Equipment Validation Standardization for Project Implementation Time Reduction of Automated Manufacturing Platforms

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Abstract *— Medical Device regulated industry requires extensive validation work. Using the latest automation technology for the process equipment to eliminate the operator interaction brings the challenge of how fast the company implements complex equipment requiring validations. After designing the manufacturing equipment of next generation products defining standard manufacturing platforms enables the standardization of requirements between systems. Nevertheless, Installation Qualification brings its challenges for the project timelines due to the nature of the requirements of this process. The project goal was to minimize the project timeline of the next generation product lines using the standard manufacturing platforms by improving the installation qualification process. The DMAIC methodology was used to organize information, delimit process scope, and gather the necessary information needed to make appropriate decisions. The results of the process improvements documented in this research showed an improved process with approximately 50% time reduction.*

Key Terms *— Automation, Installation Qualification, Standard Testing Protocol, Equipment Automation.*

INTRODUCTION

Manufacturing of medical devices is an industry regulated by the Food and Drug Administration (FDA) agency. Regulation also asks for evidence of product conformance with both intended use and design requirements. This evidence is generated through the validation process, which documentation deliverables are considered the objective evidence of the conformance to requirements of device manufactured. The regulation offers the guidelines and each company sets their game rules based on the interpretation of the requirements presented on 21CFR820 subpart G (FDA, 2011).

Medical Device Company has a robust validation lifecycle with actual process validation project timelines of up to 11 months once the equipment arrive our facility. Current process is well defined and designed to tailor each piece of equipment and process. This brings a major challenge for the implementation of projects requiring considerably high engineering headcount to be able to complete the highest amount of implementation work in parallel due to the time consuming testing protocol writing. Another challenge is that due to the long implementation time most improvement opportunities that could bring major productivity, higher yields and cycle time reduction of the products are not feasible to implement since the return of investment projections and net present values of the investment are impacted by this long implementation up to the point of not pursuing these opportunities.

This research scopes next generation product lines standard manufacturing platforms equipment validation. As the name implies “standard” these manufacturing stations have standard utilities requirements as well as standard human machine interface (HMI) configuration. This is the factor that enables the possibility for the definition of a standard validation methodology to the equipment validation phase of the process validation lifecycle.

RESEARCH OBJECTIVES

The objective of this research is to standardize the equipment validation requirements of the standard manufacturing platforms to achieve a standard protocol testing applicable to all manufacturing station of the next generation products and reduce the equipment validation time frame required for project implementation.

RESEARCH CONTRIBUTIONS

Achieving the research goal of defining a standard testing protocol methodology of the equipment validation for standard manufacturing platforms contributes to the company's ability to reduce project timelines in the next generation line transfers. This positively impacts the site competitiveness since the least time to complete project requirements the faster the product reach its production state therefore released for each geographic market. By reducing the validation timeframe of the project and decreasing the project implementation time also increases the return on investment of the capital necessary for equipment acquisition therefore making our manufacturing site more likely to be a project receiving site.

Additional contribution provided by this research is the quality improvement through validation testing protocols standardization. Less validation time does not mean that the quality will be adversely affected, but the process and resources will be improved through standardization. The standardization of protocols for the standard manufacturing platforms of the next generation products will contribute to an easier equipment transfer while maintaining the same level of compliance required by established company procedures. Also the standardization of the testing will assure testing completeness on equipment requirements which eliminate the risk of dependency on resources having specialized knowledge.

As a result, the project could reduce the cost of project resources needed to complete line transfers. A significant amount impact of cost per production line transfer could be avoided by achieving the goals established in this research.

RESEARCH BACKGROUND

The manufacturing of medical devices is regulated by the Food and Drug Administration (FDA). This FDA agency provides the quality system regulation for which all medical devices manufacturers needs to comply to consider the product safe for use. The quality system regulation applicable for the medical device industry is the 820 subpart G which is specific to the Production and Process Controls. The 21CFR820.75 paragraph "a" of the federal regulation states that if "the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated" (FDA, 2011) [1].

The term validation refers to the objective evidence generated through a testing performed under a controlled protocol that the product (or manufacturing process, equipment or software) conforms to the specifications. The FDA regulation is general and broad for which each corporation establishes a series of self-imposed procedures with the goal to comply with all listed requirements. Figure 1 provides an overview of the validation lifecycle established in this corporation.

