**Understanding and increasing Right First Time
(RFT) Performance in a production
environment: A Case Study**

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B.S., Northwest Missouri State University, 2007

A THESIS

Submitted in partial fulfillment of the requirements

for the degree

MASTER OF AGRIBUSINESS

Department of Agricultural Economics

College of Agriculture

KANSAS STATE UNIVERSITY

Manhattan, Kansas

2017

Approved by:

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ABSTRACT

It is estimated that the animal health biologics sector will increase by over 27% between 2015 and 2020. This projection and the increasing competition among the sector's players suggests need to find ways to enhance their efficiencies in manufacturing to sustain their relative competitiveness. One approach to enhancing efficiencies is to ensure that all work is done once, i.e., everything is done right the first time. This research focused on human error as a major source of inefficiency in manufacturing and hypothesized that addressing issues that reduce human error would contribute to reducing inefficiencies. The research used the *Kaizen* process to assess the before and after counts of human error in a biologics manufacturing unit of Z Animal Health Company (ZAHC).

The study found that human error accounted for about 51% of all sources of error in the pre-*Kaizen* period and only about 34% of all errors in the post-*Kaizen* period, a reduction in excess of 33.3%. Given that humans are directly or indirectly responsible for all activities in the manufacturing process, the *Kaizen* process also contributed to a reduction in most other error sources. For example, errors in raw materials and components went reduced by about 50%. We tested the hypothesis that undertaking the *Kaizen* was statistically effective in reducing human error compared to all other errors using a logit model. Our results confirmed this hypothesis, showing that the odds ratio of human error in the post-*Kaizen* period was about 50% of the odds of non-human error.

The research suggests that in a highly technical manufacturing environment, such as in animal health biologics, human errors can be a major problem that can erode

competitiveness quickly. Focusing employees' on root causes of errors and helping them

address these through structured quality-enhancing initiatives such as *Kaizen* produce

superior results. It is, therefore, suggested that when organizations discover human error as

a major source of inefficiency, it is prudent to help employees understand what they do and

how what they do contributes to the overall performance of the organization. This

appreciation of how their actions fit into the big picture could provide a foundation upon

which significant improvements can be achieved.

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CHAPTER I: INTRODUCTION

1.1 Background

Z Animal Health Company (ZAHC) is an up and coming animal health biologics manufacturer. The company sees opportunities in both the livestock and companion animal markets and hopes to take an increasing share of the market that is projected to reach $7.0 billion by 2020 (Markets and Markets 2015). Although a relatively young company – given that some of the players in this industry are almost a century old, and have human pharmaceutical companies as their parents – ZAHC has several hundred employees, and some of them belong to the industry's main trade union. Despite this unionized environment, the relationship between management and labor can be described as cordial and collaborative.

With a focus on animal biologics, ZAHC presents a relatively wide variety of vaccines and pharmaceutical, principally for swine, bovine, equine, and companion animals. Although the companion animal segment is projected to grow faster than the livestock (production animal) segment, about two-thirds of the company's current total revenue comes from the production animal segment (Markets and Markets, 2015). Therefore, ZAHC has focused its strategies in meeting the needs of its current customers even as it invests in research and development to position itself to seize opportunities that would arise in the companion animal segment.

A major characteristic of the livestock biologics market is that, unlike the companion animals or the human biologics, margins are really thin and customers are sensitive to price changes. This means that for ZAHC to sustain revenue and achieve performance growth targets, it needs to ensure its operations are efficient in every way.

One implication of this is that ZAHC should minimize production errors from all sources across its internal and external supply chains. One approach to achieving this is adopting, implementing and tracking the Right First Time strategy.

Right First Time (RFT) strategy, in regards to a manufacturing environment, is a strategy that emphasizes zero defects from the beginning to the end of the production process. It argues that if every step is performed accurately every time, resources will not be wasted on rework, delays, product destruction, deviations, unnecessary personnel overtime, and many other elements that negatively affect performance. Doing this increases the chance that customers will get their desired orders on time and according to specification. This leads to satisfied customers and translates into customer loyalty.

The biologics production environment presents numerous avenues for error. For example, contamination of a production batch could lead to the manufacturer or the customer rejecting the batch. Such a contaminated batch must be destroyed. The cost of this error is the time and material that went into the production as well as the manufacturer's inability to satisfy a customer's need. Sometimes, the product type could make the destruction costs for a contaminated batch higher than its production cost. For the customer, an inability to procure replacement solution from an alternate source could imply loss of livestock and unwillingness to depend on the manufacturer in future.

RFT strategy is managed by establishing performance objectives that are tracked for achievement. Three antigen production unit units at ZAHC have RFT goals: vaccine blending/filling unit, media preparation unit, and equipment preparation unit. The established goals depend on the level of difficulty assessed for each unit as well as on each unit's historical performance.

A unit's inability to achieve its RFT goal may arise from equipment issues, schedule issues/delays, inventory issues, process knowledge gaps, insufficient or inadequate communication across the production chain, and human error. However, it has been found that the single-most prevalent factor in missing RFT targets is human error and it is the most difficult to address (Carr and Christer 2003). The difficulty arises from the multidimensionality of the problem. Human error can arise from the structure of the work environment. For example, is a unionized workforce more likely to have higher levels of human errors, and hence a higher risk of missing RFT goals than a nonunionized workforce? This calls into question the level of organizational citizenship behavior of workers in these different work environments (Turnipseed 2005). Communication has been identified as a major source of human error in many institutions, including operating rooms in hospitals (Sheridan Healthcare n.d.). The number of shifts per day could increase communication errors across shifts, which could lead to increased human errors. Additionally, errors can be exacerbated by high employee turnover, which puts pressure on units to be in a continuous mode of onboarding new workers, and training them to understand and implement not only the desired production systems but also RFT protocols. This distracts the trainers and current employees from their own work, causing them to slip on achieving their own RFT goals.

