Improvements to Implementation of Single Equipment Unit Projects

Lysmariam Rivera
Master of Engineering Management-Online Program
Hector J. Cruzado, PhD, PE
Graduate School
Polytechnic University of Puerto Rico

Abstract *— The pharmaceutical industry faces daily challenges relating to resources, time and budget established by implementing projects that contemplate a single equipment unit. Many times, referring to a single unit of equipment makes it look as a simple project, and the allocated budget is one limited due to the consideration in which staff within the Organization will be responsible for completing and support most of the required activities. That's why a project was conducted to qualify a metal detector (single equipment unit) following the phases of Project Management to identify how to improve the implementation of projects which support a single unit of equipment and complying with the resources, time and budget. It was found that the guidelines used by the organization need to be more robust based on the project magnitude, and the organizational culture must be considered from the initial project phase to achieve completion within time and budget.*

Key Terms *— continuous improvement, equipment units, organization, project management*

INTRODUCTION

Annually, several projects are carried out in the pharmaceutical industry in order to maintain competitive in the market. In the cases of high magnitude projects which include the acquisition of multiple manufacturing equipments and the construction of new facilities, a timeline and costs projects could be justified for the implementation, because the budget allows using additional resources for the use of established tools for project management. In the case of the project implementation which considers only a single equipment unit, a timeline and costs projects are limiting factors. The limitations occur because in these cases the budget is not high enough, and the addition of a single equipment unit needs to be absorbed by existing resources across the organization. Most of these resources are already loaded with a high work volume with assigned deadlines. Other resources to be considered as part of the project management process are the time and the project budget. Based on this, it was observed that this kind of projects could not be achieved within the established timeline and project budget, which is an Engineering problem that needs to be improved. Assuming an attitude of continuous improvement, the business can be transformed into a more efficient, competitive, and profitable one.

The analysis and evaluation presented of the limitations in the process management: time and project budget, are show as the key factors to complete an implementation of a project with a single equipment unit. The scrutiny of the process provides a guide to the project manager about how to take other concerns during new events with other projects implementation which considers a single equipment in order to be more efficient.

The paper is organized into five parts. The first part explains the main concepts about Project Management, details the basic project's main phases and how they were applied during the project. The second part explains why the organizations pursue the continuous improvement and the importance. The third part presents the analyses approach which covers the project activities the implementation and the project cost. In the fourth part are included the results and discussion. Finally, the conclusion and final recommendations, it is argued how during the project implementation, the project manager has the control to promote project activities in order to achieve a successful project implementation, but

the organizational culture is a factor which have an impact in the project results.

WHAT IS PROJECT MANAGEMENT?

Project Management is defined by the Project Management Institute (PMI) as "the application of knowledge, skills, tools and techniques to a broad range of activities in order to meet the requirements of a particular project" [1]. The PMI identifies the five main process phases or groups included in Figure 1 as a part of a project implementation process.

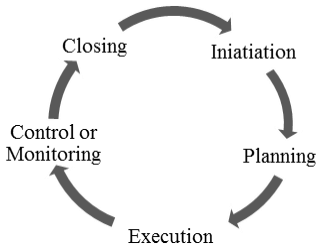

Figure 1
PMI's Five Process Phases

The phases are defined with the aim of be more strategic in the analysis of the project. The first phase of the project process is the "Initiation", which is proposed to solve a problem identified by the organization, either because of legal requirements, due to customer demand or product, among others. During this phase it is important to evaluate and determine the feasibility of the project to determine whether or not it is realistic to achieve. The organization where the project was conducted identified the necessity to evaluate and improve the implementation of projects which considers a single equipment unit within the time and budget. The process improvement consists in being more efficient in the implementation of these type of projects (single equipment unit), specifically in the case of the new metal detector equipment.

