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Fleming, Luke J. ***The Research and Development of a Quality Control System to Reduce Scrap in a Captive Injection Molding Operation Using Six Sigma***

Abstract

Revenue is paramount to a company's existence. In order for a business to stay alive it must generate revenue. The company must be profitable to sustain long term viability. There are many factors that affect profitability. Labor, overhead, and raw materials all drive costs. Many of those variables are fixed in a manufacturing process. One cost that is variable and affects the profitability of a company is scrap. Scrap is a natural byproduct of manufacturing and is intrinsic to every process. Companies can significantly decrease their profitability with excessive scrap. Company XYZ is a manufacturing and resale company. Their products are affiliated with liquid filtration and equipment to perform liquid filtration. Company XYZ has generated a significant amount of scrap and that has diminished their profits and challenged their production capacity. Using the Six Sigma tool DMAIC, a corrective action was formulated to address the scrap.

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Chapter I: Introduction

Company XYZ was a manufacturing and resale filtration company that competed in multiple markets including beer, wine, distilled spirits, and biopharmaceutical. Company XYZ had multiple manufacturing capabilities including, but not limited to, wet-laid paper manufacturing, converting, injection molding, and vibration welding. The Device Assembly Department was responsible for manufacturing the assembled filtration devices. The devices consisted of a depth media filtration, approximately .125" - .240" thick. The media was insert-molded into a "cell" using injection molding technology. The cells were then assembled into a final device with either mechanical compression or vibration welding. With in the device there were multiple injection molded components. All of the injection molding was executed in house with one of the six injection molders ranging from 150 Ton to 500 Ton. This field problem analysis was focused on the quality system around the molding of the components and aimed to reduce the scrap, increase capacity, and improve profits.

Statement of the Problem

Company XYZ's Device Assembly Department experienced high levels of waste from scrap and lost manufacturing capacity. The scrap had created a loss in profits.

Objectives

There were four main objectives of this study. The first was to quantify the scrap generated in the Device Assembly Department. Second, develop a quality system to improve yield and reduce future risk of waste. Third, propose a system that would reduce scrap of the injection molded components and assembled devices. Finally, determine the cost of quality decisions.

Purpose of the Study

The purpose of this activity was to propose corrective actions that could minimize physical scrap, save money, and optimize production capacity.

Assumptions of the Study

Capital investment was not within the scope of recommendations. The actions proposed used the systems and equipment available to the company. It was assumed that production of the current good will continue for a period of three or more years.

Definition of Terms

Critical to Quality (CTQ). The key measureable characteristics of a product or process whose performance specification must meet the customer requirements (He, Y., Tang, X., & Chang, W, 2010, p. 326).

Injection molding. The manufacturing process of forming liquid plastic into a form to create a desired geometry (All About Plastic Moulding, 2011).

Lenticular. A filtration device with capture with a plastic edge seal.

Nonconforming Material Report (NCMR). Documentation completed for any production run that manufactures materials that do not meet quality standards for that product.

Value Stream. A sequence of processes that are connected by a common customer, product, or service request (MCS Media, 2006).

Vertical Integration. The activity describing the process of moving a value added activity from an outside supplier to an in-house capability (Hovenkamp, H, 2010).

Scrap. The seventh type of waste in Lean, correction (MCS Media, 2006).

Waste. Any activity that consumes resources but creates no value for the customer (LEI Inc, 2002).

Limitations of the Study

The limitations of the study were time and business leverage. The time frame was limited to three months. The project team was restricted to changes in the Device Assembly Department. They were not allowed to invest capital or make changes to validated processes.

Chapter II: Literature Review

Introduction

Company XYZ's Device Assembly Department experienced waste in the form of scrap. The consequences of this waste were decreased profit and reduced production capacity. The study utilized Six Sigma techniques to address the waste and propose a quality system. The manufacturing processes utilized in this operation included injection molding, mechanical assembly, and testing. Because of the elements listed, the literature was reviewed on manufacturing, injection molding, Six Sigma, DMAIC, root cause analysis, waste, and quality control system.

Manufacturing

The Device Assembly Department manufactured products that were sold to customers of Company XYZ. The necessity and desire for physical products has driven manufacturing through out the world (Erasmus, P., & van Waveren, C. 2009). Manufacturing drives quality and benchmarking as a function of decreasing costs and increasing profits.

An important role in manufacturing is industrial engineering. Competition in manufacturing has driven increased quality, efficiency, and benchmarking. The industrial engineer is responsible for facilitating change and improving operations (Kuo, W. 2003). There are many tools available to industrial engineers to provide guidance in managing projects focused on improving quality and efficiency. Lean and Six Sigma are methodologies that include multiple tools to aid in process improvement.

Injection Molding

The manufacturing process of Injection Molding is one the fastest growing industries. It is on a short list of billion dollar markets in the world. Of the three major plastic processing

technologies, injection molding makes up approximately 32%. The technology of injection molding has been in existence since the late 1800s (All About Plastic Moulding, 2011).

Injection molding has a high through put and is repeatable (Rosato & Rosato, 1995). Through put and repeatability drive the demand for plastics processing. It allows companies to generate a competitive advantage over similar products manufactured using machining techniques. These advantages drove Company XYZ to utilize injection molding in the fabrication of their filtration devices.

Injection molding is similar to other manufacturing. It requires quality control to ensure acceptable parts. Production runs using this technology require continuous visual inspection of key characteristics of the component or assembly (Rosato & Rosato, 1995). The key characteristics are defined by the component form, fit, and function.

There are many variables that contribute to the quality of a product using injection molding. The raw materials and their pre-processing conditions have an impact on the final part quality. The injection molding machines inputs also affect the quality of the product. Some of these inputs include barrel temperature, injection velocity, injection pressure, pack pressure, pack velocity, pack time, and cool time. The four critical variables to injection molding are temperature, shear, pressure, and cooling (RJG, Inc. 2010). The temperature of the process is the actual temperature of the resin. Resin temperature is an output and does not describe the temperature input on the injection molding machine. Shear is the injection velocity or the volumetric rate at which the plastic is moved into the cavity. Pressure is the amount of pack pressure applied during the packing phase of the injection molding cycle. Pack pressure is pressure experienced by the molten plastic and not the pressure applied. Cooling describes the

process of removing heat from the molten plastic. This causes the physical change from liquid to solid (RJG, Inc. 2010).

Six Sigma

The American Society for Quality defines Six Sigma as the following:

> Six Sigma is a fact-based, data-driven philosophy of quality improvement that values defect prevention over defect detection. It drives customer satisfaction and bottom-line results by reducing variation and waste, thereby promoting a competitive advantage. It applies anywhere variation and waste exist, and every employee should be involved. (www.asq.org)

George Eckes defines Six Sigma as Business Process Management (Eckes, 2003). Six Sigma is a well defined, organized, methodical approach to problem solving that maximizes the return on a company's effectiveness and efficiency. The Six Sigma problem solving process was utilized for the road map of the project.

