DEFINITION AND DEPLOYMENT OF QUALITY TOOLS FOR QUALITY AND UPTIME IMPROVEMENT IN A MANUFACTURING ENVIRONMENT

By

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ABSTRACT

In order to be able to prevail nowadays all companies must have knowledge of the new technologies and advances that arise daily, specially the manufacturing sector regulated by the FDA. As result of this, companies need to continuously review and renew their processes and products. The work presented in this thesis was done in the division of Baxter, Maricao. Three studies were made in which different quality strategies were used to obtain improvements in the processes. The initiative includes different processes within the plant: (i) improvements to an existing manufacturing process, (ii) development of a new process and (iii) development of a model in which the quality-manufacture-engineering functions work effectively in process changes. The work completed goes in parallel with new initiatives (CGMP's) proposed by the FDA which promote a complete knowledge of all the aspects of the process or product as well as using technologies to monitor quality within the process.

RESUMEN

Para poder triunfar en la actualidad toda empresa debe de estar al tanto de las nuevas tecnologías y avances que surgen diariamente, especialmente el sector regulado por el FDA. Como resultado de esto, las empresas necesitan revisar y renovar sus procesos y productos continuamente. El trabajo presentado en esta tesis fue realizado en la división de Baxter, Maricao. Se realizaron tres estudios en donde se utilizaron diferentes estrategias de calidad para obtener mejoras en los procesos. La iniciativa abarca diferentes procesos dentro de la planta: (i) mejoras a un proceso de manufactura existente, (ii) desarrollo de un nuevo proceso y (iii) desarrollo de un modelo en el cual las funciones de calidad-manufactura-ingeniería trabajen efectivamente en los procesos de cambios. Los trabajos realizados van en paralelo con nuevas iniciativas (CGMP's) propuestas por el FDA las cuales promueven un conocimiento total de todos los aspectos del proceso o producto y el utilizar nuevas tecnología para monitorear la calidad dentro del proceso.

DEDICATION

To my parents Abigail Arzola Rivera and Carlos Galán Montijo, for your unconditional love and ongoing support, for always being there and believing in me. Thanks for always helping me to remember what is important in life and just hearing me out when I needed it the most.

To my special friends, Carlos Andrés Gómez Villa and Juan Guillermo Gómez Villa, it has been an unexpected and unique experience being able to get to know the two of you on some many different levels. Thank you for your love, friendship, and making me feel as part of your family.

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LIST OF ACRONYMS

BPU: Blood Packing Unit

CDRH: Center for Devices and Radiological Health

CGMP: Current Good Manufacturing Practices

DMAIC: Define-Measure-Analyze-Improve-Control

DRB: Division Review Board

FDA: Food and Drug Administration

FIFO: First In First Out

FMEA: Failure Mode and Effects Analysis

GMP: Good Manufacturing Practice

MCC: Master Change Control

MFMEA: Machinery Failure Mode and Effects Analysis

MOST: Maynard Operation Sequence Technique

MRP: Materials Requirements Planning

MTTF: Mean Time to Failure

OEM: Original Equipment Manufacturer

PAT: Process Analytical Technology

PDPC: Process-Decision-Program Chart

PFMEA: Process Mode and Effects Analysis

PM: Predictive Maintenance

PRB: Plant Review Board

QFD: Quality-Function-Deployment

RACI: Responsible-Accountable-Consulted-Informed

RCM: Reliability Centered Maintenance

RPN: Risk Priority Number

SIPOC: Supplier-Input-Process-Output-Customer

SPP: Stochastic Production Planning

TQC: Total Quality Control

CHAPTER 1 – INTRODUCTION

1.1 INTRODUCTION

Manufacturing replaced agriculture as the greatest contributor to Puerto Rico's national income largely because of Operation Bootstrap, which from the 1940s attracted U.S. firms to the island through the use of tax exemptions. The United States is by far Puerto Rico's chief trading partner. The leading exports include pharmaceuticals, medical devices, apparel, and electronics, along with machinery, chemicals, plastics, and oil refining [12].

Baxter Healthcare Corporation, Transfusion Therapies Division is a leading provider of products and services to the blood industry from the collection, separation and storage of blood and blood components to new technologies for improving the safety and availability of the blood supply. In November 2003, Baxter was named one of the 20 best employers in Puerto Rico in an annual survey sponsored by Hewitt Associates, PricewaterhouseCoopers, Gaither International and "El Nuevo Día" newspaper. While individual Baxter facilities in Puerto Rico have been honored before, this is the first time Baxter's entire operations on the island have been recognized [4].

This thesis will focus on the definition and deployment of strategies and tactics for performance improvement applicable to the manufacturing sector regulated by the Food and Drug Administration (FDA). The research work will be performed in Baxter Transfusion Therapies Division in Maricao, Puerto Rico. This intervention pursues the definition and deployment of approaches by which functions such as Production, Quality and Engineering work together effectively in achieving common business goals.

1.2 OBJECTIVES

This thesis pursues the following objectives:

1. Identification of current FDA practices that impact product and process changes. The motivation for acquiring an in-depth understanding of FDA regulatory aspects is the fact that pharmaceutical, biotechnology and medical devices manufacturing are key contributors to Puerto Rico's economy. During 2004 alone, new documents were deployed by FDA concerning current good manufacturing practices, process analytical technologies, and quality system model elements. Additional documents are in preparation regarding electronic records and signatures, and software use on the manufacturing shop-floor.

2. Design of a Production-Quality-Engineering process change model to facilitate continuous improvement within the FDA regulated environment. The incentive for addressing this issue is the fact that historically these functions or departments maintain an adversarial relation. Given the productivity imperative for Puerto Rico manufacturing, these critical functions must demonstrate a teamwork attitude and use appropriate methodologies and tools to accelerate continuous improvement. The author will work with a cross-functional team (including Production, Quality, Engineering and others) to improve the change approval process. This business process is required in all improvement initiatives pursued in the manufacturing plant where the research will be performed (Baxter Transfusion Therapies).

3. Identification and deployment of tools for effective process improvement. The author will use current methodologies and tools deployed in manufacturing in an innovative way, such as the failure mode and effects analysis (FMEA) and the flowchart. In the former (FMEA), the elements included in the risk priority number calculation (RPN) for the Kiefel line will divide severity into two components: downtime severity and scrap severity; thus the RPN calculation will include four terms. In the case of the process FMEA prepared for the new automated process, its

size will require two-dimensional tables: failure modes will be placed in rows and failure causes will be placed in columns. A total of eleven tables will be required to cover the complete process. A Visual Basic (VBA) code will be developed to accelerate the RPN updating when changes are made to the severity, occurrence and detection scores. In the latter (flowchart), the logic developed addresses real-time decision-making issues that the equipment designers will incorporate in the development of the control software. This use of the flowchart is a new idea.

1.3 CONTRIBUTIONS

This research work has three main contributions:

1. The innovative approaches followed in the construction of the two failure mode and effects analyses (FMEA). In the Kiefel line, for which a machine FMEA was developed, the risk priority number (RPN) used four elements (downtime severity, scrap severity, occurrence and detection). In the new automated process, for which a process FMEA was developed, the problem size required: (i) an innovative layout to display severity, occurrence and detection, and (ii) software code using Visual Basic to accelerate RPN updating.

2. The innovative approach in using the flowchart to define real-time decision-making issues that must be integrated into the equipment control logic. The tool for real-time system specification known since the 1980's, attributed to Hatley and Pirbhab [17], cannot compare in terms of ease of use and popularity to the flowchart.

3. The breakthrough in improving the change approval process in one FDA regulated business (Baxter Transfusion Therapies in Maricao, Puerto Rico). This effort can be leveraged to other FDA-regulated plants, since this cross-functional improvement effort used the DMAIC (define-measure-analyze-improve-control) approach, which is an improvement methodology widely used in plants embracing Six Sigma and Lean Manufacturing programs.

CHAPTER 2 – LITERATURE REVIEW

2.1 FOOD AND DRUG ADMINISTRATION

The FDA is a federal science-based law enforcement agency mandated to protect public health and safety. The agency's mission is to: (i) promote public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner, (ii) protect public health by ensuring there is reasonable assurance of the safety and effectiveness of devices intended for human use, (iii) participate with representatives of other countries to reduce the burden of regulation, coordinate regulatory requirements, and achieve appropriate equivalent arrangements, and (iv) carry out the tasks defined earlier by consulting with experts in science, medicine, and public health, and by cooperating with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products.

FDA's non-field activities are organized into several specialized program centers that are responsible for protecting the public's health, one of these centers is the Center for Devices and Radiological Health (CDRH). The mission of the CDRH is to ensure the safety and effectiveness of medical devices and the safety of radiological products.

The Food, Drug and Cosmetic Act defines a medical device as any healthcare product that does not achieve its principal intended purposes by chemical action or by being metabolized. Medical devices are classified and regulated according to their degree of risk to the public. The FDA establishes three different regulatory classes to ensure that each device is subject to regulations that are appropriate, the controls range from: (i) general controls which require the registration of manufacturers, general recordkeeping, and compliance with GMP regulations, (ii) special controls which require specific regulations in order to provide assurance of the product's safety such as requirements for meeting performance standards recognized by the FDA, post-market

surveillance, patient registries, and other appropriate requirements, to (iii) premarket approval for devices that are life-supporting or life-sustaining, or is important in preventing impairment of human health.

CDRH works with dynamic and innovative medical device and radiological health industries that produce high quality and increasingly complex products. Products cleared and approved by CDRH set the "gold standard" in the international market. FDA further assures the safety and effectiveness of medical devices by regulating their manufacture through establishing GMP's for medical devices, regularly inspecting manufacturers to assure they comply with these regulations and continuously analyzing reports to ensure that products are safe[14].

2.1.1 RECENT SIGNALS FROM FDA

In August 2002, the FDA announced a new initiative, Pharmaceutical Current Good Manufacturing Practices (CGMPs) for the 21st Century, to enhance and modernize the regulation of pharmaceutical manufacturing and product quality. As part of this initiative, the pharmaceutical, chemistry, manufacturing, and controls regulatory programs were evaluated with the objectives of: (i) encouraging the early adoption of new technological advances, (ii) facilitatoing industry application of modern quality management techniques to all aspects of production and quality assurance, (iii) encouraging implementation of risk-based approaches that focus both industry and Agency attention on critical areas, (iv) ensuring that regulatory review, compliance, and inspection policies are based on state of the art pharmaceutical science, and (v) enhancing the consistency and coordination of FDA's drug quality regulatory programs by further integrating enhanced quality systems approaches into the Agency's business processes and regulatory policies concerning review and inspection activities.

Early in the initiative, a number of multidisciplinary working groups were formed to complete an assessment of the existing CGMP programs; practices as well as available new tools of enhancing manufacturing science were assessed. This helped in the creation of a new framework for the regulatory oversight of manufacturing quality that is based on quality systems and risk management approaches. Implementation of the envisioned new framework requires a highly educated, well-trained and integrated team of individuals throughout the FDA who use risk-based and science-based approaches for regulatory decision making throughout the entire life-cycle of a product.

A number of specific accomplishments have resulted from the CGMP Initiative; one of these accomplishments is the *Science based regulation of product quality*. The key objective of this initiative is to use a scientific framework to find ways of mitigating risk while facilitating continuous improvement and innovation in pharmaceutical manufacturing. This new system will encourage the implementation of new technologies, such as process analytical technology (PAT), and facilitate continuous manufacturing improvements via implementation of an effective quality system.

2.1.2 PROCESS ANALYTICAL TECHNOLOGIES INITIATIVE

PAT refers to the optimal application of process analytical chemistry tools, feedback process control strategies, information management tools and product/process optimization strategies to the manufacture of pharmaceuticals. It is a platform for continuous process verification (or validation) and/or quality assurance. The motivations for this initiative are the significant potential and need for improving the efficiencies of pharmaceutical manufacturing and associated regulatory processes and improve quality (remove the risk in moving to the next stage, prevent manufacturing of unacceptable end product quality) in order to provide significant benefits to both industry and public health [19].

This initiative pursues: (i) the establishment of appropriate control of all relevant critical attributes of in-process materials to allow the process to manage the inherent variability in physical attributes of Pharmacopeias materials that can impact their process ability and (ii) providing a means for “greater assurance” of quality “than analytical data derived from an examination of finished units drawn from that batch” [21]. PAT provides an opportunity to move from the current “testing to document quality and rejecting (or recalling) products of unacceptable quality” paradigm to a “continuous quality assurance” paradigm that can improve the ability to ensure quality is “built-in” or is “by design”.

A desired goal of the PAT framework is to design and develop processes that can consistently ensure a predefined quality at the end of the manufacturing process. Such procedures would be consistent with the basic principle of quality by design and could reduce risks to quality and regulatory concerns while improving efficiency. Gains in quality, safety and/or efficiency will vary depending on the product and are likely to come from: (i) reducing production cycle times by using on line measurements and controls; (ii) preventing rejects, scrap, and re-processing; (iii) considering the possibility of real time release; (iv) increasing automation to improve operator safety and reduce human errors; and (v) facilitating continuous processing to improve efficiency and manage variability using small-scale equipment and dedicated manufacturing facilities; and improving energy and material use and increasing capacity. [13]

On-line versus off-line quality control testing can greatly impact overall cycle times because: (i) off-line quality testing is discontinuous; (ii) quality control testing times are large; (iii) quality control cycle times are typically larger than process cycle times; and (iv) off-line testing queues might not respond to the priorities of the manufacturing activity. Industries are hesitant to introduce PAT in the U.S. because regulatory uncertainty and risks lead to “don’t tell” or “don’t use” practice. The success

of this initiative is driven by a few leading companies who are willing to explore such new approaches [20].

2.1.3 PROCESS VALIDATION

Process validation is a requirement of the GMP regulations for Medical Devices; it is defined as establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its determined specifications and quality characteristics [36].

Assurance of product quality is derived from careful attention to a number of factors including selection of quality parts and materials, adequate product and process design, control of the process, and in-process and finished-product testing. Due to the complexity of today's medical products, routine end-product testing alone often is not sufficient to assure product quality. The basic principles of quality assurance have as their goal the production of products that are consistently fit for their intended use. These principles may be stated as follows: (i) quality, safety and effectiveness must be designed and built into the product, (ii) quality cannot be inspected or tested into the finished product; and (iii) each step of the manufacturing process must be controlled to maximize the probability that the finished product meets all quality and design specifications.

Process validation is a key element in assuring that these quality assurance goals are met. It is through careful design and validation of both the process and process controls that a manufacturer can establish a high degree of confidence that all manufactured units from successive lots will be acceptable. Successfully validating a process may reduce the dependence upon intensive in-process and finished-product testing. Process validation is required by the medical device CGMP Regulation, the regulation requires every finished device manufacturer to: "Prepare and implement a

quality assurance program that is appropriate to the specific device manufactured…" A manufacturer should evaluate all factors that affect product quality when designing and undertaking a process validation study. Process Validation includes the following elements:

1. *Equipment Installation Qualification:* establishes confidence that the process equipment and ancillary systems are capable of consistently operating within established limits and tolerances. This phase includes the examination of equipment design; determination of calibration, maintenance, and adjustment requirements; and identifying critical equipment features that could affect the process and product.

2. *Process Performance Qualification:* provides rigorous testing to demonstrate the effectiveness and reproducibility of the process. In challenging a process to assess adequacy, it is important to simulate those conditions that will be encountered during actual production, including "worst case" conditions.

3. *Product Performance Qualification:* before reaching the conclusion that a process has been successfully validated, it is necessary to demonstrate that the specified process has not adversely affected the finished product. After actual production units have successfully passed product performance qualification, a formal technical review should be conducted and should include: (i) comparison of the approved product specifications and the actual qualified product; (ii) determination of the validity of test methods used to determine compliance with the approved specifications; and (iii) determination of the adequacy of the specification change control program [16].

Statistical methods and tools are helpful to improve validation protocol and process. Understanding key process variables that affect product quality characteristics

is imperative in order to understand sources of variation and errors. Obtaining a process that consistently conforms to requirements requires a balanced approach using both mistake proofing and variation reduction tools [37].

2.2 QUALITY AND MODELING TOOLS

Quality tools are organizational or analytical techniques that assist in understanding and solving a problem. There are many different quality tools, these can be divided into Traditional or “Old” Quality Tools because of the amount of time they have been in use and “New” Quality Tools that have been in use for the last 10 or 15 years. Other tool taxonomies are possible; such as leadership tools, customer satisfaction tools, quality planning and assurance tools, human resource tools, and information/analytical tools.

The traditional tools have their roots in basic statistics; in fact, a number of the basic tools simply implement well-known basic statistical tools. Other basic tools were original creations and still others are a product of the early American efforts in quality. The newer tools tend to be less statistical in nature and more 'human-side' oriented; that is, less mathematically and more behaviorally oriented. [34]

The traditional, best known as seven TQC (for Total Quality Control) tools, include the following: (1) Flowchart, (2) Cause-and-effect or Fishbone Diagram, (3) Pareto chart, (4) Histogram, (5) Scatter or X versus Y diagram, (6) Control Chart, and (7) Check Sheet. The new, best known as seven management and planning tools, include: (1) Affinity Diagram, (2) Interrelationship Diagram, (3) Tree Diagram, (4) Matrix Diagram, (5) Prioritization Matrix, (6) Process-decision-program chart (PDPC) or Contingency Diagram, and (7) Activity Network Diagram. Failure mode and effects analysis (FMEA) and Simulation, even though not classified as quality tools, are very useful for understanding, analyzing and solving problems.

2.2.1 SIX SIGMA INITIATIVES

Quality has become one of the most important consumer decision factors in the selection among competing products and services. Consequently, understanding and improving quality is a key factor leading to business success, growth, and an enhanced competitive position. The quality of a product can be evaluated in several ways such as performance, reliability, aesthetics, features, perceived quality and conformance to standards [26].

Six Sigma is a rigorous and systematic methodology that utilizes information and statistical analysis to measure and improve a company's operational performance, practices and systems by identifying and preventing defects in manufacturing and service-related processes in order to anticipate and exceed expectations of all stakeholders to accomplish effectiveness [37]. Improvement, problem solving, and process-design teams are the most visible and active component of a Six Sigma effort. The teams are created to solve organizational problems and to capitalize on opportunities. In bringing a diverse team together, it is critical to have a common process, or model, that all members can share to get their work done. The answer to this need in Six Sigma is the DMAIC process [11].

2.2.2 DMAIC

DMAIC is an acronym for five interconnected phases: Define, Measure, Analyze, Improve, and Control and refers to a data-driven quality strategy for improving processes, and is an integral part of companies embracing the Six Sigma Quality Initiative. In working through this process, the team is also interacting with the larger organization, interviewing customers, gathering data, and talking to people whose work will be affected by the team’s solution recommendations [29]. The process steps are:

2.2.2.1 DEFINE

On this step, the team or analyst has to define the customer, their requirements and expectations for products and services, their "critical to quality" issues, and the core business process involved. Define establishes boundaries (the start and stop of the process) which can be described in detail by a process map [11]. The goals of the improvement activity can also be defined at this stage.

The most important goals are obtained from direct communication with customers, shareholders, and employees. At the top level the goals will be the strategic objectives of the organization, such as greater customer loyalty, an increase in market share, or greater employee satisfaction. At the operations level, a goal might be to increase the throughput of a production department. At the project level goals might be to reduce the defect level and increase throughput for a particular process [32]. Once these issues are defined, the DMAIC sketch can be developed. This project blueprint is intended to define and narrow the project focus, clarify the results being sought, confirm value to the business, establish boundaries and resources for the team, and help the team communicate its goals and plans [29].

2.2.2.2 MEASURE

This step defines the current baseline, establishing valid and reliable metrics to help monitor progress towards the goal(s) previously identified, and developing a data collection plan for the process. Data is collected from many sources to determine types of defects [5]; exploratory and descriptive data analysis is used for data understanding [30]. Six sigma teams take a process view of the business and use that view to set priorities and to set good decisions about what measures are needed. A process has three main categories of measures: output, process and input.

The DMAIC team's first priority is the output measures that best quantify the current problems. This baseline measure is the data used to complete the charter. Once the baseline measure has been determined, the team has to establish a data collection plan. A common milestone in this step is to develop an initial "sigma measure" or performance goal for the process being fixed [29].

2.2.2.3 ANALYZE

The third step, analyze the system, identifies ways to eliminate the gap between the current performance of the system or process and the desired goal. Statistical tools are used to guide the analysis of the data collected in order to determine root causes of defects and opportunities for improvement. Improvement opportunities are prioritized and sources of variation are identified [32].

In this step, the DMAIC team looks into the details, enhances its understanding of the process and problem, and identifies the "root cause" behind the problem. One of the principles of good DMAIC problem solving is to consider many types of causes, so as to not let biases or past experience cloud the team's judgment. Some of the common cause categories to be explored follow the traditional categories of the cause-and-effect diagram and are: (i) methods, (ii) machines, (iii) materials, (iv) measures and (v) people.

The cycle begins by combining experience, data/measures, and a review of the process and then forming an initial guess, or hypothesis of the cause. The team then looks for more data and other evidence to see whether it fits with the suspected cause. The cycle of analysis continues, with the hypothesis being refined or rejected until the true root cause is identified and verified with data. One of the biggest challenges in the Analyze step is to use the right tools [29].

2.2.2.4 IMPROVE

Once potential solutions are proposed, these are evaluated using several criteria, including costs and likely benefits. This step aims at implementing solutions that improve the target process by designing creative and innovative solutions to fix and prevent problems using technology and discipline. The most promising have to be tested and refined prior to implementation, using statistical methods to validate the improvement. At this point “improve” becomes “implement”.

DMAIC solutions have to be carefully managed and tested; teams must go through careful “potential problem analysis” to determine what could go wrong and prepare to prevent or manage difficulties. New changes have to be “sold” to organization members whose participation is critical. Data must be gathered to track and to verify the impact and unintended consequences of the solution [29].

2.2.2.5 CONTROL

Control implies sustaining the gains, keeping the process on the new course and preventing it from reverting back to the "old way". This step requires the development, documentation and implementation of an ongoing monitoring plan. Improvements are institutionalized through the modification of systems and structures (staffing, training, incentives) [11]. The main objective of this step is avoiding getting back to old habits and processes. Ultimately, having a long term impact on the way people work and ensuring that it lasts is as much about persuading and selling ideas as it is about measuring and monitoring results.

The DMAIC problem-solving process and the phases of the project cycle work hand-in-hand. The DMAIC process is iterative; the line from “define” to “control” is not straight but rather moves back and forth, revisiting earlier assumptions and filling places

passed over in a rush. Table 1 presents a list of tools commonly used in each of the stages of a project.

