high-quality standards and customer services. However, during the last six months, this company has been facing problems to achieve the validations/projects lead times established, especially during generation of documentation. As consequence, projects related to quality and continues improvements are experimented a considerable delay during the implementation phase.

The name of this medical device was changed to LMR Company, in order to maintain the confidentiality of the process of this company. Company LMR started its operations in Puerto Rico in 1957 with the manufacture of thermometers. In 1987, LMR Company expands the manufacturing operations with the introduction of needles, caps and adapters used in different medicals/surgical process, some of these are: specialty, anesthesia, radiology, biopsy and regional block needles. In September 2014, the company acquired a new building dedicate to manufacture of blood collection tubes, lancets to be used for the blood collection of premature babies and infants, and devices that enable the safe transfer of blood.

LMR is a medical device regulated company and some of the registrations that the plant holds are: FDA (21CFR820), ISO13485:2016, ISO14001:2015, ANVISA (Agencia Nacional de Vigilancia Sanitaria) and AEMPS (Agencia Espanola de Medicamentos y Productos Sanitarios). Approximately 350M units are manufactured by Company LMR annually. A general description of these products is as follow: Anesthesia Needles, catheter used for bladder drainage, device for safe transfer blood, blood collection tubes, caps, adapters and kits.

In order to improve the manage and implementation of the projects/validations, the company implemented an aggressive Lean Six Sigma Green Belt Certification in which all the associates involve in project/validations were training in this methodology. According with the ASQ (American Society for Quality), Six Sigma is a people-driven process. The Six Sigma project performance level tends to match the level of persistence, expertise, and commitment of the individual members of the team. Green belts are skilled team players, and their aim is to improve process quality. Green Belt training teaches candidates the basic tools used by a project team

and how to apply DMAIC skills that relate to a Six Sigma project.

To obtain the Lean Six Sigma Green Belt Certification in LMR Company, associates need to select one of the company projects and performed this follow the five phases of the DMAC Methodology (Define, Measure, Analyze, Improve and Control). One of the projects selected as part of this certification was titled “Validation and Project Process Improvement Using DMAIC Methodology” and was focused to improve the project/validations lead times, implement corrective actions and monitoring the process to assure that the corrective actions were effectives, and the re-defined process is sustainable.

The research of this project is focused on identify the root cause associated to the delay in the projects/ validations. For this, the DMAIC methodology will used. The methodology seeks to improve the quality of a product or service by concentrating not on the output but on the process that created the output. The idea is that concentrating on processes leads to more effective and permanent solutions. The heart of DMAIC is making continuous improvements to an existing process through objective problem solving. DMAIC provides structure because each phase of the process contains tasks and tools that will lead the team to find an eventual solution.

The first phase of the DMAIC methodology is define. The project begins by creating a project charter to identify team members, project milestones and due dates. Other lean tool used in this phase is the Voice of Customer (VOC), in which the project team identify the CTQs to help measure the impact the problem has on the customer. This phase is completed when the team plot a high-level of the process map that includes the process’s inputs and outputs.

Measure is the second phase of the DMAIC Methodoly and is critical throughout the life of the project since it provides key indicators of process health and clues to where process issues are happening. This phase includes creating and executing a data collection plan that provides reliable and significant data. In this phase also is developed the current state Value Stream Map (VSM) used to plot in detail the validations/projects process.

The third phase of the DMAIC methodology is Analyze, here the process is analyzed to find any defects and their root causes. During the fourth phase the process is improve by addressing the root causes founded during the third phase. Finally, during the fifth phase is controlled the improved process and future process performance to correct any deviations before they result in defects.

The objective of this investigation is finding the root cause associate to the delay in the implementation/manage of validations/projects. As consequence, the lead time associate to documents generation will improved by 15% to achieve project due dates.

In order to find the root cause associated to projects/validation delay, identify opportunities for improvements, waste, bottlenecks, and establish a sustainable process the five phases of DMAIC Methodology were used.

The objective of this investigation is finding the root cause associate to the delay in the generation of validation/project documentation. In addition, development corrective action to address the findings. As consequence, the lead time associate to documents generation will improved by 15% helping to achieve project due dates. For this, the five phases of the Six Sigma Methodoly (Define, Measure, Analyze, Improve and Control) will be used.