Six Sigma was created by Motorola in early 1980's. Motorola "aims at the enhancement of customer satisfaction with products or services by improving the manufacturing processes" (He, Y., Tang, X., & Chang, W. 2010, p.325). Companies have massaged and optimized Six Sigma to further benefit their specific business model. General Electric and Honeywell are examples of organizations that have used best practices and benchmarking to expand and improve Six Sigma (He, Y., Tang, X., & Chang, W. 2010).

DMAIC

Define-Measure-Analyze-Improve-Control (DMAIC) is a Six Sigma tool that lays out the foundation of a project. Each of the phases has a specific objective and associated activities and tools to achieve that objective. The steps of the process are sequential.

DMAIC is a simplified version of a Japanese process that originated in the 1960s. Plan-Do-Check-Act is considered the foundation of DMAIC. Each step in the process has its own set of activities. The Plan phase establishes the goals of the project and lays out a rationale for the exercise. The situation is accessed and causes for the pain points are identified. The last step of the Plan phase is to establish corrective actions. The next step is the Do phase. This phase entails implementing the changes proposed in the Plan phase. Check phase is the next step. The primary activity in this phase is to evaluate the results of the changes implemented in the Do phase. The final step is the Action phase. The activities executed in this phase are standardization, reflection, and future planning (Jens J. Dahlgaard, & Su Mi Dahlgaard-Park. 2006). There are many parallels between Plan-Do-Check-Act and DMAIC. They both have the same objective of systematically solving problems.

Define is the first phase in the DMAIC process. In the definition phase, the team members will articulate the purpose of the project (Breyfoggle, 2003). The Define phase objective is to identify the customer and their needs. A project charter is scripted. Additional activities completed during the Define phase can include Voice of the Customer (VOC), process mapping, and Affinity Diagrams (MCS Media). The Define phase is the foundation of the project. It outlines the team members, the goals, timelines, and stakeholders.

The Measure phase is intended to identify the critical data that will illustrate the problem. Some examples of activities in the Measure phase include selecting attributes to measure; establishing operating parameters, developing the collection and sampling plan, (Breyfoggle, 2003). Tools utilized during the Measure phase include document tagging, check sheet, and data collection (MCS Media, 2006). The activities executed during this phase provide the data necessary to generate accurate root cause analysis and the subsequent corrective actions.

The Analyze phase is arguably the most important phase in the DMAIC process (Eckes, 2003). This is the stage in the project where the data and information generated is dissected. The conclusions and recommendations for the plan of action are created here. This is a pivotal decision making step. Incorrect judgment could result in the failure of the project. The Analyze phase generates the root cause(s) for the problems being addressed. Tools utilized during this phase include histograms, Pareto charts, scatter diagrams, and DOEs (MCS Media, 2006).

The Improve phase of the DMAIC process is usually associated with Design of Experiments (DoE). The purpose of the Improve phase is to challenge the process with the intent of making it more capable of meeting the expectations of the customer (Breyfoggle, 2003). All of the work completed in the first three phases culminates in the Improve Phase. This is the phase in the project where the problem is solved and the corrective action is implemented. Tools often leveraged in this phase include process mapping, flowcharting, and using Paynter Charts (MCS Media, 2006). The Improve phase is the milestone in the project where the pain points that incited the project are alleviated or minimized. The final phase of a DMAIC project is the Control phase.

The objective of the Control phase is to control the improved process. It also generates an action plan to ensure the new process maintains its ability to meet the needs of the customer (Eckes, 2003). Six Sigma tools that can be used in the Control phase include control charts, run charts, Paynter charts, and standard work papers. The purposes of the tools in this phase are to aid the organization in securing and maintaining the gains achieved in the Improve phase (MCS Media, 2006).

Root Cause Analysis

The first and most important step in solving a problem is properly defining the problem. (PRI, 2006) states: "If you cannot say it simply, you do not understand the problem." The path to identifying the root cause is found only by understanding the problem. Root Cause Analysis is critical in accurately addressing a problem. If the root cause is not identified, there is a risk of implementing a corrective action that addresses a symptom, not the problem. There are a number of tools available to identify the root cause to an issue. Typical tools for determining root cause are 4 M's, 3M's, flow chart/cause-and-effect diagram, 5 Why analysis, Force Field Analysis, Checklist, Pareto chart, graphs, and histograms (MCS Media, 2006).

The "5-Why" process is executed by asking the question "why" five times. The target of the "why" is focused on the problem. It seeks out why the failure has occurred. After asking the question five times it is probable the root cause has been identified. Not all situations will require exactly five questionings. Some problems will only need four and others may require six or more (PRI, 2006).

Determining root cause can be lengthy process. (MCS Media, 2006) recommends identifying at least three potential causes for the problem. In the case where only cause can be identified, it is reasonable to conclude that the true root cause has been identified. During the root cause analysis, it is likely that additional problems will be revealed. Each of those problems should be addressed with a root cause analysis.

Waste

McBride (2003) describes the elimination of waste as "the most effective way to increase profitability to any business." Eliminating waste is the foundation for Lean and for the Toyota Production System. Before you can eliminate waste, you must be able to identify and understand

what constitutes waste (McBride 2003). Most members of the Lean community would state there are seven types of waste. MCS Media (2006) argues that there are eight: overproduction, waiting, conveyance, over-processing, inventory, motion, correction, and people utilization.

The waste of overproduction occurs when product is manufactured that the customer has not ordered. Potential causes of overproduction could be lack of proper scheduling, incorrect lot size for production runs, or lack of pull system (MCS Media, 2006). Overproduction is wasteful because it consumes company resources unnecessarily.

The waste of waiting describes time lost because a process is delayed for anything critical to that process. Examples could include waiting for raw materials, bottlenecks, and lost time in searching for tools (MCS Media, 2006). Waiting is often a hidden waste since it does not show up on scheduled production reports.

Waste of transport is the loss due to moving or conveying raw material, tooling, or product further than necessary. This is waste as it does not add value to the customer and should be optimized (MCS Media, 2006). Examples of transportation waste include moving raw materials long distance, staging materials in multiple locations through out the process, and any other motion that can slow down the manufacturing process or cause delays.

The waste of over-processing is the most difficult to identify. It is defined by the extra processing that goes into a part that does not add value to the customer. This constitutes waste because it consumes resources that the customer is not willing to pay for (MCS Media, 2006). An example of over-processing is any feature on a product that the customer does need or want.

Waste of inventory describes excess raw materials that take up space, finances, and risks obsolescence. Inventory waste can also indicate issues with scheduling, purchasing and forecasting (MCS Media, 2006). Waste inventory can go unnoticed because floor personnel

perceive inventory as a positive sign. Manufacturing requires raw materials and an excessive amount of inventory could be interpreted as security and longevity of uptime.

Waste of motion is the excessive movement of any component critical in the manufacturing process. It can be driven by poor floor layout for equipment or misplaced tools (MCS Media, 2006). An example of waste of motion could be an operator walking long distances to locate tools and other implements necessary for completing their job.

