Validation and Implementation of a New Enterprise Resource Planning (ERP QAD) on Receiving Area

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Abstract *— In this competitive world people need to be in vanguard; therefore a better Enterprise Resource Planning (ERP) system will help them to do a better work. V group implement a new ERP system for the improvement the financial process and get a better scheduling program to comply with Code of Federal Regulations. V Group has determined that all plants operating on the QAD ERP will operate in the same manner with limited exception. The validation and implantations of QAD systems is very extensive and complex, therefore this investigation will be focus on the area of Material Receiving & Incoming Inspection. A Material Receiving & Incoming Inspection is an administrative function that involves checking of the quality, quantity, and condition of the incoming goods followed by identifying, sampling handling, inspecting and disposal of raw material received at V Group.*

Key Terms *— Enterprise Resource Planning (ERP), Implantations, Material Receiving & Incoming Inspection, Validation.*

INTRODUCTION

V- Group has chosen the ERP from QAD to be the Enterprise Resource Planning System as well as Eagle RF Express to be the RF Data Collection system and Preactor to be the Production Planning system. The three systems are comprised of functional modules allowing V Group to operate in a cGMP and FDA compliant manner. Many of the modules are required to be validated by the FDA. Because of the FDA requirements that V Group falls under, a project was initiated to validate those processes and functions falling within the FDA Guidelines.

QAD, Eagle and Preactor are applications designed to address the operational requirements of medically related companies such as V Group. A number of documents will be generated during the execution of this project. The Functional Requirements document is a key to defining company requirements and provides the basis, along with the Functional Design Document, for the development of test protocols used as the acceptance criteria.

The purpose of this project is to document the computer system validation activities to be performed for the initial deployment of V Group Puerto Rico as additional plant on the previously validated QAD Standard Edition Enterprise Resource Planning system, the Eagle RF Express Data Collection System and the Preactor Production Scheduling System at The V Group.

Also, this project is summarize an approach to the System Validation activities for the V Group, Inc. QAD Enterprise Resource planning project which is adding Puerto Rico as an additional plant on the already validated QAD Enterprise Resource Planning Software. The QAD Standard Edition Software will replace several legacy systems. Also to be installed and integrated into QAD are the following third party application(s):

- Data Collection Bar Code software from Eagle Corporation – previously validated and only security will be tested;
- Preactor Production Planning from Preactor International. This will be a new install which will require validation. V Group has made a business decision that only changes to dates as they relate to production scheduling will be made in Preactor and any other changes to a work order will be made in the previously validated QAD system and re-imported into Preactor. Only security to the Preactor system will be validated as a result of this decision;

- The area of receipt is one of the area's most important because it is the feeds the plant serving the materials for the area of manufacturing. One of the objectives of the implementation of the QAD system is to see how system helps the receiving area to be leaner, dynamic, rapid, and efficient in receipt of the raw material and supplying materials to the manufacture area.

Research Description

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Research Objectives

The objectives of the project were:

- Verify that all gaps between the previously defined and validated processes and processing at V Group Puerto Rico are defined and documented.
- Verify that the "off-the-shelf", configurable QAD Standard Edition application system performs as intended in the computing environment established by V Group.
- Verify that the "off-the-shelf" Configurable Eagle RF Express Data Collection system performs as intended in the computing environment established by V Group.
- Verify that the "off-the-shelf" Configurable Preactor Production Scheduling system performs as intended in the computing environment established by V Group.
- Verify the accuracy and completeness of the plan and data conversion effort from The Manufacturing Manager (TMM) ERP system for plastics processors to the respective QAD Standard Edition System.
- How QAD system helps the receiving area to be leaner, dynamic, rapid, and efficient in receipt of the raw material and supplying materials to the manufacture area.

Validation is required of any and all not previously validated computer system hardware and software or new installations of previously validated software used "as part of production or the quality system".