The multidimensionality and attendant complexity of human error implies management spends significant amount of its time and effort on searching for solutions. ZAHC management decided on deploying a multi-day *Kaizen* program as one approach to develop a culture to minimize human error in the company. The program encompassed short-term operational and process improvement projects that focused on improving units'

ability to achieve their RFT goals by focusing on reducing human error. Units with the most difficulties meeting their RFT goals were that ones that participated in the *Kaizen* program. This ensured that unit members were trained and engaged in appreciating how they could address human errors in their production activities.

1.2 Problem Statement

ZAHC is not unlike many companies experiencing challenges dealing with human error in their production process. We observed above that human error is complex and multidimensional and can have far-reaching implications within the firm and across its supply chain. Therefore, among all the other sources of error in the manufacturing process, finding ways of reducing human error could significantly prove to be the most lucrative despite it being the most difficult.

To what extent was the *Kaizen* program initiated at ZAHC effective in reducing human error in its production activities? Answering this question is important because it provides an empirical assessment of the program's outcome. It potentially reveals how the initiative succeeded in achieving its objective and offers insights into other opportunities that could be leveraged to enhance RFT goals' achievement.

1.3 Objectives

Given the research problem, the overall objective of this research is to assess the effectiveness of the *Kaizen* process in achieving a reduction in human error in the biologics production unit. The specific objectives are as follows:

1. Analyze human error's contribution to the company's inability to meet its RFT goals prior to the implementation of the *Kaizen* event.

2. Evaluate the human error's contribution to the company's RFT performance after the *Kaizen* event.

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3. Evaluate the odds of human error being a source of RFT target being missed with the *Kaizen* event compared to other errors.

1.4 Methods

The three objectives were tackled using statistical analysis to assess and establish the pre-*Kaizen* situation and compare them with the post-*Kaizen* outcome. *Kaizen* is a business philosophy designed specifically to explore current practices to identify where waste occurs and subsequently create improved practices that will continuously improve all job functions. The study is framed using literature on human error in production and strategies to minimize human error. Thus, it draws on the Quality literature to form its methods foundations.

1.5 Outline of Thesis

The rest of the thesis is presented as follows. The next chapter presents the review of the literature on the problem of the research, the methods employed and the analytical framework used. Chapter 3 provides an overview of the data used and describes the analytical approach used with specific reference to the study. Chapter 4 presents the results of the analyses. The final chapter presents the summary, conclusions and recommendations emanating from the study.

CHAPTER II: LITERATURE REVIEW

The literature review begins with a discussion of the Right First Time concept. We observe that it has its foundations in the quality movements from the 1960s and the Japanese quality process known as *Kaizen*. Thus, the second section of the chapter explores *Kaizen*, providing examples of tools used in the process. The third and fourth sections look at value added and Six Sigma as alternative presentations of this concept as well as exploring what it means to have a Speak-Up Culture. The final section introduces the idea of human error and how it influences quality and performance across organizations.

To achieve the objectives previously stated, we must first understand what Right First Time is and what it means to management, clients, and stakeholders. The Right First Time percentage or ratio, as it is called in other studies, is a measurement that allows the construction of a trend over past results and future expectations/goals. Once these measurements are collected over time, they become a useful indicator to determine where issues exist and where operational activities are proceeding successfully (Steiner 2009).

2.1 Definition of Right First Time

Right First Time (RFT) percentage is a quality management concept used in production facilities (and other areas of business) to track the quality of the goods or products being made (Buisness Dictionary.com n.d.). This concept strives for defect prevention through quality checks and specified procedures to complete tasks error free and without production delays. Right First Time means that a job is done correctly the first time, every time. To do so is a great advantage to production facilities and businesses in order to remain cost effective, defect free, and competitive in the market (Manktelow n.d.).

Some of the negative outcomes from failing to do the process right the first time are production rework, delays, product destruction, deviations from specifications, unnecessary personnel overtime. Some of these do not always translate into direct dollar losses. For example, to have a deviation against a product specification may not necessarily mean that the product impacted is bad and needs to be discarded, just that the production process deviated from the batch record for which is was to adhere to. So perhaps the question is why does it matter if there is a deviation to a product as long as the product is still released for sale. The answer is that although deviations do not necessarily translate into direct costs, they have been shown to increase processing time, leading to downstream costs in the supply chain, such as reduced shelf life.

One of the challenges associated with defect prevention is accepting the costs that go along with it. Costs associated may be additional equipment, labor, stricter regulatory or internal procedures, or higher cost of raw materials. The question then becomes, "Is it worth it?" The idea of RFT was created by Philip Crosby (1979) in the book, "Quality is Free". It was his opinion that if there are no defects, then there are no additional costs associated with the poor quality, production delays, or reworked material, therefore quality becomes free (Manktelow n.d.). RFT is calculated by:

$$RFT = [1 - \left(\frac{\# \ of \ Deviations}{\# \ of \ Batches \ Produced}\right)]x100$$

$$RFT = \left[1 - \left(\frac{d}{B}\right)\right]x100 \tag{2.1}$$

where d is the number of deviations for specifications and B is the number of batches produced. For each given number of batches, an increase in d will reduce RFT. As an example, consider B = 164 and d = 3. This will produce RFT of 98.1%. On the other hand,

when $B = 352$ and $d = 6$, RFT is 98.3%. The critical observation is that the RFT resulting from d and B are themselves not valuable until they are compared with the goal. Thus, if the goal is 100%, as indicated by Crosby (1979), then both examples failed. On the other hand, if the goal is set at 98.2%, then the first example failed but the second passed.