Table 1 Commonly used Six Sigma Tools

Project Phase	Candidate Six Sigma Tools
Define	• Project Charter • Voice of Customer Tools (surveys, focus groups, etc.) • Process map • QFD, SIPOCs • Benchmarking
Measure	• Measurement systems analysis • Exploratory data analysis • Descriptive statistics • Data mining • Run charts • Pareto analysis
Analyze	• Cause and effect diagrams • Tree Diagrams • Brainstorming • Process behavior charts • Process maps • Design of Experiments • Enumerative statistics (hypothesis tests) • Inferential statistics (Xs and Ys) • FMEA • Simulation
Improve	• Force field diagrams • 7M tools • Project planning and management tools • Prototype and pilot studies
Control	• Statistical Process Control • FMEA • ISO 900x • Change budgets, bid models, cost estimating models • Reporting system

2.2.3 FLOWCHARTING

As a whole, flowcharting has been around for a very long time. In fact, flow charts have been used for so long that no one individual has been identified as the "father" of such tool. The reason for this is obvious. A flowchart can be customized to fit any need or purpose; this is why they have innumerable uses and applications. For this reason, flow charts can be recognized as a very unique quality improvement method.

2.2.3.2 DEFINITION

A flowchart is defined as a pictorial representation describing a process being studied. Flowcharts can be used for: (i) defining and analyzing processes; (ii) building a step by step picture of the process for analysis, discussion, or communication purposes; (iii) defining, standardizing, or finding areas for improvement in a process; (iv) comparing and contrasting the actual work flow of a process with an ideal flow; and (v) to help train employees [8].

There are several different types of flowcharts, including: (i) document flowcharts, (ii) program flowcharts, and (iii) system flowcharts. A document flowchart shows the flow of a physical document, primarily used to depict manual processes and can be used to pinpoint weaknesses in internal controls. Program flowcharts show the program logic; depict tests conducted by a computer program as it processes data. System flowcharts portray the flow of data from the entry or creation or creation of the data on the system. The sequential steps that the data goes through as it is processed are shown, as well as any output generated by the system.

When constructing a process flowchart, two separate stages of the process should be considered: the finished product and the making of the product. Figure 1 presents the basic flow chart symbols and Figure 2 presents the basic ANSI standard symbols.

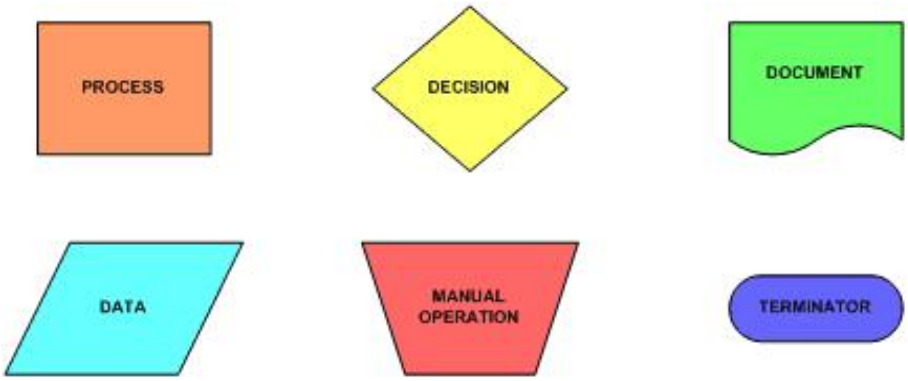

Figure 1 Basic Flowchart Symbols

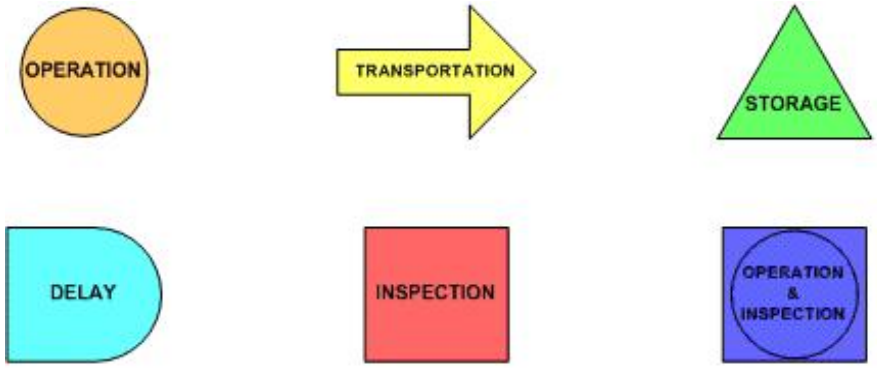

Figure 2 ANSI Standard Flowchart Symbols

The typical steps for constructing a flowchart are:

1. Familiarize the participants with the flowchart symbols;

2. Brainstorm major process tasks. Ask questions such as: (i) what really happens next in the process; (ii) does a decision need to be made before the next step; and (iii) what approvals are required before moving on to the next task?

3. Draw the process flowchart using the selected symbols and complying with: (i) every process will have a start and an end; (ii) all processes will have tasks and most will have decision points; (iii) elimination of process repeats, duplication of efforts and unnecessary tasks; and (iv) when appropriate include time per event and classify tasks as value-added versus non-value added.

2.2.3.2 APPLICATIONS

A great deal of the work that engineers and analysts perform in manufacturing, distribution and service organizations involves process flow analysis and design. In designing a new process or modifying an existing one, designers want an efficient flow of people, materials, equipment and information. Proper uses of modeling and analysis techniques help to ensure a successful design and implementation. A modeling framework needs to be worked out before embarking on a detailed process analysis and design; the starting point is constructing a flowchart.

The modeling approach to process flow design has proven its effectiveness in a number of application projects. The approach to take is to build a conceptual flow model around a process flow chart and then formulate the model as an analytical or computer model for design experiments. The approach reduces the time and effort expended for process modeling by perhaps as much as half. For instance, it took less than three weeks of one person's effort to develop a base case process flow simulation model for a high tech manufacturing plant in a plant-wide material handling system design.

Flow modeling application can be extended to any process showing queue characteristics. Queues are caused by randomness in job arrivals and/or the variability of process times. Process flow modeling is useful in predicting the effect of productivity improvement measures such as combining similar operations, eliminating non-value added activities and implementing a new method. Flow models will be an effective tool

foe special task teams set up for streamlining business processes. The models can also be used as training tool for supervisors and new employees [1].

2.2.4 FAILURE MODE AND EFFECTS ANALYSIS

FMEA is a procedure that helps to identify every possible failure mode of a process or product by weighing the effect of such failures to determine if a preventative action is warranted or not. The analysis calls for measuring severity, frequency and detect ability which are combined into the risk priority number (RPN). Resources are assigned to those failure causes with larger score for prompt resolution.

An FMEA is a structured approach to find out: (i) how the systems and interfaces contribute to customer dissatisfaction, (ii) how the design contributes to product weakness, (iii) how manufacturing and assembly processes contribute to poorly built products, (iv) how service of the product, once it is in the field, affects it's performance, and (v) the reliability and maintainability of equipment and tooling required to manufacture a product.

Among the numerous benefits of FMEA's are the following: (i) better knowledge of the product, (ii) time savings: if failure modes and their causes are identified before prototype parts are made and assembled, much time can be saved testing poorly designed or built parts, (iii) cost savings: poorly designed prototype parts are quickly replaced by better designs as the weaknesses are revealed, (iv) reduced warranty repairs and recalls, (v) increased quality which results in increase in customer satisfaction, (vi) history: a properly conducted and documented FMEA provides a record of design development of the product while preventing past mistakes from being repeated, (vi) improved or modified design verification planning, (vii) facilitation, translation, and selection of critical and significant characteristics that are linked from product function through manufacturing, and (viii) prioritized list of risks to work on and thereby

separating the vital few failures and causes which affect safety, non-compliance and customer satisfaction from the trivial many which may tie up resources for a minimal gain. [18, 39]

There are various FMEA versions; the most widely used are the following:

1. Design FMEA (DFMEA): risk analysis for the design of a system, subsystem or component to assess risk, reduce it, and assure the product is launched successfully;

2. Process FMEA (PFMEA): risk analysis for identifying potential product related failure modes, caused by a manufacturing or assembly process; and

3. Machinery FMEA (MFMEA): risk analysis for evaluating equipment and tooling during its design phase in order to improve operator safety, reliability and machinery robustness.

Constructing an FMEA table for a complex product, process or equipment requires human resources involvement and time to put together the required details. However, the benefits for managers and engineers from the effort include: (i) improved product/process reliability and quality; (ii) increased customer satisfaction; (iii) early identification and elimination of potential product/process failure modes; (iv) understanding of criticality on product/process deficiencies; (v) reduction of late changes and their associated costs; (vi) documentation of actions pursued for risk reduction; (vii) emphasis on problem prevention; (viii) development and testing tactic improvement; (ix) improved teamwork between functions involved in FMEA preparation; and (x) gathering of engineering/organization knowledge [10].

Booth in [7] suggests that in addition to identifying potential failure modes the FMEA can be a tool for organizational learning. When testing reveals a flaw and

corrective actions are taken the FMEA must be updated as part of the change control process, then the rationale behind the change will be captured and preserved. The FMEA's for future, similar, designs that are based on prior FMEA documents pass on the knowledge of failure modes and effective mitigations to the next generation of designers.

2.2.4.1 DEFINE THE TEAM

To construct a good FMEA, resources with vast understanding and experience in the system under study are required. The participants will come from functions that participate with the product, process or machinery in question. The team must include a resource knowledgeable in the FMEA methodology to assure that the FMEA table is constructed with all the required information and that the methodology is standardized throughout the organization.

2.2.4.2 DEFINE THE SYSTEM

The second step when performing a FMEA is to organize as much information as possible about the system concept, design, and operational requirements. By organizing the system model, a rationale, repeatable, and systematic means to analyze the system can be achieved. One method of system modeling is the system breakdown structure model; a top down division of a system into functions, subsystems, and components.

2.2.4.3 IDENTIFY POTENTIAL FAILURE MODES

A failure mode is the manner in which a failure is observed in a function, subsystem, or component. Failure modes of concern depend on the specific system, component, and operating environment. The past history of a component/system is used

in addition to understanding the functional requirements to determine relevant failure modes.

2.2.4.4 IDENTIFY THE CAUSES OF THE FAILURE MODES

The cause of a failure mode is the physical or chemical process, design defect, quality defect, part misapplication, etc. which are the reasons for failure. It is important to note that a failure mode could have multiple causes. All potential causes of failure must be identified including human error. The involvement of experienced personnel in the system under study is a must.

2.2.4.5 EVALUATE THE EFFECTS ON THE SYSTEM

The failure effect is the impact, or severity, such failure mode or cause has on the system. The effect should consider conditions that influence the system performance and the goals established by management. In the FDA-regulated industry, the aspect of safety is most important. The effects should be examined at different system levels in order to determine possible corrective or preventative measures for the failure. The consequences of the failure mode can be identified by a severity index indicating the relative importance of the effect due to a failure mode.

2.2.4.6 IDENTIFY DETECTION METHODS/CORRECTIVE ACTIONS

Part of the risk management portion of the FMEA is the determination of failure detection sensing methods and possible corrective actions. There are many possible sensing device alternatives such as alarms, gauges, and inspection. An attempt should be made to correct a failure or provide a backup system to reduce the effects propagation to rest of system. If this is not possible, procedures should be developed for reducing the effect of the failure mode through operator actions, maintenance, and/or inspection [41].

2.2.4.7 FMEA DOCUMENTATION

The results of the FMEA must become a living document for those involved in product, process or machinery improvement. Those failure causes with highest score should be addressed first taking into consideration the cost of such changes. As improvements are made, the scores for the improved failure modes and cause are modified, decreasing their criticality. Other items that become most critical are next for improvement.

2.2.3.2 FMEA PRFORMANCE VALIDATION

Pollock in [31] presents the manner in which organizations leverage the value of effectively applying FMEA's by creating a framework for giving feedback about FMEA performance. The effectiveness of FMEA performance can be measured by what happens after the product or process is being carried out. Typical measures include warranty data, customer satisfaction or process rework. Less typical is the implementation of a shared learning process. This feedback loop connects the customer experience to the project team. This shared learning is built on two ideas: (i) when starting an FMEA, it is important to understand how its performance will be measured from the customer viewpoint and (ii) it is helpful to know how other FMEA's performed so any mistakes can be avoided in the future.

A cross functional team developed a flowchart of the validation process and used DMAIC to organize activities within a matrix and as a training aid. Three new measurements for validating FMEA's were identified to test the FMEA performance for a recent model of a primary product: (i) failure mode capability is the ratio of the number of failure modes divided by the number of warranty failure modes. The goal is to score at least 2.00. This measurement uses the statistical process control capability

concept of comparing performance to target, (ii) evaluation of failure mode control effectiveness as measured by warranty statistics and dollars saved, and (iii) identification of which warranty failure modes were missed during the FMEA process.

This process can also be implemented in transactional settings to more effectively control projects after implementation. A major challenge in these settings is how to effectively monitor performance over time when the concept of trend analysis is less mature than in more traditional manufacturing applications.

The time and effort involved in validating FMEA performance is a value added activity because: (i) it is a key tool in the ongoing control of a project, (ii) design engineers and improvement teams value the insight gained by seeing how well their risk assessment worked, (iii) employees in transactional or administrative settings find it valuable to link identified potential failures (risks) to their control plan, (iv) project management professionals who promote the lessons learned discussion at the end of a project also support FMEA validation as part of the discussion, and (v) it is cost effective, requires no capital outlay and can encourage more awareness about total cost through its use.

2.2.4.9 FMEA APPLICATIONS

The analysis of failures and its effects on a system can be applied to a broad range of processes. Layzell and Ledbetter [23] describe the application of the traditional FMEA methodology in the construction industry, specifically cladding systems for risk of failure reduction. Cladding accounts for up to 25% of the cost of a building, has a major impact on its integrity and service life as well as providing and preserving its appearance. The term cladding embraces a broad range of building envelope constructions including traditional fully-sealed and modern pressure-equalized cladding panels, curtain walling and structural glazing systems.

An essential concept when performing an FMEA is to divide the system into its main components, in order to identify the failures of the cladding system it was divided into the three major components that affect its functioning, namely: (i) sealant, (ii) glass and (iii) finishes. The causes of failure of the three components were determined according to the experience of component manufacturers and specialist companies. The occurrence ranking was determined based on qualitative failure data that have been compiled which has the cladding system failure modes listed in order of occurrence. The severity ranking, which refers to the effects of the failures on the system, was determined based on the cost of repairs, cost of loss of building use and the cost of injury among others. The detection ranking which is a measure of the probability control procedures detecting the cause of failure mode before reaching the customer was based on the quality control checks. This criterion was especially difficult to rank because of the variable level of quality control of a labor intensive process in the construction industry.

The final stage is the implementation of positive and effective actions to the critical areas identified by the FMEA. The failure data was translated into several forms of concentrated actions, specifically: (i) Reducing/eliminating the likelihood of failures by design, (ii) Reducing/eliminating the likelihood of failures by detection, (iii) Reducing the impact of a failure, (iv) Defining the basis for training and product development, and (v) Aiding fault diagnosis when failures occur.

The principles of FMEA have a wide application with many possible extensions. As a result, each industry tends to develop its own system and style peculiar to its own circumstances. In the case of the cladding industry a simplified form of FMEA was shown to be useful, however, some questions related to the implementation of FMEA's within the construction process remain, such as: (i) motivation, (ii) participation and responsibility, and (iii) feedback.

Franceschini and Galetto [15] present a new approach for performing the calculus of the RPN of failures which consists of new management of data provided by the design team, normally given on qualitative scales, without necessitating an arbitrary and artificial numerical conversion. The authors argue that the characteristic failure mode indexes are expressed on ordinal qualitative scales identifying the various levels of 'dangerous' situations and that in the RPN calculation, the assigned values on the three index qualitative scales are interpreted as being numbers. The proposed method consists in defining the order to analyze the failure mode effects of the considered product. Data processing is performed by working exclusively on the ordinal features of qualitative scales used to collect information from designers.

The main innovative elements of the proposed method are: (i) it does not require any arbitrary and artificial scaling of collected information, (ii) it is able to deal with situations having different importance levels for three failure mode component indexes, (iii) it is able to aggregate design team information, even if they are expressed on ordinal qualitative scales, and (iv) it is easy to computerize.

2.2.5 COMPUTER SIMULATION MODELS

Since its introduction in the industrial engineering community in the 1970s, discrete event simulation has become the most frequently used technology in the design and analysis of complex systems. During this period, simulation tools have also become more sophisticated; i.e., they now include improved user interfaces for the development of the model and analysis of results, advanced animation capabilities for the visualization of the system's behavior, and enhanced computational capabilities [9]. As the engineering community is forced to consider systems of increasing complexity, the utilization of simulation based procedures is bound to increase.

2.2.5.1 DEFINITION

Ingalls [22] defines simulation as the process of designing and creating a computerized model of a real or proposed system over time for the purpose of conducting numerical experiments to give us a better understanding of the behavior of that system for a given set of conditions. The difference and the power of discrete event simulation is the ability to mimic the dynamics of a real system. It is the ability to mimic the dynamics of the real system that gives discrete event simulation its structure, its function, and its unique way to analyze results. The main reason for simulation's popularity is its ability to deal with very complicated models of correspondingly complicated systems. This makes it a versatile and powerful tool.

2.2.5.3 TYPES OF SIMULATIONS

Because of their complexity, simulations can have a lot of different characteristics. A simulation can be either static or dynamic. In static models time does not play a role, it typically involves the use of random sampling in order to obtain statistically based results. Static simulations are also referred to Monte Carlo. In contrast, a dynamic model involves the passing of time.

A simulation can be either continuous or discrete; it may be possible to model the same system with either a discrete or a continuous change model. In most simulations time is the major independent variable, other variables included in the simulation such as machine status and number of parts in inventory, are functions of time and are the dependent variables. When modifying a simulation, discrete and continuous refers to the behavior of the dependent variables. The dependent variables are used to calculate the operations performance measures. Discrete simulation occurs when the dependent variables change discretely at specified points in simulated time, referred to as event times.

The time variable may be either continuous or discrete in such a model, depending on whether the discrete changes in the dependent variable can occur at any point in time or only at specified points. In a continuous simulation model, the state of the system is represented by the dependent variables that changes continuously over time. To distinguish continuous change variables from discrete change variables, the former are referred as state variables. A continuous simulation model is constructed by defining equations for a set of state variables whose dynamic behavior simulates the real system.

A simulation can be either deterministic or stochastic; deterministic models that have no probabilistic or random components. All inputs, processing times, and outputs of a deterministic simulation are constant. In stochastic or probabilistic models one or more variables are random and as a consequence the results of interest are also random.

2.2.5.4 MODELING CONCEPTS

A model is a representation of a system or process. A simulation model is a representation that incorporates time and the changes that occur over time. There are two types of models; a discrete model is one that changes only at discrete points in time when an event occurs. A continuous model is one in which the state of the system is changing continuously over time. A model may incorporate logical, mathematical and structural aspects of the system or process.

An event is an occurrence that changes the state of the system. Events include the arrival of a customer for service, the beginning of service for a customer, and the completion of a service. There are both internal and external events, also called endogenous and exogenous events, respectively. For example, an endogenous event is the beginning of service of the customer since that is within the system being simulated. An exogenous event is the arrival of a customer for service since that occurrence is outside of the simulation [3].

The system state variables are the collection of information needed to define what is happening within the system to a sufficient level at a given point in time. The selection of system state variables is a function of the purpose of the investigation, so what may be the system state variables in one case may not be the same in another case even though the physical system is the same. After defining the system state variables, a contrast can be made between discrete event models and continuous models based on the variables needed to track the system state. The system state variables in a discrete event model remain constant over intervals of time and change value only at certain well defined points called event times. Continuous models have system state variables defined by differential or difference equations giving rise to variables that may change continuously over time. Some models contain both kind of variables discrete event and continuous. There are also continuous models that are treated as discrete event models after some reinterpretation of system state variables, and vice versa.

An entity represents an object that requires explicit definition. An entity can be dynamic in that it "moves" through the system, or it can be static in that it serves other entities. Dynamic entities are created at time zero or at other times by an arrival event. Dynamic entities usually represent some real world object that is flowing through the system. An entity may have attributes that pertain to that entity alone. Thus, attributes should be considered as local values. A resource is an entity that provides service to dynamic entities. The resource can serve one or more than one dynamic entity at the same time. A dynamic entity can request one or more units of a resource. If denied, the requesting entity joins a queue, or takes some other action. If permitted to capture the resource, the entity remains for a time, and then releases the resource. There are many possible states of the resource. Minimally, these states are idle and busy. But other possibilities exist including failed, blocked, or starved. Entities are managed by allocating them to resources that provide service, by attaching them to event notices thereby suspending their activity into the future, or by placing them into an ordered list.

Lists are used to represent queues. Lists are often processed according to FIFO, but there are many other possibilities.

An activity, such as a service or inter-arrival time, has a duration that is initiated by an event in conjunction with the model being in a certain state. The duration of an activity is known prior to its commencement. The duration can be a constant, a random value from a statistical distribution, the result of an equation, input from a file, or computed based on the event state.

A delay is an indefinite duration that is caused by some combination of system conditions. When an entity joins a queue for a resource, the time that it will remain in the queue may be unknown initially since that time may depend on other events that will occur in the future. Discrete event simulations contain activities that cause time to advance. Most discrete event simulations also contain delays as entities wait. The beginning and ending of an activity or delay is an event.

2.2.5.5 ADVANTAGES AND DISADVANTAGES

Competition in the computer industry has led to technological breakthroughs that are allowing hardware companies to continually produce better products. What is unique about new developments in the computer industry is that they often act as a springboard for other related industries to follow. One industry in particular is the simulation software industry. As computer hardware becomes more powerful, more accurate, faster, and easier to use, simulation software does too. The number of businesses using simulation is rapidly increasing. Many managers are realizing the benefits of utilizing simulation for more than just the one time remodeling of a facility. Rather, due to advances in software, managers are incorporating simulation in their daily operations on an increasingly regular basis. Some of the advantages of conducting a simulation study are the following:

1. Simulation allows testing every aspect of a proposed change without committing resources to their acquisition. This is critical because once the decisions have been made changes and corrections can be extremely expensive.

2. By compressing or expanding time, simulation allows speeding up or slowing down events so that it can be investigated thoroughly.

