



### Abstract

- Designing a tracking tool, to increase visibility of the activities at a QC Laboratory, is the focus of this project.
- DMADV (Define, Measure, Analyze, Design and Verify) is chosen as the methodology to integrate structured strategic quality management techniques to improve operational results.
- A Dashboard display was selected as the tracking tool format for the QC Lab activities. 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.

### Introduction

- Transitioning from startup operation to growing stage is a remarkable process that requires detailed actions.
- The QC Laboratory operation under evaluation is experiencing an increase in material processing and its relocation to the Manufacturing site is planned for the near future.
- Upper Management needs to have visibility of QC Laboratory's activities of product undergoing testing and the laboratory testing capacity.

### Background

- A laboratory, within a pharmaceutical manufacturing context, 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 [1].
- Kaplan and Norton [2] emphasized that a Balance Scorecard convert into action the organization's designed strategies in the areas of financial, internal process, customers, learning and grow. 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.
- Pauwels, Ambler, Clark, LaPointe, Reibstein, Skiera, Wierenga, and Wiesel [3], cite four driving forces behind the need for a dashboard: 1- to improve the gathering of data that is relevant to decision making, 2- to decrease biases on information and decision processing, 3- increase accountability for growth and 4- keeping down costs and cross departmental integration with respect to reporting and resources allocation practices. Dashboard are viewed as the evolution of business intelligence system.
- An international consulting firm conducted a survey within 15 biopharma industries to benchmark QC labs practices. The following characteristics were recognized for a world class lab: a) visible "key performance indicators" that were understood, relevant to the operation, easy to measure and achievable b) having lab support personnel c) laboratory function and documentation adjacent where its services are needed, along with managerial presence[4].

### Problem

- This project aims to:
  - develop a tracking tool easy to use and implement, that provides an outlook of the testing processing at a QC Laboratory and,
  - to prove that structured strategic quality management techniques, such as DMADV, are effective to achieve a streamline transition process.

### 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 which describes the stages required to achieve the design project as seen on Figure 1, [5] [6][7].

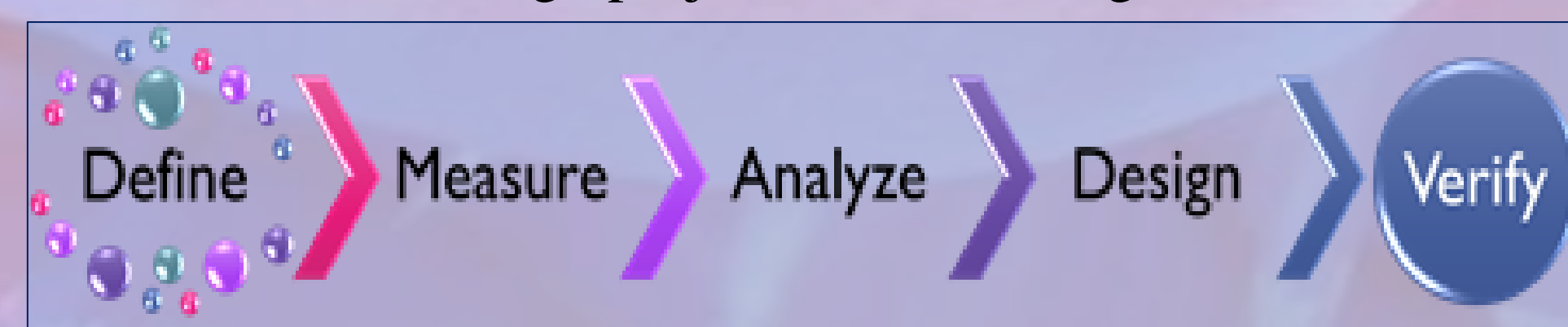


Figure 1. DMADV Process Diagram

- Define-** Projects and targets are demarcated. Opportunities are recognized, and a project charter is established after assigning resources and agreeing on the project plan.