Waste of correction is scrap or defective parts. It encompasses any processing, motion, capital, etc needed to replace the scrap parts already manufactured (MCS Media, 2006). An example of waste of correction is the bad parts manufactured.

The waste of people's skills describes the loss experienced when the skilled labor at the company is lost or repeated as a result of waste (MCS Media, 2006).

Quality Control Systems

The objective of the study was to develop a quality control system for the Device Assembly Department. There are many quality control techniques that are widely published and documented. These include Statistical Process Control (SPC), DoE, Failure Mode Analysis (FMEA), Six Sigma, and acceptance sampling (Judi, Jenal, Genasan, 2009). The most important was to identify which of the techniques would be most effective for the application. A study of Malaysian manufacturing companies found that there were three driving factors in identification of the appropriate quality control techniques: ease of use, capacity to measure the specification (ie. customer needs), and ability to improve the quality issues (Judi, Jenal, Genasan, 2009).

Summary

The elimination of waste is an important part of business operation. Prior literature identifies waste reduction as the most affective strategy for decreasing cost and

increasing profit. Six Sigma has been an effective tool in organizing project structure for 30 years. It has powerful tools for optimizing project flow and maximizing results. DMAIC is a Six Sigma tool for directing activities in a project. For a waste reduction project, DMAIC generates the necessary project objectives and members to achieve the goals set forth with in the organization. The end result of the tools is going to be a Quality Control System for ensuring minimal loss due to waste.

Company XYZ manufactured devices for filtration applications. Their manufacturing processes have generated waste in the form of correction. This project utilized Six Sigma's DMAIC process to establish the project flow and objectives. With in the DMAIC process correction waste was targeted and root cause analyses were conducted. With the actions executed through out the project, a corrective action plan was formulated to eliminate waste. The next chapters will illustrate how the company was able to identify and quantify the waste they were generating. The root causes and corrective actions will be illustrated, along with the recommendation for sustaining potential gains.

Chapter III: Methodology

Introduction

Company XYZ was a filtration company that injection molded parts for its assemblies. The parts were molded for internal use only. They are not sold to outside customers. Injection molding is not the core competency of XYZ and as a result they experienced elevated levels of scrap. The intent of this study was to determine the root cause of the scrap and propose a strategy to minimize or eliminate the loss. This study used the Six Sigma DMAIC process for identifying the root cause and proposing a solution.

Design

In the design phase of the project the scope and objectives were established. The problem was fully described and the end product was identified. Additionally, the CTQs factors were documented and the project timeline was generated. The team members and stakeholders were identified. Their corresponding responsibilities were documented in a project charter. The project savings was established in the design. The target savings was a realistic percentage of the scrap generated during the period of observation.

Measure

In the measure phase the scrap, in terms of dollars, for each of the parts was measured and organized by part or device. The scrap was broken down into scrap types (ex: start up, molding defect, incorrect process parameters, tool damage, etc). The purpose of the investigation was to target the parts with the highest scrap. Additionally, the type of scrap was evaluated to identify trends in the type of scrap. Data collection comprised most of the activities during the Measure phase. The data was collected and documented into spreadsheets. Pareto charts for scrap events and dollars in scrap were assembled to generate illustrations of the waste.

Analyze

The scrap data was evaluated and parts with the highest scrap (in dollars) were addressed first. The type of scrap with the dollar value and quantity was quantified and used as the basis for implementing a strategy to decrease each specific type of scrap. Using the data generated from the scrap, a root cause analysis was completed to identify the root causes of the different types of scrap. The root cause analysis generated the target areas for the corrective action. Tools utilized during the Analyze phase included root cause analysis and Pareto charts.

Improve

The data and root cause analysis completed in the analyze phase create the structure for the corrective action. The intent of the corrective action is to eliminate/minimize the loss due to scrap. It addressed the problem on two fronts; part specific and type specific. The corrective actions were formulated and an implementation plan was generated. The impact to the business was calculated based on the corrective actions suggested. The results of the Improve phase made a business justification for the project. In addition, the results of the Improve phase were compared to the expectations identified in the Design phase.

Control

The final step of DMAIC methodology is control. The implementation was not in the scope of the project. As a result, the Control phase proposed guidelines for controlling the changes if they were implemented. Also, the Control phase outlined a strategy for handling similar scrap issues in the future. Long term monitoring recommendations were made to sustain the savings potential. As a part of the monitoring portion, benchmarks were established for acceptable scrap levels. Those benchmarks would act as triggers for corrective action.

Chapter IV: Results

Define

In the Define Phase, the pain point(s) were identified. The primary pain point was dollars lost from scrap. During the period of observation $53,250.99 was lost due to faulty product. The scrap value was calculated using the cost of the raw materials coupled with labor and overhead costs. One hidden cost, not evaluated in this study is the loss in capacity. As business increases for Company XYZ, capacity will become a more important issue. After the problem was identified, the project was organized and documented.

To ensure organization and timeliness, a project charter was scripted. The project charter detailed the key stakeholder, leaders, and project objectives. Each of the stages were allocated time with documented deadlines. The project charter also addressed the risks in the project. The key stakeholders were part of a cross functional team. Areas represented among the stakeholders included R&D, Production, Quality, and Corporate management. Company XYZ does not have certified Six Sigma personnel. The project manager fulfilled the role of the black belt. The research technician acted as a green belt. The project timeline started on September 1, 2011 and ended December 22, 2011. The goal of the project is to have a Quality Control plan developed by December 22, 2011.. The proposed savings target is approximately 75% of the scrap value; $45,000. Figure 1 shows the project charter.

XYZ Company

Resource Requirements		General Information		Tollgate Schedule	
Project No:	11-973	Location:	Wisconsin	Activity	Date
Project Name:	Device Room Quality Control System	Business Segment:	XYZ	Define	9/1/2011
Green Belt or Black Belt:				Measure	9/30/2011
Master Black Belt:		Business Objective:	Minimize loss associated with scrap	Anylize	11/15/2011
Finance Partner:				Implement	12/1/2011
Champion:				Control	12/22/2011
		Customer CTQ(s):	Internal		
		Current Process Capability:	Manufacturing		
		Date:			

Team Members: Name	Function	Initials
Luke Fleming	Development Engineer	LF
John Doe	Research Tech	JD

Project Definition

Project Problem Statement:

Company XYZ's Device Assembly Department has experienced elevated levels of waste from scrap and lost manufacturing capacity.

Project Objective Statement:

The objective of this activity is to accurately describe the scrap generated in the Device Assembly Operation. This study will take the scrap information and use it to generate a quality control system.

Project Scope/Limitations:

This project will focus specifically on the Device Assembly Department. It's charter is to use the tools currently available to the organization. Capital expenditures will not be a part of the recommended solution.

Project Goals and Targets:

The goal is to have a recommended Quality Control Plan assembled for implementation by 12/22/2011.

Risks

The recommendations generated in this study could increase labor costs with in the Device Assembly Department.