Research Contributions

V- Group has chosen the ERP from QAD to be the Enterprise Resource Planning System as well as Eagle RF Express to be the RF Data Collection system and Preactor to be the Production Planning system. The three systems are comprised of

functional modules allowing V Group to operate in a GMP and FDA compliant manner. QAD, Eagle and Preactor are applications designed to address the operational requirements of medically related companies such as V Group. A number of documents will be generated during the execution of this project. The Functional Requirements document is a key to defining company requirements and provides the basis, along with the Functional Design Document, for the development of test protocols used as the acceptance criteria.

Also at receiving area QAD most improve reduce time dedicated to the receiving process through the raw material is release. The parts were cannot be released to inventory or production until they have been verified against the inspection criteria. Immediate access to the goods pending inspection provides the planners, production team, and accounts payable with the inventory status needed to manage material, production plans, and supplier invoices efficiently. Receiving and Incoming inspection is a standard part of the process to ensure that product and services conform to specified requirements. The quality team is responsible for developing the quality plans to support inspection and dispositions for incoming inspection. To support these procedures, the inspectors need tools that will allow them to easily identify product and services that need inspection, document inspection results, and segregate nonconforming product. The tool that is going to be incorporated to the operation will permit and guarantees meeting of all specific requirements.

BACKGROUND

Computers are widely used during development and manufacturing of medical devices. Proper functioning and performance of software and computer systems play a major role in obtaining consistency, reliability and accuracy of data. Therefore, computer system validation (CSV) should be part of any good development and manufacturing practice. It is also requested by FDA regulations and guidelines through the overall requirement that "equipment must be suitable for its intended use"[1]. Specific requirements for computers can be found in section 211.68 of the US GMP regulations. The objective of validation is to produce documented evidence, which provides a high degree of assurance that all parts of the facility will consistently work correctly when brought into use. Validation requires documented evidence, if the validation process is not documented then it cannot be proved to have occurred. The FDA has developed several specific guidance documents on using computers for development and validation of software used in medical devices.[2] Most detailed is the Industry Guide: General Principal of Software Validation; it deals with development and validation of software used in medical devices.

Because of their importance, computer validation issues have been addressed by several industry organizations and private authors, like The Good Automated Manufacturing Practices Forum (GAMP) has developed guidelines for computer validation and Huber has published validation reference books for the validation of computerized analytical and networked systems[3]. All these guidelines and publications follow a couple of principles: Validation of computer systems is not a onetime event. It starts with the definition of the product or project and setting user requirement specifications and cover the vendor selection process, installation, initial operation, going use, and change control and system retirement. There are no detailed instructions on what should be tested. All guidelines refer to risk assessment for the extent of validation.

All validation activities should be described in a validation master plan which should provide a framework for thorough and consistent validation. FDA regulations and guidelines don’t mandate a validation master plan; however, inspectors want to know what the company’s approach towards validation is. The validation master plan is an ideal tool to communicate this approach both internally and to inspectors. It also ensures consistent implementation of validation practices and makes validation activities much more efficient.

Validation protocols are documents associated with each system identified as requiring validation. The protocol describes the scope, procedure to be followed, responsibilities and acceptance criteria for the validation. Validation protocols should comply with the SOPs; Documentation that verifies each validation activity must be generated and stored with the validation protocol in the appropriate archive. Validation documentation may include: test data, summary reports procedures, certifications forms produced during the validation process.

This project will be conducted in a Medical Device Company located in Vega Baja, Puerto Rico; V Group. V Group has brought together three of the most well-respected names in the industry to create an integrated services solution for the design, engineering and manufacturing of complex medical devices and components. This merging of capabilities creates a dynamic, comprehensive offering unlike any other. Today; this venture builds on the strong and rich histories of partner companies to create an even more promising future. V Group is wholly committed to quality at the highest levels. The strong quality focus allows bringing the clients' products to market in a timely and cost-effective way, and with the highest standards of quality and regulatory compliance already in place. The rigorous approach includes broad preventive and quality assurance initiatives, and the ongoing assessment and review of every aspect of our business. This empowers to not only continue to improve how deliver and what deliver — but to always be proactive in the face of changing regulations.