3. Once a valid simulation model has been developed, new policies, operating procedures, or methods can be explored without the expense and disruption of the real system. When modifications are incorporated in the model, the effects of those changes can be observed on the computer model first.

4. Simulation allows a better understanding of the interactions among the variables that make up complex systems. Diagnosing problems and gaining insight into the importance of these variables increases the understanding of their effects on the performance of the overall system.

5. By using simulation to perform bottleneck analysis, the cause of the delays in work in process, information, materials, or other processes can be discovered.

6. Simulation studies aid in providing understanding about how a system really operates rather than depending on an individual's predictions about how a system will perform.

7. The animation features offered by many simulation packages allow “seeing” the facility or organization actually running, resulting on the detection of design flaws. Depending on the software used, the operations can be viewed from various angles and levels of magnification, even three dimensional.

8. Using simulation to present design changes creates an objective opinion, making inferences is avoided because the designs and modifications that provided the most desirable results are the ones selected. It is much easier to accept reliable simulation results, which have been modeled, tested, validated, and visually represented, instead of one person's opinion of the results that will occur from a proposed design.

9. The typical cost of a simulation study is substantially less than 1% of the total amount being expended for the implementation of a design or redesign.

10. Simulation models can provide excellent training when designed for that purpose. The team provides decision inputs to the simulation model as it progresses and can learn by their mistakes to operate better.

11. Simulation can be used to specify requirements for a system design. For example, the specifications for a particular type of machine in a complex system to achieve a desired goal may be unknown. By simulating different capabilities for the machine, the requirements can be established.

The disadvantages of conducting a Simulation include the following:

1. Building a Simulation model requires special training.

2. Simulation results may be difficult to interpret since most simulation outputs are essentially random variables, it maybe hard to determine whether an observation is a result of system interrelationships or randomness.

3. Simulation modeling and analysis can be time consuming and expensive.

4. Simulation may be used inappropriately because it is used in some cases when an analytical solution is possible, or even preferable.

Simulation software providers are working on offsetting the disadvantages just presented for improved market penetration:

1. Some providers are actively developing packages that contain models that only need input data for their operation thus avoiding special training requirements.

2. Most simulation providers have developed output analysis capabilities within their packages for performing very extensive analysis; this reduces the statistical know-how requirements on the part of the user, although he/she still must understand the analysis procedure.

3. Nowadays simulation can be performed faster; this is attributed to the advances in hardware that permit rapid running of scenarios.

2.2.5.6 STEPS IN A SIMULATION STUDY

The following steps should be followed when conducting a Simulation study:

1. Problem formulation: every simulation study begins with a statement of the problem, it is suggested that a set of assumptions are prepared by the simulation analyst and agreed to by the customer.

2. Setting of objectives and overall project plan: the objectives indicate the questions that are to be answered by the simulation study. The project plan should include a statement of the various scenarios that will be investigated. The

plans for the study should be indicated in terms of time that will be required, personnel that will be used, hardware and software requirements if the customer wants to run the model and conduct the analysis, stages in the investigation, output at each stage, cost of the study and billing procedures, if any.

3. Model conceptualization: the real world system under investigation is abstracted by a conceptual model, a series of mathematical and logical relationships concerning the components and the structure of the system. Constructing an excessively complex model will add to the cost of the study and the time for its completion without increasing the quality of the output. Maintaining customer involvement will enhance the quality of the resulting model and increase his/her confidence in its use.

4. Data collection: for each element in a system being modeled, the simulation analyst must decide on a way to represent the associated random variables. The most difficult aspect of data collection is gathering data of sufficient quality, quantity, and variety to perform a reasonable analysis. In summary, simulation analysts should be apprehensive of the validity of any data set that is derived from historical records. In identifying appropriate distributions to fit to the data, when these are not available, the analyst should use an empirical distribution to represent the data directly [2].

5. Model development: the conceptual model constructed is coded into a computer recognizable form, an operational model. This step includes inserting the required input data gathered in the previous step.

6. Model verification and validation: verification is the determination of whether the computer implementation of the conceptual model is correct and if the operational model represents the conceptual model; the analyst checks for

unforeseen mistakes during model construction. Validation is the determination of whether the conceptual model can be substituted for the real system for the purposes of experimentation. A variety of subjective and objective techniques can be used to validate the conceptual model. Simulation output can be analyzed using a finite horizon versus a steady state approach.

7. Model experimentation: simulation experiments are typically performed to compare two or more system designs. Designs of experiment approaches are desirable to reach statistically valid conclusions in an efficient manner. Response surface designs can also be applied if optimal results are wanted.

8. Documentation and reporting: if the simulation model is going to be used or modified in the future, it is necessary to understand how the simulation model operates. This is greatly facilitated by adequate documentation.

9. Simulation results implementation: communicating the proposed system changes is critical. Ideally the people affected from such changes should have participated throughout the simulation study to avoid surprises. If the customer has been involved throughout the study and the simulation analyst has followed the simulation study steps rigorously, then the chances of a successful implementation are high.

2.2.5.7 COMPUTER SIMULATION MODELS APPLICATIONS

There are a wide variety of scenarios in which simulation can be used as a means of solving problems, but it is still being used in only a small fraction of the cases where it might be applicable. Simulation has been successfully used in areas such as: Computer Systems, Communication Systems, Environmental and Energy Flows, Crop

Management and Ecological Studies, Transportation Systems, Policy Analysis, Project Planning and Control, Materials Handling and Manufacturing and Process Design.

Patel, et al. discusses the use of discrete event simulation automotive final process system in [30]. The final process system is an important part of the entire quality assurance system in the automobile manufacturing process. Operators and machines perform a series of crucial testing procedures before shipping a vehicle. Many complex factors impact the system throughput. The important ones are first time success rate, repair and service routing logic, process layout, operator staffing, capacity of testing equipment and random equipment breakdown. Discrete Event Simulation is a tool of choice in analyzing these issues in order to develop an effective and efficient process to ensure the system throughput.

The routing logic and the percentage repairs rates make the system a very complicated one. Manufacturing and Industrial Engineers need to conduct analysis to answer questions such as: (i) what is the impact of percentage repairs on the throughput, (ii) what is the best layout for the system, (iii) how many repair stations are required to meet the throughput, and (iv) what are requirements for driver and operator staffing. Discrete Event Simulation is widely used to answer these types of questions in manufacturing process design and operations. It is a highly effective tool for the design of a manufacturing system relative to its ability to meet throughput goals within constraints of operational complexity.

Rockwell's ARENA was used for model constructions and analysis in this study. As a first step, a base model was developed which depicted a system without process variation. Model verification and validation was done by structured walkthroughs of model logic, extensive use of execution traces and by reasonableness of the animation. The second model added stochastic variation, consisting of rejection probabilities, randomness of vehicle repair times, unscheduled downtime occurrences, randomness of

equipment repair times. The initial results were also discussed with manufacturing engineers and compared with previous plant performance.

Discrete Event Simulation has been widely used in the automotive industries and other manufacturing environment for a long time. The experiments in the case study demonstrate the ability to use simulation for optimizing resources and identifying constraints.

A major problem in production planning is to determine when to release products into production to meet forecasted requirements. Recently, Riaño et al. (2002) proposed the Stochastic Production Planning (SPP) model for a multiperiod, multi-product system, where the lead time to produce a product may be random. SPP determines release times for the products that ensure the requirements in each time period are met with desired probabilities at a minimum cost. Riaño et al in [35] describes how an advanced planning model like SPP can be integrated with discrete event simulation models to make the simulations more realistic and informative. They also compare the performance of the SPP model with the classical MRP (materials requirements planning) model, and with a stochastic variation of the MRP model in a simulation study.

The proposed model is a dynamic stochastic optimization planning model that determines when to release raw materials into a production system or supply chain network. The model is applicable to a variety of systems whose lead times are random variables distributions of which can be estimated under “typical” operating conditions. Because this is a dynamic approach, it is flexible to various review policies, customer quality levels and costs.

2.2.6 LEAN MANUFACTURING

Both the Lean and the Six Sigma methodologies have proven over the last twenty years that it is possible to achieve dramatic improvements in cost, quality, and time by focusing on process performance. Whereas Six Sigma is focused on reducing variation and improving process yield by following a problem solving approach using statistical tools, Lean Manufacturing is primarily concerned with eliminating waste and improving flow by following a defined approach to implement Lean principles.

The impressive results companies such as Toyota, General Electric and Motorola have accomplished have inspired many other firms to follow their example. As a result, most companies have either a Lean or Six Sigma program in place. However, using either one of them alone has limitations: Six Sigma will eliminate defects but it will not address the question of how to optimize process flow; and the Lean principles exclude the advanced statistical tools often required to achieve the process capabilities needed to be truly "lean". Therefore, most practitioners consider these two methods as complementing each other. While each approach can result in dramatic improvement, utilizing both methods simultaneously holds the promise of being able to address all types of process problems with the most appropriate toolkit [5].

The Production System Design Laboratory at the Massachusetts Institute of Technology states that "Lean production is aimed at the elimination of waste in every area of production including customer relations, product design, supplier networks and factory management. Its goal is to incorporate less human effort, less inventory, less time to develop products, and less space to become highly responsive to customer demand while producing top quality products in the most efficient and economical manner possible" [24]

The National Institute of Standards and Technology offers the following definition of lean manufacturing: "A systematic approach to identifying and eliminating waste through continuous improvement, flowing the product at the pull of the customer in pursuit of perfection.

As with most other production philosophies and management practices, lean principles cannot be universally applied. However, because they are fundamentally customer value driven, they are suitable for many manufacturing environments. There are five basic principles of lean manufacturing:

1. *Understanding Customer Value:* Value must be externally focused. Only what your customers perceive as value is important.

2. *Value Stream Analysis:* Once you understand the value that you deliver to your customers, you need to analyze all the steps in your business processes to determine which ones actually add value. If an action does not add value, you should consider changing it or removing it from the process.

3. *Flow:* Instead of moving the product from one work center to the next in large batches, production should flow continuously from raw materials to finished goods in dedicated production cells.

4. *Pull:* Rather than building goods to stock, customer demand pulls finished goods through the system. Work is not performed unless the part is required downstream.

5. *Perfection:* As you eliminate waste from your processes and flow product continuously according to the demands of your customers, you will realize that there is no end to reducing time, cost, space, mistakes, and effort.

These five lean principles work together and are fundamental to the elimination of waste. Lean benefits include reduced work in process, increased inventory turns, increased capacity, cycle time reduction, and improved customer satisfaction. According to a recent survey of forty companies that had adopted lean manufacturing, typical improvements included: (i) operational improvements of: 90 percent reduction in lead time, 50 percent increase in productivity, 80 percent reduction in work in process inventory, 80 percent improvement in quality and a 75 percent reduction in space utilization, (ii) administrative improvements such as reduction in order processing errors, streamlining of customer service functions so that customers are no longer placed on hold, reduction of paperwork in office areas, reduced staffing demands, documentation and streamlining of processing steps, reduction in turnover and the resulting costs of attrition and implementation of job standards and pre-employment profiling, (iii) strategic improvements such as reduced lead time, reduced costs, and improved quality providing opportunities for new marketing campaigns allowing your company to gain market share from competitors that are slower, have higher costs, or have poorer quality [25].

2.2.7 RELIABILITY CENTERED MAINTENANCE

Until recently, product development and manufacturing engineering have been the dominant technical disciplines in the U.S. industrial community, with operations and maintenance occupying a back seat in the priority of corporate success strategies [37]. Reliability centered maintenance (RCM) is the maintenance approach used when following a process that assesses equipment condition and determines the maintenance requirements of any physical asset in its operating context [33]. A critical methodology used by RCM is Failure Mode & Effects Analysis (FMEA), discussed in Section 2.2.4.

The RCM methodology addresses key issues not dealt with by other maintenance programs. Some common maintenance problems are:

1. *Insufficient proactive maintenance:* the largest expenditure of maintenance resources in plants typically occurs in the area of corrective maintenance.

2. *Frequent problem repetition:* because all of the corrective maintenance being made there is never enough time to know why the equipment failed or information on how to correct the deficiency permanently. The same problem keeps occurring over and over.

3. *Erroneous maintenance work:* human error is the cause of more than 50% of plant forced outages, and that some form of human error might be occurring in some locations in one of every two maintenance tasks that are performed.

4. *Sound maintenance practices not institutionalized:* collectively, industries have a great deal of knowledge and experience on how equipment should be handled. Individual plants are usually informed on only a small percentage of this collective picture, what is known is infrequently committed to a formalized process (procedures, training, etc.)

5. *Unnecessary and conservative Predictive Maintenance(PM):* it is not uncommon to examine a plant PM program, and find that five to ten percent of the existing tasks could be discarded and the plant would never know the difference. Most plants never revisit their PM tasks. A second form of this problem is that the PM task is right but too conservative, it is done too frequently.

6. *Sketchy rationale for PM actions:* absence of information on PM task origin or any documentation to clearly trace the basis for plant PM tasks.

7. *Maintenance program lacks traceability/visibility:* there is no traceable record of PM actions and costs to be found anywhere except in the heads or desks of the plant staff; if they leave, memory walks out the door with them.

8. *Blind acceptance of OEM inputs:* The original equipment manufacturer (OEM) almost always provides some form of operations and maintenance manual with the delivered equipment. Two problems arise from this: the OEM PM recommendations are not necessarily comprehensive and cost effective because these recommendations are often last-minute thoughts that tend to be aimed at protecting the manufacturer in the area of equipment warranty and the OEM sells equipment to several customers that operate the equipment in a variety of different applications.

9. *PM variability between like/similar units:* some companies assume that because sister plants use similar machinery their PM programs should be the same but each plant location tends to be its own separate entity with many of its operations and maintenance characteristics different from its sister plants within the company.

10. *Scarceness of predictive maintenance applications*: there is an entirely new area of maintenance technology that has been developing, usually described under the name of condition monitoring, some of this technology is fairly sophisticated but to a large extent has not been introduced into plants and facilities [26].

RCM recognizes that all equipment in a facility is not of equal importance to either the process, to facility needs, and safety concerns. Focusing on reliability of equipment implies recognizing that equipment design and operations differ, and that each piece of equipment will have a different probability of undergoing failure from degradation than another. A reliability-focused approach suggests structuring a

maintenance program based upon the understanding of equipment needs and priorities, as well as limited financial and personnel resources, to plan activities such that equipment maintenance is prioritized while operations are optimized.

RCM is a systematic approach of evaluating a facility's equipment and resources to best match the two needs. This results in a high degree of facility reliability and cost-effectiveness, and is highly reliant on predictive maintenance. On the other hand, RCM also recognizes that maintenance activities on equipment that is inexpensive and less important to overall facility reliability may be best left to a reactive maintenance approach, focusing both labor and financial resources on higher priority and more costly equipment [38].

The RCM approach utilizes all available maintenance tactics but the predominant strategy promoted is predictive: 0-10% Reactive, 25-35% Preventive and 45-55% Predictive. Because RCM is so heavily weighted on utilization of predictive maintenance strategies, its program advantages and disadvantages mirror those of predictive maintenance. In addition to these advantages, RCM will allow a facility to more closely match its resources to operational needs and at the same time improve both reliability and also reduce associated maintenance costs.

CHAPTER 3 – METHODOLOGY

3.1 INTRODUCTION

The following methodologies are aligned with the objectives of the thesis, specifically:

1. The need for quality strategies and tools relevant for manufacturing improvement such as identifying opportunities with and FMEA followed by the identification of sensor solutions for quality and uptime improvement.

2. The need for quality strategies and tools relevant to new process development; such as the combination of flowcharting (aiming at automated line control definition), computer simulation (to identify automated line bottlenecks) and FMEA (to assess risk and define actions to resolve weaknesses).

3. The need for Quality strategies and tools relevant to functional interaction in the pursuit of plant-wide improvement by means of defining a process for DMAIC application and defining a model to strengthen the collaboration between the production, quality and engineering functions.

3.2 QUALITY STRATEGIES AND TOOLS RELEVANT TO MANUFACTURING IMPROVEMENT

The Baxter Healthcare Division at Maricao, PR manufactures plastic bags used for the collection and processing of blood. The Kiefel machines are dedicated to the assembly and sealing of various plastic bags. Machine Failure Mode and Effects Analysis (MFMEA) is a standardized technique for evaluating equipment and tooling in order to improve operator safety, reliability and robustness. An MFMEA was developed for the Kiefel Machines with the purpose of: (i) identifying potential failure modes, (ii)

identifying the effects of the failures on the system, (iii) rating the severity of the effects, (iv) determining the causes of failures, (v) identifying robust designs or controls that will prevent the failure from occurring, (vi) identifying corrective actions required to prevent, mitigate or improve the likelihood of detecting failures early, and (vii) establishing priorities for design improvement actions. Among the main benefits that arise from performing such an exhaustive analysis are the improvement in safety, reliability, equipment uptime, productivity and quality. The methodology followed for this initiative is presented on Figure 3.

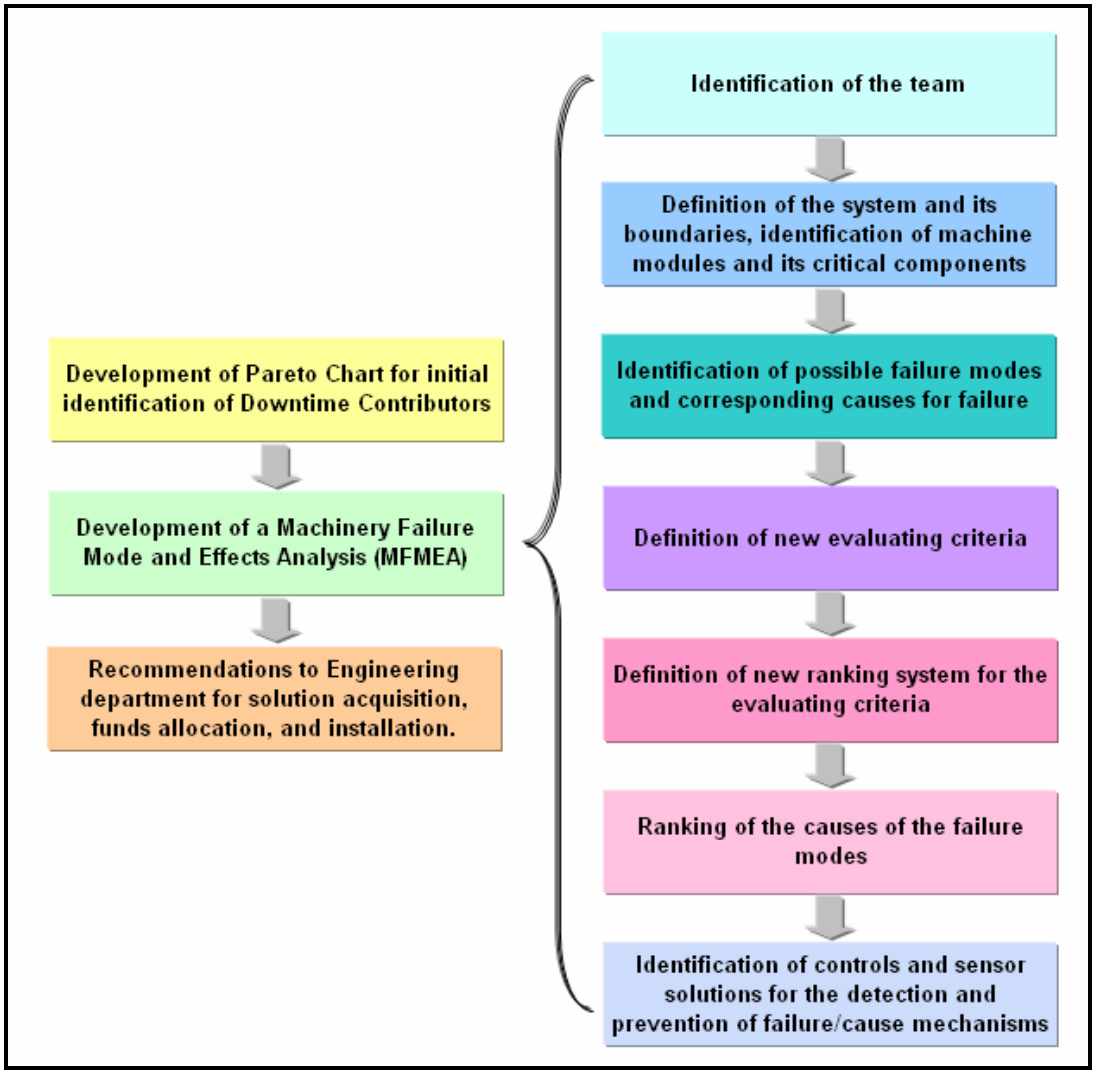

Figure 3 Manufacturing improvements by means of MFMEA methodology

An initial Pareto of downtime contributors was constructed for the Kiefel Machines in order to have an initial idea of the most critical components; it is presented on Figure 4.

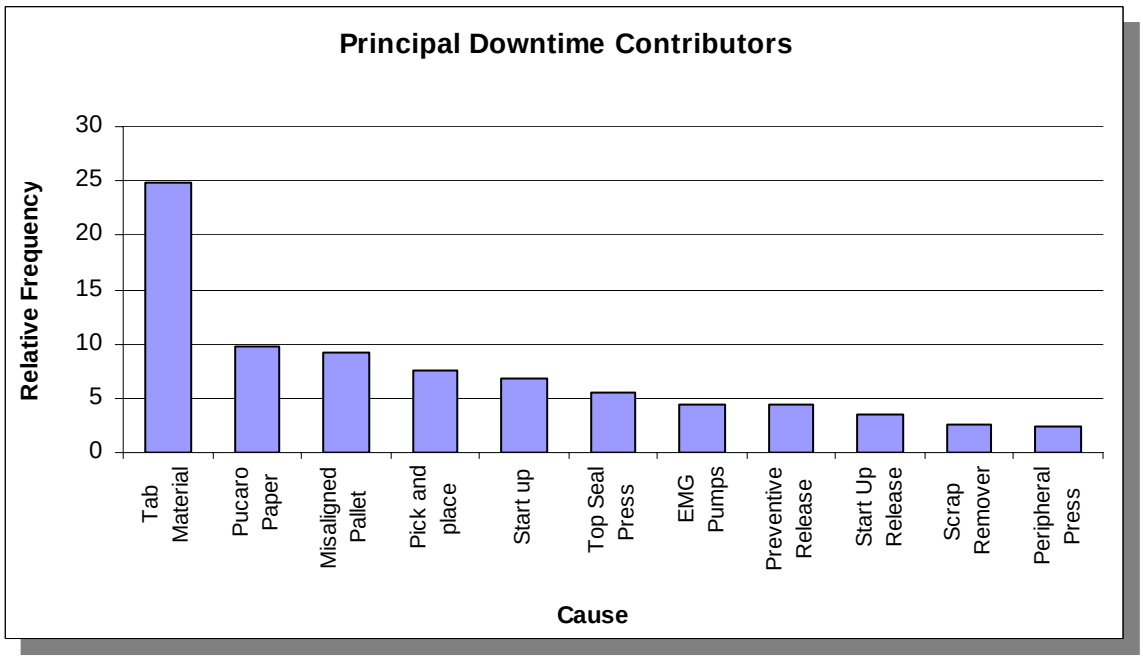

Figure 4 Pareto of Principal Downtime Contributors – June 2004

3.2.1 MACHINERY FAILURE MODE AND EFFECTS ANALYSIS

Parting from the traditional methodology for conducting MFMEA the author made a series of modifications and improvements to the evaluation and scoring phases, these modifications make the overall process easier to use and implement without eliminating fundamental aspects of the analysis. The suggested changes where presented, employed and implemented on the MFMEA initiative performed on the Baxter Healthcare Division at Maricao.