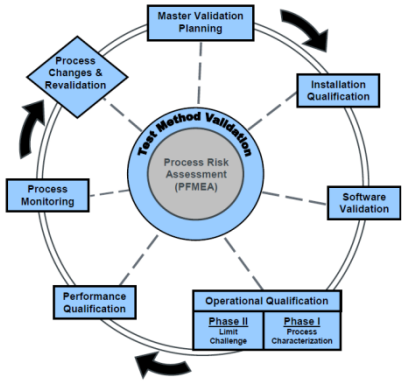

Figure 1
Overall Validation Lifecycle

This research focuses in the Equipment Installation Qualification concurrent to the Equipment Process Software Validation which from now on will be referred to in general as the

equipment validation [2]. Understanding the actual deliverables required to complete this equipment validation is essential to identify the areas that enable an improvement in reducing the time required to complete the validation work. Similarly knowing the standard manufacturing platform requirements can provide us with a standard testing elements applicable to all the equipment in the line that are verified in the equipment validation [3].

The validation cycle starts at the same time the equipment development process is initiated. The equipment development process is where equipment is being defined for the specific need. Depending on the equipment type and complexity, equipment is classified in different category each having unique deliverables specific for the equipment needs. Equipment requirements are defined and options from different suppliers are evaluated. Selection will depend on best functional design for application requirements established. Once selection process is completed and equipment procured, a factory acceptance testing (FAT) takes place to review equipment functionality and verify conformance to the established requirements. Also after equipment is shipped, a site acceptance test (SAT) is performed as a verification of equipment was not damaged during shipment. This part of the validation cycle is formerly known as the equipment development process.

After equipment development process is completed and system is installed on site, the equipment starts the commissioning phase consisting in the documentation deliverables for equipment identification, calibration, preventive maintenance, manuals and spares. From a requirement standpoint all the equipment have to be serialized with a unique identification number to be traceable within the quality system. Once equipment is serialized, the equipment calibration procedures, maintenance procedures, lock out/tag out and relocation procedures are defined, documented, approved and assigned to the equipment on the asset management system. System including software (either PC based, PLC base or a combination of both) requires a software commissioning phase for which the software is assigned a unique identification number for traceability in the quality system and include definition of the software backup and restore processes as well as software control mechanisms. Once this process is completed the machine component structure is defined with parent and child equipment. This structure represents the equipment configuration that is going to be validated.

Once equipment structure is defined, equipment documentation is approved and commissioning phase is completed the equipment validation protocol is drafted and approved. Execution raw data is verified and formal approval of the equipment validation is performed trough a validation report. For the case on which equipment validation is combined with the software validation deliverables, an initial revision of the protocol is approved to serve as the formal software assessment classification and software requirements and design. Then the complete equipment and software qualification protocol with the tests to be executed is approved. Similar to the equipment validation, the equipment and software validation execution raw data is verified and formal approval of the equipment validation is performed trough a validation report.

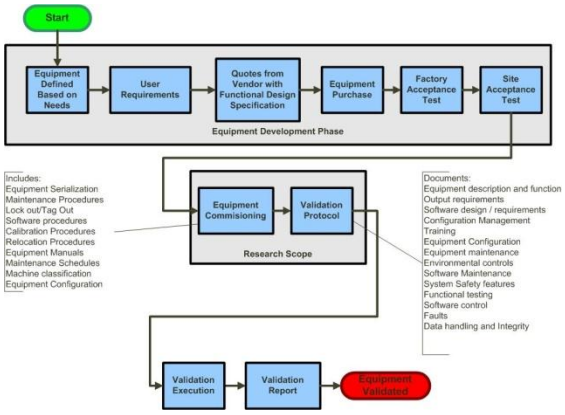

Figure 2
Equipment Validation Deliverables

This equipment validation process as explained, and illustrated in Figure 2, requires several tasks that are related in nature. Approval

process for each of the requirements explained requires multiple resources working on every deliverable. As an example, the least cross-functional or interdepartmental resources required are three (3) resources for the equipment maintenance procedures which requires the author performing the change, the area engineer or technician and the quality assurance engineer review. The document requiring most cross functional team to be completed are the validation documents which require at least four (4) different roles including area engineer, quality assurance engineer, subject matter expert and manager level signatures. Additional roles that could expand this review task are the software quality assurance engineer, cross site reviewer or multiple subject matter experts depending on the complexity of the equipment.