The research contribution of this project is finding the root cause associate to project delay related to documentation generation. In addition, establish corrective actions to address the possible issues during the generation of projects/validation documents and decrease the lead time. Finally, LMR Food Company will be able to complete the projects according with the established due dates improving the product quality and customer services.

The foreseen benefits of this project include, but is not limited to:

- Harmonization for develop, manage and approval process of the documents generated during validations/projects.
- Flexibility for the manufacturing department that will allow the release per separate of the manufacturing lines, equipments or products at soon the validation process will completed instead to waiting for the completion of all the items included in the validation/project.
- Will result in the reduction of the workload in the validations/projects owners that can be used in value added activities, increasing the capacity to adopt more projects.
- Reduce lead time total days it takes to perform validations/projects.

LITERATURE REVIEW

Due to increased competitive, companies are under huge pressure in order to reduce their costs and provide products of higher quality in shorter lead times. This is possible if they improve their performance. Lean manufacturing can be used by manufacturing organizations to achieve these and obtain a competitive advantage over their rivals. This competitiveness is obtained by increasing efficiency and decreasing costs through the elimination of non-value-added steps and inefficiencies in the production process. Lean was first introduced by Womack and Jones (1990) in their book "The Machine That Changed the World", which describes the Toyota production system (TPS).

As a Six Sigma Green Belt partitioner, the best way to find opportunities for improvements is using the Lean Six Sigma (LSS) approach. LSS impacts positively on organizational profitability, efficiency, customer satisfaction, and quality [1]. For process improvement, Six Sigma is carried out using the DMAIC methodology [2] throughout the define, measure, analyze, improve, and control phases. This approach is regularly applied to manufacturing process, however, take in consideration that a systemic process like validations, projects, generation of documentation to perform the manufacturing process in compliance also will be improved using this methodology. The reason is that both process (manufacturing and systemic) presents the same type of waste in terms of waiting time between stages, duplicate processing, and non-value added activates.

A systemic process (in contrast to manufacturing process) is one that transforms information and data. The manufacturing process is highly structured and have procedures to explain step by step the process and activities in order to avoid variations of the process/product. On the other hand, systemic process is human dependable and the activities thru a process may vary depending on the associate although the final result is the same. Other difference between the manufacturing and systemic process is that the outputs and results are more tangible in the manufacturing process since is possible quantify the outputs like quantity of units or defects, production rate, waste and downtime. However, the systemic process depends on data collection to evaluate the time spent per step or quantity transactions. DMAIC Methodology can be used for a systemic process to establish a data collection plan, to quantify the time spent in each step and to identify duplicity and/or unnecessary transactions.

As mentioned in the paragraph above, systemic process is human dependable and the activities thru a process may vary depending on the associate. Nevertheless, LMR as a regulated company have a Standard Operating Procedure (SOP) titled "Validation/Project Master Plan" in which are define the minimum requirements in terms of documentation that the project owner needs to know to guarantee that the process is in compliance with the regulatory agencies.

The following is a flowchart (Figure 1) that define the steps during the validation/project implementation.