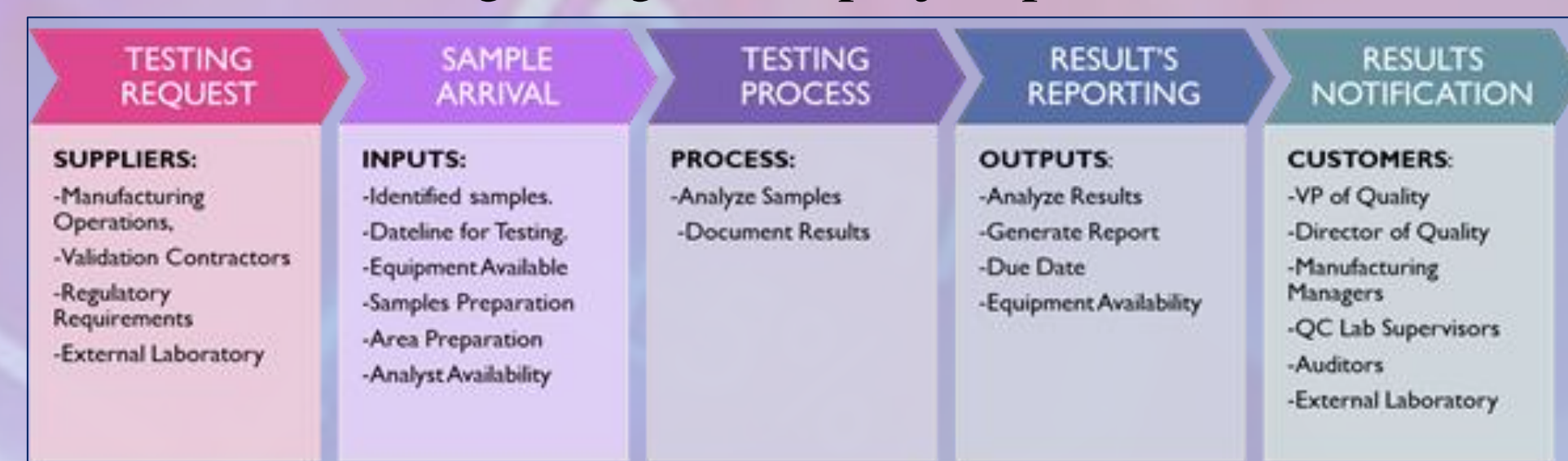


Figure 2. SIPOC Process Map

- Measure-** Customers and their needs are identified and translated to Critical to Qualities (CTQ's) attributes. A measurement systems is developed to establish a baseline for the process performance.

