Assay Report Documentation and Storage Process Improvement Using DMADV Methodology

Author: Manuel J. Cartagena Méndez

Advisor: Rafael A. Nieves Castro PharmD.

Industrial Engineering Department

Abstract

As part of the Process Engineering team, one of our goals is to identify areas with opportunities in our current manufacturing processes. It was identified an opportunity to improve the assay hard copy documentation generated in the Analytical Laboratory area because the reports are printed in hardcopy, and the audit process requires 3 signs in every paper. The assay hardcopy documentation and audit trail process will be changed to a paperless process following the Design for Six Sigma (DFSS) systematic approach and DMADV to reduce costs of the process, transforming the documentation repository in an electronic data base for the client convenience.

Problem Statement Introduction

In an Analytical Laboratory (AL) located in a Manufacturing Building, the Analysts perform Protein Concentration assays in a daily basis, Protein Concentration assays are performed using a Variable Pathlength Fiber-Optic Spectrophotometry Technology instruments which are connected to a Computer System (CS) using a Software Application. Every assay performed, generates a report with the data sample measurements, graphics, regressions and results. The report is printed in Cleanroom paper and attached to another cleanroom paper, for every page of the assay reports requires signatures from two (2) Analyst as Perform and Verify and a third signature for Review from a Quality Assurance (QA) Associate, then the assay report is placed on a binder.

Objectives

This research has pursued the initiative to improve an existing process by identify unnecessary tasks with no value added, measure current process tasks, analyze the options for the ideal design and optimize the process into a paperless one.

Methodology

The methodology used within the Project will be DMADV which is an aspect of Design for Six Sigma (DFSS) usually used for Process Improvements where we will collect data/information by performing interviews and a Kaizen event with the Subject Matter Experts (SMEs) from the functional areas that are directly related to manufacturing process and can be impacted somehow their processes/procedures and redesign the current process more robust. The data/information gathered will be detailed in systematic approach with the DMADV methodology which is divided in the following phases five (5) phases:

- 1st Phase – Define

In the Define Phase we are going to evaluate if there is an area with opportunity, define the goal for the improvement in order to formalize the Project Plan.

- 2nd Phase – Measure

In the Measure Phase, the intention is to understand the Voice of the Customer (VOC), identify our requirements and project an established baseline.

- 3rd Phase – Analyze

In the Analyze Phase, we are going to analyze the data/information gathered from the previous phase, to select the design options that fits better for our processes taking in consideration the requirements.

- 4th Phase – Design

In the Design Phase, the goal is transforming the best fit designed selected in the Analyze Phase into a detailed one.

- 5th Phase - Validate

In the Validate Phase, the objective will be to transfer the functioning designed process into the area.

Results and Discussion

During the **1st Phase (Define)** a Project Charter (Refer to Figure 1) with brief and concise information was created to obtain the Endorsement in the Project Management Forum. The goal is to Transform the assay documentation and storage in into a paperless process.

Project Charter: Assay Report Documentation and Storage Process Improvement

Goal: Transform assay documentation into a paperless process

Project Lead: Manuel J. Cartagena Mendez

Project Mentor: Rafael A. Nieves Castro

Opportunity/Problem Statement:
In an Analytical Laboratory (AL) located in a Manufacturing Building, the Analysts perform assays in a daily basis, assays are performed using a Spectrophotometry Technology instruments which are connected to a Computer System (CS) using a Software Application. Every assay performed, generates a report with the data sample measurements, graphics and results. The report is printed in Cleanroom paper and attached to another cleanroom paper, for every page of the assay reports requires signatures from two (2) Analyst as Perform and Verify and a third signature for Review from a Quality Assurance (QA) Associate, then the assay report is placed on a binder.