The process of conducting a FMEA can be examined in two levels of detail. The first consists of the identification of potential failures, the effects of the failures on the

performance of the system and the cause(s) of these failures. The second consists of calculating the risk of each failure. This method is intended to provide information for making risk management decisions.

The first step followed in the development of the MFMEA was to define the team that was going to be working together in this initiative; because of the extensive analysis that was going to be conducted of the machine, a vast knowledge of every mechanical and electrical aspect of the machine was needed. A group of technicians and operators was assembled and weekly meetings where scheduled in order to construct the table.

The second step corresponded to the definition of the system and its boundaries. In this case the system is the Kiefel Machine, the boundaries were defined as the machine itself, leaving out the materials fed at various stations. The Kiefel machine was divided into 17 modules (labeled A, B, C, 1, 2... 14) given the different tasks performed by the machine for assembling the bag as shown in Figure 5. Critical components were then defined for each module, as summarized in Tables 2 and 3.

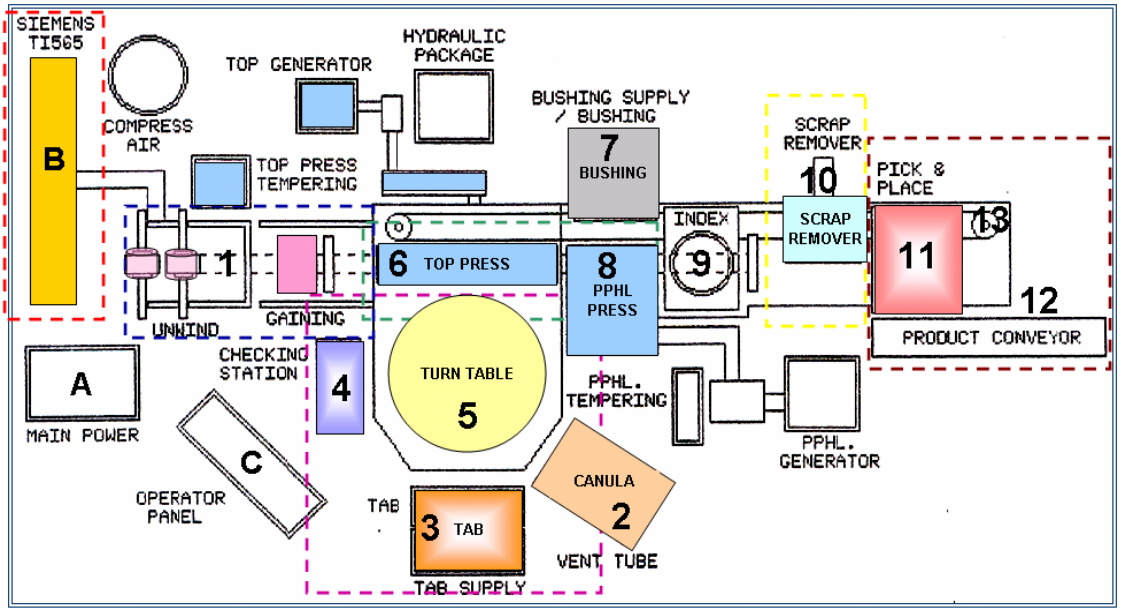

Figure 5 Top View of the Kiefel Machine with Main Modules Identified

Table 2 Modules and corresponding Critical Components

Module ID	Module	Component ID	Critical Component
A	Main Power	**A1**	Power Supply
		A2	Fuses
		A3	Contactor
		A4	24V Power Supply
		A5	Rectifier
		A6	120V Power Supply
		A7	Relays
B	PLC Siemens	**B1**	PLC
		B2	24V Input Card
		B3	120V Input Card
		B4	120V Output Card
		B5	Analog Card
C	Operator Panel	**C1**	Panel
		C2	Relays
1	Unwind and Gaining	**1.1**	Motor
		1.2	Proximity Sensors
		1.3	Rollers
		1.4	Tack Welder
		1.5	Clamp
		1.6	Dancers
		1.7	Side edge control
2	Cannula	**2.1**	Transfer Clamp
		2.2	Motor
		2.3	Transfer Tube
		2.4	Bowl Feeder
		2.5	Lamp
3	Tabs	**3.1**	Electric Transfer
		3.2	Pneumatic Transfer
		3.3	Blades
		3.4	Grippers
4	Checking Station	**4.1**	Up-down Cylinder
		4.2	Position Sensor
		4.3	Contact Sensor
5	Turn Table	**5.1**	Mandrels
		5.2	Guide/Nose piece
		5.3	Pallet
		5.4	Stripping Cylinder
		5.5	Camco motor & Transmission
		5.6	Ground contacts
		5.7	In-Out Motor
6	Top Press #1	**6.1**	Dies
		6.2	Hydraulic Cylinders
		6.3	Tempering

Table 3 Modules and corresponding Critical Components (Continued)

6	Top Press #1	**6.4**	Generator (RF Systems)
		6.5	RF Switch
		6.6	Variable Capacitor
		6.7	EMR
		6.8	Hydraulic Pumps
		6.9	Coaxial Lines
		6.10	Variable Inductors
7	Bushing	**7.1**	Transfer Clamp
		7.2	Holding Clamp
		7.3	Cylinder
		7.4	Checking Station
		7.5	Blades
		7.6	Proximity Sensors
8	Bushing Position	**8.1**	Positioning Bar
9	PPHL Press #2	**9.1**	Dies
		9.2	Hydraulic Cylinders
		9.3	Tempering
		9.4	Generator (RF Systems)
		9.5	Variable Capacitor
		9.6	EMG
		9.7	Hydraulic Pumps
		9.8	Coaxial Lines
10	Index	**10.1**	Motor & Transmission
		10.2	Arm + Cam follower
		10.3	Contactor
		10.4	Brake
		10.5	Pucaro Paper
11	Scrap Remover	**11.1**	Grippers
		11.2	Station Cylinder
		11.3	Hold down plate
		11.4	Blades
12	Pick and Place	**12.1**	Pneumatic Cylinder
		12.2	Motor and Transmission
		12.3	Pneumatic Valve
		12.4	Vacuum Pumps (6)
		12.5	Stripping Cylinder
		12.6	Retracting Bar
13	Product Conveyor	**13.1**	Belt
		13.2	Motor + Axis
		13.3	Velocity control
14	Mandrel Chain	**14.1**	Chain
		14.2	Base
		14.3	T
		14.4	Mandrel

The third phase of the analysis was to identify the potential failure mode(s) of each of the critical components of de modules. Each of the critical components was carefully examined and, based on the knowledge and previous experience of the technicians and operators, all of the possible failure modes where identified.

The fourth phase of the analysis was to identify the cause(s) of each of the failure modes. Each of the failure modes was carefully scrutinized and, based on the knowledge and previous experience of the technicians and operators, all of the causes for the possible failure modes of the critical components where determined. This was a very exhaustive and time consuming effort given the complexity of the machine and its components.

The fifth phase of the analysis corresponds to the evaluation of the failures, the effects of failures on the system and the ability of the current machine and/or process controls to detect or prevent failures. The most commonly used methodologies for performing MFMEA's suggest that the evaluation of the system should be based on three principal criteria, to be exact: (i) Severity (*S*), (ii) Occurrence (*O*), and (iii) Detect ability (*D*); which individual scores are determined on the ranking phase and later combined to obtain the risk priority number (*RPN)*, such that *(RPN = S * O * D)*

According to Baxter's Standard Operating Procedures (SOP's) the criteria traditionally used to evaluate the MFMEA are defined as follows:

1. The severity rating corresponds to the seriousness of the effect(s) of a potential equipment failure mode. Severity is comprised of three components: (i) safety considerations to equipment operator or downstream customer, (ii) equipment downtime, and (iii) defective parts. The effects on downtime and defective parts are independent events, and the team should select the highest rating that meets

the individual criteria. Table 4 presents the ranking criteria suggested for the Severity rating.

Table 4 MFMEA Severity Rating Criteria

Effect	Criteria: Severity of Effect	Ranking
Hazardous (without warning)	Very high severity ranking: affects operator, plant, or maintenance personnel, safety and/or affects noncompliance with government regulations.	10
Hazardous (with warning)	High severity ranking: affects operator, plant, or maintenance personnel, safety and/or affects noncompliance with government regulations.	9
Very high downtime or defective parts	Downtime of more than 8 hours or defective parts loss than 4 hours of production	8
High downtime or defective parts	Downtime of 4 to 7 hours or defective parts loss of 2 to 4 hours of production	7
Moderate downtime or defective parts	Downtime of 1 to 3 hours or defective parts loss of 1 to 2 hours of production	6
Low downtime or defective parts	Downtime of 30 minutes to 1 hour or defective parts loss of up to 1 hour of production	5
Very low downtime or defective parts	Downtime up to 30 minutes, no defective parts	4
Minor effect	Process parameter variability exceeds upper/lower control limits. Adjustment or other process controls need to be taken, no defective parts.	3
Very minor effect	Process parameter variability within upper/lower control limits. Adjustment or other process controls need to be taken, no defective parts.	2
No effect	Process parameter variability within upper/lower control limits. Adjustment or other process controls not needed or can be taken between shifts or at normal maintenance, no defective parts.	1

2. The occurrence rating corresponds to the likelihood that a particular failure mode will occur within a specific time period. Because process controls are used to prevent or minimize the likelihood that failure cause(s) will occur, the presence or application of the current controls should be considered when estimating this

rating. The occurrence of the failures can be based upon historical data, including the service history, complaint data, and maintenance experience with similar or surrogate parts. Table 5 presents the ranking criteria suggested for the Occurrence rating.

Table 5 MFMEA Occurrence rating criteria

Occurrence	Possible Failure Rates / Mean Time Between Failures (MTBF)	Ranking
Very High	Intermittent operation resulting in 1 failure in 10, or MTBF of less than 1 hour	10
Very High	Intermittent operation resulting in 1 failure in 100 production pieces or MTBF of 2 to 10 hours	9
High	Intermittent operation resulting in 1 failure in 1000 production pieces or MTBF of 11 to 100 hours	8
High	Intermittent operation resulting in 1 failure in 10,000 production pieces or MTBF of 101 to 400 hours	7
Moderate	MTBF of 401 to 1000 hours	6
Moderate	MTBF of 1001 to 2000 hours	5
Moderate	MTBF of 2001 to 3000 hours	4
Low	MTBF of 3001 to 6000 hours	3
Low	MTBF of 6001 to 10,000 hours	2
Remote	MTBF greater than 10,000 hours	1

3. The detect ability rating is an assessment of the ability or effectiveness of the Design and/or Machinery Controls to detect a potential cause/mechanism or to detect the potential failure mode. The team should assume that the failure mode has occurred. In the case that several controls are listed, a detect ability rating should be estimated for each control and then the best (lowest) rating should be selected. Table 6 presents the ranking criteria suggested for the detect ability rating.

Table 6 MFMEA Detect ability rating criteria

Detection	Likelihood of Detection by Design or Machinery Controls	Ranking
Absolute Uncertainty	Current controls cannot detect a potential cause and subsequent failure, or there is no design or machinery controls.	10
Very Remote	Very remote chance a design/machinery control will detect a potential cause and subsequent failure mode.	9
Remote	Remote chance a design/machinery control will detect a potential cause and subsequent failure mode, will provide indicator of imminent failure.	8
Very Low	Very low chance a design/machinery control will detect a potential cause and subsequent failure mode, will provide indicator of imminent failure.	7
Low	Low chance a design/machinery control will detect a potential cause and subsequent failure mode, will provide indicator of imminent failure.	6
Moderate	Moderate chance a design/machinery control will detect a potential cause and subsequent failure mode, will provide indicator of imminent failure and isolate the cause.	5
Moderately High	Moderately high chance a design/machinery control will detect a potential cause and subsequent failure mode, will provide indicator of imminent failure and isolate the cause. Machinery control may be required.	4
High	High chance a design/machinery control will detect a potential cause and subsequent failure mode, will provide indicator of imminent failure and isolate the cause. Machinery control may be required.	3
Very High	Very high chance a design control will detect a potential cause and subsequent failure mode. Machinery control not required.	2
Almost Certain	Design control will almost certainly detect a potential cause and subsequent failure mode. Machinery controls not required.	1

The evaluation criteria and ranking system presented above is traditionally used on the Baxter facility when performing MFMEA's. As presented, this methodology requires the team to evaluate the machine based on both objective and subjective criteria, adding some level of uncertainty to the process.

This thesis proposes a new method for the evaluation of risk priorities of failure modes in a FMEA. The evaluation phase of the MFMEA performed for the Kiefel machines was based on a different perspective, based on time, leaving out any subjectivity. The proposed method derives from the traditional methodology, the main difference is that it evaluates the causes assigned to the particular failures and incorporated an additional criteria, namely, scrap severity. The causes of each of the failure modes where evaluated according to four main criteria:

1. Occurrence - rating corresponding to the likelihood that the cause being rated is responsible the occurrence of the particular failure mode.

2. Detection - assessment of the capability of the current machinery controls to detect a potential cause or to detect the potential failure mode.

3. Downtime severity - rating corresponding to the seriousness of the cause of the failure mode and its effect on equipment downtime.

4. Scrap severity - rating corresponding to the seriousness of the cause of the failure mode and its effect on yield loss or scrap generated.

Table 7 presents each of the criteria that were used to evaluate the causes of the failures and the corresponding ranking in each of the situations. The ranking system for the evaluation criteria was developed by the author with inputs from the team; the greater part of this system was constructed based on one common denominator: time. How often are the specific causes responsible for the failures, how long does it take to detect that the specific cause is responsible for the failure and how long does it take to repair the failure based on the specific cause.

The developed ranking system facilitates the evaluation phase of the MFMEA because it provides the team with a system that is easier to interpret and to relate to.

Instead of dealing with chances and probabilities the developed ranking system provided the team with a more straightforward set of criteria in which they can match the incidences of failure with the causes that were found to cause them, how often the causes are the responsible for the specific failure (occurrence), they can match the causes with the time it took to detect them (detect ability), how much downtime it caused or how much time it took to repair it (downtime severity). Furthermore, because of the great amount of scrap the machine was generating, the criteria of scrap severity was added to rank and determine which causes were the major contributors to this fault. Table 8 presents a small portion of the MFMEA illustrating the scoring performed by machine module.

Table 7 Kiefel Machine FMEA Rating Criteria

Occurrence	Ranking	Severity & Detect ability	Ranking	Scrap	Ranking
Daily	10	One month	10	High	10
Weekly	8	Two weeks	9	Moderate	6
Monthly	6	One week	8	Low	3
Quarterly	5	Three days	7	None	1
Biannual	4	One day	6		
Yearly	2	Eight hours	5		
Every three years	1	Four hours	4		
		One hour	3		
		Thirty minutes	2		
		Five minutes	1		

After scoring and rating the causes of failures the next step was to categorize the causes according to their score. The main causes of failures that where obtained through the analysis agreed with the main causes of failures the operators have been observing through the years. This fact validated our scoring system. After this phase was completed our emphasis was directed towards trying to eliminate the primary causes of failure by identifying solutions that would detect or prevent the failures from occurring. Table 9 presents the list of failures that obtained the highest RPN's. The right side of the Table provides recommendations made to the Engineering Department that would lower the score of the failures, allowing improvements in quality and uptime.

Table 8 Section of the FMEA developed for the Kiefel machine

ID - MODULO	COMPONENTES CRITICOS	NUM. FN	FUNCIÓN	NUM. MF	MODO DE FALLA	NUM. CF	CAUSA DE FALLA	OCURR	SEVER	DETECT	SCRAP	TOTAL
1 - Alimentador de vinil	Motor	1.1	Mueve los rodillos para alimentar el plástico	1.1.1	Motor no se mueve	1.1.1.1	No hay salida del PLC	1	3	4	1	12
						1.1.1.2	Frenos eléctricos no se activan	2	3	3	1	18
						1.1.1.3	Motor defectuoso	1	4	3	1	12
						1.1.1.4	Material entra demasiado en zona del soldador de punto	10	1	1	1	10
						1.1.1.5	No hay energía	2	1	1	1	2
				1.1.2	Motor se mantiene en movimiento	1.1.2.1	Sensor del "dancer" dañado	1	2	1	3	6
	Sensores de Proximidad (4)	1.2	Detectan posición del "dancer" y cantidad de vinil en el rollo	1.2.1	No se activa	1.2.1.1	Sensor de proximidad defectuoso	1	4	1	3	12
						1.2.1.2	No hay voltage desde el PLC	1	3	4	1	12
				1.2.2	No se desactiva	1.2.2.1	Sensor de proximidad defectuoso	1	4	1	3	12
						1.2.2.2	Señal ruidosa de componente cercano (radiofrecuencia)	1	1	6	3	18
	Rodillos	1.3	Guian/mantienen la posicion del rollo de plástico	1.3.1	Vinil desalineado	1.3.1.1	Caja de bola defectuosa	1	3	2	3	18
						1.3.1.2	Rodillos desalineados	1	3	1	3	9
				1.3.2	Vinil con demasiada tensión	1.3.2.1	Caja de bola defectuosa	1	3	2	10	60
	Soldador de punto	1.4	Solda dos capas de plástico para mantener alineamiento	1.4.1	No hay soldadura	1.4.1.1	Cable roto	6	3	1	1	18
						1.4.1.2	Fusible quemado	1	2	1	1	2
						1.4.1.3	Generador dañado	1	3	3	1	9
						1.4.1.4	Material entra demasiado en zona del soldador de punto	10	1	1	1	10
				1.4.2	Soldadura en el área de la bolsa	1.4.2.1	Sensores de proximidad dañados (1,2)	1	2	2	3	12
	Abrazadera ("Clamp")	1.5	Previene la alimentación excesiva del plástico para mantener la tensión	1.5.1	Se mantiene cerrado	1.5.1.1	Cilindro defectuoso	1	3	1	1	3
						1.5.1.2	Válvula selenoide dañada	1	3	2	1	6
						1.5.1.3	Sensor de presencia de plástico defectuoso	1	2	1	1	2
						1.5.1.4	Sensor de terminación de rollo defectuoso	1	3	1	1	3
				1.5.2	Se mantiene abierto	1.5.2.1	Cilindro defectuoso	1	3	1	1	3
						1.5.2.2	Válvula selenoide dañada	1	3	2	1	6
2 - Cánula	Abrazadera de transferencia	2.1	Coloca las cánulas en los mandriles	2.1.1	El sujetador no agarra las cánulas debidamente	2.1.1.1	Cilindro defectuoso	1	4	3	3	36
						2.1.1.2	Válvula defectuosa	1	3	2	3	18
						2.1.1.3	Sujetador suelto	5	4	1	3	60
						2.1.1.4	Sujetador roto	5	4	1	3	60
						2.1.1.5	Pistón atascado	1	1	1	3	3
				2.1.2	Estación no está bien ajustada (la cánula es insertada muy profunda o muy superficialmente)	2.1.2.1	Brazo del motor suelto	5	4	2	6	240
						2.1.2.3	Estación no está bien ajustada	4	4	3	6	288
						2.1.2.4	Paleta de la mesa girtatoria necesita ajuste	5	2	3	6	180
						2.1.2.5	Sensor de proximidad defectuoso o mal posicionado	1	3	4	6	72
	Motor	2.2	Mueve la estación	2.2.1	Juego en el motor	2.2.1.1	Desgaste en engrane	1	4	3	6	72
				2.2.2	Motor no se activa	2.2.2.1	Motor defectuoso	1	4	1	1	4
						2.2.2.2	Motor no recibe señal del PLC	1	3	3	1	9
				2.2.3	Freno pegado	2.2.3.1	Bobina defectuosa	4	3	2	1	24
						2.2.3.2	No hay señal del PLC	1	3	3	1	9

Table 9 List of failures that obtained the highest RPN's

Num. Falla	Num. Modulo	Falla	Occur	Sever	Detect	Scrap	Total	Tipo de Intervención	Intervenciones Preventivas	Proyectos
3.1.2.1	3	Estación mal alineada	5	5	4	10	1000	FF	Establecer puntos de referencia en estación	"Overhaul" de la mesa rotatoria en progreso
3.1.3.1	3	Estación mal alineada	5	5	4	10	1000	FF	Establecer puntos de referencia en estación	"Overhaul" de la mesa rotatoria en progreso
6.9.1.1	6	Mala conexión en línea o tierra	4	5	7	6	840	N/A	Usar llave de torque para garantizar ajuste debido	
9.8.1.1	9	Mala conexión en línea o tierra	4	5	7	6	840	N/A	Usar llave de torque para garantizar ajuste debido	
6.5.2.2	6	Resortes rotos	5	3	4	6	360	N/A		Eliminar resortes (ya se hizo en K1)
6.6.1.4	6	Problema con unidad EMR	6	5	4	3	360	PC	Identificar variables relacionadas con unidad EMR con problema (e.g. voltaje de salida, temperatura del transformador)	Impedir ajustes a potenciómetros
6.6.2.4	6	Problema con unidad EMR	6	5	4	3	360	PC	Identificar variables relacionadas con unidad EMR con problema (e.g. voltaje de salida, temperatura del transformador)	Impedir ajustes a potenciómetros
6.10.1.2	6	Inductores dañados	5	3	4	6	360	TB		Montar "stops" para que contactos de RF del "top" no se deflexionen mas de lo apropiado
B.5.1.3	B	Descalibración	2	7	4	6	336	PC	Medir voltage con instrumento calibrado	
5.3.1.1	5	Sección vertical/horizontal desalineada	6	3	3	6	324	FF	Establecer puntos de referencia en estación	"Overhaul" de la mesa rotatoria en progreso
5.3.2.1	5	Posición vertical de la paleta desalineada	6	3	3	6	324	FF	Establecer puntos de referencia en estación	"Overhaul" de la mesa rotatoria en progreso
5.3.3.1	5	Sección vertical/horizontal desalineada	6	3	3	6	324	FF	Establecer puntos de referencia en estación	"Overhaul" de la mesa rotatoria en progreso
14.2.1.1	14	Bases dobladas/desgastadas	6	3	3	6	324	PC	Uso de sensores antes de "bushing" para monitorear posición de mandriles	
2.1.2.3	2	Estación no está bien ajustada	4	4	3	6	288	FF	Establecer puntos de referencia en estación	"Overhaul" de la mesa rotatoria en progreso
6.7.1.3	6	Unidad EMR desajustada (calibración)	5	3	3	6	270	TB	Retar calibración cada seis meses en "shutdown"	
9.6.1.3	9	Unidad EMG desajustada	5	3	3	6	270	TB	Retar calibración cada seis meses en "shutdown"	
2.1.2.1	2	Brazo del motor suelto	5	4	2	6	240	CB	Vibración	
6.4.5.1	6	Ajuste incorrecto del potenciometro ESA	5	4	2	6	240	PC		Cambio a generadores nuevos con auto-monitoreo
9.4.5.1	9	Ajuste incorrecto del potenciometro ESA	5	4	2	6	240	PC		Cambio a generadores nuevos con auto-monitoreo
5.2.2.1	5	Retiro del mandril inapropiado	4	3	3	6	216	FF	Establecer puntos de referencia en estación	"Overhaul" de la mesa rotatoria en progreso
6.4.4.1	6	Final de vida útil de placas del circuito tanque	1	6	6	6	216	RTF		
6.7.2.1	6	Mal ajuste de unidad EMG (energía excesiva o insuficiente)	4	3	3	6	216	PC	Monitorear el " start position" (sensores de posicion)	
9.4.4.1	9	Final de vida útil de placas circuito tanque	1	6	6	6	216	RTF		
9.6.2.1	9	Mal ajuste de unidad EMG (energía excesiva o insuficiente)	4	3	3	6	216	PC	Monitorear el " start position" (sensores de posicion)	
6.9.1.2	6	Particulado en línea	1	5	7	6	210	CB	Medidor de temperatura portable; entender por qué los capacitores se sobre-calientan	

A comparison was made among the traditional and new scoring system with respect to the results that would have been obtained if the traditional scoring system was used on the top offenders that resulted from the MFMEA. The results obtained are presented on table 10. Because the new scoring systems uses an additional criteria the scores for the scrap generated for each of the failures were eliminated and new totals were calculated for comparison purposes. The results obtained from the comparison demonstrate that the two methods although similar in some aspects do not converge to the same failures modes as top offenders, mainly because of the definition and time frames given to the rating criteria. The proposed method eliminates the need to guess certain intervals that may be confusing and incorporates intervals of time that are unambiguous and easier to use.