This overview of validation requirements reveals that validation process required various resources in multiple departments on the site. The process is complex in nature, the process is lengthy and their interdependency of information and phases requirements from one deliverable to the next makes project delays not only possible, but guaranteed [4].

By reaching the goal of standardization in validation protocol testing of the standard manufacturing platforms defined for the next generation products, with the goal of eliminating the Lean waste known as over processing, enables a strong and significant positive business productivity impact [3].

RESEARCH METHODOLOGY

The methodology which followed to organize information, delimit process scope, and gather the necessary information needed to make appropriate decisions is called DMAIC [5] [2].

DMAIC is the official process improvement tool adopted in the company to drive Six Sigma and Lean Business Process initiatives. This methodology as shown in Figure 3 consist of clearly identified process phases each with an identified set of tools to reach the goal of each phase.

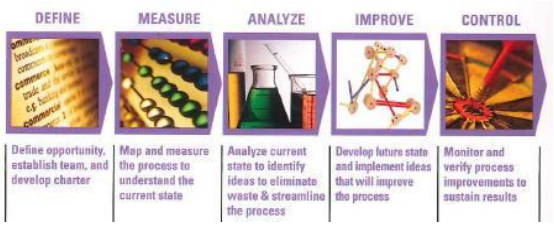

Figure 3
DMAIC Methodology

The define phase uses the Project Charter tool to document the project information. Project charter documents the Project Overview, Project Detail and the Project timeline. Project Overview defines the project tittle, sponsors, team leader and members. The Project Detail includes the project start and end dates, project type, scope, description benefits and goals. Last the Project identifies the project phases activities, resource requirements and tie project schedule.

This Project has the goal of minimizing the project implementation time reduction achieved through standard protocol testing for the standard manufacturing platforms of the next generation production lines. This will be achieved through a standard testing protocol applicable to all systems based on generalized requirements. Minimum Tailoring of this standard testing protocol will be required specifically for process sequence testing test cases and equipment faults test cases documentation. Since the documentation of the testing protocol as well as testing requirements trace matrix documentation responsibility resides on the engineering department the DMAIC methodology is being employed solely to improve the equipment commissioning phase.

The measure phase starts with the gathering of the data that measures the actual process. Current process state is mapped to understand each activity performed, the interactions and dependency of these interactions and measure current time it takes to each process step to be completed. Knowledgeable resources of the actual process being measured are the key to identify real

opportunities on the process as well to map the process as accurately as it being performed in daily operations.

Process Mapping was the measure phase tool used to define the actual (or current) state of the equipment commissioning process. The process map includes the different individual tasks related to complete the process, the flow of events related to each activity and the resources needed for each activity.

Analyze phase, as the name implies, analyzes the current state to identify ideas to eliminate the process waste (lean 7 wastes) and streamline the process. Creativity and thinking out of the box are the major enables to get the most out of this phase. The more ideas are bring to the table the more possibilities of improvement exist.

After taking a glance and understanding all the aspects of the process the analyze phase started with the challenge of the current status of the process using the 5 Why's tool. This tool was used to investigate the rationale for each step in the process map current state. Then the waste existing in the process activities as well as the established value added time versus the non value added time for each activity was analyzed in this phase.

Improve phase is where the future state of the process is defined after the elimination of the wastes identified in the Analyze phase and by implementing new ideas to improve the process. The improvements performed in the process are documented in the future state process map. Improve activities are prioritized based on quick wins, short term or long term implementation times.

The purpose of this phase is to monitor and verify process improvements to sustain results. Visual controls for the business processes are defined to monitor verify and sustain the improvements implemented. The company uses the Core Metrics and Performance Management tools to control measure the business processes compliance to the established goals. These metrics are monitored weekly in the case of Core Metrics and monthly in the case of Performance Management.

