Integrating DMADV Methodology to Develop a Dashboard Activities Tracker for a QC Laboratory

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Abstract *— This article is focused on integrating structured strategic quality management techniques to improve operational results. DMADV (Define, Measure, Analyze, Design and Verify) is the selected methodology for the project development. Designing a tracking tool to increase visibility of testing processing at a QC Laboratory undergoing a growing & transfer process phase is the goal. A Dashboard display was selected as the future tracking tool format for the QC Lab activities. The benefits of the dashboard implementation showed the activities and workload from the QC Lab Operations, improve resources utilization in the terms of personnel, equipment and expand communication between functional areas. In addition, a Value Stream Map (VSM) analysis was performed and two Opportunity for Improvement (OFI) were identified, which will be considered for application on an upcoming relocation.*

Key Terms *— Dashboard, DMADV, QC-Lab., VSM*

PROBLEM STATEMENT

The "learning enterprise" where continuous learning leads to continuous improvement of the organization, is part of the Strategic Quality Management [1]. It may sound ideal but committing to this as a goal, at the start of an organization, results in a streamlined organization working to deliver quality products and services from the beginning.

Transitioning from startup operation to growing stage is a remarkable process that requires detailed actions. In addition, if the operation belongs to an organization considered a regulated industry, these processes must be documented to demonstrated compliance with the required directives and guidelines.

This project is focused on how integrating structured strategic quality management techniques improve operational results. The goal is to develop a tracking tool and increase visibility of material processing at a QC Laboratory undergoing a growing and transfer process phase. Therefore, DMADV method (Define, Measure, Analyze, Design and Verify) [2] is the main selected approach since currently, this tool does not exist and needs to be develop [3] [4].

LITERATURE REVIEW

The pharmaceutical industry was originated in the early 1900s, from the use of chemical synthesis to obtain medicines for therapeutic purposes. The discovery of new drugs was based on studying natural products to identify the component that treated the ailment, which will be known as the "active ingredient". Then, a synthetic version, called new chemical entity (NCE) was developed [5]. Commonly, these processes occurred at a laboratory that maintained safe practices. However, events in recorded history has demonstrated instances were unsafe drugs affected the health and lives of many people [6]. Therefore, legislations were set in place to promote the origin of regulatory entities with authority to develop rules to ensure that processes from drug manufacturing organizations are in compliance with guidelines that safeguard the wellbeing of patients and public in general. In the United States of America (USA), the regulatory agency that oversees these processes is the Food and Drug Administration (FDA). In summary, the regulated areas for pharmaceuticals are: a) required animal studies for toxicology testing and that these complies with Good Laboratory Practices (GLP); b) required clinicals trials are carried out in accordance with Good Clinical Practices (GCP) to determine

safety and efficacy; and c) Good Manufacturing Practices (GMP's) conditions exists, each and every time, that drugs are being manufacture.

But before there is a manufacturing process in place, and an operating laboratory to analyze the product, there *was* a need identified, that required fulfillment and expansion. The development process to produce medications that treat disease can be provided either by a 'for profit' or non-profit organizations. Both are considered *businesses*, which requires professional, industrial, and commercial transactions [7]. Business are referred as 'organizations' which are defined as "a social group deliberately created and maintained for the purpose of achieving specific objectives" or in simpler terms, a group of people working together to deliver a benefit [8]. Within this context a manufacturing laboratory can be considered a sub-organization within an organization. And to grow the organization, the volume of work must increase, so throughout the organization's subunits, strategies need to be set in motion to understand, adapt and adopt the tasks required that may entails changes to current practices.

Kaplan and Norton [9] proposed the Balance Scorecard concept, which is a strategic measured approach that is based on evaluating business perspectives such as financial, internal process, customers, learning and grow. The authors emphasized that rather than being a performance management tool, a Balance Scorecard convert into action the organization's designed strategies. After measuring specific functional areas results, information on adherence to key intended policies can be obtained and acted upon. Hence the importance of implementing Balance Scorecard strategies during the initial phase.