Project Plan:

Expected Benefits:		Time frame:
Hard Dollar Savings*:	$45,000	16 Weeks
Soft Dollar Savings:	TBD	
Strategic:		
Other Benefits:		

Stakeholders

Name	Role	Stake
Luke Fleming	Project Manager	Core responsibility to ensure the completion
Sally Jane	Production Coordinator	Utilize equipment to reduce manpower and lower operating costs
Stu Niberg	Director	Core responsibility to ensure completion of capital projects
Chris, Marla, Dave	Board of Directors	Financial Investment and ensuring ROI
Internal	Customer	To continue to distribute quality product to their customers
Stack Room Operators	Main Operators of automation	Perform tasks in less time and be capable of running equipment
Maintenance	Maintain equipment	Maintain equipment and keep in good running condition

Figure 1. Project Charter

Measure

The objective of the Measure Phase was to sift through the data collected during the Production runs that experienced scrap and organize it into ways that would facilitate analysis. It was reported to the project team leader that the Device Assembly Department had experienced scrap in excess of $50,000. After creating a detailed project charter, a plan was assembled to measure and analyze the scrap. The documentation from each scrap event was gathered. The data was organized by part and the associated value in scrap. Pareto charts, organized by part, were created for occurrences and dollars in scrap.

Figure 2 illustrates the Pareto Chart for the quantity of scrap events. It is organized by part number and shows the number of Production runs that experienced a scrap event.

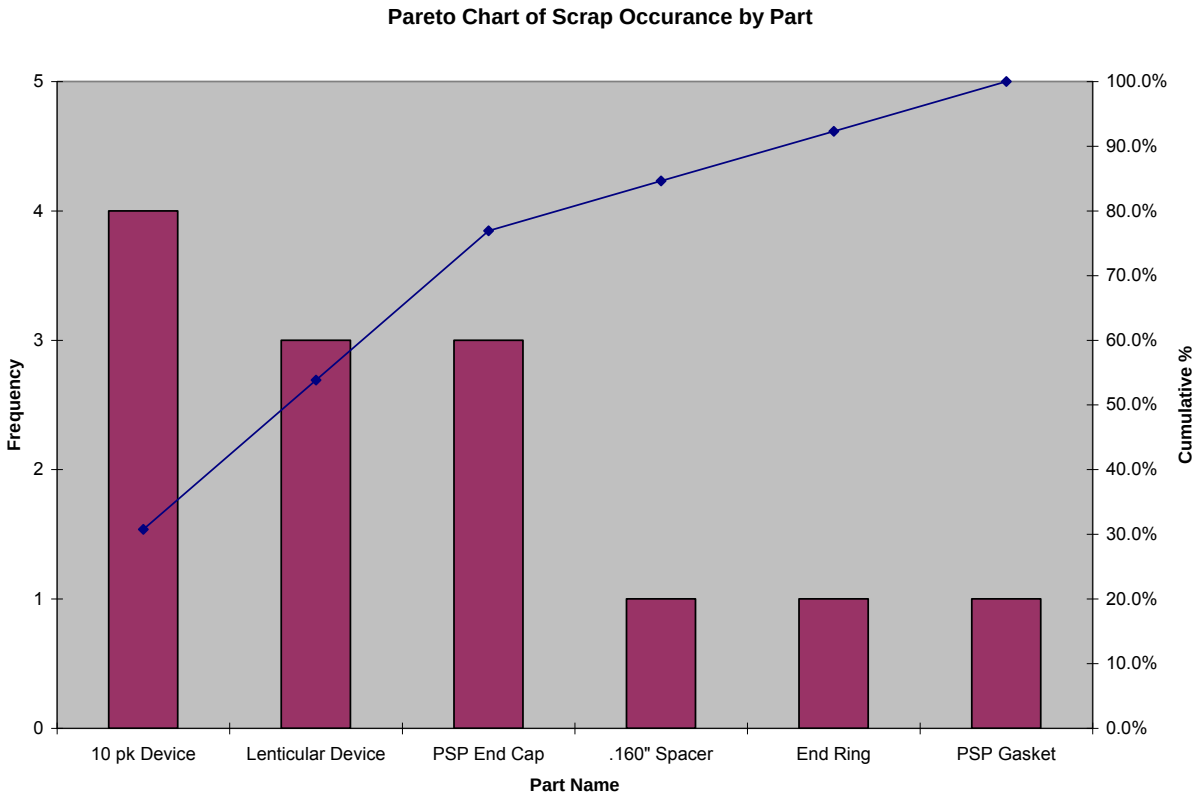

Figure 2. Scrap Occurrence Pareto Chart

10 Pack devices had the most occurrences at four. Lenticular Devices and PSP End Caps had two incidents, and the remainder experienced one scrap event.

Figure 3 is a Pareto Chart for the dollars lost in the scrap events. It is also organized by part. 10 Pack Devices drove the highest value in dollars. The dollars lost during 10 Pack production runs exceeded $42,900 dollars. This made up over 80% of the dollars lost due to scrap.