Table 10 Comparison among scoring systems

		New Scoring System						Traditional Scoring System			
Module Identification	Failure Identification	Occurrence	Downtime Severity	Detectability	Scrap Severity	Original Total	Total	Occurrence	Severity	Detectability	RPN
3	3.1.2.1	5	5	4	10	1000	**100**	5	8	4	**160**
6	6.9.1.1	4	5	7	6	840	**140**	4	8	8	**256**
6	6.5.2.2	5	3	4	6	360	**60**	5	6	4	**120**
6	6.6.1.4	6	5	4	3	360	**120**	6	8	4	**192**
6	6.10.1.2	5	3	4	6	360	**60**	5	6	4	**120**
B	B.5.1.3	2	7	4	6	336	**56**	2	9	4	**72**
5	5.3.1.1	6	3	3	6	324	**54**	6	6	5	**180**
5	5.3.2.1	6	3	3	6	324	**54**	6	6	5	**180**
14	14.2.1.1	6	3	3	6	324	**54**	6	6	5	**180**
2	2.1.2.3	4	4	3	6	288	**48**	4	7	5	**140**

Section 2.1.1 and 2.1.2 discussed the FDA's new initiative, Pharmaceutical Current Good Manufacturing Practices (CGMP's) for the 21st Century, to enhance and modernize the regulation of pharmaceutical manufacturing and product quality. Among

the main objectives of this initiative are the early adoption of new technological advances and the application of modern quality management techniques to all aspects of production and quality assurance. An outcome of this initiative is PAT, which refers to the optimal application of process analytical chemistry tools, feedback process control strategies, information management tools and product/process optimization strategies to the manufacture of pharmaceuticals.

The desired accomplishments of the analysis done on the Kiefel Machines aligned with PAT, with the failures evaluated the final step of the analysis was to incorporate sensor solutions that continuously monitor the process in order detect and control the failures before the product is finished while the machine is running. This guarantees a predefined quality at the end of the manufacturing process. These procedures are consistent with the basic principle of quality by design and could reduce risks to quality and regulatory concerns while improving efficiency as stated in the PAT description.

A variety of innovative sensor solutions were explored in order to determine what types of sensors could facilitate the detection of product defects while the product is being assembled. One of the sensor solutions explored was the use of White Light Chromatic Aberration Sensors (CHR) with the purpose of determining whether they where appropriate to measure the seal thickness of the bags right after the process occurs. The staff of Micro Photonics Inc. tested the sensors on the material of the bags and determined that the CHR worked and gave a thickness measurement of ~ 400 micron. This new breakthrough was presented to the engineering department for implementation.

An increase in equipment uptime, productivity, quality and safety are a result of the reduction of production cycle times by using on line measurements and controls, reduction of scrap by means of detecting failures early in the process, an increase in

automation to improve operator safety and reduce human errors, and promoting continuous processing to improve efficiency by eliminating a majority of the tests and inspections done to the product off-line.

3.3 QUALITY STRATEGIES AND TOOLS RELEVANT TO NEW PROCESS DEVELOPMENT

In all industries nowadays there is a constant need to reduce costs while optimizing the quality and reliability of their processes. This is the case of the Baxter Division at Maricao. This facility at the present has a manual assembly line for the manufacturing of Blood Pack Units (BPU), the purpose of the BPU Automation Project is to automatically fill and assemble BPU's in its two major configurations. Knoll Feinmechanik (Knoll) is to build an automatic machine with the flexibility and robustness to fill, assemble and stack BPU's. The construction of the machine will follow Knoll's conceptual quote while obeying all applicable Baxter specifications for the manufacturing of BPU's and also all applicable regulations and laws of the FDA. Figure 6 presents an illustration of the proposed Automation Line.

BPU's are a rather complex assembly consisting of five bags and four tubes. The challenging part of this assembly is that all components have to be arranged in a specific order on top of each order and all the tubes have to be organized according to specifications. The new automated assembly line will consist of a Two-up Principal Indexed Conveyor, seven manual loading stations, one offloading conveyor and ten principal stations.

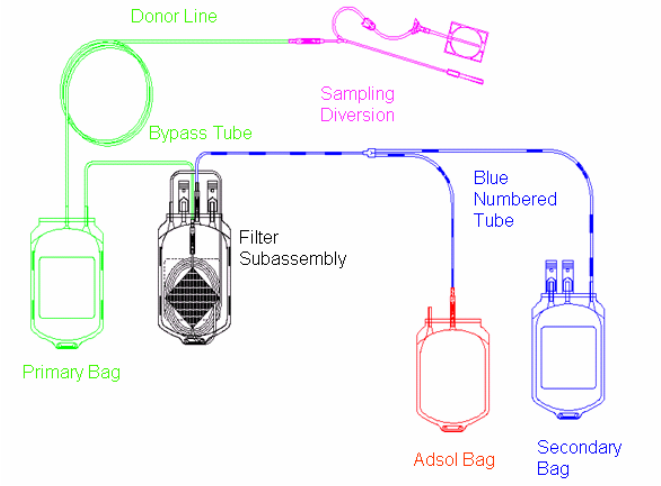

Figure 6 BPU's Components

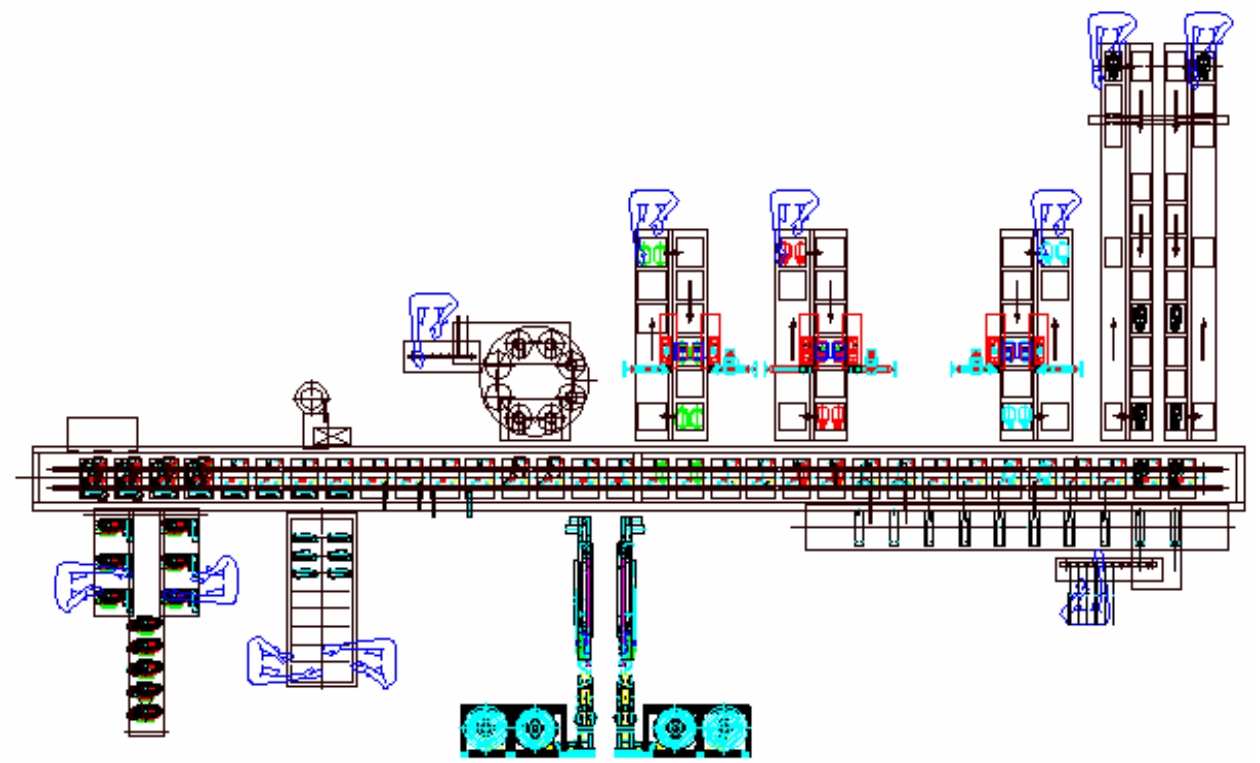

Figure 7 Top View of Proposed BPU Automated Line

3.3.1 PROCESS AUTOMATION FLOWCHART

A flowchart was constructed for the new automated process; this flowchart is a detailed visual representation of the sequence followed by the new machine to assemble the final product. The flowchart was constructed using the basic symbols and following the steps described in section 2.2.3. A brainstorming of the major process tasks was conducted and the process was inquired by asking questions such as: (i) what happens next in the process; (ii) how the process is conducted, (iii) does a decision has to be made before the next steps, etc. After the proposed process was carefully scrutinized the process flowchart was constructed using the appropriate symbols.

Because the flowchart describes the process in detail the resulting drawing is particularly large. To facilitate the reading and understanding of the process flowchart a special structure was designed and some key features where incorporated to the design. First of all the shape of the flowchart resembles the shape of the new machine, as it was presented on Figure 7. The machine consists of a main conveyor and several perpendicular loading conveyors; the process starts in the station on the right-hand side and continues in the same direction until the offloading station on the far left-hand side. This characteristic is depicted on the flowchart because the stations are visually represented in the same manner as they are arranged on the proposed automation machine. With the developed structure the reader locates the processes and stations as these are located in the actual machine.

For ease of management a color coding was established for the BPU components and is presented on Figure 6, the same color coding was used on the process flowchart symbols representing the processes related to the components. As the components are loaded and the assembly processes take place, the process symbols on the flowchart are represented by the color coding and when two or more components become a sub-

assembly the process symbol depicts the union of the components as shown on the BPU Automation Process Flowchart on Figures 8-11.

The flowchart also contains several labels that help the reader to identify the stations, positions of the processes on the main conveyor as these are performed on the pallets that carry the product through the stations.

The automation process flowchart not only details the processes being performed on all of the stations, loading and offloading conveyors; it also details the decisions that have to be made by the system in order to function appropriately such as: (i) the decision to stop the main conveyor if the product is defective, (ii) the decision not to load additional components on the main pallet if it arrives empty at a subsequent station, and (iii) the decision to disregard a move on the offloading station if the pallet of the main conveyor arrives empty.

The construction of the flowchart and the construction of the new machine stations prototypes by the Knoll team were done simultaneously; every time a station in the flowchart was completed it was presented to the Knoll group for a detailed discussion of every aspect incorporated to the proposed stations. This exercise was very successful because it helped in the visualization and understanding of the process and in the early detection of design flaws. This flowchart served as an input to the Simulation model and the PMEM done subsequently and will also be of great help for the process validation phase, the control logic development and the operator training phase.