A project management team, working on an airport terminal expansion, decided to apply the Balanced Scorecard principles to the infrastructure development [10]. The project started with developing key objectives and involving contractors and suppliers. Thoroughness on developing a common purpose, data monitoring and collection structure plus a diligent compliance agreement were the foundation of the implementation process. Key performance indicators in the areas of planned verifications, assets inspection and protection, compliance, training, work progression among others, were stated. In addition to the agreement between the major consultants and contractors, a multi-tier approach that incorporated a campaign for integrated communication, implementation of benchmarked' best practices, promoting support for a quality culture and a solid stakeholder's commitment were adopted. As a result, the massive expansion project achieved a successful outcome [10].

Pauwels, Ambler, Clark, LaPointe, Reibstein, Skiera, Wierenga, and Wiesel [11], defined dashboards as "small collection of interconnected key performance metrics and drivers that reflects short- and long-term interest to be viewed throughout the organization". Four 'driving forces' are cited behind the need for dashboard: to improve the organization of data that is relevant to decision making, to decrease biases on information and decision processing, increase accountability for growth and keeping down costs and cross departmental integration with respect to reporting and resources allocation practices. They are viewed as the evolution of business intelligence system. Integration is an important requirement that need to be reflected within a dashboard in the following aspects: a) data- from different sources and levels in variant time periods; b) processes- that relates inputs to performance; and c) viewpoints- different departments, that can even be in different locations, can view and share the same organization's measure input through the same lenses. In addition, consistent enforcement, performance monitoring, strategic planning and stakeholder communication are described as common purposes for dashboards. Moreover, the authors outline dashboard potential benefits such as establishing the organization's culture, recognize, diagnose, and remediate performance, provide organizational learning, assess profitability, and improve decision making [11].

A dashboard strategy was implemented during the relocation of a laboratory located in a university

center. To achieve success, identification and monitoring of parameters relevant to the center's mission such as user's classification, instrument, and area usage among others, were paramount. The findings showed that the dashboard was readily implemented and useful for managers and contributors. In addition, the dashboard was flexible enough to tolerates changes when specific views require it [12].

An educational hospital clinical laboratory that faced the challenge of limited funding and resources, increasing costs and pressures to decrease spending while keeping required quality standards, was looking for innovative approaches applicable to utilization management. They realize that not only laboratory performance and bottleneck activity identification was important but also the identification of indicators that measure the efficiency and effectiveness of daily operations. The authors found that dashboard design and implementation were helpful to identify behaviors, patterns and establishing protocols [13].

An international consulting firm conducted a survey within 15 biopharma industries to benchmark QC labs practices. These companies were registered with the FDA. Initial findings demonstrated that, regardless of laboratory type (for active pharmaceutical ingredient, microbiology, biotechnology, or packaging), similar operational issues were found. These were: that the lab and analyst utilization depended on different factors such as test's accumulation ('backlog'), type and quantities of samples undergoing testing, training flexibility, amount of analyst available for testing and the effectiveness of the lab's layout. With respect to support system, it was found that not all labs have a Laboratory Information Management System (LIMS) and those that lacks one, have an alternate control system or alternatively, an 'in house' database. As a result of the benchmarking process, the following characteristics were recognized for a world class lab: visible "key performance indicators' that were understood, relevant to the operation, easy to measure and achievable. Also, identified as important features are having lab support personnel, laboratory function and documentation adjacent where its services are needed, along with managerial presence. In addition, reduced testing, visual lab inclusion, planning, scheduling system, and employee's continuous improvement programs aiming to balanced compliance, cost, customer service and effectiveness were distinctives feature of world class laboratories [14].