2.2 Definition and History of *Kaizen*

Kaizen grew out of the continuous improvement movement and was first practiced in Japanese business after World War II. It became notably popular after "The Toyota Way" in 2001 as the Toyota Corporation captured their values and manufacturing ideals as well as business philosophy during this time (Kaizen 2017). To identify the sources of waste, *Kaizen* often employs the Corrective Action Preventative Action (CAPA) approach (Figure 2.1). There are two independent components to the CAPA Decision Model presented in the figure. The "Corrective Action" pathway [green boxes] begins when an event that is considered an error happens. This immediately triggers a corrective action to contain any potential damage emanating from the event. Once the risks are contained, decision-makers have the space to undertake a risk assessment of the event that triggered the corrective action. If there are no risks beyond the action taken, then action ends or stops. Contrarily, if further risks emerge that have not been considered in the immediate response to the event, then a root cause analysis is conducted with the view to enhancing understanding of antecedents to the event. Success here engenders an improved corrective action that recognizes the new information revealed by the root cause analysis. The improved corrective action is implemented, tracked and trended for continuous assessment or improvement of the situation.

Figure 2.1: Corrective Action and Preventative Action Decision Flow Model
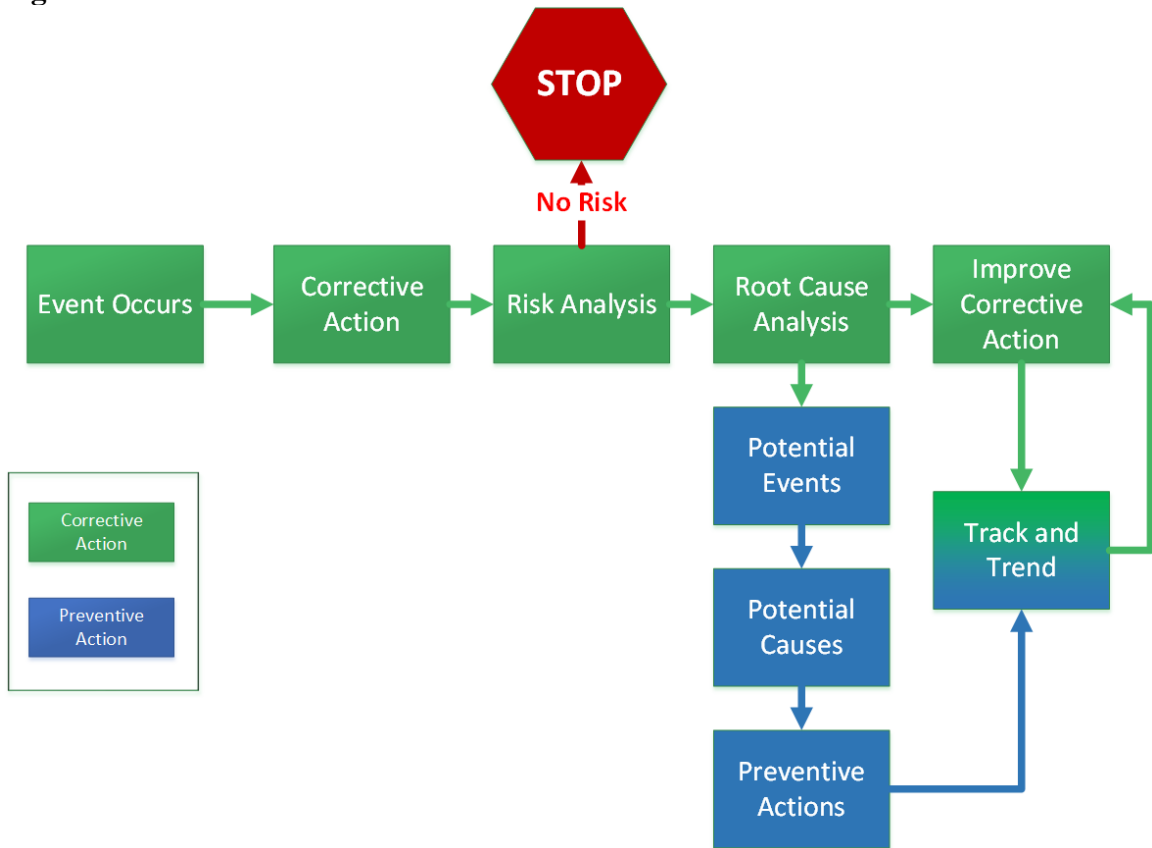
The "Preventive Action" pathway [blue boxes in the figure] begins when the root cause analysis occurs under the "Corrective Action" activities. The root cause analysis could reveal potential events that could happen but have not yet happened due to the vulnerability of existing protocols, procedures, or instructions. This revelation triggers an assessment of potential causes of such potential events, unleashing actions to prevent these potential events from occurring. The actions are monitored and trended to ensure that they are indeed achieving their objective of preventing the identified events from occurring. Should any preventive action fail to achieve its purpose, the event occurring as a result of the failure becomes a candidate for corrective action and the pathway for addressing such events is triggered. The primary analytical tool for both pathways is statistical process analysis. It helps identify causes of events and uses data associated with those causes and

their analyses to develop corrective actions that address those events and prevent their

future occurrence. The primary advantage of employing the statistical analyses is that it

reveals the relative importance of the different error sources, allowing effective

identification of solutions that contribute most to the stated objective of the *Kaizen* strategy.

Kaizen is a business philosophy within the quality movement. The quality

movement may be conceived of as being guided by five steps, with each step demanding

more and using the results from the previous step (Figure 2.2). The steps begin with the 5

Sigma protocols, which focus on the structure of the work environment, the processes and

protocols guiding production and ensuring that deviations from specifications are visible to

all those involved with those protocols and processes. *Kaizen*, the second step, focuses on

developing understanding and insights about key performance indicators (KPIs) and

developing the structures and systems to manage them. These structures and systems

include work in process (WIP) controls that minimize errors and ensure KPIs are attained.

