New Purified Water System for the QC Laboratory

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Abstract *— The project consists of providing the Quality Control Laboratory with a Purified Water supply system to cover the Lab water needs for chemical testing and Laboratory equipment. Currently the laboratory uses water from another site building. A literature review was carried out to get information on the regulatory requirements for design, installation and validation of water systems. Agencies such as the Food and Drug Administration, World Health Organization, International Committee Harmonization and International Society for Pharmaceutical Engineers were part of the information assessed. Project management framework, lean Value Stream Mapping tool and cost analysis were part of the methodology used for the project implementation. The cost analysis by the Equivalent Uniform Worth analysis method determined that the most viable alternative for the project was to buy a system that can produce one gallon per minute of Purified Water. This recommendation was accepted by the management. The equipment was purchased, installed and is at the validation stage which requires 15 days of sampling and testing. The percent completion of the project is 65%. Once fully implemented, the project will comply with the objectives and benefits established.*

Key Terms *— Cost Analysis, Lean Value Stream Mapping, Cost Analysis, Project Management Framework, Validation Requirements*

INTRODUCTION

The Quality Control Laboratory of a Pharmaceutical Industry lacks from its proper Purified Water system to supply the Laboratory daily operations. To supply the water requirements, the Laboratory personnel gets the water from a different building system that is far from the Laboratory building. This causes interruptions to the Laboratory normal operations since the same Laboratory technical personnel, such as Chemists and Biologists, are sent to the other building to get the water. A new project was raised to pursue an alternative to supply water to the Lab and avoid the cost of using qualified Lab personnel for this task. The project implementation has been managed using the project management framework from the Project Management Institute [1] including the five project phases; Justification, Planning, Execution, Control and Closing. Lean Value Stream mapping tool (VSM) and Cost Analysis were also methods use for the project development.

A literature review was performed to understand the requirements of design, installation and validation of this type of systems. Purified Water is legally defined under the United States Pharmacopeia and is regulated by the Food and Drug Administration [2] and monitored and inspected by the World Health Organization [3], International Society for Pharmaceutical Engineering [4] and other agencies in Puerto Rico, Unites States and Europe. Extended and detailed validation requirements under these agencies must be considered for the project implementation. A typical system requires 15 days of sampling and testing.

PROJECT METHODOLOGY

The methodology used for the project implementation is the project management framework methodology from the Project Management Institute (PMI). The five project phases included are Justification, Planning and Scheduling, Execution, Cost Control and Monitoring and Project Closing. The project was justified in terms of cost. A total of $290,000 were approved for the project development and

implementation. The second phase, Planning and Schedule, consisted of the project planning. This phase included a complete schedule of all the project activities. The third phase was the project execution. This phase included the request for proposals to different purification equipment suppliers. The selected suppliers were Caribe Water Technology (CWT) and Fisher Scientific. To evaluate the actual process and understand how the process runs and what are the Laboratory water requirements, the Lean Tool Value Stream Mapping (VSM) was used and Cost Analysis to evaluate the alternatives.

LITERATURE REVIEW

A literature review was performed to get information on the requirements for water purification equipment. Guidelines from the Food and Drug Administration [2], The World Health Organization [3] and the International Society for Pharmaceutical Engineering [4] were reviewed to understand the design and validation requirements. The complete validation of a new Purified Water system requires two phases of sampling and testing for the water to be released for Pharmaceutical use. A third phase is required for collecting water samples in a weekly basis in different points of use of the system. A sampling period of 7 to 15 days minimum is required to test the water for chemical and microbial specifications and must comply with the required specified parameters.

COST ANALYSIS

A cost analysis was made to evaluate the cost of the actual process. Also, the cost analysis evaluated the project alternatives in terms of costs. Performing the mapping of the activities to collect the water in containers from the Laboratory to the other building, the time required is 1.5 hours. From the cost analysis was obtained that the cost of the actual process is about $16,200 annually. This considered the use of four laboratory technicians to perform the tasks of getting water to the other building performing three travels per week at a cost of $25/hr and a task duration of 1.5 hours. The Laboratory water requirements on a weekly basis is a total of 360 liters of Purified Water.

ALTERNATIVES EVALUATION

The project proposals were received from the two different equipment suppliers. The options were the following:

- One complete equipment supplying one gallon per minute of Purified Water at a cost of $285,000.
- A total of five individual units bench type supplying 0.5 gallons per minute of Purified Water at a cost of $152,000. Five units are required to comply with the water requirement of 360 liters of water in a weekly basis.

An Equivalent Unit Worth Analysis, EUWA was made for the two options to select the best of the two alternatives. The equations included the equipment cost plus the Maintenance Costs (MC). The maintenance costs are the costs incurred to operate the equipment in an annual basis. The equations are as follows:

EUWA= **(**$285,000**) (**A/P, 10%, 5**)** + MC (1)

EUWA= **(**285,000**) (**0.2638**)** + $800 = $75,983

EUWA= **(**$152,000**) (**A/P, 10%, 5**)** + MC (2)

EUWA= **(**152,000**) (**0.2638**)** + $40,000 = $80,097

Equation (1) is used for the calculation of the first equipment option and Equation (2) for the second option. From the cost evaluation base on the Equivalent Unit Worth Analysis, the best of the alternatives is the alternative resulted from Equation (1). The recommendation was to buy the one gallon per minute equipment which resulted in the lower cost, $75,983 < $80,097. The resulted option was discussed with the customer, the Laboratory Manager and agreed with the implementation of the selected solution.

RECOMMENDATIONS

Due to Act of Nature, Hurricane Irma and Hurricane Maria, the project suffered a significant delay. The option one was selected and recommended as the best alternative. The equipment was purchased, received and installation is about to be completed to start the validation exercise.

PROJECT COMPLETION

From the total of the five project phases, Phases 1 and 2 are fully completed. The execution phase was started and will continue with the equipment installation, and validation activities once the equipment is completely installed and operational. The project control phase, which monitors the project activities, is ongoing. Estimated project completion, as the project schedule has been moved due to the hurricanes situation, is end of November to first week of December 2017.

Table 1 shows the percent completion of all the projects phases. This is a comparison between the projected percent versus the actual achieved percent. The project has achieved a 65% completion.

Table 1
Comparison of Phases Percent Completion

Phases	Projected	Actual
Justification	10%	10%
Planning	25%	25%
Execution	40%	20%
Control	15%	10%
Closing	10%	0%
Project Completion		65%

CONCLUSION

A new Purified Water system was proposed for the QC Laboratory daily operations. With this new system, the Laboratory area will avoid the use of the highly qualified technical personnel performing a secondary task that was causing interruptions of their usual assigned tasks. With the full implementation of the project, objectives and benefits will be achieved.

REFERENCES

[1] Project Management Institute, Project Management Body of knowledge", 5th ed., 2013. Published by the Project Management Institute, Inc.

[2] US Food and Drug Administration. Guide to Inspection of High Purity Water Systems, 2009. Available: http://www.fda/ICE/Inspections/InspectionsGuides/ucmo74905.htm.

[3] WHO Good Manufacturing Practices: Water for Pharmaceutical Use. 2003, Annex 2. Available: https://www.who.int.

[4] International Society for Pharmaceutical Engineering, ISPE. ISPE Water and Steam Systems Baseline Guide. Available: https://www.ispe.org.