Lean concepts were made public trough the research performed by James Womack and Daniel Jones. Their work described the production system applied by Toyota Motor Company in Japan, that gave them an advantage over USA automotive manufacturers. Nowadays, lean concepts are being applied to many organizations outside a manufacturing setting [15]. The central theme behind the Lean Manufacturing principles is the identification and elimination of waste activities from the value stream operational flow.

A pharmaceutical company appointed a team of designers, lean experts, and lab personnel to develop a structure based on lean principle's implementation to improve future QC lab subsidiaries across the globe. They establish key focal areas: internal work, communication, customer interaction and operational performance. The process was performed incrementally, first by developing a draft layout and design guidelines based on lean principles, that were reviewed in a two days' workshop with the stakeholders. An important statement disseminated was that the 'real intent of lean is to maximize value by minimizing *wasteful* practices. A chief finding was the realization of "short term volatility" that was translated as "unpredictability of the mix of samples type and overall workload". This had a direct impact on productivity and lead time [16].

A common thread that ties these initiatives is the presence of the following elements: a) quality planning; b) quality control; and c) quality improvement, which for some quality professionals are known as the 'Juran trilogy'. Within the planning category, designing for quality and

innovation is essential and consist of simple steps that leads to understand customer's need [2].

Commonly integrated with Lean initiatives are Six Sigma's tactics. Six Sigma is a methodology first develop by Motorola Company. The philosophy behind Six Sigma entails: a) assign well-defined projects to teams; b) training in statistical thinking at all levels; c) DMAIC approach to problem solving (define, measure, analyze, improve and control); d) management support that see these initiatives as business strategies; and c) continual effort to decrease variation within the organization's process [17]. The Design for Six Sigma model commonly known as DMADV (define, measure, analyze, design, and verify) includes similar steps and tools depicted by Juran's trilogy [2]. This method is recommended when products or process does not exists and needs to be develop or when an actual product or process does exists but need to be optimized since it still does not fulfill the customer or organization's needs or requirements [3, 4].

Is important to put in perspective that there are many implications of having the responsibility of evaluating the product that reach a community. If the evaluation is delayed, the product release is affected and it translates to increasing costs, potentially altering manufacturing schedules, and in extreme cases, resulting in product scarcity. But when undetected nonconforming product is released to the market, the repercussions can be devastating for the manufacturer in terms of product recall, financial loss, reputation damages and judicial regulatory actions. Nonetheless, evaluating the product quality, although paramount, is not the only purpose of a QC Lab. Entrusted with multiples responsibilities from evaluating incoming material, environmental monitoring, potential contamination events, among many others, Lab's activities are crucial for the company's operation and a point of interest during regulatory inspections. Compliance with governing requirements and good practice's implementation are essential for the wellbeing of the organization and the public. Streamlining daily activities workflow by implementing Lean and Six Sigma concepts, applying best training practices, adherence to data integrity will increase precision and productivity on the QC lab [18].

METHODOLOGY

A combination of Design for Six Sigma, Juran's Quality by Design methodologies and Lean Value Stream Mapping technique will be implemented to evaluate important factors to design a dashboard for the specific needs and thus, improve current practices. DMADV is an abbreviation that stands for Define, Measure, Analyze, Design, and Verify, as seen on Figure 1, and describes the stages required to achieve the design project [2] [3][4].

Figure 1
DMADV Process Diagram

Define Phase Description

Define stage in the DMADV process is where projects and targets are demarcated. Opportunities will be recognized, and a project plan will be established after assigning resources and agreeing on the project plan. The Define stage was subdivided in subphases as shown in Figure 2 [19]:

- **Define the Project:** Develop a tracking tool that provides visibility of activities in a QC Laboratory operation. Problem Statement: Due to an increase in material processing and transference process to a manufacturing site, a QC Laboratory operation need to evaluate its material processing capability and develop a tool to display information. Goal Statement: Produce a planning tool that makes easier to provide information and improve communication across functional areas of the organization.