V group implement a new Enterprise Resource Planning (ERP) system (QAD) for the improvement the financial process and get a better scheduling program, one step to achieve and be competitive in today's world. Programs and investments necessary to achieve total quality and compliance are in place to meet and exceed the needs and expectations, every time. After careful research and consideration, the QAD Standard Edition Enterprise Resource Planning System was chosen to be the Enterprise Resource Planning System to be used at all V Group production facilities. Also chosen were the Eagle RF Express Data Collection system and the Preactor Production Scheduling system. The QAD Standard Edition ERP is an "off-the-shelf, configurable" application software package with the functionality to maintain electronic records throughout the life cycle of the production process for manufacturing, distribution and lot traceability of finished goods product at V Group. The Eagle RF Express Data Collection system is an "off-the-shelf, configurable" application software package with the functionality to collect data via a Radio Frequency handheld terminal or thru a desktop emulation session that is exactly the same as the hand held terminal. The Preactor Production Scheduling system is an "off-the-shelf, configurable" application software package with the functionality to import data from QAD, perform production scheduling functions and export updated scheduled data to QAD.

The system validation master plan ("SVMP") documents the computer system validation activities to be performed for the initial deployment of V Group additional plant on the previously validated QAD Standard Edition Enterprise Resource Planning system, the Eagle RF Express Data Collection System and the Preactor Production Scheduling System at V Group International. Validation is required as part of production or the quality system. With this system we want to promote agility, mobility, reliability and global effectiveness; deploying technologies that make our day work more simpler to support and more rapid and effective to use and learn; and using implementation methods to reduce risk and simplify effort.

Receiving department is an administrative function that involves checking of the quantity, quality, and condition of the incoming goods followed by their proper storage. The function of the receiving department is to: unload and unpack incoming materials; check quantities received against the shippers packing list; identify goods received with descriptions on the purchase order;

prepare a receiving report; notify the purchasing department of descriptions discovered; arrange for inspection when necessary; notify the traffic department and the purchasing department of any damage in transit; and rout accepted materials to the appropriate factory location. The receiving report shows the purchase order number, the account number to be charged, the name of the vendor, details relating to transportation, and the quantity and type of the goods receive. The form also provides a space for the inspection department to note either the complete approval of the shipment or the quantity rejected and the reason for the rejection, in inspection does not take place immediately after receipt of the materials.

The objective of receiving inspection is to verify and document that all applicable specifications and requirements pertaining to raw materials and customer product specifications and requirements are satisfied by outside suppliers. Receiving inspection will also verify and document the condition of customer supplied materials as received.

The result of the receiving inspection process shall be objective evidence that raw materials and product processed by outside suppliers satisfies all specifications and requirements and that customer supplied materials are in useable condition. Receiving inspection shall be used to improve customer product quality and improve the overall effectiveness of the quality management system.

METHODOLOGY

The following activities will be performed during this validation effort:

- Complete review of business requirements;
- Inclusion of the documented business requirements in the functional requirements and functional design documents;
- Creation of all Documents necessary for the validation effort;
- Application Operational Qualification;
- Data Migration Qualification.

The list of major deliverables to be completed during the QAD validation effort is as follows:

- Validation Project Description – Describes the validation project and the approach taken to ensure that the defined computer hardware and software are in a validated state;
- System Validation Master Plan – Describes the validation activities to be conducted during the course of the validation effort. The plan identifies responsibilities, training and qualification requirements, key SOPs and policies, schedules, and additional instructions necessary to complete the validation effort. Specific objectives to be addressed include*:*
- The system, as installed, meets any environment requirements;
- The system, as implemented, satisfies the user requirements;
- Any issues identified during the validation process are properly documented and remediated;
- Functional Requirements Specification – Describes user requirements the computer system must be performing to satisfy these requirements. May also define any non-critical requirements and constraints such as time and costs. This document provides necessary input into the preparation of the validation test protocols;
- Functional Design Specification – Describes how the computer system will be configured to satisfy the functional requirements. Also described are the facilities to be provided and any design objectives. This document provides necessary input into the preparation of the validation test protocols;
- Validation Test Protocols – All tests designed to provide proof that the Functional Requirements and Design Specifications have been satisfied;
- Operational Qualifications – Describes the methods to verify that the computer system produces results as defined within the Functional Requirements Specification (FRS).