After the initiation, the next phase is the "Planning". During the planning phase, the purpose is to define the project details, considering the tasks required to be completed and the resources required [1]. At this phase the possibility of reducing documentation time, in the process of implementation of the project that includes a new single equipment unit is identified. By being assertive during the timing associated with each task, you can provide savings in the project budget or as otherwise being consequences like incurring in additional costs or also profit loss. This type of project does not happen every day, therefore good planning would provide space for the restructuring of the tasks of staff assigned to these projects (which have other daily tasks already assigned). In the planning phase the project management needs to evaluate and analyze the human capabilities of each project team member to identify the right member ability, and maintain the right team that works in accordance with the project's challenges [2]. There are four conditions that are contribution factors required to achieve effective project teams in a project: professionally stimulating work environment, good project leadership, qualified personnel, and a stable work environment [3]. Also, during the planning phase, it is very important to consider adding a contracted person assigned to perform or support various tasks in different areas of the organization, so that the staff is available to meet the project's deadline.

After planning and defining tasks with their respective deadlines, projects are implemented in the next phase called "Execution". At the execution phase, it is mandatory to evaluate all the required tasks and the activities performed. This phase allows for productivity and efficiency, evaluated in the next phase called "Control and Monitoring".

The phase of "Control and Monitoring" is based on cost control, schedule control, critical path activities, and deviation evaluation from plans, team collaboration and conflict resolution [4]. Project control is continuously worked throughout the project duration covered during weekly meetings, direct or e-mail communications, software programs for project schedule control, among others. Finally, the "Closing" phase evaluates that all project activities were completed. Any project impact is analyzed and any lessons learned that can be incorporated for future projects are identified.

WHY AN ORGANIZATION PURSUES CONTINUOUS IMPROVEMENT?

Today, the organizations pursue a continuous improvement process to improve the quality and customer services with the elimination of waste and time response by achieving the simplification of the existing process and products design, thus accomplishing an improvement in their operations [5]. This process allows for a broader horizon always seeking for excellence and innovation that will lead entrepreneurs to increase their competitiveness, decrease costs and direct efforts to meet the needs and expectations of customers.

The Deming Wheel, the Deming Cycle or PDSA Cycle is a systematic series of steps used to achieve valuable learning and knowledge for the continuous process or product improvement [6]. The cycle consists in applying and repeating the four steps: Plan, Do, Study and Act (PDSA) for continuous improvement, at the point in which the perfection is never achieved but is ever pursued.

Based on the review of the concepts of project management and continuous improvement processes, it can be determined that the constant review of processes in the organization resulting in increased effectiveness, better planning develops and competitiveness remains organization within the market [3].

ANALYSIS APPROACH

A project which considers the qualification of a metal detector (single equipment unit) was conducted to improve the existing guidelines used within the organization. The project initiation arises on the observation of similar projects which could not be completed successfully in the past due to project budget and timeline issues. Project planning identified the project activities and methodologies required and implemented as follows:

- Assessment of the existing Commissioning and Qualification guidelines
- Identification of the project critical activity
- Evaluation of the resources required to support project workflow based on the defined project activities and budget
- Establish meetings times and frequency for project follow up
- Reduction of documentation timelines associated with project activities

Details of each project activity conducted are included as a part of the project implementation.

Project Implementation

During the performed assessment of the organization guidelines, a series of established documentation required to conduct the metal detector project were identified. The first phase of the project began with an evaluation of the guidelines established at the organization in which the implementation of a project that added a new metal detector was carried out. During the evaluation, the first area of opportunity identified was to improve and simplify the process established to complete projects that contemplates a single equipment unit. The guidelines were general and did not differentiate in the amount of documentation required for a single equipment unit project or for a multiple equipment units project. A total of eight general documents were identified, whereas five of them could be simplified for the project case in which a single equipment unit was considered. Decreasing the amount of documentation established in the guidelines represents a decrease in the amount of resources required to conduct the project. The new opportunity to improve the existing organization guidelines was discussed with Quality Assurance (QA) department which are in charge of the control system of the organization. Based on the short time to complete the project, an agreement to perform a guideline revision and include the final recommendations of the metal detector project completion was established with QA, the project strategy was included the Change control document.

The Change control is the first document that opens and closes the project activities. This

document details current project activities' status and proposes any change to be performed within the organization. In addition, the change request includes an evaluation assessment providing the rationale and justification of the documentation that is not being generated for the project.

Once the guidelines assessment were completed, an identification of the project specific activities was conducted. A total of fifteen activities were identified. Table 1 includes the detail of the project activities; some of them represent the same document, but in different sub-phases required: generation, execution, approval and/or closing.