Out of Scope:
Any other manufacturing process that includes the needs of print reports

Project Goals/Solutions:
- Conduct a Kaizen Event to evaluate:
  - The current Assay Report Documentation and Storage process map
  - Develop a list of recommendation to improve the current Process
- Prioritize and develop Project Plan
- Identify unnecessary tasks with no value added
- Increase Customer Satisfaction

Cross Functional Team:
- Information Systems (IS)
- Quality Assurance
- Process Engineering
- Manufacturing Management
- Manufacturing Execution Systems (MES)
- Validations
- Automation

Milestone / Phase	Owner	Proposed Date	Status
Define	Manuel Cartagena	5/4/21	
Measure	Manuel Cartagena	5/8/21	
Analyze	Manuel Cartagena	5/12/21	
Design	Manuel Cartagena	5/16/21	
Validate	Manuel Cartagena	5/20/21	

Figure 1: Project Charter

A Kaizen pre-work meeting section was conducted where the team discussed the Assay Report Documentation and Storage of the reports. During the Kaizen, the team:
Create the current process in the Value Stream Map (Refer to Figure 2)

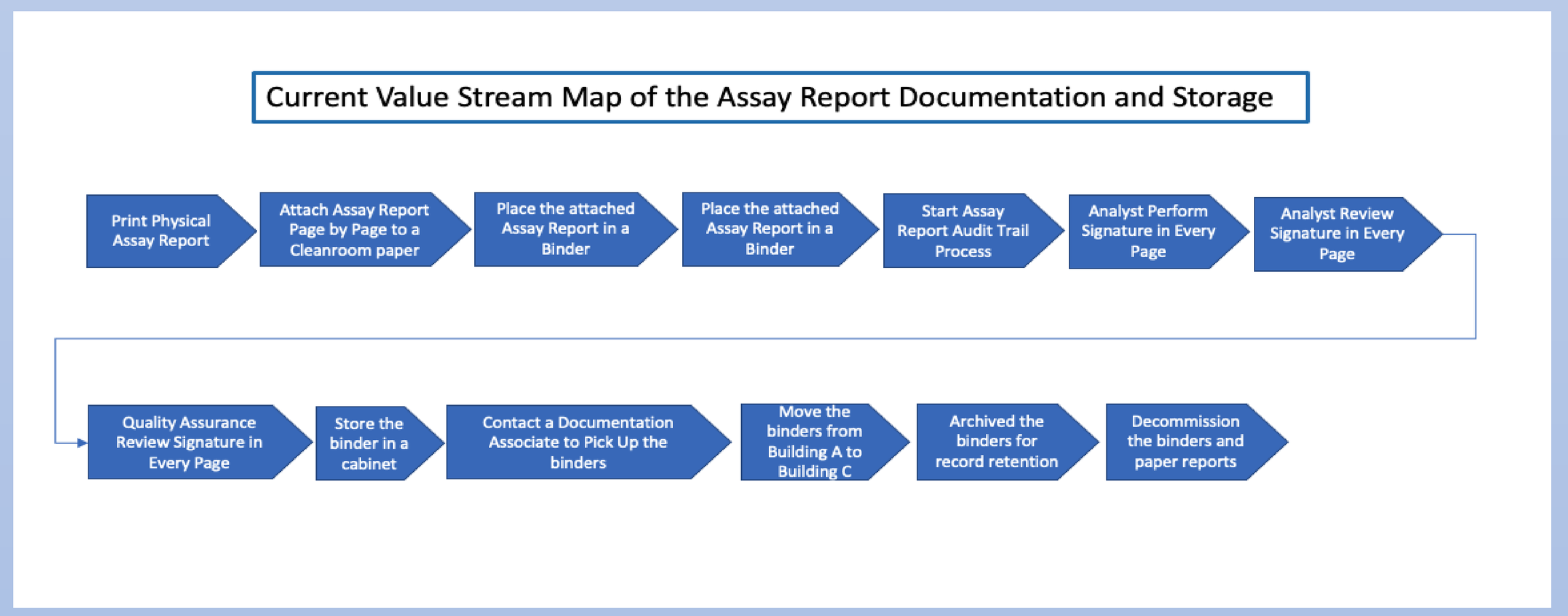

Figure 2: Current Value Stream Map (VSM)

The current Value Stream Map (VSM) demonstrates that the process had an opportunity to improve the process by eliminating the hardcopy documentation which can leads the organization to be more environmental conscious and eliminating waste from the process.

During the **2nd Phase (Measure)** the Kaizen pre-work continues to collect data and feedback from the customer to explore the Assay Reports and Audit Trail documentation. The Value Stream Map (VSM) from the 1st Phase was updated by collecting the time and resources needed per task (Refer to figure 3).

The team noticed that the opportunity is the gap that we have is to perform digital signatures regarding assay reports and audit trail, also the need of access to the folders where the raw data is storage. Also, with the elimination/reduce of the need for assay hardcopy reports, the process will be improved.