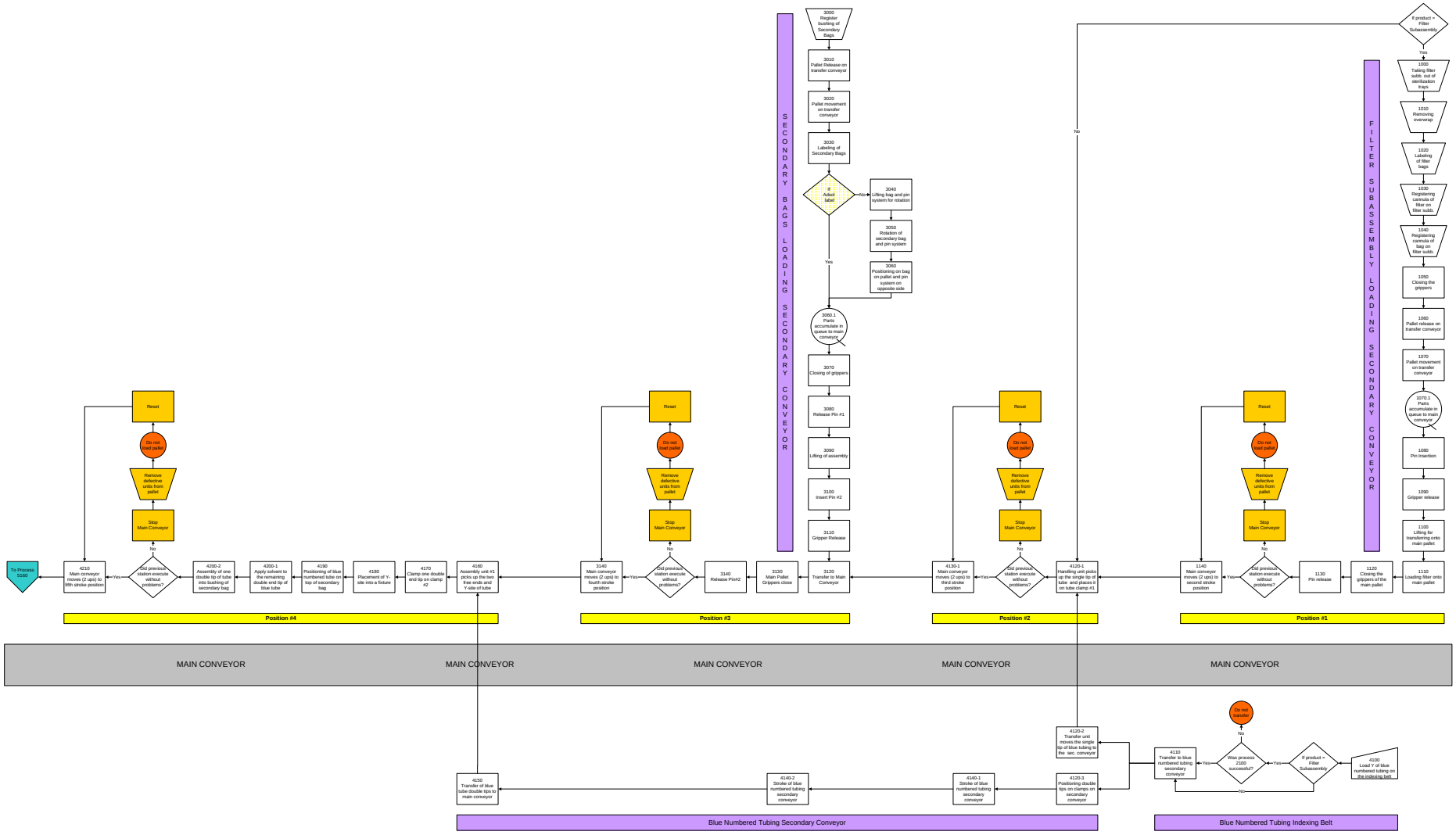

Figure 8 BPU Automation Process Flowchart, Positions 1-4 of Main Conveyor

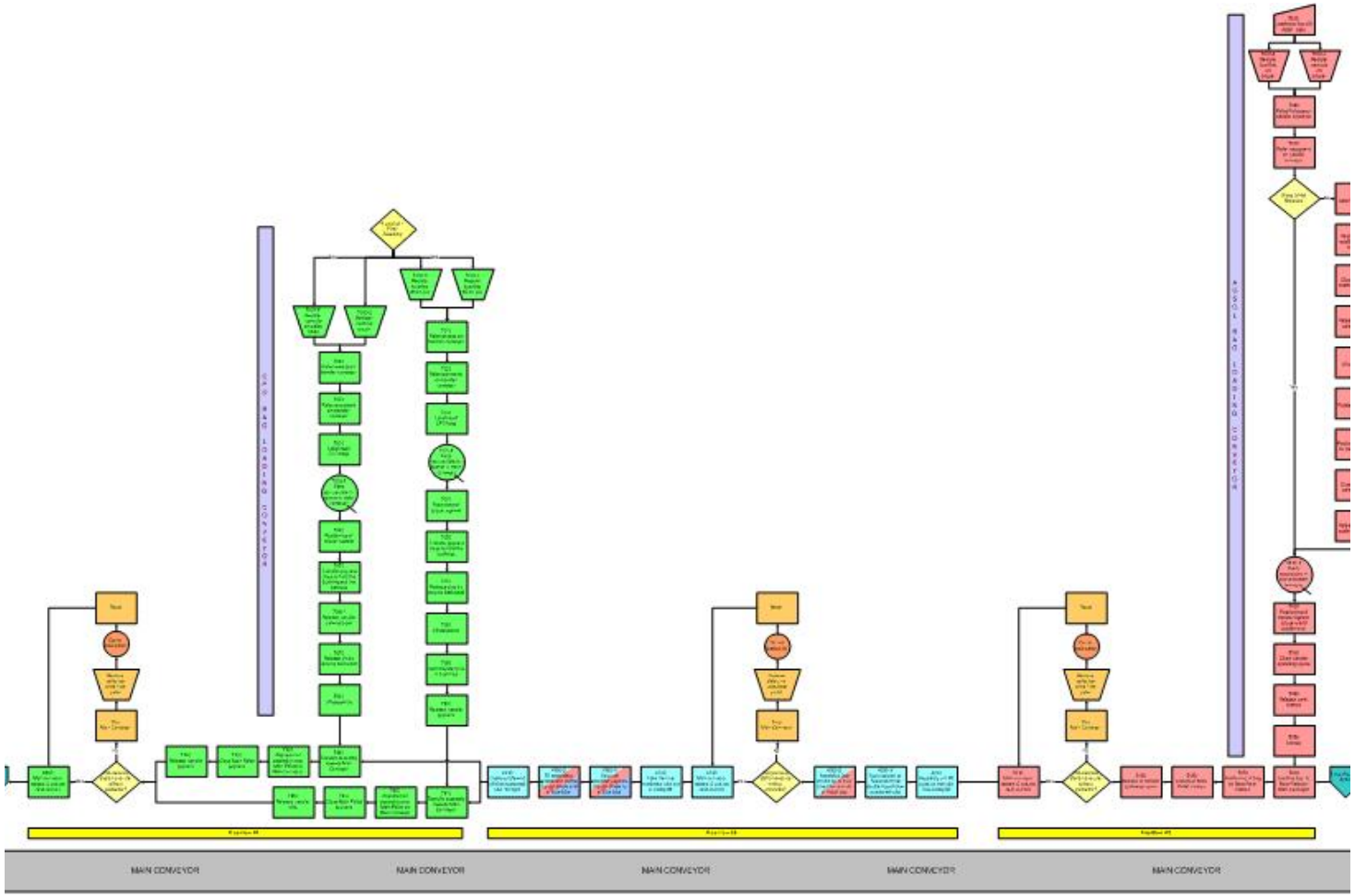

Figure 9 BPU Automation Process Flowchart, Positions 5-7 of Main Conveyor

65

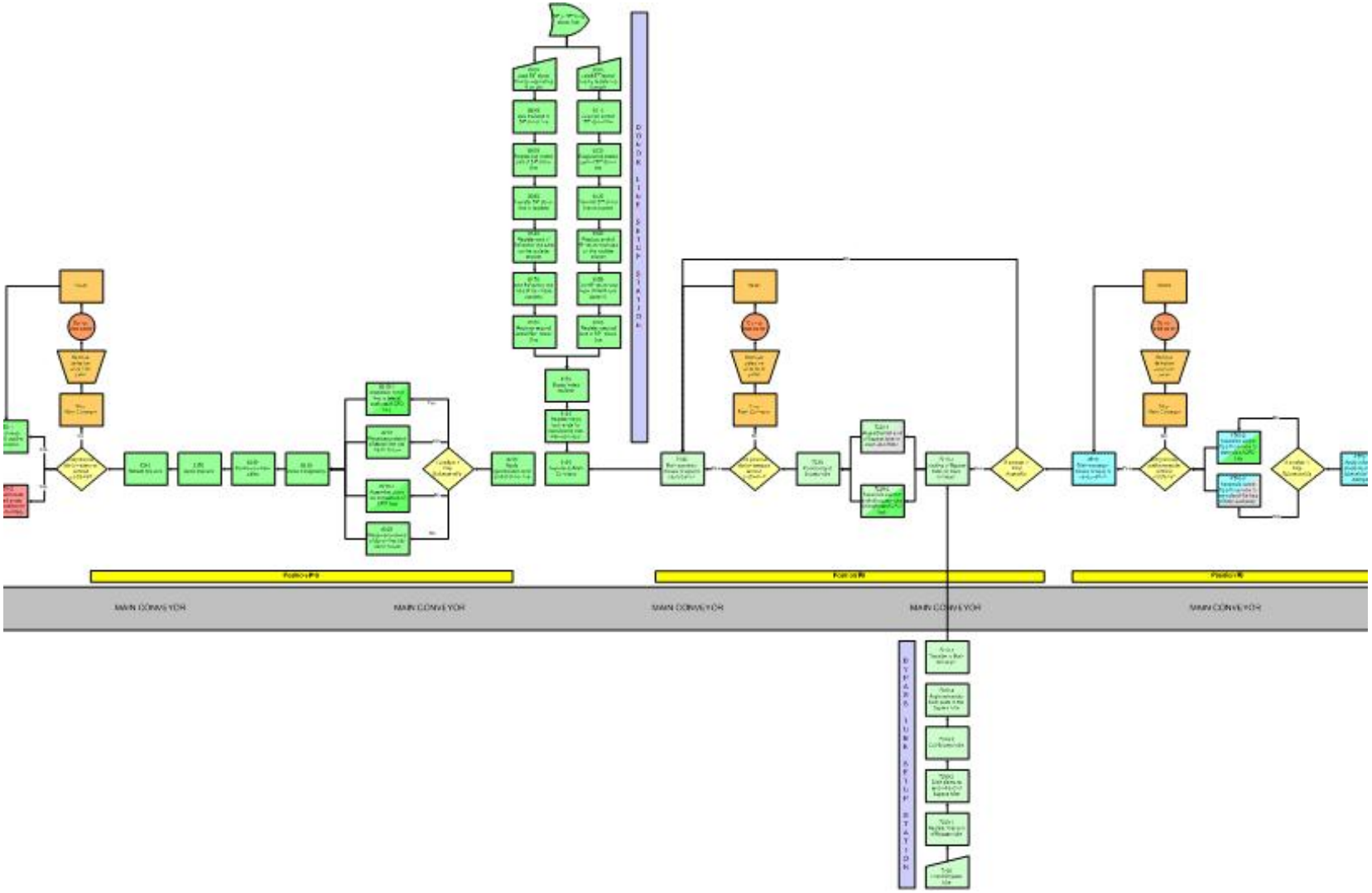

Figure 10 BPU Automation Process Flowchart, Positions 8-10 of Main Conveyor

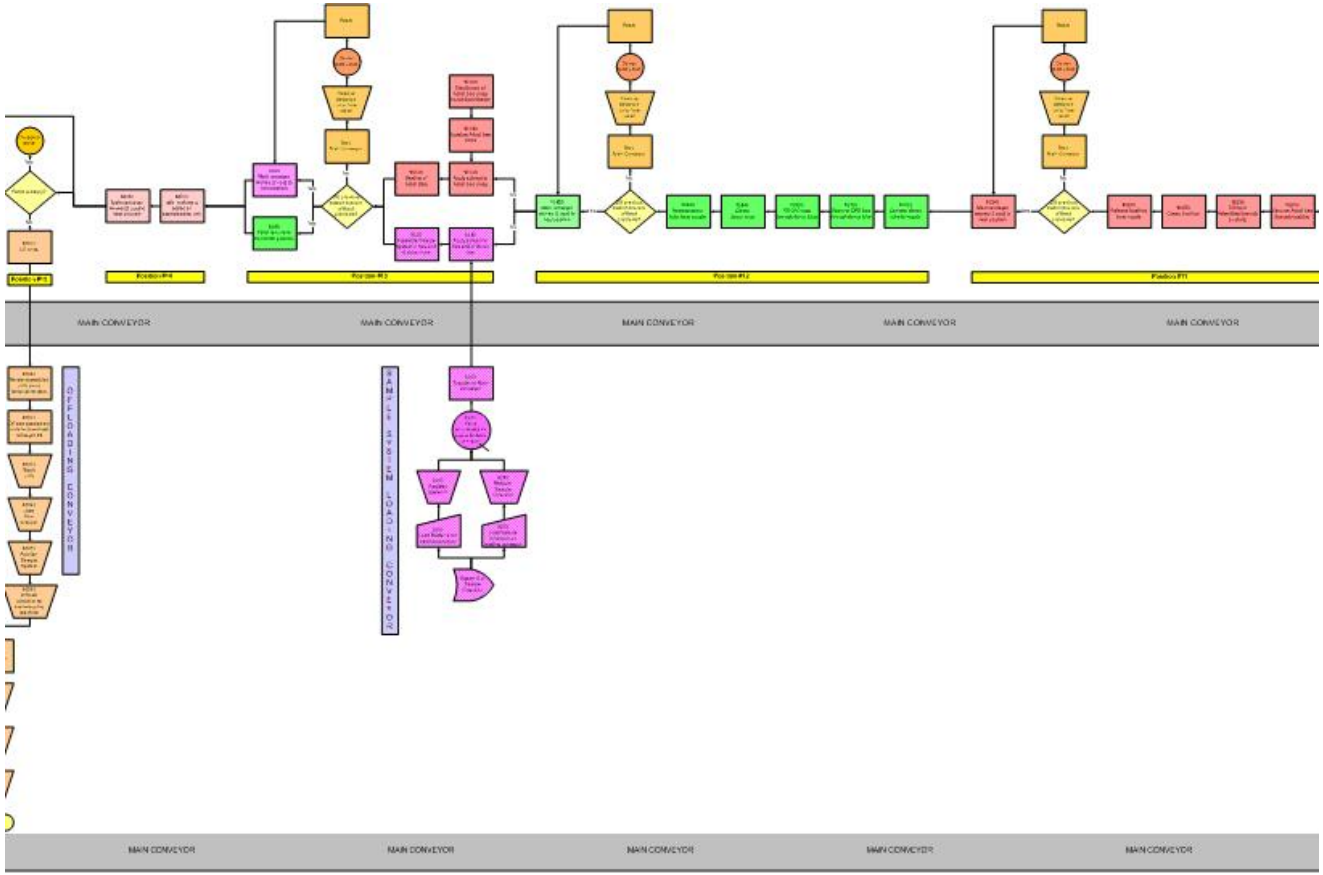

Figure 11 Automation Process Flowchart, Positions 10-16 of Main Conveyor

3.3.2 PROCESS FAILURE MODE AND EFFECTS ANALYSIS

PFMEA is a design verification activity that can help avoid process design problems before the process design is finalized. The PFMEA: (i) identifies potential process and/or product related failure modes, (ii) assesses the potential customer effects of the failures, (iii) identifies the potential manufacturing or assembly process causes and identifies process variables on which to focus controls for occurrence reduction or detection of the failure conditions, (iv) develops a ranked list of potential failure modes, thus establishing a priority system for corrective action considerations and, (v) documents the results of the manufacturing or assembly process.

After the BPU automation process flowchart was constructed work began on developing a PFMEA, the purpose of this analysis is to identify and correct weaknesses in the equipment to reduce the likelihood of process failures after the machine is released for production. By asking questions such as: (i) what could go wrong, (ii) how badly can it go wrong and (iii) what needs to be done to prevent failures among many others different approaches can be taken in order to eradicate, detect and prevent failures from occurring. This analysis goes hand in hand with the construction of the machine because it gives support to the revision of the proposed processes as well as the development of the process controls. The PFMEA table was developed with active involvement of the engineers that work in the BPU Automation Project.

The process of conducting a PFMEA can be examined in two levels of detail. The first level of analysis consists of the identification of potential failures, the effects of the failures on the performance of the system and the cause(s) of these failures. The second level of analysis consists of calculating the risk of each failure through measurements of severity, occurrence and detection. The steps that should be followed when conducting an FMEA were discussed in Section 2.2.4.

The first step followed in the development of the PFMEA was to define the team for this initiative; since this project involves the automation of an existing manual

process the team consisted of the engineers working on the project and the group in charge of the construction of the machine. The second step taken was the definition of the system and its boundaries. In this case the system is the new automation machine, leaving out the materials fed at various stations.

The proposed BPU automation process was divided into eleven separate FMEA documents for manageability and convenience according to the principal stations and/or processes. Each station/process was divided into sub-processes and a label or ID was assigned to each document, process and sub-processes. Table 10 on the following page is an example of the Filter station, the processes into which it was divided and the label or ID assigned to each of the processes.

The third step of the analysis was to identify the potential failure mode(s) of each of the sub-processes. Each of the sub-processes was carefully examined and, based on the knowledge and previous experience with similar machines/processes of the team, all of the possible failure modes where identified. The fourth step of the analysis was to identify the effects of each failure mode in the system and/or product. The fifth step was to identify the cause(s) of each of the failure modes. The causes of the failure modes range from machine failures to human error because all of the components are loaded manually. This was a very exhaustive and time consuming effort given the complexity of the machine and its components.

Table 11 Summary of Filter Station processes

Station /Process	Process Step ID	Process Step/Function
Filter Station	1000	**Removing from Trays:** The operator takes the filter subassemblies out of sterilization trays.
	1010	**Removing over wrap:** The operator removes the over wrap from the filter subassembly.
	1020	**Labeling:** Manual labeling of filter bags. See Labeling FMEA
	1030	**Registering:** Operator registers both cannulas of filter subassembly on the corresponding clamps on the pallet.
	1040	**Closing of the Grippers:** The grippers that hold the cannula close after the cannula has been registered.
	1050	**Pallet Release:** After the grippers are closed the pallet is released in order to move.
	1060	**Pallet movement:** Pallet moves forward to the next position on transfer conveyor.
	1070	**Pin insertion:** A pin is inserted into the cannulas in order to guide the transferring process.
	1080	**Gripper release:** After the pin has been inserted on the cannula the grippers release the unit.
	1090	**Lifting:** Unit lifting and fingers positioning for cassette lifting and transferring to main pallet.
	1100	**Loading:** Unit loading on main conveyor.
	1110	**Closing of the Grippers:** The grippers that hold the cannula close after the cannula has been registered.
	1120	**Pin Release:** after the grippers close to hold the unit the pin retracts from the unit.
	1130	**Clamps release:** Transfer pallet clamps open to release the cannula and bushing.
	1140	**Lifting:** Product lifting for transferring onto Main Pallet on Main Conveyor.
	1150	**Loading:** Unit loading on main conveyor.
	1160	**Positioning:** After transferring the product is lowered and positioned on the Main pallet.
	1170	**Closing of the Main Pallet Clamps:** the Main Pallet clamps close to hold the bag.
	1180	**Transferring System Grippers release:** Transferring System grippers open to release the cannula and bushing.

The evaluation phase of the PFMEA conducted for the new automation machine was performed according to the Standard Operating Procedures of the Baxter Division at Maricao. The criteria suggested are the following:

1. Severity – is an assessment of the seriousness of the effect of the potential failure mode to the process and/or product, it applies to the effect only and its criteria are presented on Table 11.

Table 12 BPU Automation Process Severity Ranking Criteria

Effect	Criteria: Severity of Effect	Ranking
Hazardous (without warning)	May endanger machine or assembly operator. Very high severity ranking applies when a potential failure mode affects safe device operation and/or involves non-compliance with government regulation.	10
Hazardous (with warning)	May endanger machine or assembly operator. Very high severity ranking applies when a potential failure mode affects safe device operation and/or involves non-compliance with government regulation.	9
Very High	Major disruption to production line. 100% of product may have to be scrapped. Device/part is inoperable, loss of primary function. Customer very dissatisfied.	8
High	Minor disruption to production line. Product may have to be sorted and a portion (less than 100%) scrapped. Device/part is operable but a reduced level of performance. Customer dissatisfied.	7
Moderate	Minor disruption to production line. A portion (less than 100%) of the product may have to be scrapped (no sorting). Device/part is operable but some Comfort/Convenience item(s) inoperable. Customer experiences discomfort.	6
Low	Minor disruption to production line. 100% of product may have to be reworked. Device/part is operable but some Comfort/Convenience item(s) operable at reduced levels of performance. Customer experiences some dissatisfaction.	5
Very Low	Minor disruption to production line. The product may have to be sorted and a portion (less than 100%) reworked. Fit & Finish/Noise & Rattle does not conform. Defect noticed by most customers.	4
Minor	Minor disruption to production line. A portion (less than 100%) may have to be reworked on-line but out-of-station. Fit & Finish/Noise & Rattle does not conform. Defect noticed by average customers.	3
Very Minor	Minor disruption to production line. A portion (less than 100%) may have to be reworked on-line but in-station. Fit/Finish/Noise & Rattle does not conform. Defect noticed by discriminating customers.	2
None	No effect.	1

2. Occurrence – is a measurement of how frequently the specific failure cause/mechanism is projected to occur. The PFMEA team should estimate the likelihood of the occurrence using Table 12. Only occurrences resulting in the failure mode should be considered for this ranking; failure detecting measures are not considered here. The following occurrence ranking system should be used to ensure consistency. The "Possible Failure Rates" are based on the number of failures, which are anticipated during the process execution. If available from a similar process, statistical data should be used to determine the occurrence ranking. In all other cases, a subjective assessment can be made by utilizing the word descriptions in the left column of the table, along with any historical data available for similar processes.

Table 13 BPU Automation Process Occurrence Ranking Criteria

Probability of Failure	Possible Failure Rates	Cpk	Ranking
Very High: Failure is almost inevitable	≥ 1 in 2	> 0.33	10
	1 in 3	≥ 0.33	9
High: Generally associated with processes similar to previous processes that have often failed	1 in 8	≥ 0.51	8
	1 in 20	≥ 0.67	7
Moderate: Generally associated with processes similar to previous processes, which have experienced occasional failures, but not in major proportions.	1 in 80	≥ 0.83	6
	1 in 400	≥ 1.00	5
	1 in 2,500	≥ 1.17	4
Low: Isolated failures associated with similar processes.	1 in 15,000	≥ 1.33	3
Very Low: Only isolated failures associated with almost identical processes.	1 in 150,000	≥ 1.50	2
Remote: Failure is unlikely. No failures ever associated with almost identical processes.	1 in 1,500,000	≥ 1.67	1

3. Detection - is an assessment of the probability that the proposed process controls will detect a potential cause/mechanism, or the probability that the proposed process controls will detect the subsequent failure mode, before the part or component leaves the manufacturing operation or assembly location. A “1” to ‘10” scale as shown in Table 13 shall be used by PFMEA team to rate the effectiveness of detection methods. Assume the failure has occurred and then assess the capabilities of the proposed “Process Controls” to prevent shipment of the part having this failure mode or defect. Do not automatically presume that the detection ranking is low because the occurrence is low, but do assess the ability of the process controls to detect low frequency failure modes or prevent them from going further in the process. Random quality checks are unlikely to detect the existence of an isolated defect and should not influence the detection ranking. Sampling done on statistical basis is a valid detection control.

Table 14 BPU Automation Process Detection Ranking Criteria

Detection	**Criteria: Likelihood the Existence of a Defect will be Detected by Process Controls Before Next Process, or Before the Component Leaves the Manufacturing or Assembly Location**	**Ranking**
Almost Impossible	No known control(s) available to detect the failure mode.	10
Almost Remote	Very remote likelihood control(s) will detect the failure mode.	9
Remote	Very remote likelihood control(s) will detect the failure mode.	8
Very Low	Very low likelihood control(s) will detect the failure mode.	7
Low	Low likelihood control(s) will detect the failure mode.	6
Moderate	Moderate likelihood control(s) will detect the failure mode.	5
Moderately High	Moderately high likelihood control(s) will detect the failure mode.	4
High	High likelihood control(s) will detect the failure mode.	3
Very High	Very high likelihood control(s) will detect the failure mode.	2
Almost Certain	Control(s) almost certain to detect the failure mode. Reliable detection controls are known with similar processes.	1

Because of the large size of the FMEA documents some modifications were made to the original format in order to make the document easier to read and interpret. The new design groups all of the causes at the top of the document, providing a table (two dimensional) format. This reduces the length of the document significantly without eliminating information and creates a matrix in which the effects are coupled with the causes and the resulting Risk Priority Number is displayed. Table 14 illustrates the new FMEA document format for the Filter Station. PFMEA's are living document and changes to it are imperative in the construction, implementation and validation phases of the new automated machine, a Visual Basic program was made in order to facilitate the updating of the effects, causes and scoring of each. This program reads the effects and causes of failures from a list and assigns the severity and occurrence scores accordingly when the user selects the *update* push button included in each of the documents; an illustration of the VBA routine for the Donor Line station is presented on Figure 12.

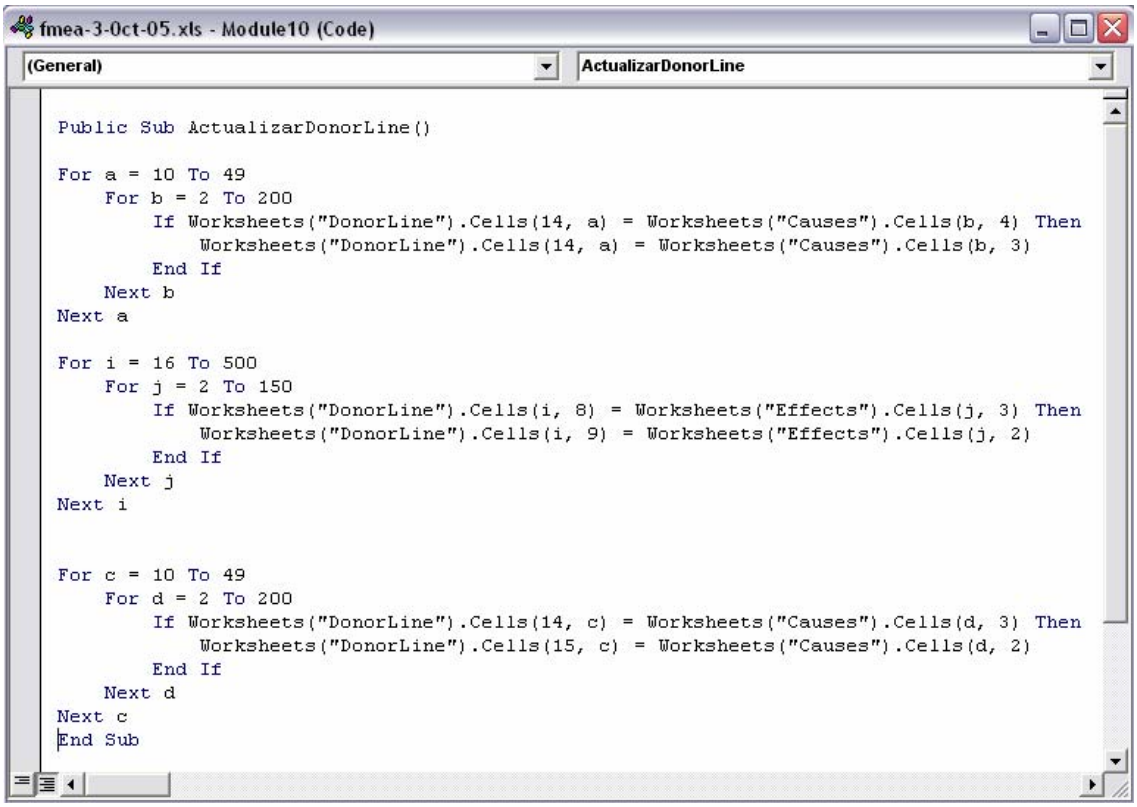

Figure 12 PFMEA VBA routine for the Donor Line Station

Table 15 Section of New FMEA document format for the Filter Station

Process Step ID	Process Step/Function	Failure ID	Potential Failure Mode	Current Process Controls	Detection	Effect ID	Potential Effect(s) of Failure	Severity	Potential Cause(s) / Mechanism of Failure																																				Occurrence
									Incorrect product positioning by operator	Not enough time to perform the operation	Cannula and/or bushing out of specifications	Misaligned cannulas	Skirt out of specifications	Coiling from previous process is defective	Bent grippers (pallet, lifting system, transferringsystem and/or rotating system)	Grippes do not close appropriately	Incorrect pallet on conveyor	Misaligned gripper/pallet system	Misaligned/damaged pallet on conveyor	Misaligned pin/pallet system	Coiling from previous process is defective	Pick and Place system misaligned with pallet	Incomplete pin movement	Bent Pin	Missing Pin	Misaligned clamp/pallet system	Bent clamp	Product obstructing pallet trajectory	Product interference on pin moving trajectory	Product interference on gripper opening/closing trajectory	Product interference on lifting system moving trajectory	Product interference on conveyor transfer section	Product interference on finger-pallet trajectory	Product interference on clamp opening/closing trajectory	Clamps and/or grippers interfere with lifting system trajectory	Mechanical Failures (Grippers with uneven surfaces, no parallelism,close too tightly and/or closed during loading)	Mechanical Failures: loss of pressure, grippers fail to open and release product, failing conveyor, lifting system and/or fingers.	Mechanical Failures (Clamps close too tightly, have uneven surfaces/contours and/or no parallelism)	Bent fingers	Fingers cannot access pallet	Incomplete system rotation (X and/or Y axis)	Incomplete system translation	Material becomes loose due to rotation and/or translation inertia	PM coming from machine on product	No synchronization between conveyors	
									5	3	2	3	3	2	2	3	1	3	2	2	2	1	1	2	2	2	2	2	3	2	1	3	3	3	2	2	2	2	3	2	2	3	3	1	
1000	**Removing from Trays:** The operator takes the filter subassemblies out of sterilization trays.	1000.1	Operator doesn't take the filter subassemblies out of the sterilization trays		1	1000.1.1	Product isn't loaded onto transfer conveyor	3																																					
						1000.1.2	Variation on the state of the buffer	1																																						
						1000.1.3	Buffer depletion	7																																						RPN
1010	**Removing overwrap:** The operator removes the overwrap from the filter subassembly.	1010.1	Operator doesn't remove the overwrap from the filter subassembly		1	1010.1.1	Product isn't loaded onto transfer conveyor	3																																					
						1010.1.2	Variation on the state of the buffer	1																																						
						1010.1.3	Buffer depletion	7																																						
1020	**Labeling:** Manual labeling of filter bags. See Labeling FMEA																																											
1030	**Registering:** Operator registers both cannulas of filter subassembly on the corresponding clamps on the pallet.	1030.1	No registering		1	1030.2.1	Product isn't loaded onto transfer conveyor	3																																					
						1030.2.2	Incorrect loading of product onto transfer conveyor	3																																					
						1030.2.3	Variation on the state of the buffer	1																																					
						1030.2.4	Buffer depletion	7																																					
						1030.2.5	Product on an undetermined position	3																																					
		1030.2	Incorrect registering		1	1030.1.1	Product isn't loaded onto transfer conveyor	3																																					
						1030.1.2	Incorrect loading of product onto transfer conveyor	3																																					
						1030.1.3	Variation on the state of the buffer	1																																					RPN
						1030.1.4	Buffer depletion	7																																					
						1030.1.5	Product is damaged by process: broken or bent cannulas	8																																					
						1030.1.6	Product on an undetermined position	3																																					
						1030.1.7	Prevents proper function of posterior processes	3																																					
		1030.3	Loading time takes longer than expected		1	1030.3.1	Variation on the state of the buffer	1																																					
						1030.3.2	Buffer depletion	7																																					
						1030.3.3	Prevents proper function of posterior processes	3																																					

3.3.3 SIMULATION

Simulation is a powerful tool employed on the analysis of new system designs, modifications to existing systems and proposed changes to operating rules among others. Simulation can be used to specify requirements for a system design; for example, when the specifications to achieve a desired goal for a machine in a complex system are unknown the requirements can be established by simulating different capabilities for the machine. Computer simulation models where comprehensively discussed on section 2.2.5. For the BPU automation machine a simulation model was developed in order to establish the required length of the loading conveyors with respect to the available space, loading times, cycle time and buffer length. The simulation model was developed using Arena 5.0 by two students attending the advanced course in Production Control [40].