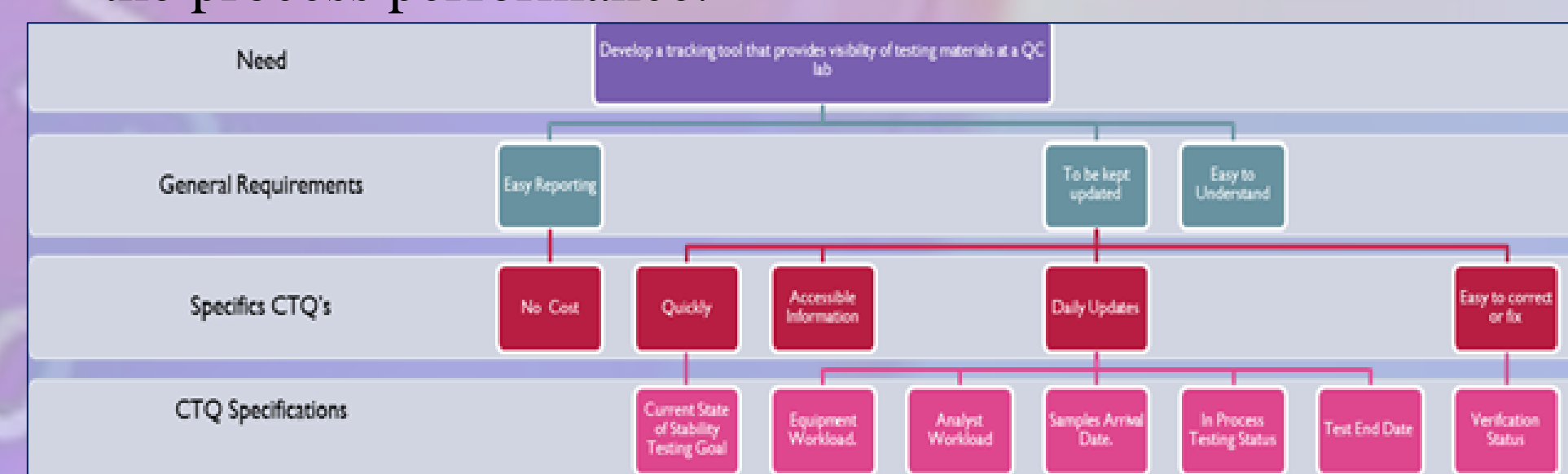
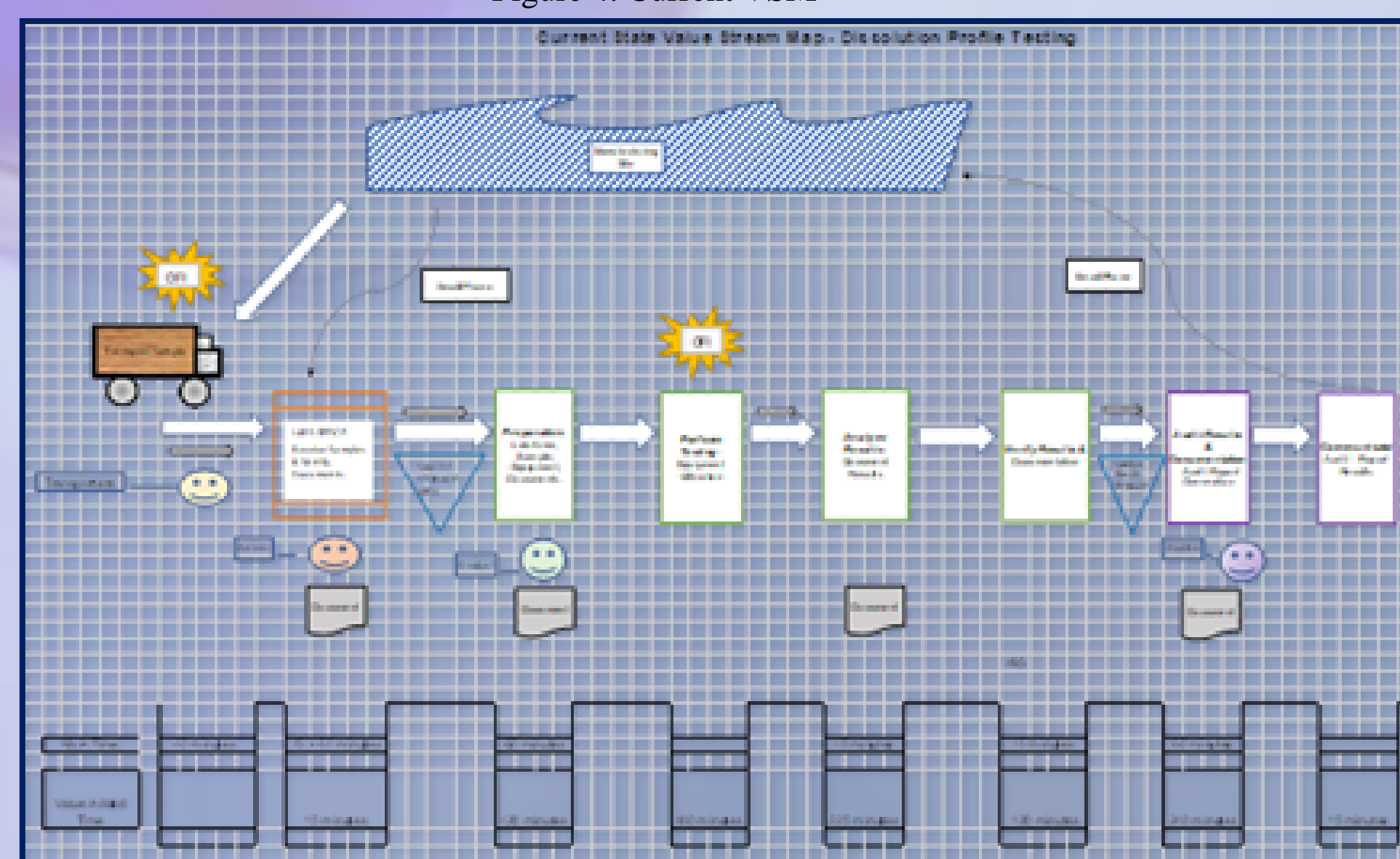