OQ testing will use individual test scripts for each requirement and be executed under normal operating conditions. These scripts can be written to test individual or multiple requirements;

- Data Migration Verification – If, required, describes all data required to support the installation or upgrade of the computer system has been manually or electronically inputted correctly to the new or upgraded computer system;
- Final Validation Report – A final report summarizing all validation protocol test results including a pass/fail status based on the acceptance criteria defined in the validation project description,
- Security, Change Control and Problem Resolution Procedures – Procedures required to assure system integrity is maintained during production usage. Typical procedures established before or during execution of the Operational Qualification protocol(s) include but are not limited to:
- Problem Reporting and Correction SOP;
- Change Control SOP including:
  - Change request process and validation assessment;
  - system(s) Validation / Revalidation, System(s) Security.

Validation Acceptance

The acceptance criteria necessary for the System Validation, includes the successful completion of the criteria below:

- Approval signatures on all required documents;
- Successful completion of the Operational Qualifications for both the hardware, if applicable, and computer software test protocols. Successful completion is the execution of all documented protocols and the resolution of any deviation(s) encountered during the execution with assurances that any deviation resolution does not compromise the integrity of the Computer System Validation.
- Completion and approval of the Computer System Validation Final Summary Report.

Validation Summary

The validation summary is a final document summarizing the results of the testing and indicates the status of the system. If accepted, the system is now in a validated state and must remain in a validated state through its useful lifecycle. If not accepted, the reasons for the failure and what remediation must take place to correct and revalidate problem areas.

The validation plan for the QAD Standard Edition software will consist of five project phases:

- **Phase 1**: Functional Requirements Specification – This is a controlled document defining the top-level functional business rules and user requirements for each business process with Quality System or GMP impact.
- **Phase 2**: Functional Design Specification - This is a controlled document defining the configuration of the system in order to support the business requirements defined in the Functional Requirements Specification.
- **Phase 3**: Data Migration Requirements – If required, this document identifies the data files to be migrated and the controls necessary to ensure that all data has been completely and accurately migrated.
- **Phase 4**: System Validation – This is the formal testing phase conducted in a "validation environment" which mirrors the production environment. The testing will include the functional operational qualifications

System validation will include the following:

- Operational Qualification (OQ) – The OQ will consist of test scripts verifying that the software functions identified in the FRS perform as required. The test scripts will be traced to a corresponding functional requirements specification in a trace matrix. The matrix is intended to verify that all requirements have associated tests and ensures the completeness of the validation effort.

Results of the test script executions will also be documented in a validation summary report. Any test deviations will be documented, tracked, resolved and maintained during test execution.

- Performance Qualification (PQ) – The performance qualification will consists of tests verifying that the software functions as required at V Group and that performance is not impacted.

Phase 5 Security, Change Control, Problem Reporting – this is the documenting of the Specific procedures which are required to ensure the integrity and validated state of the system at V Group throughout its life cycle.

At a minimum, the following procedures must be verified as in place and updated to meet the QAD Standard Edition, Eagle and Preactor needs as approved systems for use:

- Problem Reporting and Corrective Action SOP
- Change Control SOP including:
  - System Validation/Revalidation
  - System and Site Security

Final Validation Report

This document will summarize the overall validation activities, acceptance test reports, and indicate the conditions of acceptance for the QAD Standard Edition system at V Group.