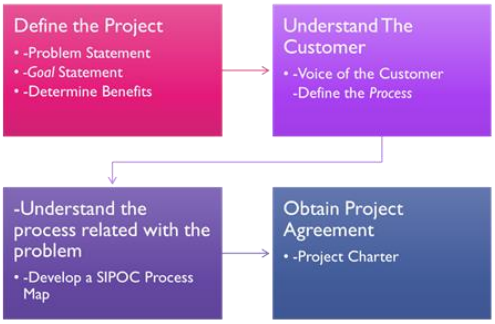

Figure 2
Define Phase Flowchart

- **Understand the Customer:** Voice of the Customer (VOC): To understand the customer needs, a direct contact method was used by means of phone calls and interviews with the QC Lab personnel, that were identified as the main customer of this project. Areas of the organization that were identified as mainly impacted by the situation were Manufacturing, QC Laboratory and Quality Operations. There were no risks identified with regards of Compliance or Health and Safety, associated with the planning tool project development.
- **Understand the Process Related with the Problem:** A SIPOC Process Map, on Figure 3, technique was employed to understand the process related with the situation. Starting with the Process segment, which was identified as the "Testing Process" a questions session was developed to gather answers for the process map.

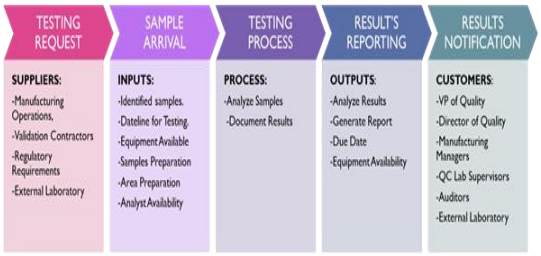

Figure 3
SIPOC Process Map

- **Obtain Project Agreement:** The define phase process findings were summarized in a Project Charter, which is a one-page document that facilitates the stakeholders the project reviewing process and assigned required support.

Measure Phase Description

The goal of the Measurement phase is to establish a baseline for the process performance by developing measurement systems that are understandable and relevant. A flow process of the Measure stage is represented on Figure 4.

Figure 4
Measure Phase Flowchart

For the Measures Development Process, a Critical to Quality (CTQ) Trees, on Figure 5, was develop. The CTQ Trees data represent the information obtained from the VOC process. The Project Data Collection Process includes:

- **CTQ**: The first level established in the CTQ Tree was the 'Need' of the customer: "Developing a tracking tool that provides visibility of the testing materials at the QC Lab".
- **General Requirements:** On the second level states, the design tool need to be easy to understand, to be kept updated and provide for easy reporting.
- **Specifics CTQ:** On the third level, these were: no cost, quickly to manage, has accessible information, daily updates and easy to correct or fix.
- **Specifications regarding the CTQ requirements:** the tool must provide current state of stability testing, the analyst and equipment workload, samples arrival date, in process, testing and verification status.

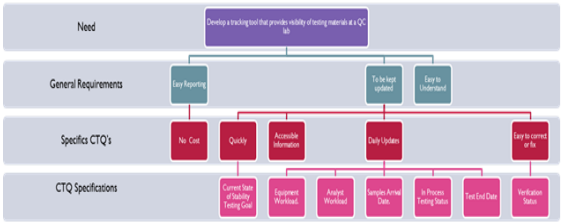

Figure 5
Critical to Quality (CTQ) Tree

Value Stream Map

To understand the behavior of the process, an evaluation of the current performance with respect to the customer was made using Value Stream Map (VSM) technique.