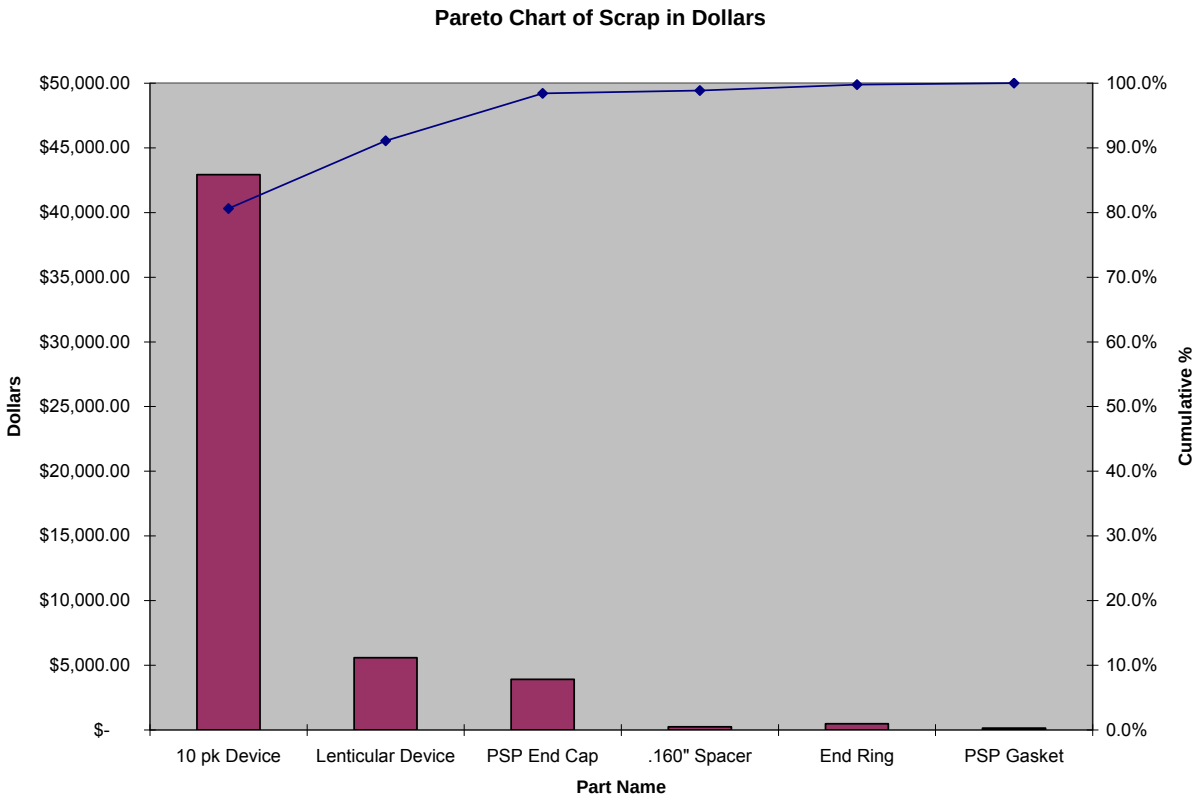

Figure 3. Scrap in Dollars Pareto Chart

Lenticular devices, PSP End Caps, .160” Spacers, End Rings, and PSP gasket combined to make up the other 20% of the scrap. The value of the scrap for the other 20% amounts to $10,323.63. After collecting and organizing the scrap data, the team was able to transition into

the Analyze phase of the DMAIC process. The Analyze phase activities were focused on using the data from the Measure phase to find a root cause and lay the foundation for corrective action.

Analyze

The objective of the Analyze Phase was to take data collected on the number of occurrences and dollars lost and interpret the data in a way that would flush out potential root causes. One of the first activities performed was to evaluate the NCMRs generated during the production runs that resulted in scrap. The NCMR documents the vital information about the product and process. It lists the reasons for the nonconformance. Table 1 lists each of the occurrences of scrap by part. The description of the problem is documented next to the part.

Part	Description
Lenticular Device	Cells molded w/ epicor - incorrect raw material
10 pk Device	Packets molded with tooling incorrect
10 pk Device	Incorrect penetration setting
10 pk Device	Media in wrong order
PSP End Cap	Tooling set up incorrectly - misaligned ribs
10 pk Device	Improper molding - short shot on handles
.160" Spacers	Excessive flash
Lenticular Device	Cells molded outside validated process parameters
PSP End Cap	Cracked port due to incorrect cooling
PSP End Cap	No epicor in end cap - lack of raw material
End Rings	Extra hole in part - incorrect tooling set up
PSP End Cap	No epicor in end cap - lack of raw material
Lenticular Device	Wrong media
PSP Gasket	Metal contamination

Table 1. Scrap description by part

10 pack devices drove the largest dollar figure in the Pareto charts documented during the Measure Phase. However, based on the table above there was not a single failure mode that drove each of the incidents. Another column was added to the table for scrap to identify the root cause of each of the scrap events. Table 2 illustrates the scrap with a root cause associated to it. It is noted that the root cause is limited to the tools that are available to the Device Assembly

group. It should also be stated that root cause was restricted to the Device Assembly Group's circle of influence.

Part	Description	Root Cause
Lenticular Device	Cells molded w/ epicor - incorrect raw material	Failure to verify correct raw materials
10 pk Device	Packets molded with tooling incorrect	No initial inspection
10 pk Device	Incorrect penetration setting	Failure to confirm process parameters
10 pk Device	Media in wrong order	Operator error
PSP End Cap	Tooling set up incorrectly - misaligned ribs	No initial inspection
10 pk Device	Improper molding - short shot on handles	No initial inspection
.160" Spacers	Excessive flash	No initial inspection
Lenticular Device	Cells molded outside validated process parameters	Failure to confirm process parameters
PSP End Cap	Cracked port due to incorrect cooling	Failure to confirm process parameters
PSP End Cap	No epicor in end cap - lack of raw material	Failure to confirm correct raw materials
End Rings	Extra hole in part - incorrect tooling set up	No initial inspection
PSP End Cap	No epicor in end cap – lack of raw material	Failure to confirm correct raw materials
Lenticular Device	Wrong media	Failure to confirm correct raw materials
PSP Gasket	Metal contamination	Insufficient routine inspection

Table 2. Scrap listed by description and root cause

Each of the scrap runs were categorized into five root causes:

1. No initial inspection
2. Failure to confirm process parameters
3. Failure to verify correct raw materials
4. Operator Error
5. Insufficient routine inspection

Figure 4 is the Pareto Chart of scrap in dollars. It is organized by root cause.