RESEARCH RESULTS

In order to be competitive in the Medical Device market, new product development and the cadence of product concept to market is the never ending race each company faces on their daily operations. Each day advances in science and technology marks the path of both product and manufacturing equipment for process control opportunities that are the enablers of improving the quality of the products manufactured. While technology keep increasing the pace on availability of new technologies, requirements in the regulated industry manufacturing keeps increasing as well to assure product meets requirements established and maintain patient safety. Each company establishes their internal procedures based on the interpretation of the actual regulation. Company X assures patient quality with the most advanced quality system covering every aspect of the risk management based validation process taking into account all aspects including Design, Process and Output failure modes and effects feeding the validation lifecycle as shown in Figure 1. This makes the process includes massive amount of documentation that are interrelated in nature bringing enough complexity to the process up to the point that product cadence from concept to market has been raised from 2-3 years to 6-8 years.

New manufacturing lines for the next generation products have been standardized in Standard Manufacturing Platforms as a strategy to reduce the product development phase of the project on the research and development business side. This standardization opens an opportunity for the manufacturing site to also decrease the amount of time from line transfer to complete all the validation work required to submit the product to regulatory approval and be able to sell the product to market.

Equipment validation standardization for the Standard Manufacturing Platforms is the opportunity out manufacturing site has to contribute to the implementation time reduction of future projects. As illustrated in Figure 2, the equipment

commissioning phase is included in the scope of this research since it consumes a considerable amount of time in the equipment validation process.

To understand the validation deliverables a system representing the elements of a standard manufacturing platform was defined to illustrate the process steps necessary to perform the validation process. The equipment consists of a workstation defined as the parent asset, equipment making a specific function, and the software controlling the system integration. Figure 4 illustrates the equipment configuration.

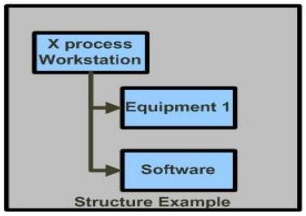

Figure 4
Equipment Configuration

From the projects documentation of projects already implemented and current projects being executed in the manufacturing facility a project timeline for similar equipment structure and complexity the actual project schedules were verified. There were different timelines between the different projects but the equipment validation phase was similar between projects. Based on the assessed project timelines current state equipment validation timeline for the defined equipment configuration is presented in Figure 5.

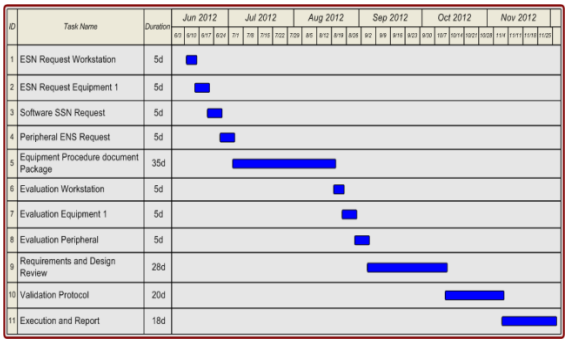

Figure 5
Current State Equipment Validation Timeline

The tasks presented in the equipment validation timeline can be summarized in the following activities formerly known as the Equipment Commissioning Phase, and Equipment Validation Phase.

Equipment Commissioning Tasks which are: Equipment Serial Number (ESN) Request, Equipment Procedure Documentation and Equipment Evaluation are individually required for each piece of equipment and requires approval from a specified cross-functional members in the organization. The equipment validation tasks can be summarized as the documentation and review of the equipment requirements, the testing protocol documentation and finally the execution of the protocol and approval of the report documenting the execution results.

Mapping of the equipment serial number request was performed initially to understand the actual process as shown in Figure 6. The process was executed and documented for the equipment configuration defined.

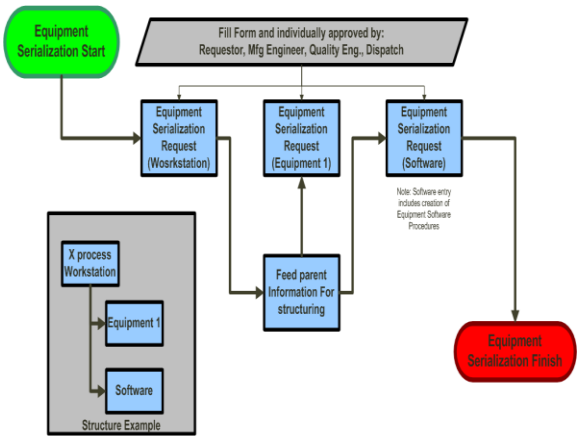

Figure 6
Actual ESN Request Process Map

Individual equipment serialization request for each of the system elements required to fill a document which needs to be approved by the cross-functional team with a total of four (4) signatures minimum. This represents a significant review and approval amount of time in which the requestor is waiting on the document to be completed in order to have the equipment traceability number assigned

to move on with the validation deliverables. Value added activity of this process is minimum so stream line of this process is a must have to minimize project implementation.