Figure 3. Critical to Quality (CTQ) Tree

- 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:

Figure 4. Current VSM



### Results and Discussion

- Analyze-** Determine how the process currently works. Analyze the information or data obtained and determine its relationship with the intended goal or outcome.
  - 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 [8].

| 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        |

Table 1. QC Lab Financials Indicators

- Design -** Detailed operational dashboard are developed, and integration is initialized.
  - A Dashboard display was selected as the future tracking tool format for the QC Lab activities.
  - 'A dashboard can provide a visible connection between daily activities of the specific department and organizational goals' (Pauwels, Ambler, et al.,[3]).
  - Integrating these definitions with the tabulated data, and using Microsoft Excel spreadsheets, dashboards for QC Lab Utilization, Analyst Allocation, Equipment and Financials indicator were designed. The actual dashboard's displays for QC Lab Financials indicator is shown in Figure 5.

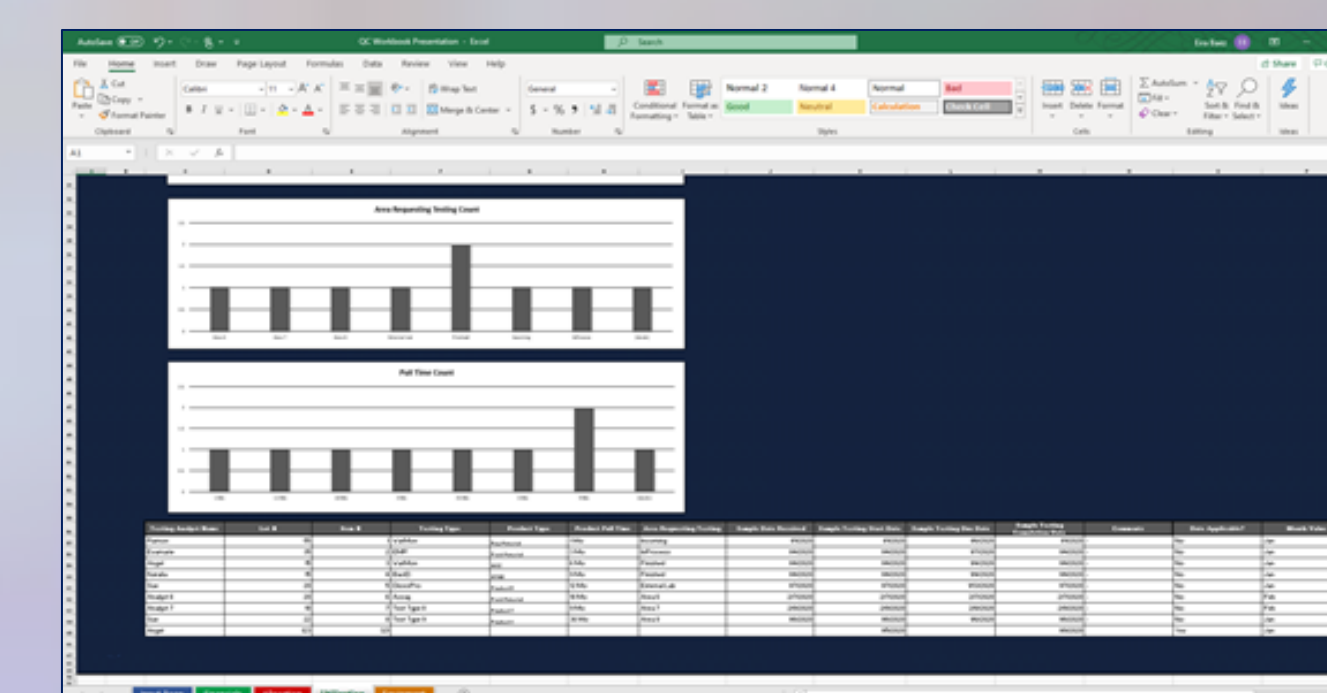


Figure 5. QC Lab Financials Dashboard

- Verify-** The goals of this stage are to confirm the design performance and, that the improvements in the process, service or products, fulfill customer original needs [6].
  - To simplify the QC Lab user experience, macro buttons were created, using coding restatements of Microsoft Visual Basic Application (VBA) programming language 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. The Actual Dashboard Display-Input Page is portrayed on Figure 6.