Receiving

ERP system will help to do a better work. A Material Receiving & Incoming Inspection is an administrative function that involves checking of the quality, quantity, and condition of the incoming goods followed by identifying, sampling handling, inspecting and disposal of raw material received at V Group. At receiving area QAD most improve reduce time dedicated to the receiving process through the raw material is release. To support these procedures, will be add tools that will allow them to easily identify product and services that need inspection, document inspection results, and segregate nonconforming product. The tool that is going to be incorporated to the operation will permit and guarantees meeting of all specific requirements. The parts were cannot be released to inventory or production until they have been verified against the inspection criteria. Immediate access to the goods pending inspection provides the planners, production team, and accounts payable with the inventory status needed to manage material, production plans, and supplier invoices efficiently.

RESULTS AND DISCUSSIONS

The following activities were performed during this validation:

- Completed review of business requirements that necessitated this effort;
- Inclusion of the documented business requirements in this document and in the functional requirements and functional design documents;
- Creation of all Documents necessary for the validation effort;
- A Functional Requirements Specification document was created listing the requirements for the server and software implementation and software operational requirements;
- A Functional Design Specification document was created outlining the design elements of the business requirements previously documented;
- A Data Migration plan was created detailing the necessary files to be ported from the legacy TMM ERP system to the new ERP and the balancing requirements to ensure data accuracy.

Test protocols were created and executed to prove that the systems were installed and operate in accordance with vendor and V- Group requirements. One of the objectives of the implementations is to see how system helps the receiving area to be leaner, dynamic, rapid and efficient in receipt of the raw material and supplying materials to the manufacture area. Also help material department in the material inventory. To support these procedures, the warehouse

personnel and Quality inspectors needs tools that will allow them to easily identify products and services that need inspection, document result, and segregate nonconforming products. The tools that are going to be incorporated to the operation will permit and guarantees of all specific requirements.

Before the implementation, warehouse personnel received the material. Figure 1 will help to understand how the process was performed before the implementation. Visual inspections were performed and corroborate that all documents were received and was corrected. Warehouse personnel generate an incoming form and a traceability label and identify the material with that label. At this moment the warehouse personnel enter all the information into the company system. Warehouse personnel place the material received in the incoming area and send all the documentation (certificate of compliance [COC], purchase order [PO], Incoming form) to the Quality Department for the dispositions. The quality inspector verifies that all the documentations received were corrected. Quality inspector released or rejected the material and documented in the Incoming Log. Finally, warehouse personnel move the material to the proper location.