Table 1
Project Activities

Activities	*Documentation*
1	Change control Generation & Pre-Approval
2	Installation and Operational Qualification Protocol-Document Generation
3	Installation and Operational Qualification Protocol-Document Approval
4	Installation and Operational Qualification Protocol-Document Execution
5	Final Summary Qualification Protocol Report-Document Generation
6	Final Summary Qualification Protocol Report-Document Approval
7	Standard Operational Procedure Revision & Training - Generation & Approval
8	Cleaning Assessment-Document Generation
9	Cleaning Assessment- Document Approval
10	Incorporation of new equipment in Preventive Maintenance System-Document Generation
11	Incorporation of new equipment in Preventive Maintenance System- Document Approval
12	Incorporation of new equipment in Spare parts System-Document Generation
13	Incorporation of new equipment in Spare parts System-Document Approval
14	Equipment First Cleaning / Microbial Testing & Result Analysis
15	Change control Closing generation & Post-Approval

In addition, resources required for each project activity identified in Table 1 were defined in Table 2. The Validation Leader role is performed by a contracted resource within the organization in which the project was conducted. This person is in charge of providing follow-up and tracking the project progress during the project. Project cost increment due to the Validation Leader resource required was not contemplated during the planning phase. This was based on the fact that the project will only contemplate one equipment unit because of the short time required for project completion.

Table 2
Project Resources

Activities	*RESOURCES REQUIRED*			
	Validation		*Organization*	
	Leader	*Consultant*	*Subject Expert*	*Technician*
1	**X**		**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**		**X**	

As part of the execution, control, and monitoring of the project's phases, weekly project meetings were established by the Validation Leader. In addition, signature parties for document revision and approval were coordinated and accepted by the organization Subject Experts resources, but cancelled at the last minute due to no participation.

The organization Subject Expert Resources are representatives of four departments: System Owner, Technical Services, Manufacturing, and Quality representatives. These resources are part of the organization, and as a part of their roles are assigned to complete additional responsibilities based on the production priority. The supports for the resources was obtained, but after the project manager contacted each one individually. The schedule of the project had a delay of one week, due to the lag on the Standard Operational Procedure approval process.

Project Costs

The could be impacted as the rate per hour of the Validation Leader resource contracted to provide support was of approximately $55 to $60 per hour, and will depend by the project time duration. The project manager determined that the cost associated with the Validation Leader resource would be was absorbed by a concurrent project based on the fast track of the project.

The Validation Consultant resource's rate is based on $40 per hour. Due to the delay observed during the approval process of the Standard Operational Procedure, the project schedule was impacted by a week, and this time represents a Change Order in the original contract amount established for the Validation Consultant resource. The project manager identifies the additional costs to be covered by the project contingency balance.

RESULTS AND DISCUSSION

As a part of the metal detector (single equipment unit) project completion, lessons learned were identified for future projects improvement. The first one was to identify the importance of maintaining robust guidelines to be followed for the implementation of projects in the organization. Existing guidelines within the Organization must be updated to simplify the documentation associated with projects which consider one single equipment unit. Another lesson learned was to follow the continuous improvements of the organization, maintaining a competitive state in the current market and reducing the costs of the project, while increasing the efficiency of the process of projects.

In addition, a lesson learned identified was the importance of the resources contracted to be part of a project team, and the support of the resources within the organization which are critical to achieve a successful project. Also, contemplate the role of the Validation Leader during the project planning, to avoid the possible impact in the project budget. This role is an essential support to the project managers who are in charge of several projects.

CONCLUSIONS

The project provides an overall discussion of the project management phases required to conduct a project; the concepts could be applied to projects which only consider one equipment unit. The control phase allows for the observation of the limitations considered at the beginning of the project (time and budget), and how these can be capitalized. However, the organizational culture was a limitation that was not considered throughout the project. During the execution phase, it was observed the delay point of the processes performed, even with improvements, and the resistance to change that the people in the organization have. These culture traits establish the need to develop staff both at individual and collective levels in the phase of the control mechanisms and the transmission of habits, and forms skills of thinking and transferring ideas, which in turn affect the application of solutions to everyday problems. Undeniably, the organizational culture must be considered as a limiting factor, and a new approach to analysis that serves as a starting point for future projects in the organization to achieve a significant improvement of the processes.

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