Results and Discussion

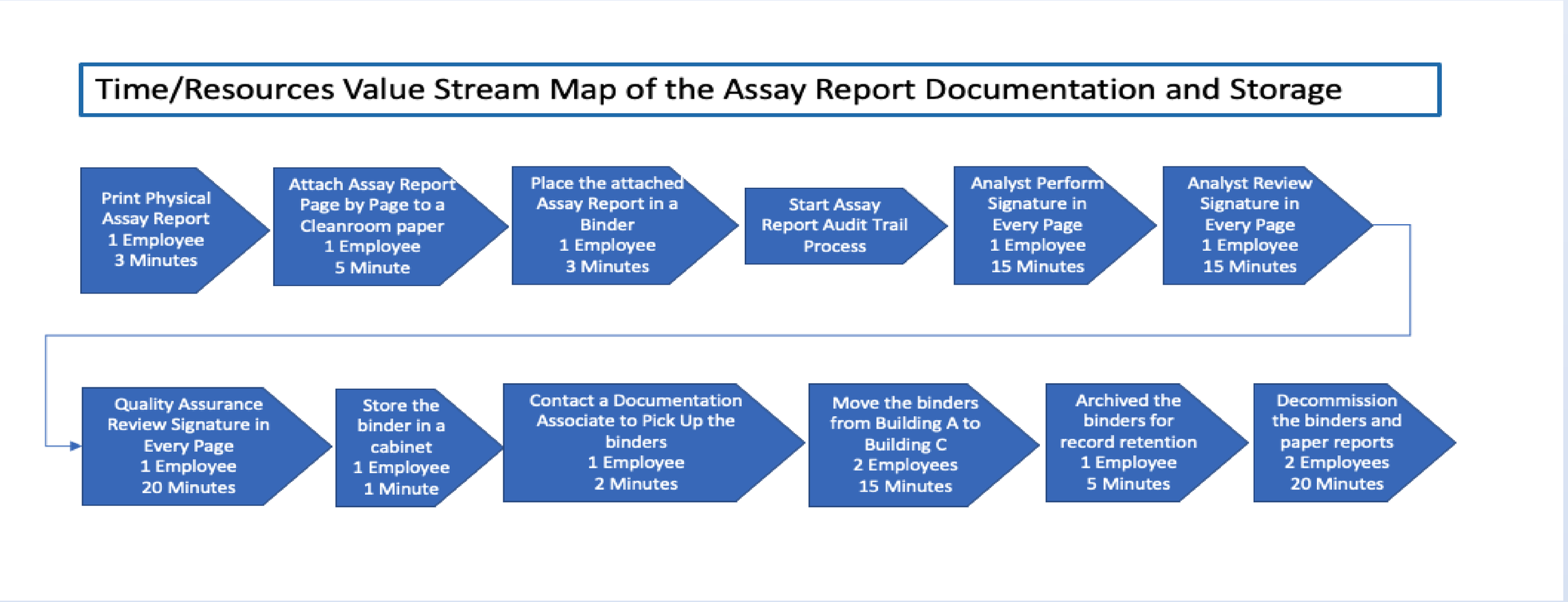

Figure 3: Time/Resources Current Value Stream Map (VSM)

The Value Stream Map (VSM) (Refer to figure 3) shows that the Assay Report Documentation Process takes approximately 119 minutes, it can be divided in two phases:

- 1st Phase Print Report and Audit Trail Review = 79 Minutes
- 2nd Phase Transportation = 40 Minutes

During the **3rd Phase (Analyze)** the team had the objective to use the information gathered during the 2nd Phase (Measure) to generate design concepts, evaluate design concepts and select the best concept in a high level that meet the functional requirements from the regulatory agencies and meet the customer requirements.

To generate design concepts using a systematic approach, the team decide to use the SCAMPER technique, refer to figure 4.