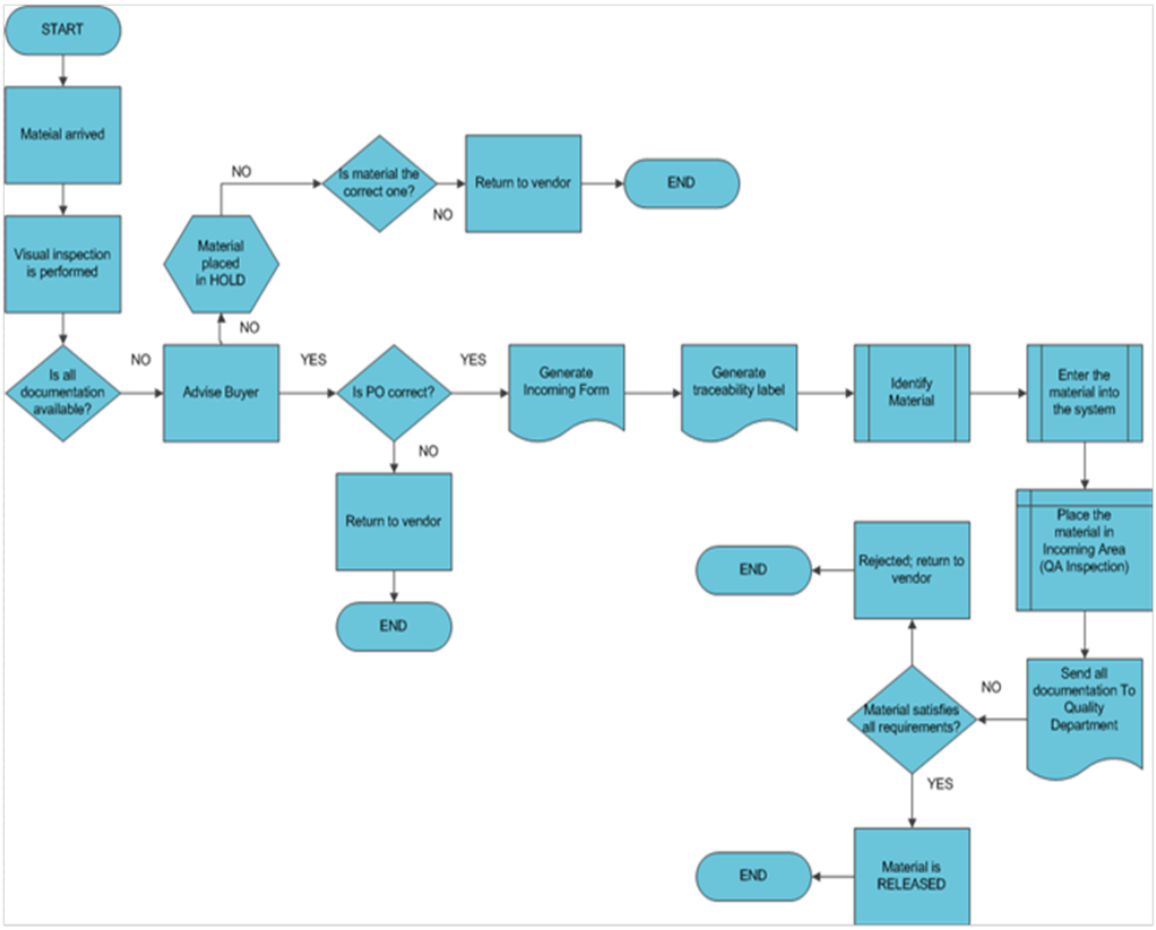

Figure 1
Process Map Before QAD Implementation

After the implementations of QAD new tools were added (software, scanners, printers, and bar coding Figure 2 and 3). They were added to improve the overall effectiveness of the receiving, material department and quality area. After the implementation of QAD (see Figure 4), material personnel received the material, visual inspections were performed and corroborate that all documents were received and was corrected. Warehouse personnel scan the product and print the traceability

label, identified the material and placed in the incoming area for the quality inspection. Warehouse personnel notify Quality department for the approvals. Quality inspector scans the materials and corroborate that the material satisfies all the requirements (COC, PO). Then quality inspector release or rejected the material. Warehouse personnel move the material to a location.

Figure 2
Terminal Devices, Printer Bar Coding Labels

Quality Personnel were in charge for updated SOP existing for the receiving and incoming area; and create new procedure for the Eagle transaction.