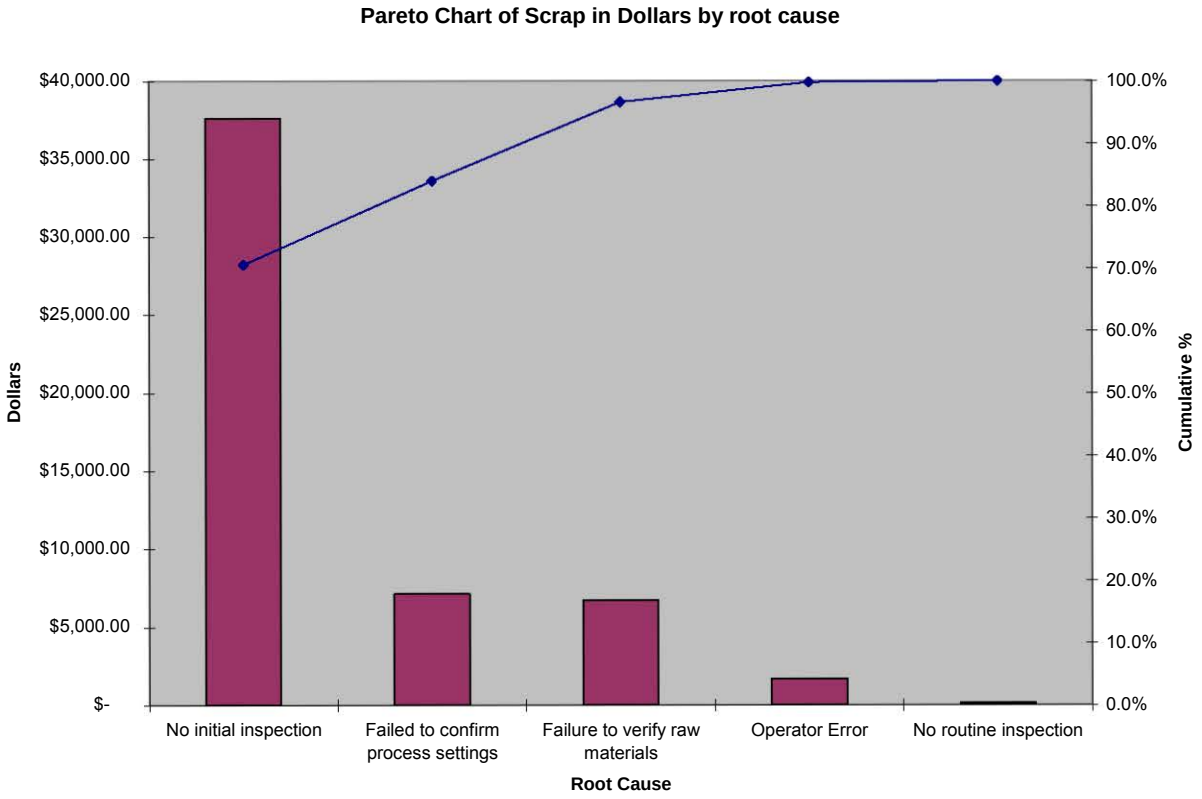

Figure 4. Root Cause Pareto Chart

The root cause was determined by a cross functional team with members from Quality, R&D, and Production. The root cause was limited by the capabilities of the Device Assembly personnel. For example, the production run with metal contamination was not the fault of the operator. However, tooling and maintenance was not a core responsibility of the Device Assembly personnel. It was their responsibility to monitor the quality of the product. Therefore, the root cause was a lack of continuous control or inspection of the process.

Some of the scrap events were a result of multiple root causes, but the cause with the greatest ability to limit or eliminate the scrap was chosen. An example that illustrates this was the scrap event for the End Rings. The tool was improperly set up. A routine inspection would have revealed this problem. However, an initial inspection of the part would have also

discovered the failure and would have eliminated a majority of the scrap. As a result, it was categorized under "No Initial Inspection".

"No Initial Inspection" described a failure mode that would have been avoided or minimized by performing an inspection of the critical features at the beginning of the manufacturing run. It accounted for $37,500 in scrap. That equaled 70% of the scrap during the observation period. "Failure to Confirm Process Settings" was the failure mode that resulted from product being manufactured with process parameters outside the validated settings. Product manufactured outside the validated process is scrap and cannot be used. It drove over $7,000 in scrap and about 13% of the scrap. "Failure to Verify Raw Materials" occurred when the incorrect materials were used to manufacture the product. "Raw Material Failures" created $6,700 and accounted for 12.6% of the scrap. "Operator Error" occurred when the operator had the correct process settings and raw materials, but assembled the device in the wrong order. It made up $1,680 and 3.2% of the scrap. "Lack of Routine Inspection" resulted in product that had the appropriate raw materials with the correct process parameters. The beginning of the manufacturing run was acceptable, but during the run there was a change that resulted in scrap parts.

The Pareto charts for the number of occurrences and dollars of scrap both identify the 10 Pack Device as the primary driver of the scrap. However, after performing a root cause analysis it is important to note how "No Initial Inspection" drove the highest scrap dollars. The initial inspection root cause also was not specific to a part. 10 Pack Devices and End Rings were affected by the absence of an initial product inspection. In addition, all products manufactured at Company XYZ are at risk of scrap from not inspecting the first parts off the line. This information was used in the Improve Phase to formulate a quality control plan to minimize

exposure to risk. The Improve Phase was the next phase in the DMAIC process. Its activities revolved around creating a corrective action to eliminate or minimize scrap in the future.

Improve

The goal of the Improve Phase was to generate a corrective action to minimize or eliminate the scrap produced in the Device Assembly Department. It was identified in the Analyze phase that 10 Pack Devices drove the largest dollar value of scrap when organized by part. Additionally, scrap resulting from "No Initial Inspection" had the largest scrap value in relation to root cause.

The root causes from the Analyze Phase were evaluated and the project team compiled potential preventative actions to address each root cause. The objective was to create a preventative action to address each of the causes. Three preventative action measures were created to cover the root causes identified in the previous phase. A Start Up Inspection Criteria document was created to address issues with part quality. It consisted of a specification for each part to confirm initial part quality. The inspection was a collection of critical parameters. It addressed the high risk areas of the part. An example of high risk was the inserts that were interchangeable on the end cap tool. The same tool manufactured multiple end caps. As a result, it was critical to inspect the ports on the end cap to confirm their correct location.

The preventative action of the Start Up Check Sheet was formulated to address the root causes of Failure to Confirm Process Settings and Failure to Confirm Correct Raw Materials. The start up sheet was a form assembled to use on any process. It is not part specific. The start up checklist adds operator accountability as they must initial that they have checked the following characteristics at the beginning of their respective shift:

- Documented Process Parameters

- All raw materials
- Tester Settings

The third preventative action was routine inspection. Routine inspection preventative action was created to address the root cause of No Routine Inspection. The routine inspection was a simplified version of the Start Up Inspection Criteria. Figure 5 illustrates the potential savings per Preventative Action.

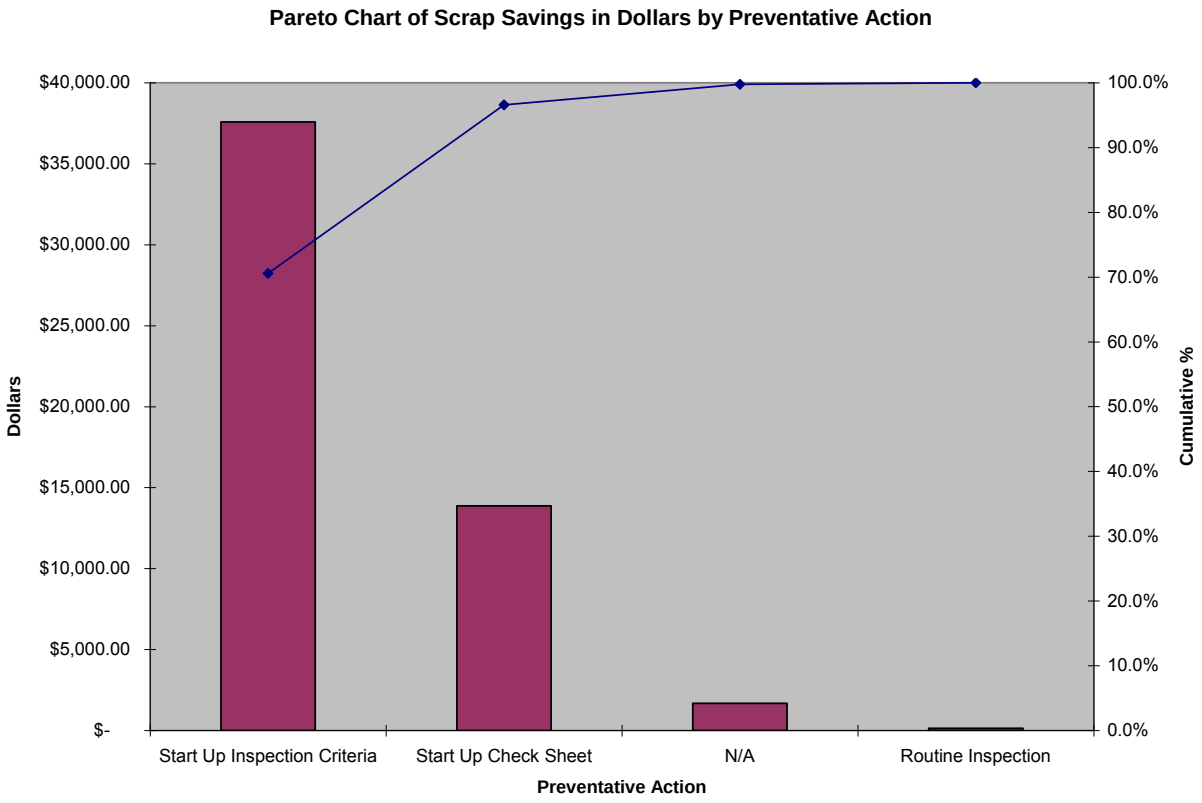

Figure 5. Pareto Chart of Savings in Dollars

The team used the Preventative Action Pareto chart to create a quality control strategy. They used the Scrap in Dollars by Part Pareto chart to define the logistics of implementing a quality control strategy. Figure 6 illustrates the start up check sheet developed for use during Production runs.