The strategy followed in this equipment serialization phase was to somehow finish with a similar level of approval at the same time the documentation of the details required were not changed. Taking the aforementioned details into account the future state map of the process was defined and presented in Figure 7.

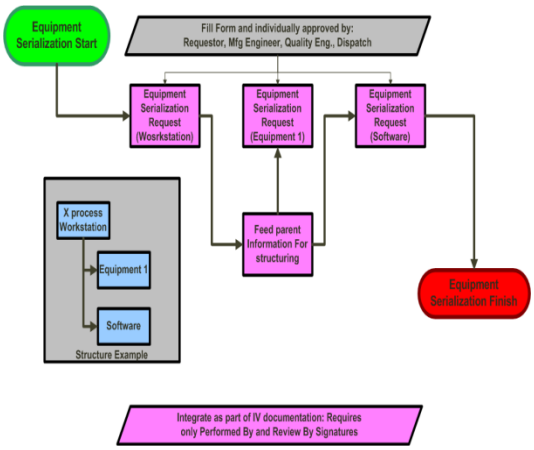

Figure 7
Future ESN Request Process Map

As presented in Figure 7 the individual elements of the process will no longer be carried out as in the current state. The equipment serialization will be documented as part of the equipment's installation verification were for execution of actual task execution requires "performed by" and "verify by" signatures and the other signatures will be leveraged from the validation report approval.

Here we introduce a new element in the equipment validation process that was not previously mentioned in this document. The installation verification is an equipment documentation deliverable introduced to the process during the investigation timeframe seeking which also seeks to minimize the time required to complete the validation of equipment. Installation verification documents the equipment configuration, documentation, utilities verification, maintenance, safety and software control elements that were originally verified in the installation qualification under approved protocol now can be performed without the need to be executed under approved protocol, but other processes as the equipment commissioning phase remained unchanged. This research capitalized on this procedure change and will eliminate redundant elements of the equipment commissioning process and integrates them in this installation verification portion as we just discussed in the future state of the ESN request phase.

The equipment evaluation phase current state was also mapped to understand individual tasks needed for the defined system. Equipment evaluation document consists of a process of answering equipment related questions to document equipment aspects such as Lock out / tag out (LOTO), calibration, maintenance, utilities and equipment documentation. The Equipment procedures are deliverables that are born from the equipment evaluation process, they document specific instructions on how to perform the tasks (calibration, maintenance, LOTO among others) and needs to be completed before equipment evaluation document is approved. Figure 8 document the result of the actual process map for the equipment evaluation process.

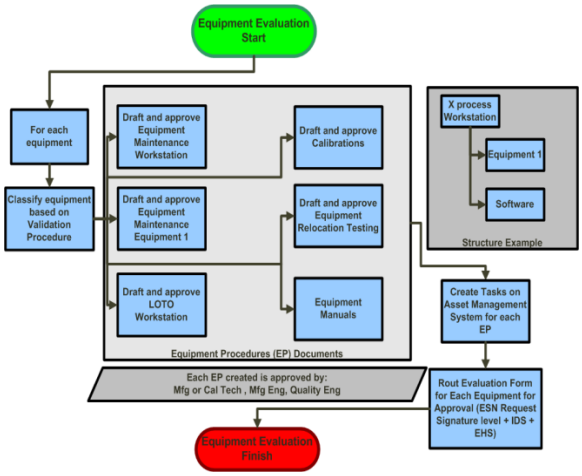

Figure 8
Actual Equipment Evaluation Process Map

The equipment similar to the ESN request process is performed to each individual piece of equipment in the system. This evaluation process explodes into additional documents that the engineer or technician performing the evaluation needs to draft and approve before completing the evaluation phase itself. For the defined system in this research a total of thirteen (13) equipment procedure documents plus the two (2) evaluation documents (because software element does not require evaluation phase) represents the total deliverables from this phase. Each equipment procedure document once drafted requires minimum three (3) signature roles to be individually approved. Even if the same resources are working all the documents, the execution of the review and approval running in serial fashion adds time to the project timeline.