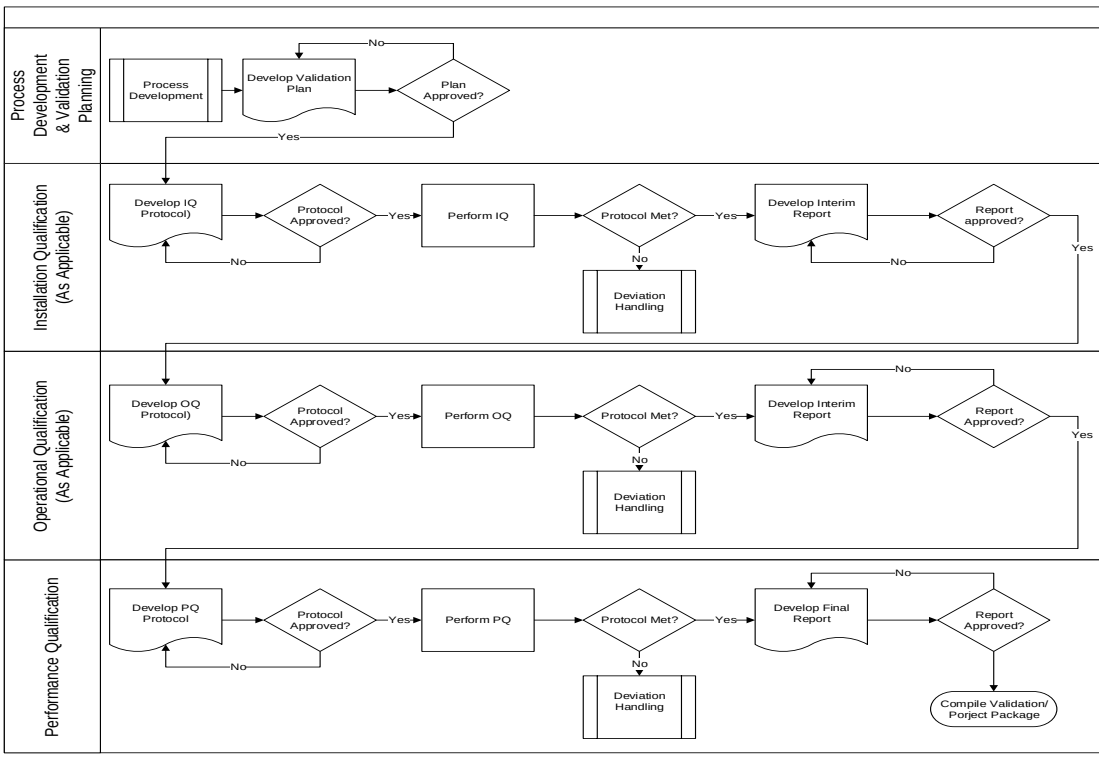

Figure 1
Validation/Project Master Plan Flowchart

METHODOLOGY

The popularity of Six Sigma, as a means for improving quality, has grown exponentially in recent years. It is a proven methodology to achieve breakthrough improvement in process performance that generates significant savings to bottom line of an organization [3]. This chapter describe the application of the DMAIC Methodology to find the root cause associate to projects delays and reduce the lead time associate to the generation of validation/project documents. In addition, its demonstrated that with the used/application of the corrects tools, great cost savings could be obtained also.

To achieve the goal of reduce the lead time in the validation/projects during the document's generation of a food company LMR, the five phases of the DMAIC Methodology are applied. The first is "Define", that is related to identify the objective, scope and goals. In this phase a generical project charter (gantt chart) is generated to define investigation steps, team members and actions with due dates. In this phase also was performed a survey (VOC) to know the complaints/concerns and identified opportunities for improvement during the generation of project documentation. The second phase is "Measure", here the data collection structure is defined, and the Value Stream Map (current state) is development to fully understand the investigated process, identify opportunities for improvements and to estimate the process lead time.

In the third phase "Analyze", a pareto chart with the data obtained is developed to identify the possible root causes that are impact the project time lines. According with the 80/20 rule, about 7 conditions have a mayor contribution in the project documentation delays. Additionally, in this phase is develop the fishbone analysis in which four categories (people, system, process, and management) were used for the creation of this.

In the next phase "Improve", the process is redesign/improve to mitigate the causes found. A VSM (future state) is created reflecting the improvements. An action plan is created to list the

actions, assign the responsible for the execution of these and completion dates.

Finally, new metrics and process controls are implemented to monitoring the progress of the process and assure sustainability of the changes. This phase is named like “Control” phase.

In conclusion, the application of the Six Sigma methodology in the identification and improvement of any process (systematic and manufacturing process) is a good and structured method. In addition, using this methodology many opportunities for improvement are identify and corrective actions also could be implanted as part of this methodology.

RESULTS

The investigation related to the use of Six Sigma Methodoly to reduce the lead time related to the generation of validation/project document was successfully implemented. As consequence, the lead time associate to validation/project documents generation was improved more than 15%, meet with the target established. Additionally, was estimated a cost saving of 1M.

To identify the root causes associated to the delay in validations/projects, the first step was performed a survey (VOC) to the validation practitioner and project managers, in which 95% of the participants identified documentation issues and gaps during the process implementation.