Additionally, the consciousness about continuous improvement of everything the

organization does becomes embedded in the tracking of its KPIs to ensure that all activities

contributing to quality are constantly being monitored. The third step focuses on stability

or lean processes, further enhancing the *Kaizen* step. Its focus is on eliminating all waste,

ensuring processes are stable and the flow and pull systems in the production process are

optimized. Six Sigma or capability is the fourth step. Its focus is on reducing variability in

performance to a sixth decimal by focusing on statistical process controls and in-process

controls. Data-driven communication ensures all involved in the process appreciate how

their actions influence the six sigma outcome, from management to lower level employees.

The final step is robustness of the systems that have been developed through the stepwise

improvement in quality. In this step, the manufacturing or production process should be robust and immune to external disruptions because quality has become a *culture*. Every action in the process and the process itself are designed to produce six sigma outcomes.

Figure 2.2: The Five-Step Model of Quality Improvement

Design for Six Sigma (DfSS) [Robustness]
- Robust Processes
- Quality Function Deployment
- DfSS

6 Sigma [Capability]
- Variation Reduction
- In-Process Control
- Statistical Process Control

Lean [Stability]
- Waste Elimination
- Stable Processes
- Flow & Pull

Kaizen [Understanding & Insight]
- Visual KPI Mgt
- WIP Controls
- Continuous Improvement

5 Sigma [Structure]
- Work Environment
- Procedures, Processes & Protocols
- Visible Deviations

Source: Developed by author from the literature

Because this study focuses on the effect of *Kaizen* on one dimension of quality improvement, i.e., human error, we present a more detailed overview of the *Kaizen* process. *Kaizen* is a business philosophy with the potential to create substantial long-term value both in terms of dollars saved as well as improving operational culture. The basic idea of *Kaizen* is to involve all parties of the manufacturing process – from upstream and downstream activities – so that the process can be improved or identified problems can be solved (Lean Production n.d.). Various tools are used in this process, such as value stream mapping, and "the five whys". "The five whys" is a series of questions that begin with asking "why" and continue with the expectation that the five whys develop a clear pathway

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to a solution. This series of "whys" leads to the root cause of the problem. Consider a situation where a machine has broken down.

Statement: The machine quit working.

Question: Why?

>   **Answer**: Because the ball bearing came off the agitator.

Question: Why?

>   **Answer**: Because the agitator has not been serviced.

Question: Why?

>   **Answer**: Because it was only month three on a six month scheduled preventative maintenance. It was in the manufacturer guide that it only needed to be checked every six months

Question: Why?

>   **Answer**: They tested their product in-house and that is what they deemed necessary

Question: Why?

>   **Answer**: They had to provide some sort of testing procedures, so this is what worked for them.

We may not need exactly five whys to find the root cause of the problem. However, once the root cause is determined, it provides a clear pathway to a solution. In the example above, the root cause seems to be that the testing specification from the manufacturer was not applicable for the actual work environment in which the machine was used. Perhaps the suggested fix would be to shorten the time between the preventative maintenance on the agitator. One of the benefits to the *Kaizen* is that many of the action items that are assigned

from the event do not require large capital expenditures, but rather a change in procedure or understanding of roles (Lean Thinking and Methods n.d.).

The Kaizen Institute (http://www.us.kaizen.com) reports numerous success stories resulting from the application of *Kaizen* in various industry settings, from manufacturing through health care and services to logistics and retail. Coretec is a prime example of *Kaizen* success in the manufacturing industry (steel). Coretec is a company that used *Kaizen* and another lean manufacturing tool called 5-S (sort, shine, set in order, standardize, sustain). It conducted a four-day *Kaizen* workshop to reorganize the production floor layout to create more space. As part of the *Kaizen* workshop, the team identified areas of waste, areas the needed reorganization for job simplicity, and new machinery that would make the jobs more efficient. The results were quite impressive, as they were able to reduce total floor space by 40% by the new design and decrease material movement by 10 km. It involved bringing people and processes closer together in the physical production space.

Another example is found in the automotive sector, from the Keystone Automotive Group, which reduced processing time per piece by 30% and processing space by 47%. Sonae Retail, active in 16 countries within the logistics/food based supply chain industry, also employed the *Kaizen* and 5-S strategies to increase sales by 15%, productivity by 27%, client satisfaction by 7%, and stock reduction by 12%. Other non-measureable benefits that Sonae Retail improved due to the *Kaizen* and 5-S tools are food safety, occupational health and safety, breakages, and people motivation (Kaizen Institute 2017). These are just a few examples of how Kaizen has been utilized by different companies in various industries and processes.

2.3 Value Added Activities/Wastes through Six Sigma

When a process is broken down into individual steps, the steps can be classified as either value added or non-value added activity. According to an undated report from Value Adding Activities (Value Adding Activities n.d.), in order for an activity to be classified as value added, it must meet three specific criteria:

- Customers must value it enough to pay for it,

- The activity/step must only be done once (RFT), and

- The activity/step must advance the item towards completeness.

If an activity is not found to be value added, then it can be classified into a non-value added activity. Non-value added activities can be further broken down into eight commonly accepted wastes that can be very costly to manufacturing organizations (8 Wastes n.d.):

- **Defects:** Mistakes that cost money and additional time to fix.

- **Overproduction:** Not paying attention to demand or inaccurate demand so that there is not a need for the product at the time it is made. This can cause a build-up in working capital.

- **Waiting:** Down time due to breakdowns, failed steps, poor planning, or running out of product or inputs. These cause a stop in production that causes underutilization of resources.

- **Non-Utilized Talent**: Having the right skilled people for the job, but not using them for their fullest potential. Companies may fail to recognize the talents of their employees.

- **Transportation:** Moving things around unnecessarily to the point of creating extra work and additional cost of moving materials more often than necessary.

- **Inventory:** By having too much inventory, a false customer demand due to overproduction is created. This is symptomatic of a misunderstanding of customer needs.

- **Motion**: Excess movement either by people or machines that is not adding any value to the product or the production process.

- **Extra Processing**: Additional and unnecessary work performed during production.