Various opportunities were identified in this equipment evaluation phase to improve the process and reduce time required to complete this documentation requirement. First, instead of approve individual equipment instruction document, generalized equipment instruction document can be defined containing sections for each individual set of instruction to for which a specific task can be assigned in the asset management system. This simplifies the equipment documentation as it reference just one document number and avoid proliferation and complexity of documentation. The evaluation document itself can be integrated to the installation verification documentation avoiding the six (6) required review signatures to approve the evaluation document and similar to the ESN request, the signatures can be leveraged from the validation report approval.

Another opportunity in this evaluation phase resides in the utilities required in the system which is documented in the equipment evaluation document. Utilities verification results can be documented in the equipment evaluation were the requirements are documented. This eliminates the need of additional tables including redundant documentation of the requirements as the expected results. This also eliminates unnecessary rework for transcribing errors induced when preparing the data collection tables.

Considering the opportunities discussed, the future state map was defined and presented in Figure 9.

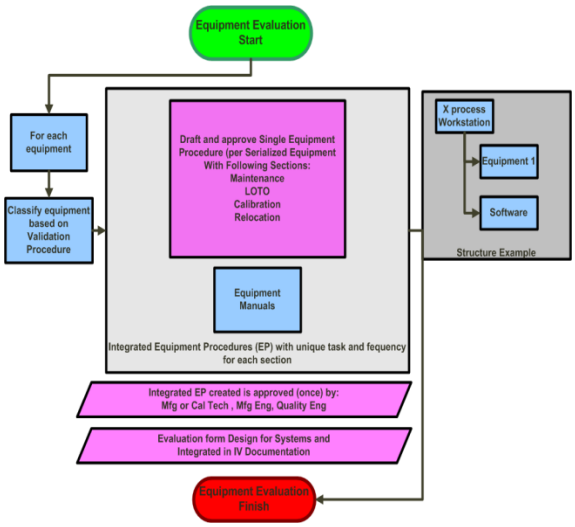

Figure 9
Future Equipment Evaluation Process Map

As presented in figure 9 the individual elements of the documentation of equipment procedures will no longer be individually drafted and routed and are integrated into a single document. The equipment evaluation will be documented as part of the equipment's installation verification were for execution of actual task execution requires "performed by" and "verify by" signatures and the other signatures will be leveraged from the validation report approval.

Standard manufacturing platform requirements and generalized testing applicable to all stations was defined and documented along with their respective test cases including the instruction of were the testing is carried out (installation verification portion or approved protocol installation qualification portion). This testing protocol also includes the integration of the equipment commissioning phase in the installation verification as well as the elimination of redundant verifications within the validation documentation. After elimination of wastes and applying improvement proposed to the validation process the

future state validation timeline is presented using the same scale as the actual validation timeline in figure 10. Figure 5 and Figure 10 are being showed side by side to provide a clear perspective of the improvements from the actual process to the future process.