Device Assembly Startup Checklist

Date:_____

The following items need to be checked upon start up, at the beginning of the shift and when grades are changed. **N/A anything that is not applicable.**

	1st	2nd	3rd
Initial:			
1. Enter mold that is running_____			
2. Are molding parameters set correctly for this mold?			
3. Has the barrel tip been checked for build up?			
4. Are dosing units plugged in and operating correctly?			
5. Are correct water lines turned on?			
6. Is the Hydraulic pump on if needed?			
7. Is the media set up in the right orientation? (If multi-layer)			
8. Do lot numbers for the materials used match from container to paper?			
9. Are you using the printer?			
a) Is the correct item entered?			
b) Is the correct lot number entered?			
c) Is information on the printer screen correct?			
10. Performed Start Up Inspection			
11. Are you using the PSP testers?			
a) Is the H2 tester set up correctly?			
b) Are the test & calibration gas turned on?			
c) Is the aerosol tester set up correctly?			

By initialing above, you are verifying everything is set up correctly.

If Maintenance, R&D or anyone else other than the operator works on this molder while running the above mold, go through this checklist again to ensure that nothing has been changed.
Also, anytime there is a mold change, grade change i.e. that requires program change etc. this checklist should be gone over again.
If anything is not set up correctly for the mold being run, please fix and record in the comments section below and initial.

Comments with Initials: _____

Figure 6. Start Up Check Sheet

The operator that started up the Production would be required to fill out this form before producing product. It forced them to confirm that the process parameters were set to the validated settings. It ensured that the correct raw materials were used in the Production run. This form also provides a tool for the operator to ensure that the process and tooling is setup

properly to avoid damage to the capital equipment. This tool was also designed to require operators to periodically check the process. They would need to perform confirmation at the beginning of the run, at the beginning of their shift, and if there any changes to the process. This form addressed the root causes of "Failed To Confirm Process Settings" and "Failure to Verify Raw Materials". Table 3 illustrates the inspection criteria for each part.

Lenticular Device	
	Inspect Edge Seal Quality
	Inspect for over and under shots
	Inspect for proper assembly alignment
10 Pk Device	
	Inspect device for damage
	Inspect for Left and Right End Caps
	Inspect for contamination in the plastic
PSP End Cap	
	Inspect for damage around port detail
	Inspect for contamination in the plastic
	Inspect for proper port and alignment features
.160" Spacers	
	Inspect for damage at ejector pin witness lines
	Inspect for ejector drive and part distortion
	Inspect for contamination in the plastic
	Inspect for flash
End Rings	
	Inspect for damage at ejector pin witness lines
	Inspect for ejector drive and part distortion
	Inspect for contamination in the plastic
	Inspect for flash
PSP Gasket	
	Inspect for part distortion
	Inspect for contamination in the plastic
	Inspect for flash

Table 3. Part Inspection Criteria

In addition, each part would have a part specific print that goes along with it. The print would have a picture or diagram of the part. There would also be detail views to illustrate for the operator where they need to inspect. The Device Inspection Criteria work sheet was specific to each part. It would also be advisable to add critical dimension inspection to understand how the

part falls within the tolerance. The Device Inspection Criteria work sheet was created to address the root cause of "No Routine Inspection". The part specific Device Inspection Criteria for each part or assembly manufactured is listed in Appendix A.

The final root cause, not covered by the other three preventative actions was insufficient training. As training is not with in the scope of the project, it was forwarded to Production Management for them to deal with on a case by case basis. If in the future there is a trend of operators incorrectly producing product as a result of training, a corrective action should be taken on the training activities of the company.

The root causes have been addressed through the two preventative action measures; Device Assembly Checklist and Device Assembly Inspection Criteria. Assuming similar volumes of Production, the checklists could save the company approximately $51,000 and over 96% of its scrap. The final step in the DMAIC process is the Control Phase. Its focus was to create a system to ensure the changes implemented in the Improve Phase continue to be effective.

Control

Traditionally, the purpose of the Control Phase is to track and measure the effectiveness of the changes implemented during the Improve Phase. Measurement and monitoring were not in the scope of the project, due to time constraints. However, control measures were recommended as continuous action for future improvement.

The project team recommended that Production and Quality continue to compile scrap data on each of the components manufactured. The data should include a description of the scrap and the associated cost. The data collected should also include a potential root cause for the scrap. On a quarterly basis, the scrap should be evaluated by the Quality Council. The

expectation for scrap reduction should be over 90%. If that reduction is not achieved, it may be necessary to initiate another Six Sigma project to analyze why.

Another recommendation from the team was to annually readdress the preventative actions implemented as a part of the project. It is paramount to the business operation to evaluate the value stream and ensure all actions are necessary and value added. The Production and Quality departments will need to confirm that the additional time and cost are creating an appropriate pay back. In the spirit of continuous improvement, the inspection and start up processes should be evaluated for necessity and effectiveness.

Chapter V: Discussion

Company XYZ is a manufacturing and resale filtration company that competes in multiple markets including: beer, wine, distilled spirits, and biopharmaceutical. Company XYZ has multiple manufacturing capabilities including, but not limited to, wet-laid paper manufacturing, converting, injection molding, and vibration welding. The Device Assembly Department is responsible for manufacturing the assembled filtration devices. The devices consist of a depth media filtration, approximately .125" - .240" thick. The media is insert molded using injection molding technology into a "cell". The cells are then assembled into a final device with either mechanical compression or vibration welding. With in the device there are multiple injection molded components. All of the injection molding is executed in house with one of the six injection molder ranging from 150 Ton to 500 Ton. This field problem analysis focused on the quality system around the molding of the components to reduce the scrap, increase capacity, and improve profits.

This study was successful in identifying the scrap manufactured. Using the data on the scrap the main drivers of scrap were flushed out. It also identified the root causes that were driving the scrap. Using the root causes and the associated quantitative analysis, preventative actions were created to address the scrap. Finally, an implementation plan was formulated along with the expected savings. Using the information in this study the company should be able to justify the corrective actions with a fiscal business case.