The operation selected was 'Testing Processing', which is the core process for the QC Lab. Currently, QC Lab operation's configuration involves four analysts and a QC Lab leader in one shift of eight hours. On the existing building location, the equipment and laboratory areas are shared with a research and development laboratory operation. Is important to clarify that the VSM described in this report is the outcome of a 'high-level analysis' and it is based on estimated times provided by a QC Lab assistant. A time study analysis for the detailed testing's processing steps was not part of the scope of this project. The VSM current state is displayed on Figure 6. The operational activities required for the testing processing represented in the VSM are:

- **Sample's Transportation**: The manufacturing site is approximately 15 miles away from the QC Lab and the average time to deliver the samples is 30 minutes. The carrier arrives at the QC Lab but needs to wait to deliver the samples for approximately 10 minutes. Value-Added-Time {VAT} = 0 minutes; Non-Value-Added-Time {NVAT}=40 minutes. Processing Time {PT} = 40 minutes.
- **Receive Samples:** Lab Assistant receive the samples and places them on the evaluation area were the condition and identification documents are verified. If found acceptable, the samples are then moved to an environmental controlled storage area, where they wait until its testing process starts. For this project, a period of 60 minutes was agreed. VAT = 15 minutes; NVAT = 76 minutes; PT = 91 minutes.
- **Preparation of Testing Area**: Analyst needs to prepare a day ahead of starting the testing process. This include gathering the reagents, utensils, fixing testing area and setting up the equipment. In addition, filled records with information and data detailing the operation's progress. The estimated VAT = 420 minutes; NVAT = 60 minutes; PT= 480 minutes.
- **Perform Testing:** Highly specialized analytical equipment performs the actual testing and generates a report with the outcome. There are different areas that provides samples and two separate functional units that utilize QC Lab facilities. Thus, the testing workload cannot be precise and conflicts with equipment's utilization requests occurs. The VAT = 480 minutes; Non-Value-Added-Time NVAT = 0 minutes. Processing Time PT = 480 minutes.
- **Analyze and Verify Results:** The report must be analyzed to determine if results are as expected and records are filled, detailing the testing development. VAT = 345 minutes; NVAT = 30 minutes. PT = 375 minutes.
- **Audit and Communicate Results:** Records from Analysis and Verification stage are sent to an Auditor for a reassessment process according to applicable standards procedures and regulations. Documents pending to be audit are stored. VAT = 255 minutes; NVAT = 60 minutes. PT = 315 minutes.

Total process time for the "disso-assay" test was 1,781 minutes (baseline) as per VSM current state. The identified 'wastes' or NVAT activities were in the form of transportation, storage and waiting and the total time was 266 minutes. Is important to note that the QC Lab operates within a regulated industry context. Therefore, there are documentation and reporting requirements that must comply with the applicable regulations or standards. For that reason, documentation related with preparation, analysis, verification, auditing, and reporting were considered as VAT.

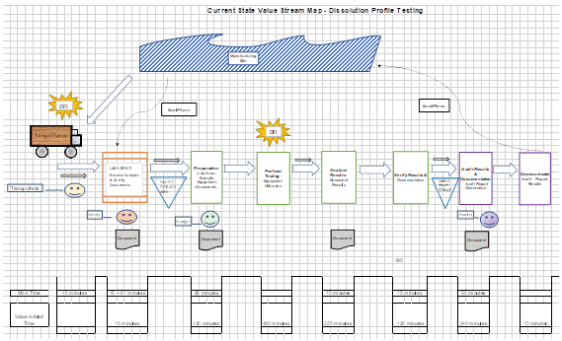

Figure 6
VSM-Current State

RESULTS ANALYSIS AND DISCUSSION

Analysis Phase Description

Figure 7 shows the Analyze Phase Flowchart, which is the next stage in the DMADV methodology. The intention of this phase is to determine how the problem or process currently works. This understanding comes from analyzing the information or data obtained and determining its relationship with the intended goal or outcome [19].

Figure 7
Analyze Phase Flowchart

Currently, QC Lab Leader log important activities of the QC Laboratory daily operations in an Excel table. After revising this table, two key segments were identified: QC Lab Utilization, and QC Lab Analyst allocation. Then, equipment status and financials categories were considered as important features for the QC Lab operation. The resulting QC Lab indicators were: QC Lab Utilization, QC Lab Analyst Allocation, QC Lab Equipment Utilization and QC Lab Financials. The objectives, description of the key measures and how to measure indicators for QC Lab Financials are described in Table 1 [10]. Similar tables were also designed for QC Lab Utilization, QC Lab Analyst Allocation and QC Lab Equipment Utilization but no included on this article.