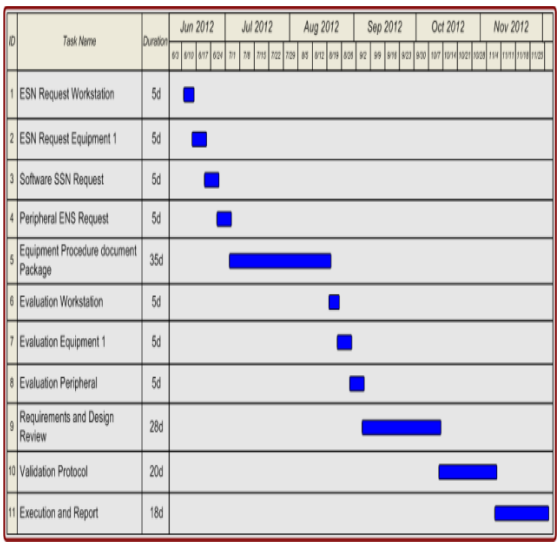

Figure 5
Current State Equipment Validation Timeline

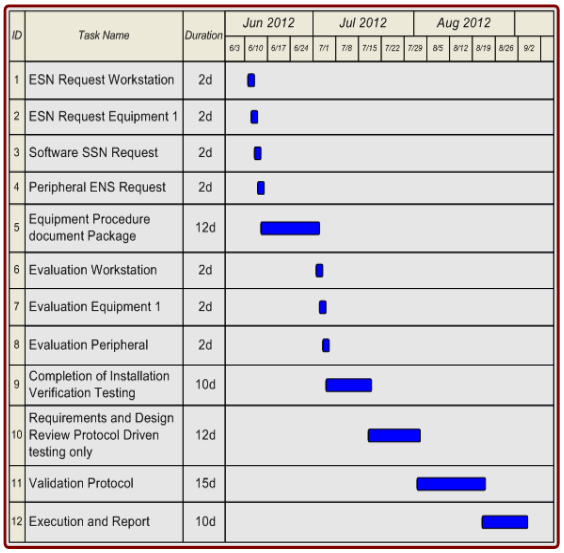

Figure 10
Future State Equipment Validation Timeline

Figure 11 shows a bar chart comparing activity durations for the current state and for the future state. Figure 12 shows a bar chart of the overall process comparison side by side.

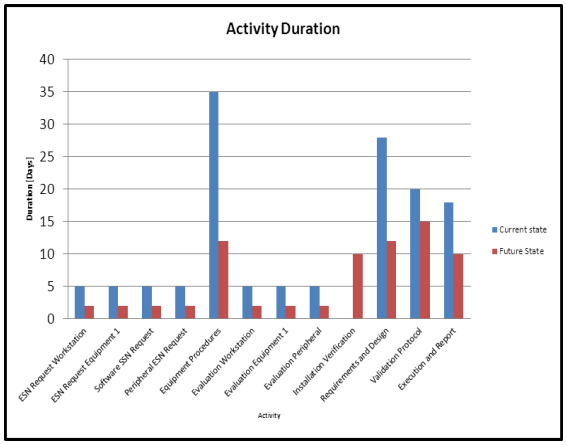

Figure 11
Activity Duration Bar Chart

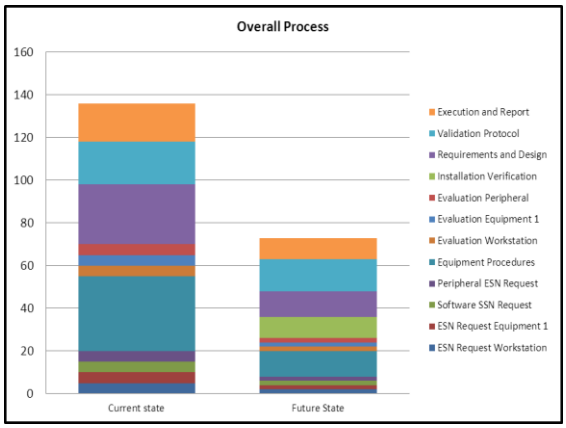

Figure 12
Overall Process Bar Chart

CONCLUSIONS

The integration of the equipment commissioning phase in the installation qualification proposed through this research and presented in the future state process maps significantly improves the equipment validation timeline. Surpassing all expectations, a reduction of about fifty percent (50%) in the project timeline can be achieved once implementation of the chances proposed is completed.

Once implementation of the process changes are implemented projects in the magnitude of line transfers will show increased rate of returns of the capital invested in new equipment. Instead of waiting the time depreciating the useful life of the equipment purchased without reaching the

production state, in the future state the company can position our site in a more competitive position to receive line transfers minimizing the absorption and depreciation costs impact in the financial aspects of the manufacturing site.

Not only the project time reduction brings significant impact, but the standardization of validation testing protocols and requirements also provides quality advantages. The changes proposed in this research represent a way to comply with the same requirements with elimination of redundant and non-value added work but maintaining all deliverables in essence keeping the same level of compliance in the process. The standardization of the testing assures testing completeness on equipment requirements and eliminates the risk of dependency on resources having specialized knowledge.

This research presents changes that falls in the long term implementation category of the manufacturing site since validation procedures applies to all sites within manufacturing company division. The design of the future state was presented to company management which is currently evaluating the necessary changes required in the documentation to implement this process improvement.

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