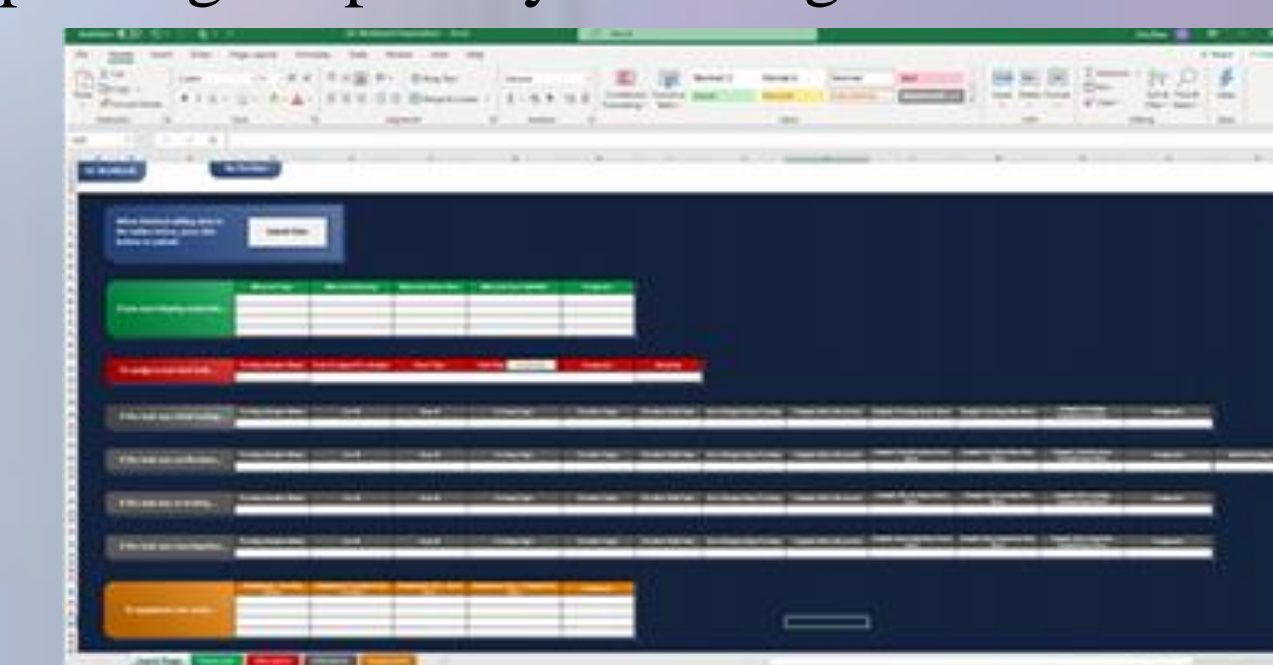


Figure 6. Actual Dashboard Display-Input Page

### Conclusions

- 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.
- 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 eliminate them, thus, streamlining the process.

### Future Work

- 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 [2]. In addition, setting targets for measures indicators, which would set the framework for continuous improvement.
- Having a software or information system that extracts the required data from a database, facilitates the dashboard implementation and usage, based on the experiences from Martin & Di Bernardo [8] and Azadmanjir, Torabi, et al.,[9].
- Being in the transfer process to a new working space offers the opportunity to accommodate the QC Lab process in a format that is more effective and productive. Important elements to consider when designing a pharmaceutical QC Laboratory are: laboratory location, space needs (in terms of quality and quantity), bench configurations, consumable inventory management and storage [10].

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