Table 1
QC *Lab Financials* Indicators

Indicators	Objectives	Key Measures Description	How to Measure
QC Lab Financials	To know consumption rate and what types of material are used.	Materials Type	QC Lab Financials
		Quantity of Material	# Testing per Month
		Quantity of Testing per week, month, year.	Materials Demand
		Type of Testing per week, month, year.	Type of Material Demanded
		Cost of Testing?	$Cost of Materials
		Cost of Materials?	$ Cost of Testing

Design Phase Description

Design Phase is next, following the DMADV methodology, as shown in Figure 8. It entailed developing the design according with QC Lab user's expectations and then adjusting, if necessary, before distributing the final product [3]. An adapted pilot study was made to test the design before the implementation [19].

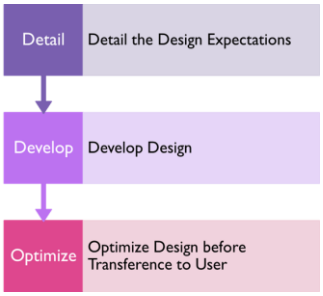

Figure 8
Design Phase Flowchart

One of the design challenges was developing meaningful measures and metric. A measurement is "simply a numerical assignment to an observation" [4]. From the measurement description, metrics were generated. The metrics for this project design

provides information of the QC Lab's activities rather than the process performance. The set of measurement or data was categorized as either quantitative, if the measure was a numerical quantity or amount, or qualitative if they can be categorized [21]. Then graphical methods were selected based on the type of data. Then, designing a tracking tool for QC Lab representative was next. The actual dashboard's displays for QC Lab Utilization is shown in Figure 9. Most of the table headings for QC Lab Utilization and QC Lab Analyst allocation are like the ones found in the Excel file used by QC Lab Leader to log activities. This makes easier to use the new dashboard tracker tool. However, several additions were made to address QC Lab Leader needs, such as 'Area Requesting Testing' field. A compilation of different activities, related with QC Lab operations were arranged, in a dropdown menu format for "Task Assigned to Analyst" field, such that the number of tasks per analyst can be graphically portrayed.

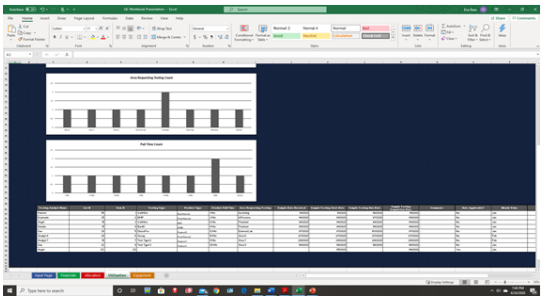

Figure 9

Actual Dashboard Display-QC Lab Utilization

Some indicators required new data fields for the QC Lab User, and these were: Material Type, Quantity, Order Date and Cost for "Financials" and Equipment 'status, equipment assigned for testing and dates of use for "Equipment".

Verify Phase Description

The last stage in the DMADV methodology is Verify Phase, as seen in Figure 10. The goals of this stage are to confirm the design performance and improvements in the process, service, or products, fulfill customer original needs [3].

Figure 10

Verify Phase Flowchart

A pilot testing period was carried out to trial the design, receive practical feedback from the QC Lab users and look for potential optimization opportunities before final implementation. As a result, to simplify the QC Lab user experience, macro buttons were created. These "macro buttons" use coding restatements of Microsoft Visual Basic Application (VBA) programming language. This process was made in collaboration with an Excel VBA coder expert. The outcome is that after entering the specific data in the fields, the information and graphs are automatically updated in the corresponding theme tab: 'Financials', 'Allocation', 'Utilization' and 'Equipment', by just clicking the "Submit Data". In addition, a color code theme was used to identify the specific segment indicators and corresponding tab within the Excel workbook. The Actual Dashboard Display-Input Page is portrayed on Figure 11.