Substitute	What can I **Substitute** in the currently Assay Report Documentation and Storage Process? • The assay report hardcopies can be substituted with electronic files. • The signatures in the hardcopies could be substitute with electronic signatures. • The storage space in the documentation building could be substituted with a specified database location.
Combine	What can I **Combine** in the currently Assay Report Documentation and Storage Process? • The current Assay Report Documentation (Hardcopy) and Storage Process could be combined as a second option backup plan.
Adapt	What can I **Adapt** in the currently Assay Report Documentation and Storage Process? • The Standard Operating Procedure (SOP) used within the process could adapt instructions for the new process scenarios (Paperless) and the current process (Hardcopies). • The privilege access of the associates which needs to access the folder where the Assay Report are storage could be adapted. • The Manufacturing Execution System (MES) designs where the Analysts and the Quality Assurance associates documents data and information about the batch-assay that are working with could be adapted to fit the new process expectations
Modify	What can I **Modify** in the currently Assay Report Documentation and Storage Process? • The process to perform the signatures in the Assay Reports and Audit Trail could be modified from manual signatures to electronic signatures. • Paper inventory will be lower due to the modification of the paperless process.
Put to another use	What can I **Put to other use** in the currently Assay Report Documentation and Storage Process? • The space used in the Analytical Laboratory to storage the binders with the hardcopies could be used to storage new instruments and/or consumables used in the area. • The space used in the Documents Management building to storage the binders with the hardcopies could be put to other use.
Eliminate (or Minify)	What can I **Eliminate or Minimize** in the currently Assay Report Documentation and Storage Process? • The needs of assay report hardcopies could be eliminated by implementing electronic signatures. • The needs from the Quality Assurance (QA) associates to do the audit trail review in the Analytical Laboratory with the hardcopy reports could be eliminate by providing privileges in the specific database location where the assay reports are stored with a view access only. • The binder/paper decommission could eliminated. • The transportation of the binders could eliminate with the paperless process.
Rearrange (or Reverse)	What can I **Rearrange** in the currently Assay Report Documentation and Storage Process? There were no opportunities identified to rearrange the current process because the intend within the project is to eliminate steps.

Figure 4: SCAMPER Technique

During the **4th Phase (Design)** the team had the objective to convert the brainstorming design collected during the 3rd Phase into a detailed one with the optimization functional design which can meet the customer, processes, and business expectations.

The previous activities where the team collect data, brainstorm ideas and the Voice of the Customer (VOC) feedback, confirms that our Variable Pathlength Fiber-Optic Spectrophotometry Technology instruments had the capacity thru the Computer System (CS) Software Application to save the raw data reports generated from every Assay perform and that the data is saved in an electronic storage server.

Based on that research about that the raw data is stored and could be accessed by the employees that have access to the storage path we are going perform the design taking in consideration the Failure Mode and Effect Analysis (FMEA) (Refer to figure 5) which is a systematic tool to identify the effects of a process failure and to eliminate and/or reduce the possibility of future failures. Since we are working to improve the current process, in addition we also focus on the prevention of failures.

Results and Discussion

Process Task/Step	Potential Failure Mode	Potential Impact Effect	Severity	Potential Cause	Preventive Controls	Detection	Findings/Recommendations	Risk Level
Instrument/Computer System performance	Power loss / Data Loss	Data loss and invalid assay	1	Power loss	Innstrument/Computer are connected to battery backup Battery backup is connected to circuit with a redundant system to avoid power interruptions during operations	1	None	Low
Confirm if data is saved in the corresponding software	Data is not saved in the software	Data loss and invalid assay	2	Software Failure	Standard Operating Procedure (SOP) provide instructions to perform System Suitability before start assays Standard Operating Procedure (SOP) provide instructions to confirm data is saved in the corresponding software Standard Operating Procedure (SOP) provide instrustions to contact IS and tag equipment out of service in case of any atypical performance and/or suspicious malfuction Raw data is saved accorrding to SOP Sample will be repeat for invalid assays SOP provide instructions to confirm that each file save appears in the software window	1	None	Low
Confirm if data is back-up in the corresponding secure server	Data is not backup in the corresponding secure server	Data loss and invalid assay	2	Back-up Failure	Standard Operating Procedure (SOP) provide instructions to perform System Suitability before start assays Standard Operating Procedure (SOP) provide instructions to confirm data is saved in the corresponding software Standard Operating Procedure (SOP) provide instrustions to contact IS and tag equipment out of service in case of any atypical performance and/or suspicious malfuction Raw data is saved accorrding to SOP Sample will be repeat for invalid assays SOP provide instructions to confirm that each file save appears in the software window	1	None	Low
Confirm if data is saved and back up by Analysts and Quality Assurance	Lack of knowledge	Invalid Assay documentation	1	Process Training	Access to the system software and the secure server is a requirement of the related Standard Operating Procedure (SOP) and the access must be granted thru the Area Manager and the Information Systems associates.In order to request the privilige access, the requester must provide training certification evidence.	1	None	Low

Figure 5: Failure Mode and Effect Analysis (FMEA)

The new design (Refer to Figure 6) was run in MES using a Draft Protocol with the requirements of the test configuration before to move to last phase for validate the design. The test was successful by running an assay testing, saving the report, accessing the storage server folder and then performing the electronic signatures in the Manufacturing Execution System.