The Simulation Phase of the BPU automation project began with a meeting of the team with the client, in our case the Automation Project Leader, to conduct the problem formulation, setting of objectives, determination of performance measures, details of modeling assumptions and data requirements. The modeling assumptions are the foundation of the conceptual model because after they are established the model is constructed around them; among the principal modeling assumptions were the following:

1. The Filter Loading Station has a bridge in order to get through one side of the machine to the other, the bridge delays 20 seconds in opening/closing. There cannot be any units on top of the bridge while it is being used;

2. The Main Conveyor stops when there is a failure and/or defect on the product in order for the damaged product to be removed or the failure to be fixed;

3. The transfer time of the main conveyor lasts 0.7 seconds per cycle;

4. The main conveyor rest period lasts 3.5 seconds and the work added at each station could not exceed this time;

5. The failure rate for every station is of 0.01% or 1 in every 10,000 main conveyor cycles.

6. One entity will be defined as two BPU's because all the processes are preformed on two units at a time.

The next step in the simulation study was the data collection. As with conducting any study one of the most important steps is gathering the input data for the model; if the data is not accurate the results obtained will not be correct even if the model constructed does represent truthfully the real system. Because this is a new process and the machine is being constructed some of the required data, specifically the manual loading times for the components were not available. When the required data is not available some data sources that are commonly used are databases, manual records, automatic data collection systems, sampling studies and time studies among others.

MOST (Maynard Operation Sequence Technique) is a work measurement technique that allows a variety of repetitive work ranging from manufacturing to administrative activities to be measured with ease and accuracy. This enables the engineers and analysts to expose unproductive methods of work and rectify problems at the workplace as they arise at the design stage. Using MOST the analyst can accurately achieve work standards, capacity analysis, manpower planning, workplace design and job activity analysis for re-organization and allocation for work balancing, cost estimating for existing and new processes amongst others [42].

In order to obtain the required input data for the BPU automation machine simulation model the team decided to tape the operators performing similar activities and calculate the loading times using MOST. The resulting loading times are presented on Table 15.

Table 16 Loading Times calculated using MOST

Manual Station Number	Number of Operators	TMU's	Loading time (2 units)
1	2	120	4.32
2	1	60	2.16
3	1	80	2.88
4	1	110	3.96
5	1	110	3.96
6	1	60	2.16
7	2	80	2.88

After the manual loading times where calculated using MOST, the resulting loading times where analyzed, the stations that exceeded the allowable loading time of 3.5 seconds where attuned and the deviation was estimated using the coefficient of variation $(s/\bar{x})$. The loading times where replicated using a normal distribution, resulting times are presented on Table 16.

Table 17 Input loading data used in the Simulating Model

Manual Station Number	Number of Operators	Means	Standard Deviation
1	3	3.50	0.7584
2	1	2.16	0.4681
3	1	2.88	0.6241
4	1	3.96	0.8581
5	1	3.96	0.8581
6	1	2.16	0.4681
7	2	2.88	0.6241

For each manual station the simulation was run varying the length of the loading conveyors which connect the manual stations to the main conveyor. The selected lengths

for the conveyors could vary from 90 to 390 centimeters because each traveling pallet measures 30 centimeters long. The best alternatives for conveyor lengths are presented on Table 17.

Table 18 Resulting lengths for loading conveyors

Manual Station No.	Length of conveyor (cm)	Buffer length (pallets)
1	210	7
2	270	9
3	270	9
4	270	9
5	270	9
6	270	9
7	270	9

The results obtained from the simulation imply that the most critical station is Station 1; this is why adding a third operator should be considered. The manual loading times limit the production of the line, if another operator is added to loading station 1 the loading times for stations 3, 5 and 6 should be reduced in order to maximize the production of the automated line. Table 18 presents different modifications proposed for loading station 1.

Table 19 Proposed modifications for loading station 1

Number of operators	Loading Time	Production Efficiency
2	Norm(4.32,0.9341)	83.49%
2	Norm(3.96,0.8581)	89.81%
2	Norm(3.50,0.7584)	99.17
3	Norm(4.32,0.9341)	100%

The benefits of running the simulation for the BPU automation project can be summarized as: (i) the need to add a third operator in station 1 to feed enough parts to the main conveyor, (ii) the determination of feeding conveyor lengths (210 cm for station 1 and 270 cm for others), and (iii) a resulting production efficiency of 100% for the main conveyor.

3.4 ACCELERATING THE RESOLUTION OF CROSS-FUNCTIONAL CHALLENGES THROUGH THE DMAIC METHODOLOGY

DMAIC refers to a data-driven quality strategy for improving processes, and is an integral part of the Baxter Division at Maricao Six Sigma Quality Initiative. The DMAIC methodology divides the logical phases of a project and tasks to be achieved into various functional steps for convenience and robustness; these steps are described in detail on section 2.2.2. Each step in the cyclical DMAIC process is required to ensure the best possible results. The Baxter Division at Maricao has a specific process for the verification and approval of project proposals, the Master Change Control (MCC) process. An initiative was created with the purpose of improving the time it takes to approve a project proposal. The DMAIC methodology was used in order to achieve improvements in the existing process.

The project approval process can be summarized on the following steps:

1. The project leader presents the project at the project review meeting to the members. Representatives from areas such as engineering, quality, manufacturing and marketing participate in deciding the course of action for the project in question.

2. The project leader prepares the documentation, permits and/or signatures depending on the area(s) that are affected or involved. Because of the wide range of changes that can take place in a manufacturing environment (such as changes to product, manufacturing processes, and/or to the manufacturing facility) and because we are dealing with a regulated environment this procedure is extremely rigorous and extensive.

3. The project leader formally presents the project at the Plant Review Board (PRB), and

4. The project is presented at the Division Review Board (DRB) for approval or notification depending on the nature and magnitude of the project.

3.4.1 DEFINE PHASE OF THE DMAIC METHODOLOGY

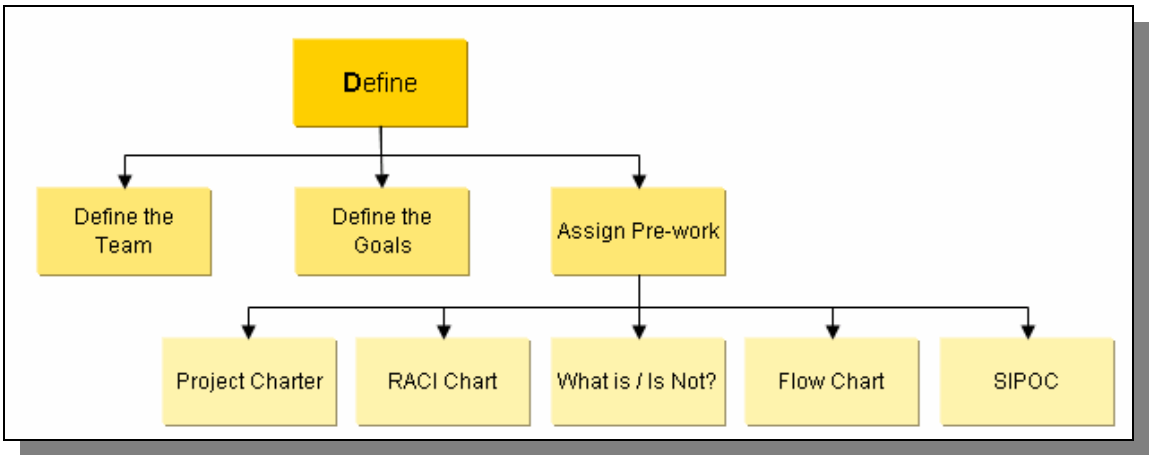

Figure 13 Define Phase of the DMAIC Process

The Define phase followed on this initiative is summarized on Figure 13 presented above. In dealing with the project, the first step consisted in defining the team that was going to be working on the initiative, defining the specific goals of the initiative and conducting pre-work that was going to help define more precisely the initiative along with the current status of the process. Since this is a process that involves mostly all of the functional areas of the plant, the selected team must include representatives of all of these areas. The selected team included among others executive sponsors, project sponsor, process owner and green, black and master black belt roles.

As was previously stated the main goal of the initiative was to reduce the time of the approval process, this is a very straightforward statement but in order to achieve it

the current process had to be carefully stated and analyzed. In order to do this various defining tools where used, such as constructing a Project Charter, current RACI Chart, What is/Is not exercise, current Flow Process Chart and SIPOC diagram.

A project charter is the first step in the Six Sigma Methodology and takes place in the define phase. The project charter concisely describes the project, resources and boundaries; it stated and answered the following premises:

1. Business Impact: (i) why should the project be done and what are the benefits, (ii) what is the quantified value of the project, and (iii) how does this project align with business strategy?

2. Problem Statement: (i) what problem is the company or the customers experiencing, and (ii) what is wrong or not working?

3. Goal Statement: (i) what is going to be done and delivered, (ii) what are the improvement objectives and targets, and (iii) how success will be measured and what specific parameters will be measured?

4. Project Scope: (i) what are the boundaries of the initiative, (ii) what isn't within the scope, and (iii) what authority does the company have?

5. Project Plan: (i) when is the work going to be completed, and (ii) what are the major milestones?

6. Team Selection: (i) who are the team members, (ii) what is their role, and (iii) how much of their time will be dedicated to the project?

A RACI Chart (Responsible-Accountable -Consulted-Informed) is a simple tool that is used for identifying roles and responsibilities during an organizational change process. In more detail: the person(s) who is responsible is the one who owns the project; the person(s) who is accountable is to whom "R" is accountable and who must approve the work before it is effective; the person (s) who is supportive can provide resources or can play a supporting role in implementation; the person(s) who is to be consulted has information and/or capability necessary to complete the work; and the person(s) who is to be informed must be notified of results. A RACI Chart was constructed by first identifying all the activities of the current process and listing them, followed by the identification of roles, and the elimination of overlaps and gaps in the activities. The RACI Chart that was developed for the MCC approval process is presented on Table 19.

Table 20 RACI Chart for the MCC process

	Prepare and complete Risk Analysis	Initiate Addendun 1 of 6, page 1 of 4 of MCC (Include feasibility summary & List of FG Affected)	Justification Document	Initiate Addendun 1 of 6, page 2 of 4 of MCC	Marketing Concurrence Signature	Medical or Clinical Affairs Concurrence signature	Environmental Assessment	Follow FE 0101-160 forward to Latex Db Admin before Foc Production	Follow FE 0101-137 Initiate and include form in change package	Document notification to purchasing or IPSO Plant	Document notification to service organization and/or customer training groups	Division RA notified and documented	ERC Reviewed and modified if warranted. Notify Div. RA. (Documented)	Follow FE 0101-167 for Dry Kits and SP 01-01-001 for Drugs/Solutions	Actualize control plans include evidence on Change Package	Initials list of inputs, outputs and acceptance criteria	Effectiveness confirmation plan	Plant Review Board Approvals	Reviewed & approved list of inputs, outputs and acceptance criteria, effectiveness and action items	Division Review Board	DRB - Reviewed & approved list of inputs, outputs and acceptance criteria, effectiveness and action items	Verifications, validations and action items conducted	Required documents, approvals and notifications collected	Complete design verification review
Project Leader	R	R	R	R	A	A	A	R	R	R	R	R	R	R	R	R	R	R	R	R	R	A/R	R	R
RB Leader	A							A	A	A	A	A	A	A	A	A	A	A	A	A	A		A	A
Manufacturing	C															C	C	R				C		
Engineering	C														R/C	C	C	R				C		
QE	C														R/C	C	C	R		R		C		
QA	C														R/C	C	C	R				C		
Regulatory												R/A	R/A			C	C	R				C		R
R&D																C	C	R		R		C		
Sterility Assurance																AR				R				
Division R&QE																AR				R				
Stability																AR				R				
Medical						R										AR				R				
Marketing					R											AR				R				
Division RB Leader																I	I			R	R			
EHS							R																	

A what is/ is not exercise was conducted; it consists of a series of questions with respect to what, when, where and the extent of the defect/problem of the process. The questions are divided in two sections, the "what is" section contains simple questions such as: what process has the defect, what is the defect, where is the defect in the process, and if there any pattern among others. On the contrary the "is not" questions ask the opposite set of questions such as: which similar processes can have the defect but don't, where the defect could be but isn't, and how many objects may have the defect but don't, among others with the purpose of trying to capture more details that might not be noticed at first glance. The guide questions that were used for this exercise are presented on Figure 14.

	Is	Is Not
What?	•What process has the defect? •What is the defect?	•Which similar objects can have the defect but don't? •What other defects could be but aren't?
Where?	•Where is the defect geographically? •Where is the defect in the process? •Where is the defect in the process? •Where else is the defect?	•Where the defect could be but isn't? •Where else in the object could the defect be but isn't? •Where else could the defect be in the process but isn't? •Where else could the defect be observed but isn't?
When?	•When the defect was first observed? (hour/date) •Since then, when it was observed? •Is there any pattern? •When in the useful life of the object the defect was observed?	•When could the defect have been first observed but wasn't? •When else could the defect have been observed but wasn't? •When in the useful life of the object the defect have been observed but wasn't?
Extent	•How many objects have the defect? •What is the size of the defect? •How many defects are observed in one object? •What is the tendency?	•How many objects may have the defect but don't? •What other the size could the defect have? •How many defects could have been observed in one object but aren't? •What other tendencies could have been observed bur aren't?

Figure 14 What is/Is not guide questions

A process flowchart was developed for the current process in order to have a more detailed description of all the procedures and ramifications that result from process changes. Because of the diversity of changes that have to be taken into consideration there are a variety of courses of action that can be taken. The first major ramification of the process is whether a MCC procedure is the course of action that has to be taken instead of some other more straightforward procedure. The second is whether the proposed change requires the approval of the DRB or just the notification. After these major ramifications the process keeps dividing with respect to the type of documentation required and which entities have to be notified such as the client, marketing and/or the Red Cross among many others. This tool became very useful for understanding and identifying opportunities for improvement; a section is presented on Figures 15-16.

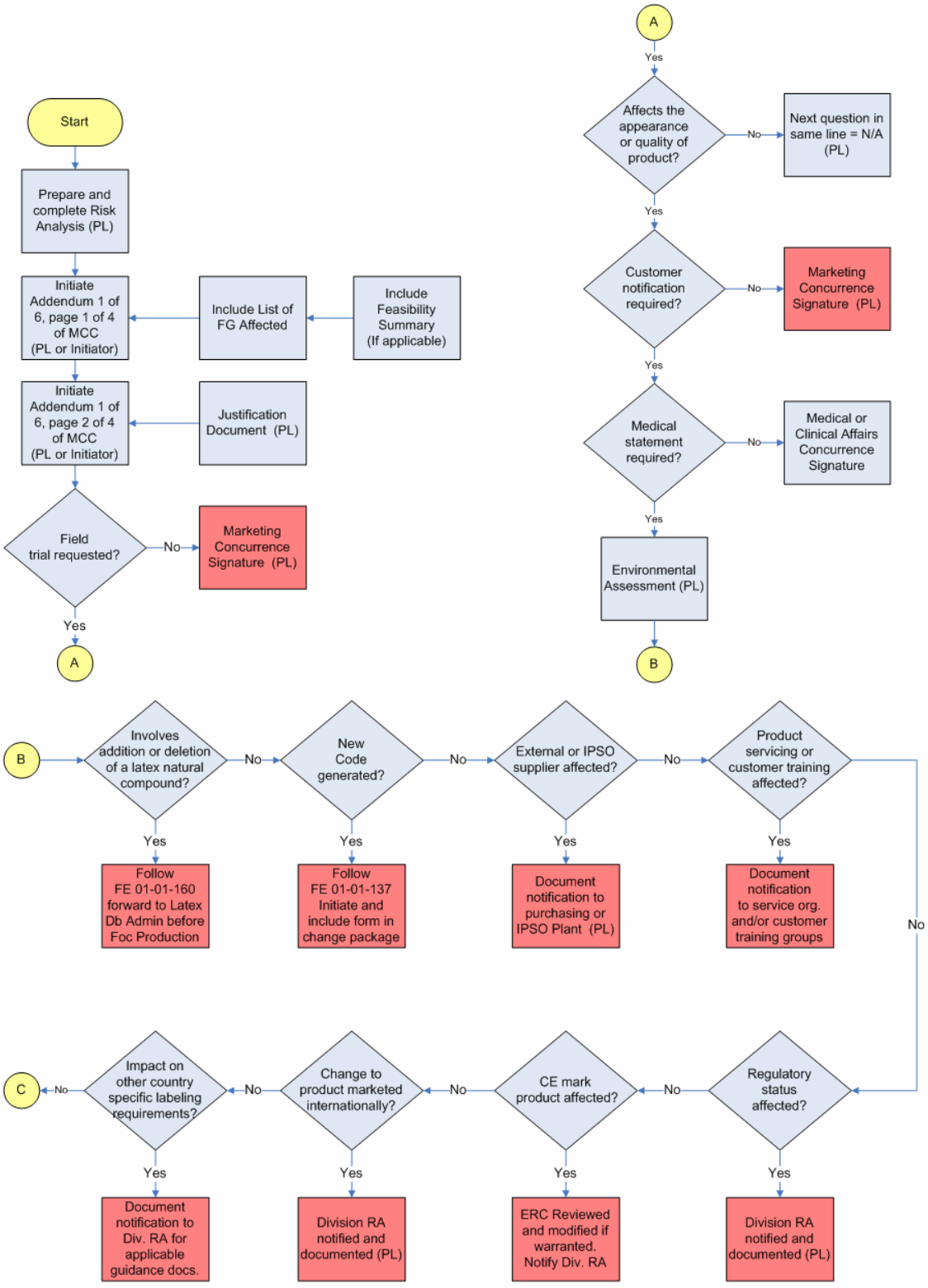

Figure 15 MCC Process Flowchart

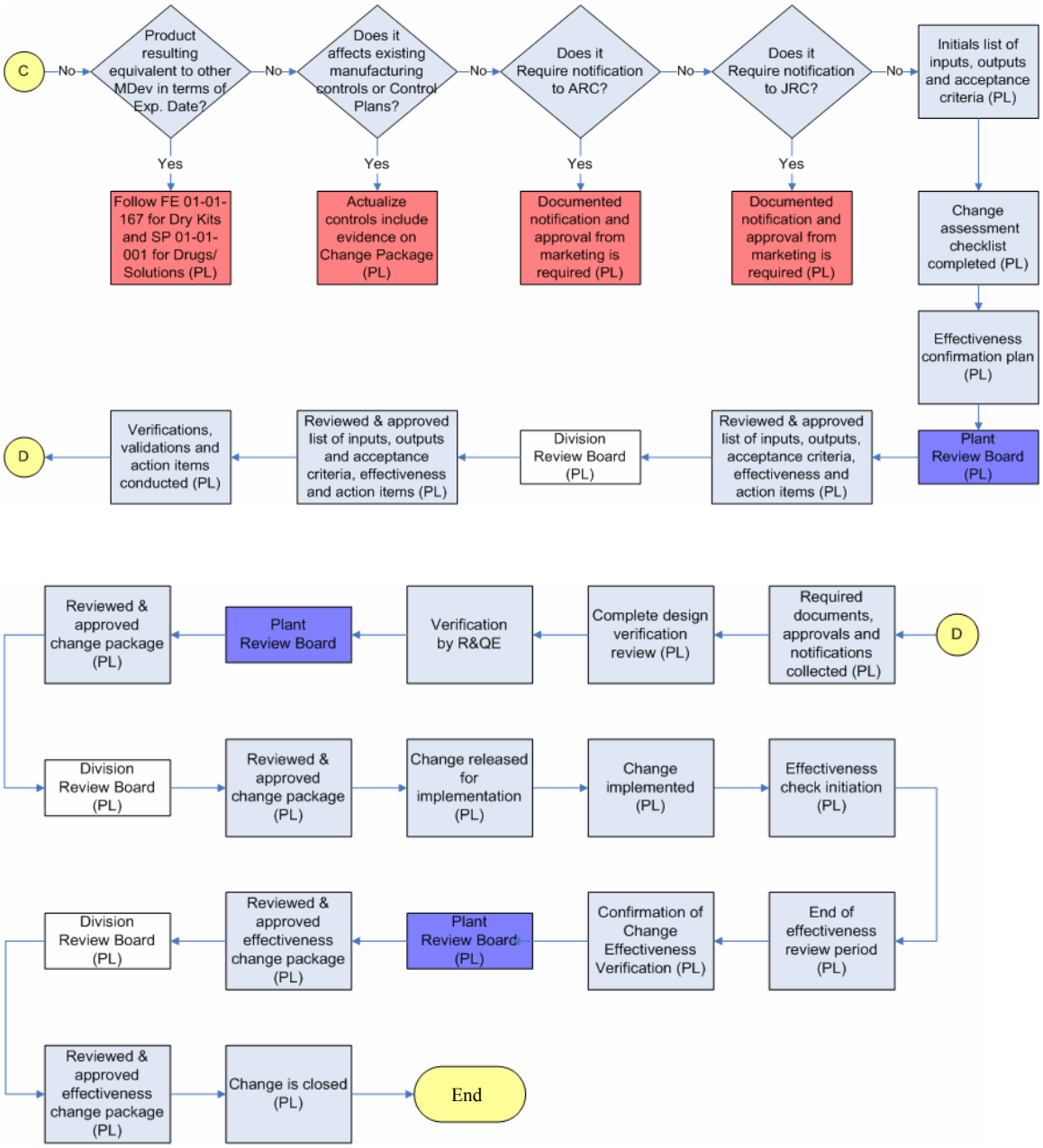

Figure 16 MCC Process Flowchart (continued)

The final step on the Define phase was the construction of a SIPOC (Supplier-Input-Process-Output-Customer) Diagram. This tool is used to identify all relevant elements of a process improvement project before work commences. As the name

implies, this tool prompts the team members to consider the suppliers of the process, the inputs to the process, the process the team is improving, the outputs of the process, and the customers that receive the process outputs. Constructing this diagram is particularly practical when some characteristics of the process are not obvious, such as: (i) who supplies inputs to the process, (ii) what specifications are placed on the inputs, (iii) who are the true customers of the process, and (iv) what are the requirements of the customers? The SIPOC diagram developed for this improvement initiative is presented on Figure 17.