2.4 Speak-Up Culture

A speak-up culture in the workplace is described as a workplace culture in which leaders truly value employee input and employees feel comfortable bringing up issues/concerns. Employee input is encouraged and even sought after as a way to gain insight that may not be evident to those who need to be aware of them. This type of workplace makes employees feel important because it suggests that management does care, and that their expressed ideas will be heard as well as acted upon. A speak-up culture benefits everyone: from those who do speak up on issues or potential issues as well as management and shareholders (Hewlett 2016).

Often the speak-up culture is viewed from a human resource standpoint. It would include issues such as reporting infractions that may not be visible to management or supervisors. Employing this culture to production allows employees on the line who might think of themselves are "only doing my job" to see their job within the context of the overall output. This would encourage them to speak out about things that could compromise their perception of the quality of output that they see themselves as contributing to. It would include employees speaking up when they notice something that

could be considered a near-miss or a potential issue for the future. In fact, research

conducted by the Center for Talent Innovation (Hewlett 2016) revealed a direct correlation

between inclusive leadership, innovative output, and market growth. The results show that

89% of members of global teams whose leaders exhibit at least three of the following six

behaviors feel open to express their opinions and views. About three-quarters of these

members also feel that their expressed ideas are actually heard and recognized. The six

behaviors are:

1. Leaders who ask questions and listen carefully to answers;

2. Leaders who facilitate constructive opposing views;

3. Leaders who give back actionable feedback;

4. Leaders who accept advice from their team and act on it;

5. Leaders who do not take credit for the team's success, but rather shares credit with the team members; and

6. Leaders who keep active contact with team members.

2.5 Human Error

Each year, millions of dollars are lost in sales and product waste due to errors that

occur during the production process. Some of these errors occur out of the most

improbable circumstances, creating the "perfect storm" for a deviation to occur, making

them difficult if not impossible to prevent. Other errors, such as human error, occur much

more frequently and tend to be more preventable if evaluated correctly with the appropriate

preventive actions put into place. Some human errors are easily corrected with corrective

actions.

Most management tends to treat human error as "just a person who made a

mistake". Unfortunately, this approach at looking at human error is ineffective in solving

the problem since it focuses attention on the actor instead of the process that created the error. CAPAs allow management to decouple errors from people and place it on the process and the events engendering them. Once this perspective is developed, then it becomes possible to train people performing tasks prone to errors to develop appropriate orientations that minimize or completely eliminate error. One approach, also discussed conceptually above, is Root Cause Analysis, which are used to determine discover the factors anteceding those errors. However, if Root Cause Analysis is not performed as completely as possible, it fails to reveal the why and the how the error came to be.

All business processes require human interaction in some segments to be completed, no matter how automated they are. This is especially true in production activities in the animal health biologics space. It is, therefore, understandable when human error occurs from time to time. When managers and their people do not make the effort to understand the causes of these errors, accepting them as human and therefore blaming people instead of solving them, then the problem becomes chronic.

Human errors may be a result of lack of proper training for people performing the tasks that are ending up producing erroneous results. They may also be a result of the people performing those tasks being overwhelmed by the sheer volume of work or the pressure of time. They may result from people not being attentive enough because of tiredness arising from overwork, sleep deprivation, distraction or even momentary lack of focus. The structure of the work environment may also cause human errors. Work schedules that do not recognize the risk of fatigue may engender human error. Sometimes, when the work environment has inappropriate lighting or ventilation, people may make mistakes that they cannot control. In addition, labeling, absence of clear guidance and

support for people could cause them to "guess" the best course of action, which may not be accurate, resulting in an error.

Finding out the factors that engenders error, both within an individual and in the work environment, can provide a powerful foundation to preventing the error. This helps incorporate "error proofing" into the work environment, taking the focus off individuals and putting it on the processes. Error-proofing has been done in many industries, consisting of ways to redesign a process, equipment, or methodology in order to make it impossible for a mistake to be made. One celebrated example of this is the change in design to the diesel fuel pumps at gas stations. Due to the change in size to the fuel nozzle, it is now impossible to add diesel fuel by mistake into a gasoline fuel vehicle, thus error proofing the process of refueling a vehicle.

2.6 Other studies

There have been several studies performed to track and improve RFT and its numerous variations, such as First-Time Right (FTR) and zero defect management. Although we used a *Kaizen* process to identify ideas that would improve RFT, it is part of the larger quality improvement process, as shown in Figure 2.2. Ryan (2008) used FTR and discussed its importance in easing data maintenance in a department or across an organization. Ryan used the Six Sigma approach to apply the FTR ratio to his study and explained its value beyond the scope of the ratio itself. He adds to the value of FTR by realizing that there are two focuses of the concept: internal and external. The internal focus resides within the company or group where the errors are most likely to occur. The external focus is toward the client and their expectations of the product. Ryan states that the FTR ratio balances customer focus with internal accountability. This is achieved at minimal cost from start-up costs and continuing maintenance costs (Ryan 2008).

In another study, Steiner (2009) highlights the process of data collection to determine what information needs to be included, and the importance of accurate data. He recognized four reasons for collecting measurements on processes and products. The first is to gain enough knowledge in order to understand the process, product, and the environment to which is it being produced in. The second is an evaluation to determine how to go about setting up a plan based on the current status. This step is also used to determine a number of other things including the impact a change in technology and process may have on the process and product. The third reason is predictions, projections, and estimations. Prediction is a tool used to plan for the future while projections and estimations are information based on past results that is used to analyze the potential risks. The fourth and final reason is for improvement. To remain competitive in the market, all companies must be in constant quest to make their processes and products more efficient and cost effective (Steiner 2009). These four reasons can be applied to determining how a higher RFT percentage can be obtained and sustained, as well as forecasting any potential issues that may come in result of a major change in a process.