Figure 3
Scanner

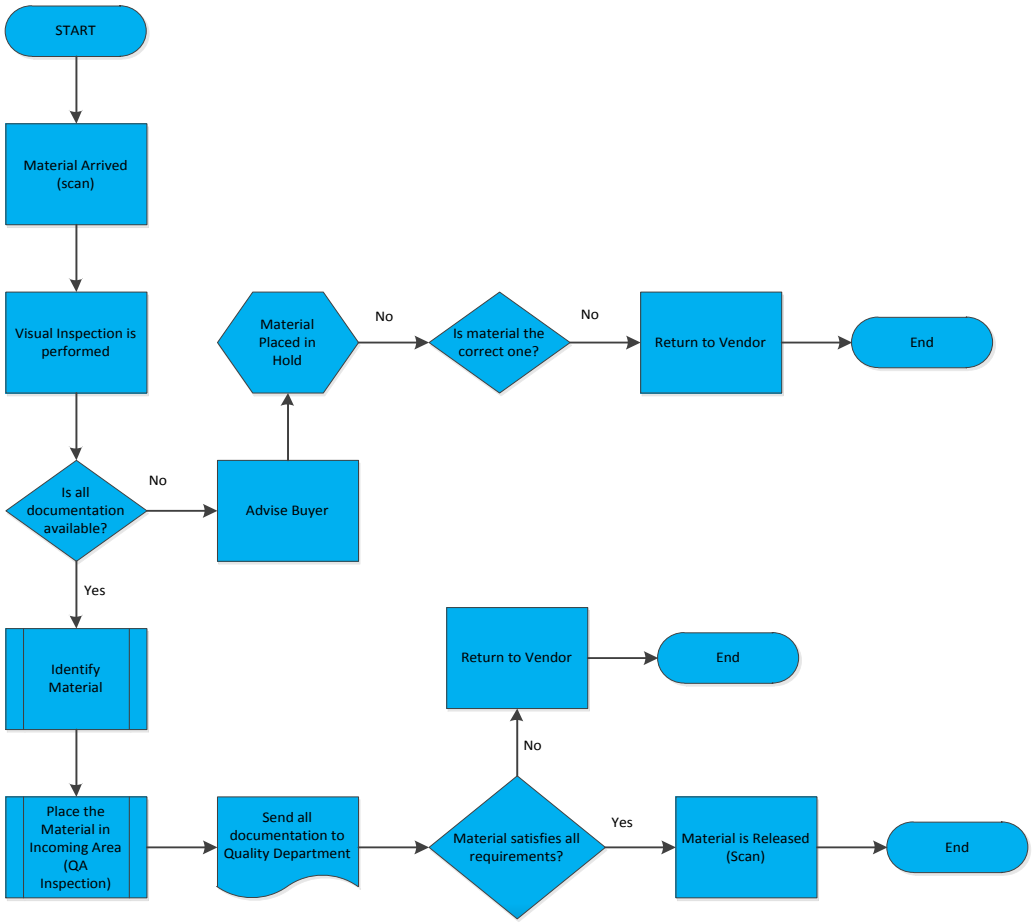

Figure 4
Process Map After QAD Implementation

CONCLUSIONS

Validation Project Description has been concluded. A total of Two Hundred and Seventy Six (276) IQ, OQ and PQ protocols broken down as follows:

- Twenty Six (26) Installation Qualifications;
- Two Hundred Forty Five (245) Operational Qualifications;
- Five (5) Performance Qualification test scripts.

Have been successfully executed and approved. Execution of the validation plan has been determined to be complete. No enhancement or improvement recommendations are made as a result of this validation. Any future development efforts involving QAD, Eagle RF Express and Preactor must be processed and approved thru the Change Control Process. The system is available for production use. If conditions exist that must be resolved in the near term but are not serious enough to fail this execution, they must be documented. A new project will be launched to address and resolve any reasons for conditional acceptance or failure.

The acceptance criteria necessary for the risk assessment, includes the successful completion of the criteria below:

- Approval signatures on all required documents;
- Approval of all parties that the risks associated with this effort have been fully documented and approved by the validation committee;
- Approval of all parties that the level of validation to be performed based on the risk assessment is fully documented and agreed upon.

After implementing QAD and new tools added, an effective incoming inspection program was implemented. Receiving area look leaner, dynamic, rapid and efficient in receipt of the raw material and supplying materials to the manufacture area. Also increase productivity, reduce inventory, cut cost, reduce human error, not to mention that shipments are made quicker, and increase customer's satisfaction.

There was a bit of resistance by the receiving personnel at first, no one likes to be told to change his ways, but the company ended up saving time, money, and increasing their sales.

REFERENCES

[1] FDA. "General Principles of Software Validation"; *Final Guidance for Industry and Staff*, January 11, 2002.

[2] FDA, information retrieved from http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm085281.htm.

[3] "GAMP Forum". *GAMP4 Guide: Validation of Automated System in Pharmaceutical Manufacture*, December 2001.