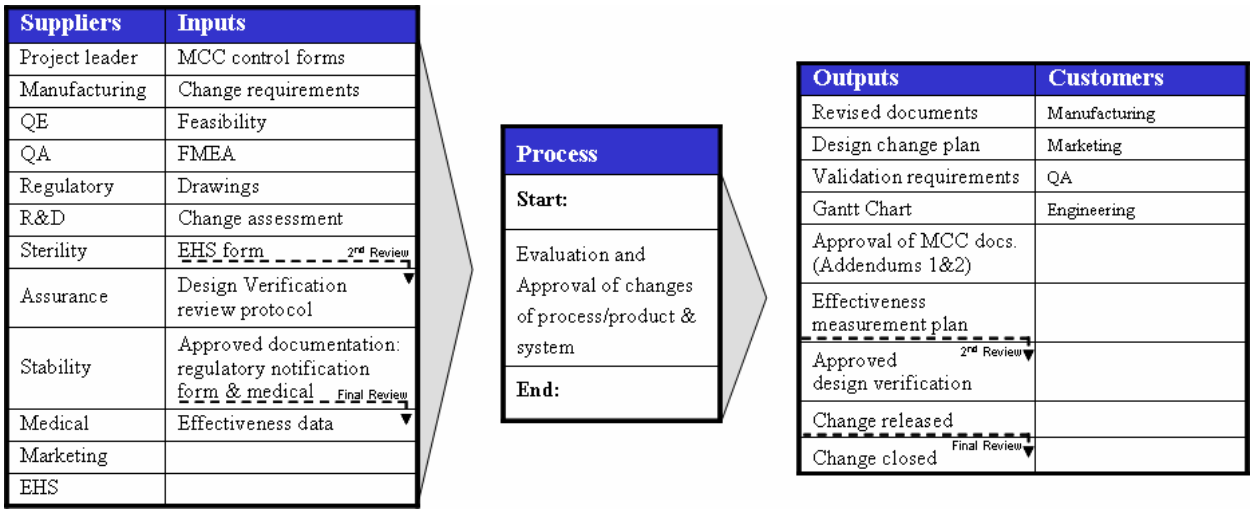

Figure 17 SIPOC Diagram for the MCC Process

3.4.2 MEASURE PHASE OF THE DMAIC METHODOLOGY

In the Measure phase, the current baseline of the project was defined, and the metrics and data collection plan were established as it was presented on section 2.2.2.2. The team concurred that the metric that should be measured to establish the current status and future improvements should be the time it takes between different required approvals. Specifically: (i) the elapsed time between the PRB approval and DRB approval and (ii) the time between DRB approval and the Design Verification Review.

This where the chosen metrics because they where considered the major milestones of the process, if there is an improvement on the time elapsed between these approvals there will be an improvement on the overall time of the project.

All of the MCC processes that were initiated and closed during the years 2004 and 2005 where revised and the desired dates where recorded. After the data was obtained, the elapsed time was calculated, graphed, and analyzed to detect any tendencies, as shown in Figures 18 and 19.

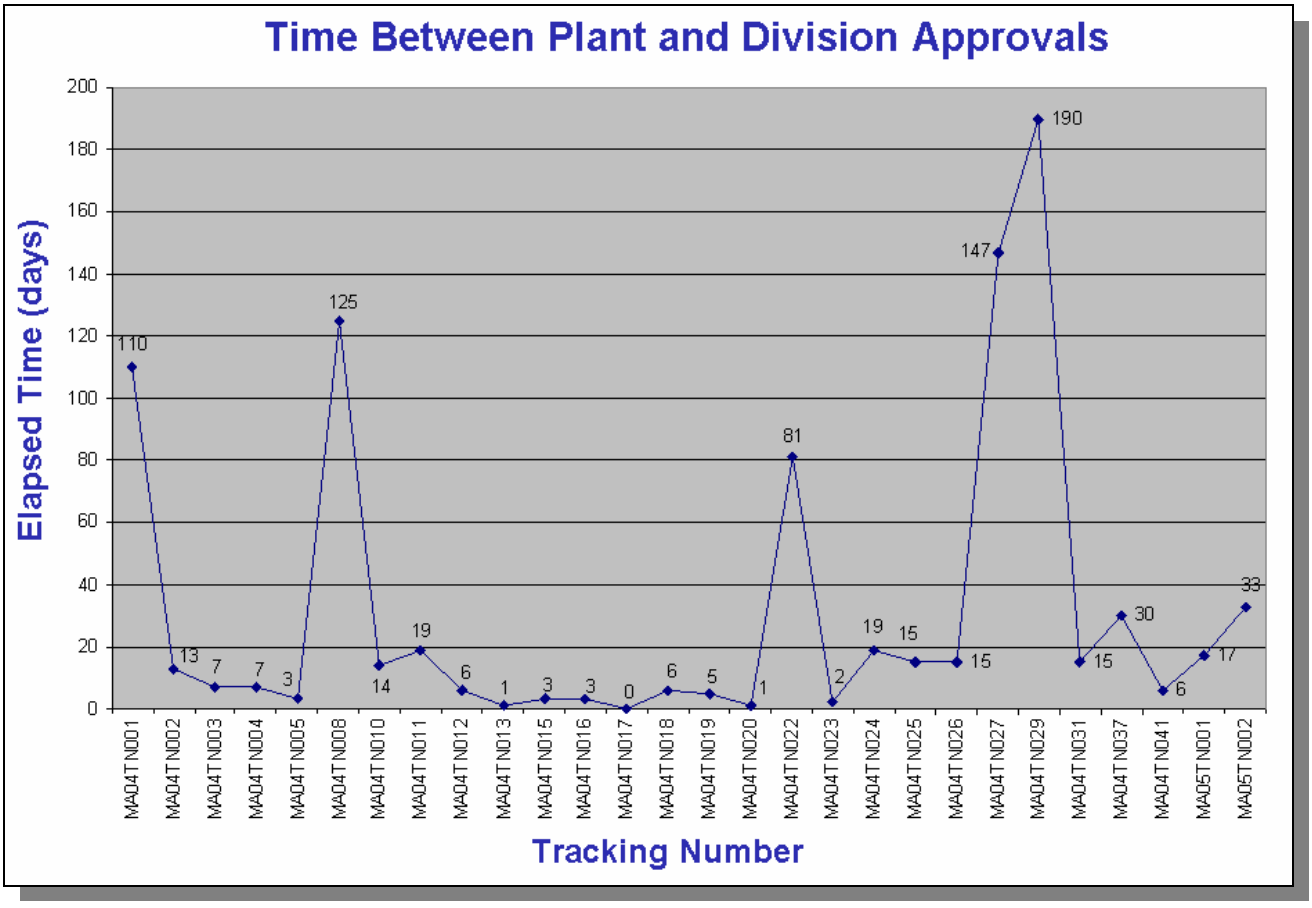

Figure 18 Graph of days elapsed between PRB and DRB approvals

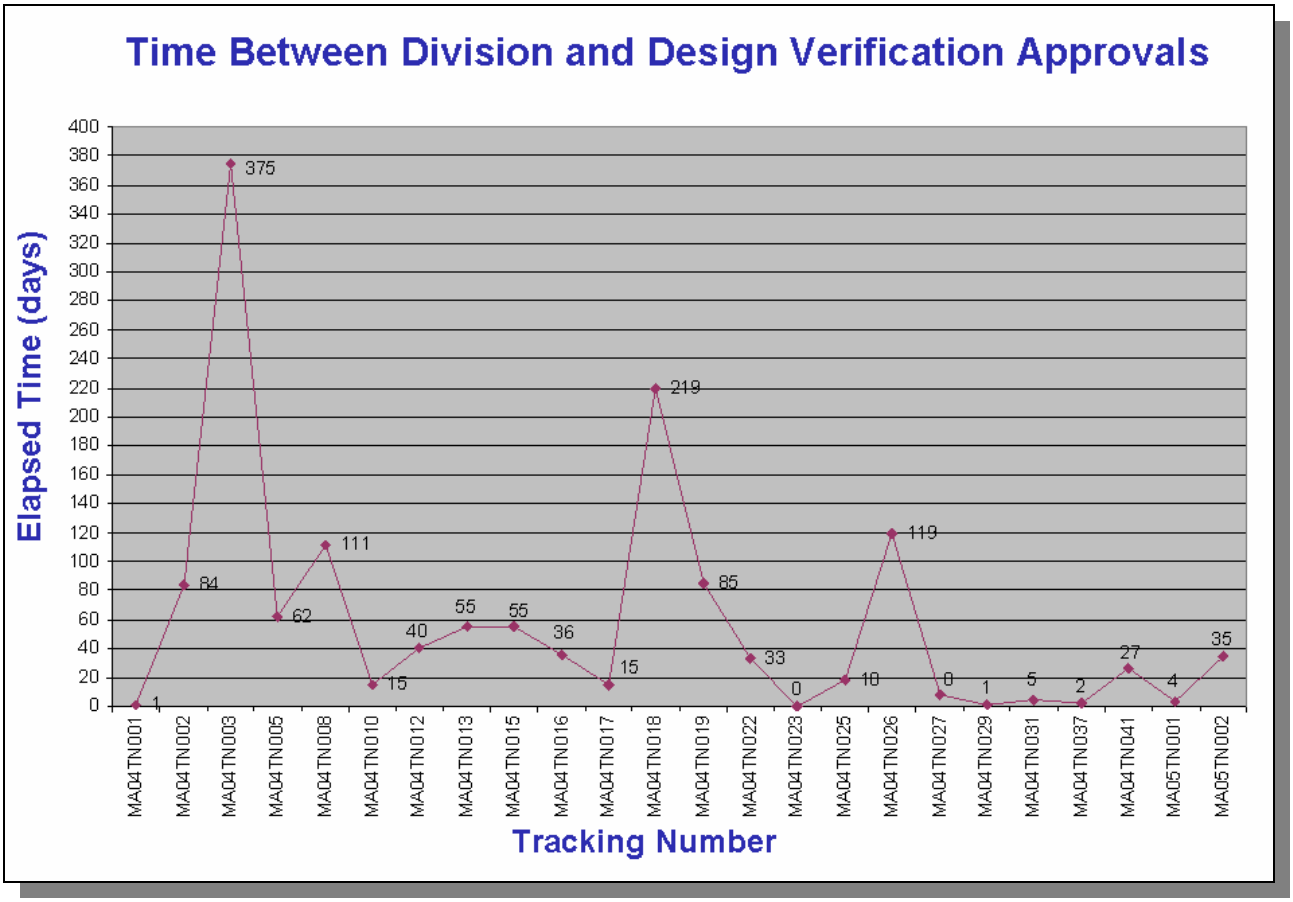

Figure 19 Graph of days elapsed between DRB and design verification approvals

3.4.3 ANLYZE PHASE OF THE DMAIC METHODOLOGY

When the data was analyzed one strong tendency that was observed was that the MCC processes that required the approval of the DRB instead of notification delayed the approval process much longer. After revising the processes conducted on the DRB and interviewing some of its members, the team concluded that the delay occurred because of the manner in which the project was presented; specifically, the members of the DRB did not receive the MCC document until the actual meeting, therefore delaying the overall process.

A cause and effect diagram was constructed in order to determine additional causes that might contribute to the delay of the approval process. The causes were grouped in the following categories: material, personnel, environment, method and machines as presented on Figure 20. The major causes identifies were: (i) incomplete documentation presented at the review meetings, (ii) lack of training on the procedures, (iii) missing delegate(s) on the meetings, (iv) no synchronization between PRB and DRB, (v) no meeting agenda, (vi) description and/or definition of change is unclear, and (vii) irrelevant changes sent to the DRB.

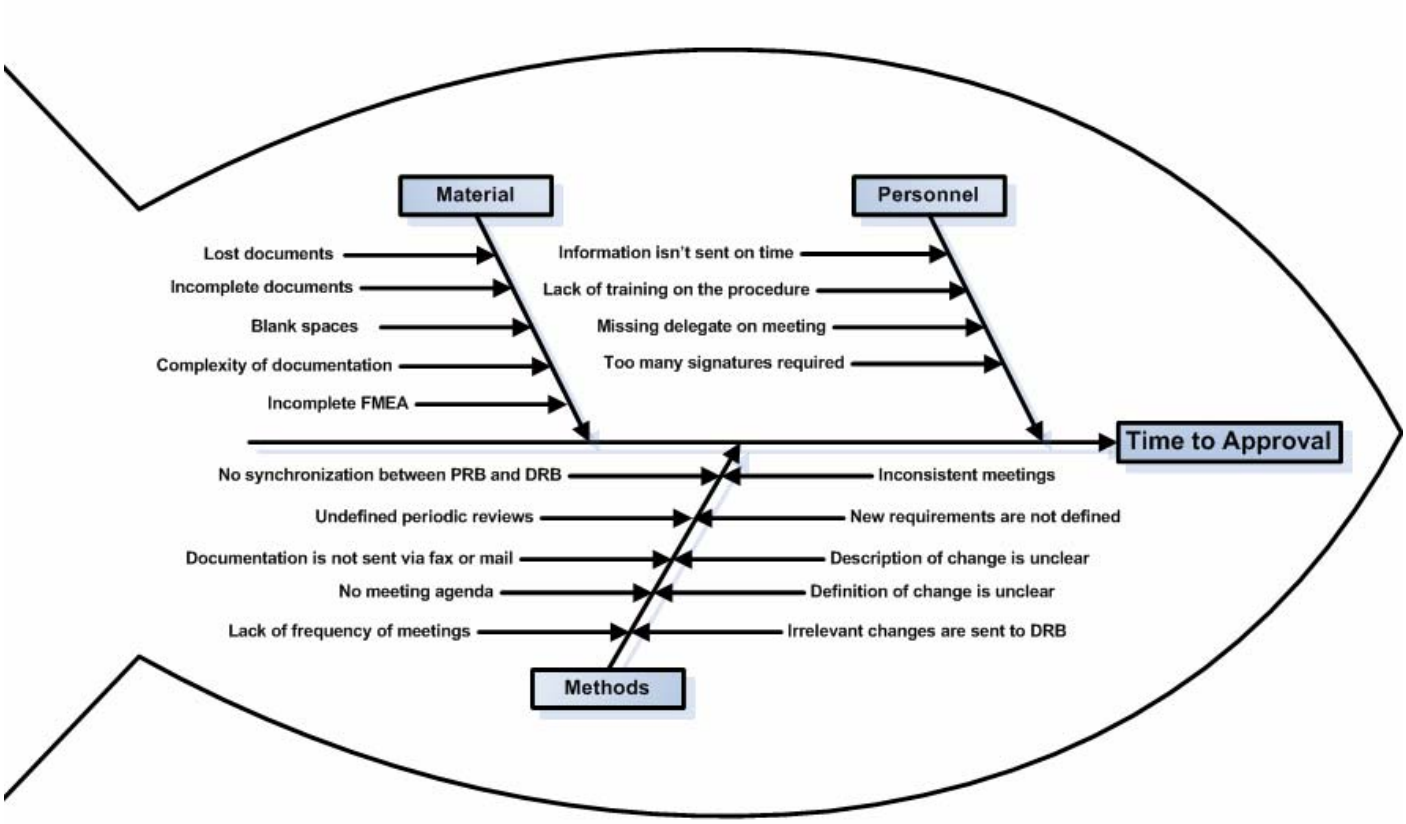

Figure 20 Fishbone Diagram

3.4.4 IMPROVE PHASE OF THE DMAIC METHODOLOGY

One of the main reasons for the delays in the process was that in the MCC documentation sent to the DRB, the project wasn't defined appropriately. A set of guidelines were created in order to correct this project definition weakness. The guidelines direct the project leader through a series of simple questions with the purpose of accurately defining the project without omitting important information in a concise and brief manner. The guidelines include the following information:

1. Project Definition
    a. What is trying to be solved or improved: process, system, defect, product and/or area?
    b. Where is the opportunity to solve or improve: physical location in plant, product, etc?

2. Project Description and Background
    a. Brief description of current process, including flowcharts, tables, diagrams and/or photos as applicable.
    b. Brief description of proposed change, including flowcharts, tables, diagrams and/or photos as applicable.

3. What is the reason for the change?

4. Has any study or concept evaluation been done?

5. Benefits (list of benefits is provided on the document)

6. Systems, processes or areas that could be impacted by the change (list of all possible processes, systems and areas is included on the document)

7. Does the change affect form, fit or function of the product?

In addition to the changes suggested for the change process where the guidelines presented above, the project leader must complete these guidelines and present the documentation at the project review meeting in conjunction with visual aids. The agenda followed on the project review meeting was revised and some changes were suggested in order to organize and give a more formal structure to it: the person in charge of conducting the meeting must notify the attendants the time and location as well as of the projects being presented and time limits per presentation. After the project proposal is presented the members would instruct the project leader on how to prepare the documentation needed for the PRB. As for the DRB, the new guidelines are presented in conjunction with the MCC document, which gives the readers a brief and concise definition and introduction to the project in question, the documents will be sent to the members via intranet or posted on a special website; this way the documents can be studied before the meeting, speeding up the process.

3.5 SUMMARY OF RESULTS

This chapter presented three main topics: (i) Quality strategies and tools relevant to manufacturing improvement, (ii) Quality strategies and tools relevant to new process development, and (iii) Defining a process for DMAIC application. In a regulated manufacturing environment there is a constant need for updating existing processes and developing new processes in order to comply with regulations, satisfy the customer needs and successfully compete in a fast paced and ever changing environment.

In the first initiative an existing automated process was rigorously scrutinized in order to detect areas of opportunity for improvement. A MFMEA was conducted with the aim of detecting the most critical failures with respect to occurrence, detection, scrap severity and downtime severity; criteria which pinpoint the main flaws that the system has as a whole. After the analysis was finished the main areas of opportunity where

identified and innovative and accurate procedures to detect critical failures during the process were identified and recommended, thus reducing scrap and machine downtime.

In the second initiative a proposed new automated process was studied with the purpose of verifying it and developing the documentation needed to create the process controls. A detailed process flowchart was developed, a PFMEA was conducted, and a simulation model was created. As a result of using these methodologies, design weaknesses were identified, the most critical failures and their causes were identified, and fundamental parameters for the construction of the loading stations were calculated.

The third and final initiative conducted at the Baxter facility dealt with a process outside the manufacturing environment. Following Six Sigma's DMAIC methodology the process of approving a project was properly defined, measured, analyzed and improved. Benefits from this initiative include: (i) establishing specific project defining guidelines, (ii) meeting protocols, and (iii) establishing a new information delivery system. These process improvements allowed a significant time reduction between project initiation and approval.

CHAPTER 4 - CONCLUSIONS AND FUTURE WORK

4.1 CONCLUSIONS

Through the spectrum of initiatives conducted at the Baxter Facility at Maricao the main objectives of this thesis were accomplished. Amongst the established objectives were the identification of current FDA practices that will impact product and process changes, the design of a Production-Quality-Engineering process change model to facilitate continuous improvement within the given regulated environment, the identification and deployment of tools for effective process improvement, and the measurement of process improvement using appropriate productivity metrics.

During the research phase of this project the current FDA's practices and new initiatives were studied. Amongst these initiatives, PAT pursues the establishment of appropriate in-process controls to obtain continuous quality assurance. Through the analysis conducted on two manufacturing processes, one mature and another new, the machine's critical failures were identified in order to recommend the implementation of process controls and new sensor solutions for the detection and prevention of failures in the process. These tasks allowed compliance with correct practices promoted by the FDA in the pursuit of risk management.

By means of quality tools such as the Failure Mode and Effects Analysis and by making modifications in order to improve the analysis and documentation phases, the methodology was satisfactorily employed. Through the machine FMEA the author was able to update and improve an existing process and give way to new advances; via the process FMEA the author was able to define the process, assist in the evaluation of the design requirements, and establish a tracking system for future developments and improvements. The excellent results obtained from both initiatives and the approval of

the group who worked in the process confirms the success and contribution to the company.

The initiative conducted on the change approval process was aimed at the development of a process change model that accelerated the process. With each project that is proposed all of the areas that are directly involved, specifically production, quality, and engineering have to work together in the development of the approval document. This was a difficult task given the lack of organization and collaboration. Through the application of the DMAIC methodology the process and duties of each member were clearly defined, and guidelines and recommendations were presented and applied in order to improve the overall organization of the process. Through this effort the process was improved; not only by reducing the elapsed time but by improving the organization and cooperation between members.

4.2 FUTURE WORK

By means of the initiatives performed on the Baxter Division at Maricao new projects can arise; such as:

1. Development of an iterative FMEA to drive continuous improvement activities in manufacturing. This would require the automated capture of defects or failures, cause for downtime and quality incidents in order to update the RPN calculations.

2. Development of an in-line change approval process with DMAIC-tool data storage capabilities, the system should have functionalities such as (i) wait time tracking, (ii) e-mail generation to speed up responses, and (iii) bottleneck statistics generation.

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