Then of this a VSM (current state) was developed, and the lead time of the process was estimated in 46 days. According with BlueCart e-commerce platform that is famous for the hospitality and food industries that helps you streamline your processes and better serve your customers; lead time is the amount of time that goes by from the start to finish of any given process [4]. In projects/validations, this means the amount of time that passes between a project/validation is confirmed and the Purchase Order (PO) is approved, project/validation is closured/ implemented, and the project is released.

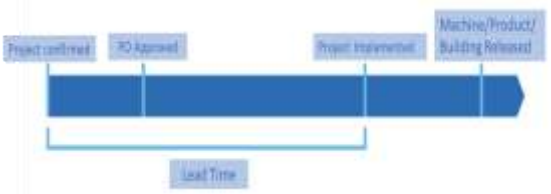

Figure 2
Lead Time Process

The Validations/Projects Total Lead Time (before and after DMAIC implementation) was calculated using the Value Stream Map (current and future state). These were development with the participation of a multidisciplinary team, composed for engineers, managers, supervisors, project managers, technicians, and clerks in which the time of each activity from project confirmed to project released was estimated based on their experiences (see Figure 2).

The Total Lead Time formula used was:

Total Lead Time = Project/Validation Execution Time + Project/Validation Release Time

Table 1
Total Lead time

Type of Document	Lead Time Before DMAIC (days)	Lead Time After DMAIC (days)	Improvement
First Article	46	5	89%
Process Verification	46	5	89%
Protocol	46	36	15%

In the Table 1, time was identified as a significant source of waste in the validation/project process, especially during for the First Articles and Process Verification that obtained and improvement of 89% of the total lead time. These processes reflect a significant improvement in comparison with the “Protocols” that had an improvement of 15% of the total lead time, since for these were developed new forms/templates that allow the documentation in a more effective and simple way avoiding the generation of a protocol.

The next step of this investigation was analyzed the data collected from a period of 6 months (about 30 documents generated) to understand the reasons

associated to the delay of projects/validations. During the evaluation, it was found that the document had an average of three revisions per document for part of the approvers (back and forwards) delaying the approval process. Also, it was found that the average per deviations was seven per document, which clearly represent issues in the documentation process associated to validations and projects.

In order to identify the protocol/project document sections defined in the templates that have mayor contribution in the back and forwards of the documents and deviations, a Pareto Principle & the 80/20 Rule was used. According with the ResumeLAb Article, the Pareto Principle, or the 80/20 rule, states that for many phenomena 80% of the result comes from 20% of the effort. What does this mean in practice? To maximize their efficiency businesses should focus on the vital 20% of activity. The 80/20 principle does not suggest that the remaining 80% can be simply ignored, it may just require less focus [5].

During the investigation, it was found that according with the principle 80/20 rule, there are seven categories (document sections) that have a mayor impact in the project delay, being the most common the "appendix/test cases follow by strategy/methodology. Refer to the Figure 3.

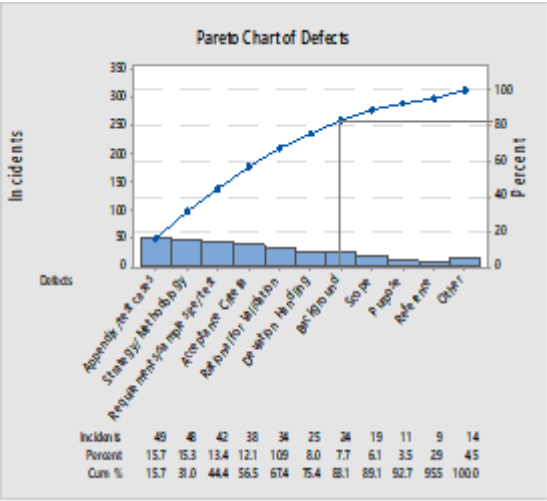

Figure 3
Pareto Chart

In addition, a fishbone analysis was performed to identify possible root causes associated to the non-conformances (deviations) and for the back and forwards during the document's generation. The causes identified in the fishbone analysis are:

- Templates/procedures are not followed.
- Approval/review process is manually.
- Lack of resources.
- Document does not have all the required information.
- Documents are not clear.
- There are not a define process to challenge minimum changes and the generation of the protocol is required.
- There are not a define process to perform a First Article Inspection and the generation of the protocol is required.