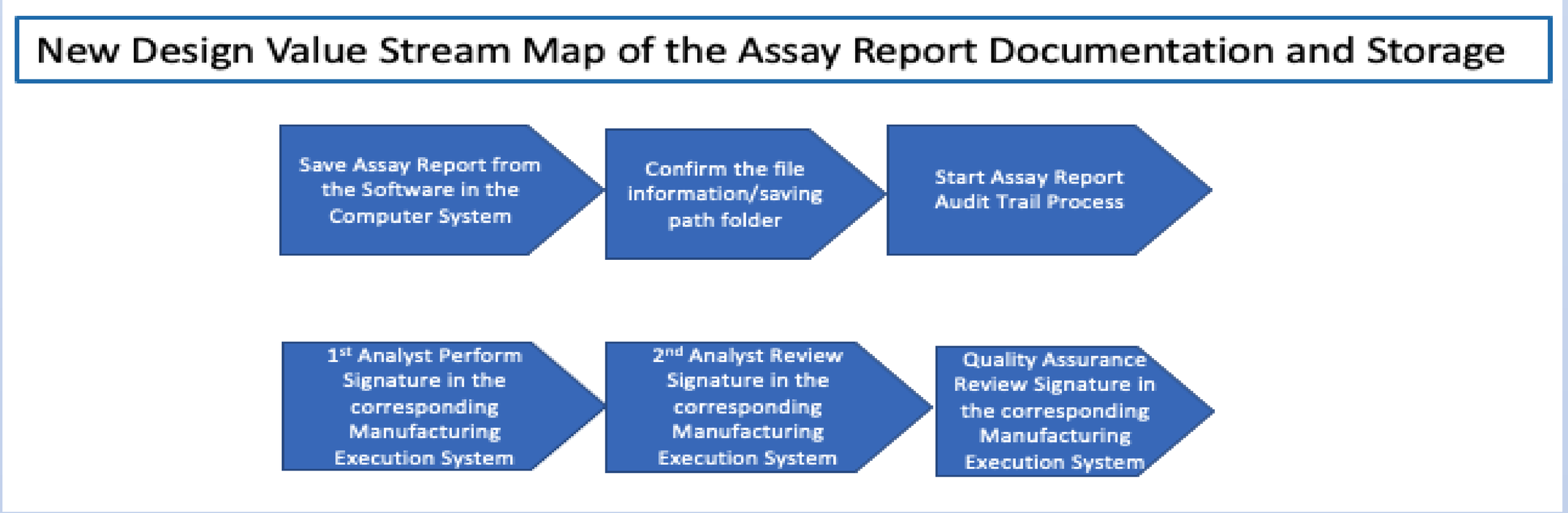

Figure 6: New Design Value Stream Map (VSM)

During the **5th Phase (Validate)** the team had the objective to transfer the completed functional design process to the Analytical Laboratory team.

An Approved Protocol was generated to run a validation exercise with the intend to cover the customer/business requirements as establish in the previous phases. The protocol will include tests to cover all the identified risks during the Failure Mode & Effect Analysis. In addition, a validation summary report will be performed as part of the requirements. Updated Standard Operating Procedures (SOPs), the Manufacturing Execution Systems (MES) will be effective within the Protocol and Validation Summary Report effectiveness confirmation.

Conclusions

The Assay Report Documentation and Storage Process was improved by using the DMADV Methodology by validating a paperless process design, the hardcopy reports were included in the Standard Operating Procedure as 2nd backup option but with our current process controls the expectation is to run paperless with a time reduction of approximately 10 minutes per assay by eliminating the needs to print the hard copies, 50 minutes to transport the binders to the documentation building. In addition, the new design provides flexibility and agility to the Quality Assurance associates to perform the audit trail process from every room in the building because of the easy access to the report in the secure server and the Manufacturing Execution System to perform the electronic signature. An approximate cost saving in paper of $8219.50 was achieved.