CHAPTER III: THEORY, DATA AND METHODS

This chapter presents the theory of Right First Time and the data and methods used to address the objectives of the thesis. It is organized into two main sections. The first section presents a theoretical foundation for the Right First Time process, focusing on the different sources of error or the different error categories. Then, based on the Quality literature, it provides the framework for considering human error antecedents with other errors in the manufacturing process. It also lays down the theory guiding the essence of this thesis, linking the nature of human resource quality and working environment to the errors that often occur and adversely affect the effectiveness of reducing costs associated with errors. The second section describes the data used in the analyses and the description of the methods.

3.1 Framing the Right First Time Concept

Right First time is a quality management concept that argues that preventing defects and errors in the manufacturing process is more beneficial to the organization than detecting and correcting them after they have occurred. The concept of Right First Time (RFT) encourages the implementation of processes that prevent errors and mistakes from happening during the manufacturing process. As the name reveals, it is based on completing all processes correctly the first time.

Right First Time recognizes that accuracy in execution is dependent on the work environment and the people doing the work. Therefore, it involves constructing the right work environment and developing appropriate procedures and practices on all levels of operations contributing to the final product. These procedures and practices include new employee training programs and continuing training programs for existing employees,

developing appropriate and specific onboarding initiatives and activities to help new

employees, automatic programming on equipment, Standard Operating Procedures (SOPs)

that describe in detail how to perform specific tasks or jobs, and detailed batch records. For

example, RFT is based on maintenance staff understanding production equipment in detail,

developing an appreciation of the maintenance cycles for such equipment, and

implementing scheduled preventative maintenance for such equipment on time. Thus, it

involves people having the right technical knowledge and skills, accurate knowledge about

what they do and why they do what they do, and a commitment to do what they need to do

when they need to do them.

RFT also involves maintaining accurate production records with detailed

instructions (such as a recipes), providing effective training and training tools required by

appropriate employees to ensure their ability to perform their work effectively, and

developing and implementing clear lines of communication upstream and downstream of

the processes. When there are multiple shifts, RFT involves ensuring that each production

shift has at least one experienced employee with knowledge across the production process

to facilitate support and interventions to prevent potential human error.

However, it must not be forgotten that making sure every detail in the process is

attended to does not address the fact that all of these processes are driven by the employees,

who are people. People's ability to perform is not independent of their environment and

their appreciation of their role in the scheme of things. Therefore, providing a higher level

of awareness about the potential for error so that people can understand the need and

necessity of protocols they are required to work with is a critical aspect of RFT processes.

An effective way to ensure people maintain awareness of the importance of following processes and protocols is providing them feedback based on performance and outcome data. The purpose is not to blame but to educate and inform. Thus, RFT involves the development and implementation of the appropriate outcome metrics for each process and process step so that people executing those processes know at every point in time how they are doing, why they are failing to achieve their performance objectives and what they can do about them. This allows people performing the processes to consciously evaluate the root causes of their performance gaps and work with management to address those gaps. Implementing RFT protocols that focus on education and learning through objective performance feedback makes the RFT initiative a total organizational activity. Indeed, as technology advances the manufacturing process, human errors in the process become more visible and increasingly expensive, making such protocols increasingly more important to manage effectively. This is because increased precision of technology has reduced some of the historical sources of error in the manufacturing process – equipment failures and malfunction, which were machine-based. The most visible are human failure to service equipment at the right time using the right processes, human failure to use the right recipes or follow the right processes, and human failure to communicate specific instructions to specific people to engender specific actions at specific times to achieve specific results.

In the end, RFT is about quality control and assurance in the most vulnerable segment of the manufacturing process – people. Developing the processes and implementing them in an environment that supports learning is foundational to achieving the economic and other benefits associated with the quality objective. When executed effectively, RFT creates a work environment that enhances the total engagement of

employees beyond merely getting their work done. It focuses them on finding new ways of getting their work done more effectively.

3.2 Analytical Model for Right First Time and Human Error

We may class all activities in the manufacturing process into two broad categories: (i) those involving direct human interaction; and (ii) those that do not. Errors are classified as human when it they are deemed a mistake resulting from employees' failure to follow procedures, processes, and/or some other form of written instructions. They may result from inadequacy of training or appreciation of instructions, lost documentation of the process or accidental errors in collecting specific samples. They may result from errors when weighing material or raw materials to use in a recipe or inadequate or incorrect communication about particular processes.

Among the second group are such error sources as equipment and system failures, procedures or method errors, process variability and material or component errors. Equipment failures are defined as some type of equipment malfunction or the lack of equipment that is required. Raw material or component errors may involve inventory errors, which occur when inventory is not available when it is needed, or inventory is simply insufficient. For example, a specific lot of antigen or component may not be released for use when it is scheduled to be used. Related to the foregoing is Just-in-Time (JIT) inventory strategy.

Just-in-Time (JIT) inventory strategy is useful in increasing efficiency in inventory management and reducing waste. Employing this strategy allows inputs to be received when they are needed in the production process and not before, thereby reducing inventory and inventory-related costs. To be effective, people involved in the manufacturing process must have excellent forecasting skills in estimating material needs as well as effective need

communication systems to ensure that needs are received and acted upon by suppliers upstream in the supply chain. JIT constraints occur when the inherent advantages of the JIT inventory strategy become disadvantages, increasing operations' cost instead of reducing them. For example, in the biologics manufacturing process, a process may schedule titer results to be released mere hours before the antigen is needed, increasing the efficiency of using staff working on the titers. However, if the JIT information ends up showing that the potency of the solution is too low to be used in the scheduled production, then the advantages of JIT become outweighed by the costs of delays in production.

Another source of non-human error is procedure or method errors. These may be related to new products or new processes, resulting from inadequate knowledge about the process at hand due to sheer newness of the process/product and errors occur due to the inexperience/vagueness of descriptions. This often happens when those who have information about the new product or process assume that what they know is known by a larger set of people than is actually the case. As a result, they do not take the time to share the knowledge and train others to understand the new processes or the characteristics of the new products. Scheduling errors include a variety of issues such as scheduling a bulk when the tank needed is still occupied, miscalculated volumes leading to waste, and delays in bulk calculations due to last minute scheduling changes.