According with the investigation and analysis performed, the root cause of the project delay is associated to documentation errors during the generation of documents. For this reason, an action plan was development and after implementation were obtained successfully results in terms of lead time and cost savings.

As part of the action plan, also was included a monitoring plan after implementation, to verify if in effect the Validation and Project Process Improvement Using DMAIC Methodology Project was effective. The Total lead Time of ten projects was documented and a statistical analysis was performed to compare the Total Lead Time before Implementation of DMAIC (Group A) and Total Lead Time after implementation of DMAIC (Group B). The Statistical analysis was performed using the two-sample t-test (also known as the independent samples t-test) that is a method used to test whether the unknown population means of two groups are equal or not. This tool can use when your data values are independent, are randomly sampled from two normal populations and the two independent groups have equal variances. Refer to Figures 4 and 5.

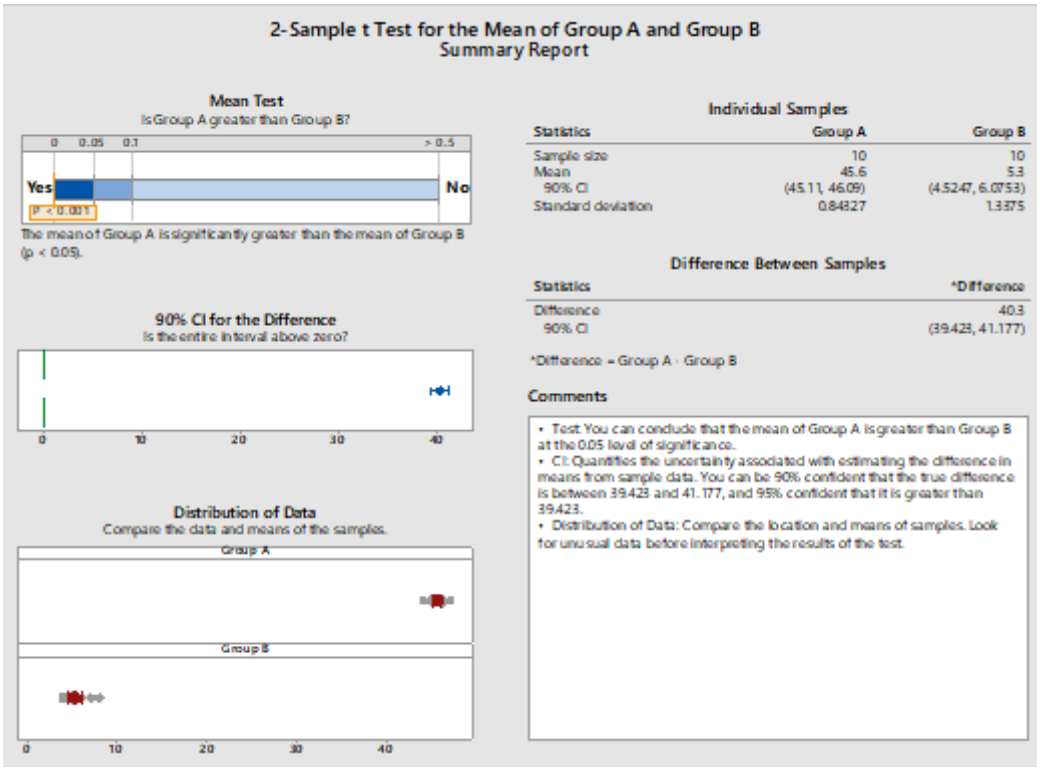

Figure 4

2- Sample t Test for Mean – % of Confidential Interval Between Samples

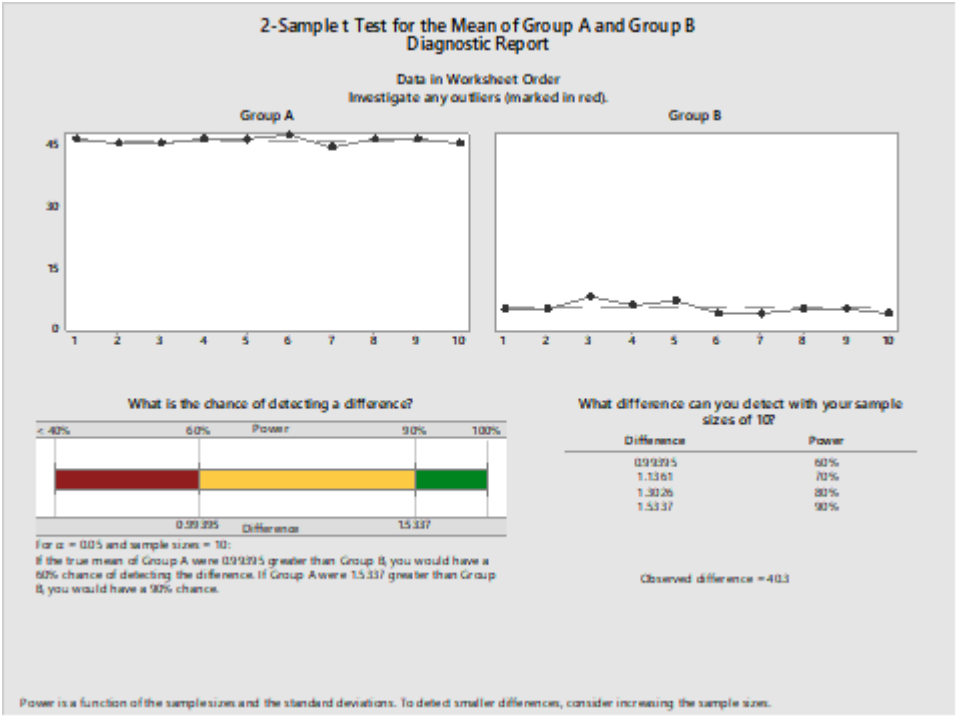

Figure 5

2- Sample t Test for Mean - Observed Difference Between Samples

As part of the statistical analysis it can be observe that the mean of the Group B (Total Lead Time after DIMAC) was 5.3 days, that is the same quantity of days that was estimated during the Value Stream Map (future state). Additionally, the difference in means from sample data was 39.423 with a % of Confidence of 95%. These results confirms that the hypothesis established, Group A is greater than Group B, is correct. This, it can be concluded that the validation/project streamline process was effective.

CONCLUSION