Limitations

The limitations of this study were time and corporate leverage. The corrective actions generated in this study were limited by the ability of the group to make changes. They were not allowed to make capital investment or changes to validated processes. As a result, many of the

root causes were not the absolute root cause, but were the root cause that the project team could implement a corrective action to remedy. Due to the limitations of the project, the Improve and Control phases were omitted at this time.

Conclusions

The objectives of this project were as follows:

1. Objectively quantify, in terms of cost, the scrap that results from inadequate quality controls
2. Develop a quality system to improve yield and reduce the risk of waste.
3. Propose a system that could reduce scrap of injection molded components
4. Determine the cost of quality decisions

This study was effective in achieving each of the objectives. The Measure Phase generated valuable data about the scrap that the company was experiencing. It created a clear picture of the magnitude of the scrap created in the Device Assembly Department. The Analysis Phase was able to take the data collected in the Measure Phase and begin to organize that data in a way that clearly illustrated what was driving the scrap. Originally, the group had expected that the scrap associated with each specific part would drive the Quality improvements. On the contrary, it was the root cause that drove the corrective actions. Part did have an influence in the logistics of the implementation, but root cause had a greater impact. With the analysis complete, it was possible to formulate a Quality system to address the main drives of scrap in the Device Assembly Department's operation. Finally, with the scrap quantities and costs documented, it was possible for the project team to accurately assess the cost of Quality. That provided the business case that justified the actions to eliminate scrap.

Six Sigma provided an excellent road map for addressing the scrap from the Device Assembly Department. It created a strategy for addressing each of the phases of problem solving, while forcing the team to maintain focus on the activities within each phase. It restricted the urge to jump directly to the implementation phase.

The cost savings goal of $45,000 could be achieved if the recommended actions were implemented. Based on current volumes, the actions could save more than $51,000. The savings is repeated annually and has the potential to increase as sales increase.

Recommendations

The recommendation for future work is to continue this study. The next step in continuation of this project would be to implement the recommended changes into the production department. Once the changes have been implemented, the scrap data should be collected for a period of one year. At the end of the year, the data collection completed in the Measure phase and the analysis completed in the Analyze phase should be completed again. The scrap values should be compared to those measured in the original study. Decrease in scrap frequency, part quantity, and scrap value should go down significantly. If it does not, the root cause for the scrap should be evaluated to determine if other corrective actions need to be implemented.

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Appendix A: Device Assembly Inspection Criteria

Device Assembly Inspection Criteria
Lenticular Device

Date:_____

Work Order:_____

The following criteria need to be checked upon start up, at the beginning of the shift and when process parameters are changed.

		1st	2nd	3rd
	Initial:			
Inspect Edge Seal Quality				
Inspect for over and under shots				
Inspect for proper assembly alignment				

By initialing above, you are verifying Quality specifications have been met.

If Maintenance, R&D or anyone else other than the operator works on this molder while running the above mold, go through this checklist again to ensure that nothing has been changed.
Also, anytime there is a mold change, grade change i.e. that requires program change etc. this checklist should be gone over again.
If anything is not set up correctly for the mold being run, please fix and record in the comments section below and initial.

Comments with Initials: _____

_____

_____

_____

_____

Device Assembly Inspection Criteria
10 Pk Device

Date:_____

Work Order:_____

The following criteria need to be checked upon start up, at the beginning of the shift and when process parameters are changed.

	1st	2nd	3rd
Initial:			
Inspect device for damage			
Inspect for Left and Right End Caps			
Inspect for contamination in the plastic			

By initialing above, you are verifying Quality specifications have been met.

If Maintenance, R&D or anyone else other than the operator works on this molder while running the above mold, go through this checklist again to ensure that nothing has been changed. Also, anytime there is a mold change, grade change i.e. that requires program change etc. this checklist should be gone over again.
If anything is not set up correctly for the mold being run, please fix and record in the comments section below and initial.

Comments with Initials: _____

_____

_____

_____

_____

Device Assembly Inspection Criteria
.160 Spacer

Date:_____
Work Order:_____

The following criteria need to be checked upon start up, at the beginning of the shift and when process parameters are changed.

	1st	2nd	3rd
Initial:			
Inspect for damage at ejector pin witness lines			
Inspect for ejector drive and part distortion			
Inspect for contamination in the plastic			
Inspect for flash			

By initialing above, you are verifying Quality specifications have been met.

If Maintenance, R&D or anyone else other than the operator works on this molder while running the above mold, go through this checklist again to ensure that nothing has been changed.
Also, anytime there is a mold change, grade change i.e. that requires program change etc. this checklist should be gone over again.
If anything is not set up correctly for the mold being run, please fix and record in the comments section below and initial.

Comments with Initials: _____
_____
_____
_____
_____

Device Assembly Inspection Criteria
End Rings

Date:_____

Work Order:_____

The following criteria need to be checked upon start up, at the beginning of the shift and when process parameters are changed.

		1st	2nd	3rd
	Initial:			
Inspect for damage at ejector pin witness lines				
Inspect for ejector drive and part distortion				
Inspect for contamination in the plastic				
Inspect for flash				

By initialing above, you are verifying Quality specifications have been met.

If Maintenance, R&D or anyone else other than the operator works on this molder while running the above mold, go through this checklist again to ensure that nothing has been changed. Also, anytime there is a mold change, grade change i.e. that requires program change etc. this checklist should be gone over again.
If anything is not set up correctly for the mold being run, please fix and record in the comments section below and initial.

Comments with Initials: _____

_____

_____

_____

_____

Device Assembly Inspection Criteria
PSP End Cap

Date:_____

Work Order:_____

The following criteria need to be checked upon start up, at the beginning of the shift and when process parameters are changed.

	1st	2nd	3rd
Initial:			
Inspect device for damage			
Inspect for Left and Right End Caps			
Inspect for contamination in the plastic			

By initialing above, you are verifying Quality specifications have been met.

If Maintenance, R&D or anyone else other than the operator works on this molder while running the above mold, go through this checklist again to ensure that nothing has been changed. Also, anytime there is a mold change, grade change i.e. that requires program change etc. this checklist should be gone over again.
If anything is not set up correctly for the mold being run, please fix and record in the comments section below and initial.

Comments with Initials: _____

_____

_____

_____

_____

Device Assembly Inspection Criteria
PSP Gasket

Date:_____

Work Order:_____

The following criteria need to be checked upon start up, at the beginning of the shift and when process parameters are changed.

		1st	2nd	3rd
	Initial:			
Inspect for part distortion				
Inspect for contamination in the plastic				
Inspect for flash				

By initialing above, you are verifying Quality specifications have been met.

If Maintenance, R&D or anyone else other than the operator works on this molder while running the above mold, go through this checklist again to ensure that nothing has been changed.
Also, anytime there is a mold change, grade change i.e. that requires program change etc. this checklist should be gone over again.
If anything is not set up correctly for the mold being run, please fix and record in the comments section below and initial.

Comments with Initials: _____

_____

_____

_____

_____