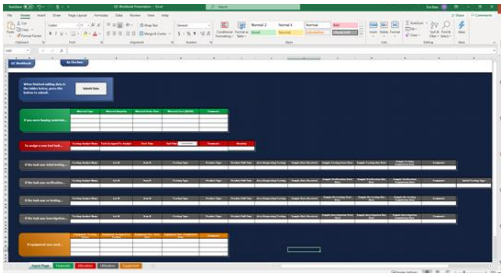

Figure 11

Actual Dashboard Display-Input Page

Discussion

From the application of Value Stream Map (VSM) technique, two Opportunity for Improvement (OFI) were identified. The first is on the *Sample's Transportation*, since an external carrier for sample's delivery could be eliminated once the QC Lab operation's is relocated. This will represent savings in transportation related cost and remove the utilization of one human resource to deliver the samples. The modified process map is compared with VSM current state process, in Figure 6, would render a future total processing time to decrease by 40 minutes. In terms of 'wastes' or NVAT activities would change from 266 minutes to 226 minutes, which will be reflected in the reduction of transportation, storage, and waiting time. It is projected that the QC Lab will be moved within the manufacturing site in the upcoming year. A time study analysis for the testing operation process was not part of the scope of this project.

The second Opportunity for Improvement (OFI) identified was related with testing equipment utilization. Adding simultaneous multiple user's capability to each equipment, can increase the testing quantity being processed and decrease the waiting time, due to availability of equipment, between the functional areas.

Having a dashboard that shows the activities and workload from the QC Lab Operations, allows better resources utilization in terms of personnel and equipment. Also, sending a weekly QC Labs Operations report improve communication between functional areas and provides buffer time to react to unplanned testing events.

CONCLUSIONS

The contributions of this project are relevant and valuable. The designed dashboard tracking tool contains vital elements to account for testing processing types, testing length, testing categorization, requests from functional units to the QC Lab, analyst's tasks assignment, equipment allocation and usage and financials in terms of consumable usage, categorization and ordering costs. The metrics designed reflect specific requirements from the QC Lab operation that will support the planning activities on the actual setting and the upcoming relocation.

Being in the transfer process to a new working space offers the opportunity to accommodate the QC Lab process in a format that the movement is more effective and productive. The location of individual labs and service or equipment that are shared among labs within the overall facility can significantly impact workflow, material transportation and traffic flow. 'Layouts should be designed to centrally locate shared services and support functions…and locate labs adjacent to production areas, simplifying sample management and facilitating flow and communication' [16]. Moreover, as the Value Stream Mapping exercise showed, providing a systematic visualization of the testing processing activities is helpful to identify wastes in the process and finding ways to improve it.

To achieve a successful dashboard adoption, some important factors need to be considered: a) alignment between demand and supply of dashboard data; b) dashboard implementation that requires top management support, user involvement, training, communication among others, c) attitude and dashboard expectation [11]. Hence, as future work recommendations, and following Kaplan and Norton's Balanced Scorecard aspects, is the inclusion of 'Learning and Grow', and 'Customers" perspectives into the dashboard tracking tool [9]. In addition, setting targets for measures indicators would set the framework for continuous improvement. Furthermore, based on the experiences from different authors [12, 13] having a software or information system that extracts the required data from a database, facilitates the dashboard implementation and usage.

Sălăgean, Bâlc and Gârbacea [20] identify training, planning, evaluation, and diversification, as important during the stages for implementation. Therefore, a solid strategy and the integration of all functional areas and employees are essential to achieve the goal. Implementing quality operational

excellence best practices and compliance with regulatory affairs, must be the objective.

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