Based on the obtained results of this project, it can be concluded that the project was successfully and achieved the goal of 15% associated to improve the lead time for project/validation documents. Lead time reduction takes time, energy, and data, but can help your business improve its sales and fulfillment capability. Calculating, understanding, and acting on changes in lead time allows a business to prevent losses and fulfill orders quickly and efficiently. Additionally, was demonstrated that the five phase of DMAIC Methodology (Define, Measure, Analyze, Improve and Control) are an excellent tool to find root cause and improve systemic process.

The benefits of this implementation include:

- Reduction of the Total Lead Time for validation/project documents in 15% (minimum), increasing the validation/project capacity. This was possible with the help of the multidisciplinary team that development the Value Stream Map (future and current state) in which were identify the time spend for each activity. Additionally, during this exercise were identify non-value-added activities and duplicity and issues with the documentation that also were improved during this project.
- Harmonization for develop, manage and approval process of the documents with the update of the templates and procedures to include the minimum requirements avoiding multiples revisions before the approval process.
- Partial release of manufacturing lines, equipments or products at soon the validation process will completed instead to waiting for the completion of all the items included in the validation/project increasing the flexibility for the manufacturing departments. This goal was achieved with the implementation of the templates/forms and procedures to document these activities, allowing the release of each item included in the validation per separate.
- Capacity to adopt new/more projects due to the reduction of the workload in the validations/projects owners that can be used in value added activities.

During the implementation of this project also were identified some opportunities for improvements that can be consider in a future. For example, establish a program for the periodical review of the validation/project process that include procedures, templates, and strategies. In addition, was identify the important of strengthening the training system for the validation/project area and assure that all the associates have the same knowledge and capacity to handle projects.

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