The revelation from the foregoing is that while these errors have been classed as separate from human error, a careful assessment indicates that the nature of manufacturing processes puts humans at the source of all decisions, and hence all errors. For example, equipment failure may be accidental breakdown of specific equipment, and no human act was involved. Yet, a careful analysis may reveal that the suggested maintenance cycle was

inappropriate for the current use environment. The establishment of the maintenance cycle was a human action and that there was a maintenance cycle specification error occurred long before the equipment arrived in the processing plant. Similarly, a scheduling error has its roots in a decision made by a human agent in the programming of a machine or in the accuracy of communicating time and location to someone else in the supply chain.

The complex relationship between human error and the other types of errors in the RFT underscores how we envision it in this research (Figure 3.1). The figure shows that RFT is determined by two sources of error as described above. However, it shows that human error plays a critical role in non-human errors, as pointed out in the preceding discussion. This is the whole idea of RFT: that reducing human errors, if well-classified, would eliminate all errors in the production process, and produce the desired outcome of eliminating waste of materials, time and money. More important, when conceived of this way, then the organization recognizes its people as central to its overall performance, acknowledging that humans cannot be disintermediated in the production process.

Figure 3.1: Conceptual Model of RFT and Human Error
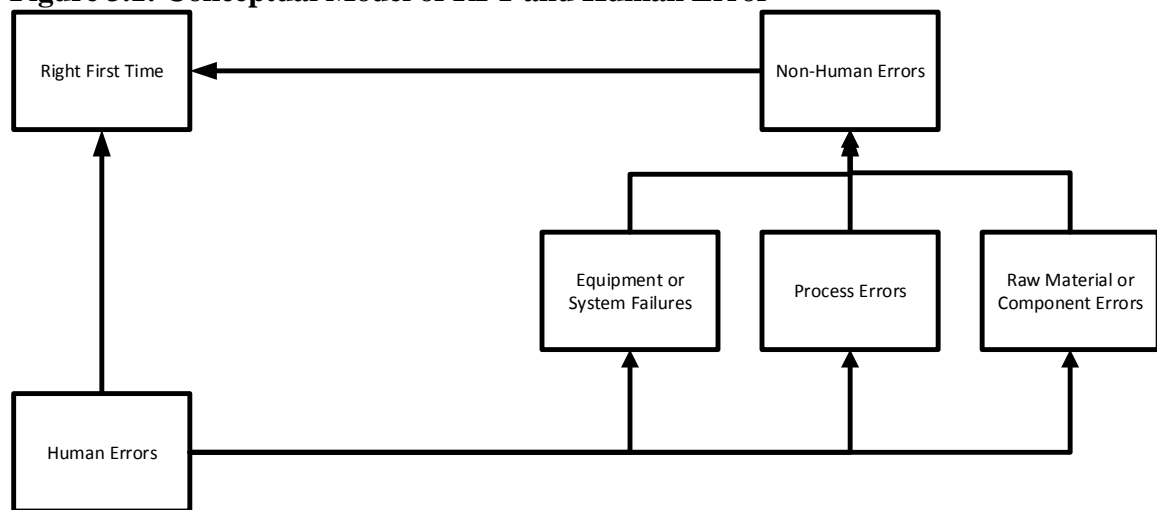
Source: Author

3.3 Data and Methods

Recall that ZAHC is an animal health products manufacturing company focused on biologics production. Biologics are manufactured in living systems, such as plants or animals cells. Unlike drugs, which are the products of the process, biologics products are also the process of their production, meaning the quality of the product cannot be characterized in the laboratory and its quality, consistency and purity must be ensured and guaranteed in the production process itself.

Data for this study were collected using the Trackwise QMS system (https://www.spartasystems.com/products/trackwise-qms) for two periods: the pre-*Kaizen* and the post-*Kaizen* periods. To balance the periods and facilitate direct assessment of changes in types of error, the pre-*Kaizen* period was defined to cover April 19, 2015 to October 1, 2015 while the post-*Kaizen* period covered November 1, 2015 to June 1, 2016. The post-*Kaizen* period is defined as the period after the *Kaizen* events took place within ZAHC. The data covered the type of errors and subcategories for these errors.

Table 3.1: Categorization of Root Causes as Used in Analyses

Error Category
Equipment/System Failure
Human Error
Procedure/Method
Process Variability
Raw Material/Component
Other

The data were analyzed using Stata 14™ statistical package. The statistical analyses focused on frequencies of error categories over time within each period, i.e., the pre-*Kaizen* and post-*Kaizen* periods. We explored the correlations between the different root cause categories and products with the view of finding out if the *Kaizen* event was successful in reducing human error.

CHAPTER IV: RESULTS AND DISCUSSION

This chapter presents the results of the research. We presentation follows the specified objectives presented in Chapter 1. The first section present the results related to the pre-*Kaizen* production environment while the second section presents the results related to the pre-*Kaizen* production environment. The third section compares the performance in the two periods to evaluate the effectiveness of the *Kaizen* program in reducing human error and improving performance.

4.1 Summary Statistics of Pre-*Kaizen* Situation

Figure 4.1 shows the frequency distribution of the errors from the different error categories. It shows that while equipment-related errors accounted for 11% and procedure or method errors accounted for about 15% of all errors in the pre-*Kaizen* period, human error accounted for 51%.

Figure 4.1: Frequency Distribution of Error Categories in the Pre-*Kaizen* Period (N = 65)
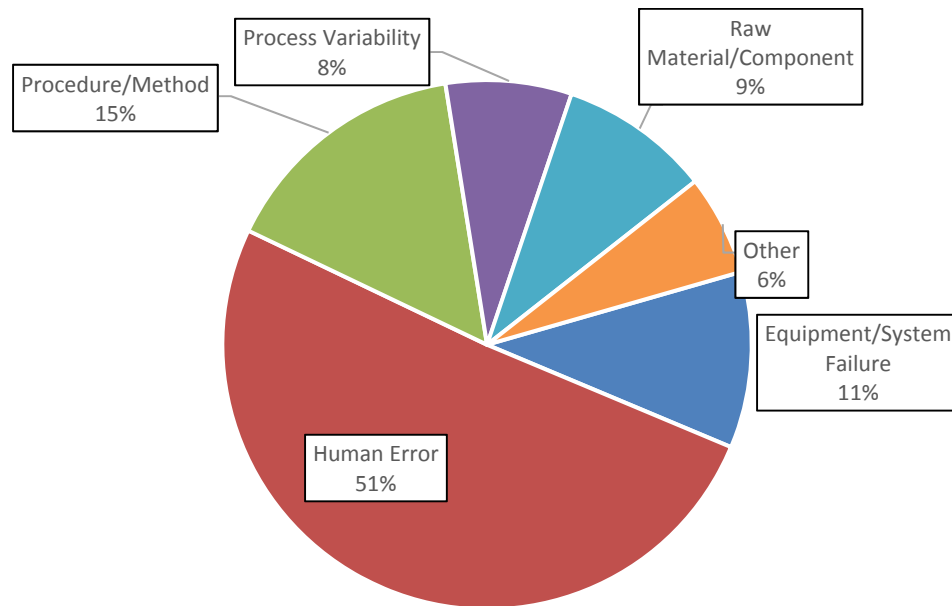
The distribution of the subcategories of human error is presented in Figure 4.2. It shows that failure to follow procedure accounted for about 61% of human error. This category includes all types of mistakes made by simply not reading or following directions as they are written. For example, this includes record detail oversights, and non-experts performing tasks without proper reference to the procedure. The next more important subcategory of error source is set-up or assembly. Examples of this error include mistakes such as an inadequate line slope (potentially resulting in a contamination), a valve that was not closed properly, and equipment that was prepared incorrectly and used without notice to the incorrect setup. Document-related and sample collection errors accounted for 3.0% and 6.1% of human error respectively. Document-related errors include deviations due to incorrect documentation on a controlled record including cleaning logs, process logs, and batch records. Sample collection errors occur when it is deemed the employee that dispensed the sample, did so in error causing a contamination to the submitted sample. Errors emanating from Communication, Training, Weighing Error, Work Environment, and Other each represent 3% of the remaining errors attributed to human error deviations. Communication errors are assigned when a deviation occurs due to miscommunication between two parties. Training errors are assigned when an inexperienced operator performs a task and makes a mistake. Weighing errors include all issues associated with incorrect formulation of a product. Work environment errors are assigned when there are environmental factors that likely were at fault for an error occurring, such as too much going on at once. Finally, "other" is anything else that does not fit into one of the other more specific categories.

Figure 4.2: Distribution of Sub-Categories of Human Error in the Pre-*Kaizen* Period (N = 65)
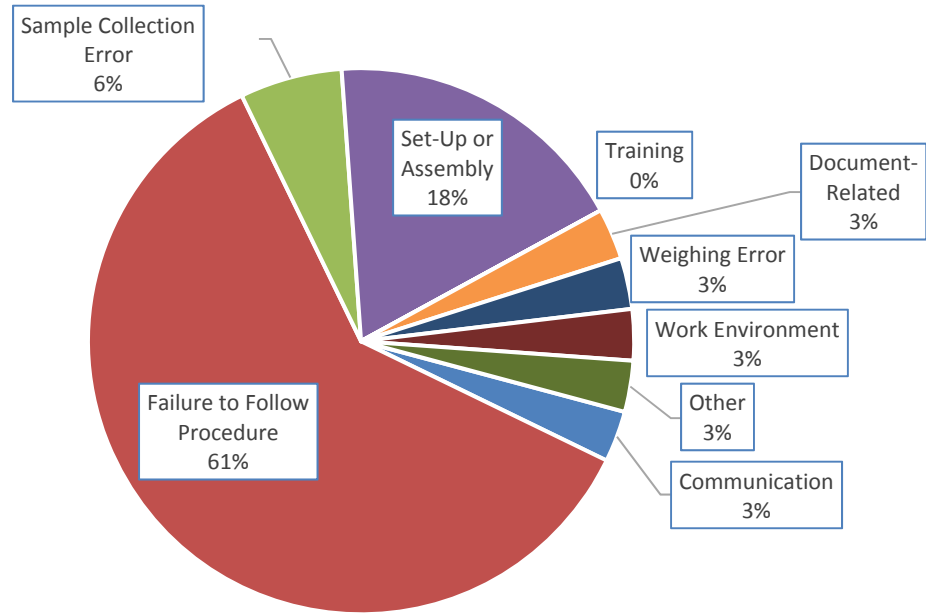

Figure 4.3 shows the sources of non-human error. Interestingly, damages account for the largest single identified source of non-human error. It includes dirty or contaminated products or inputs, equipment breakdowns due to normal wear and tear as well as damaged or broken inputs or products. This group of errors accounts for about 25% of non-human errors. Design, also accounting for about 25% of non-human errors, is defined to encompass document design errors and errors that are inherent to the process (i.e., designed into the process). In the other category are errors that were classified as not existing as well as errors that could not be classified anywhere else and were thus classified as "other". This group of error sources accounts for 31.3% of non-human errors. The error group "Lacks detail" was defined to encompass instructions that lacked adequate or sufficient detail. This group contributed about one-fifth to non-human errors occurring in the pre-*Kaizen* period.

Figure 4.3: Distribution of Sub-Categories of Non-Human Errors in the Pre-*Kaizen* Period
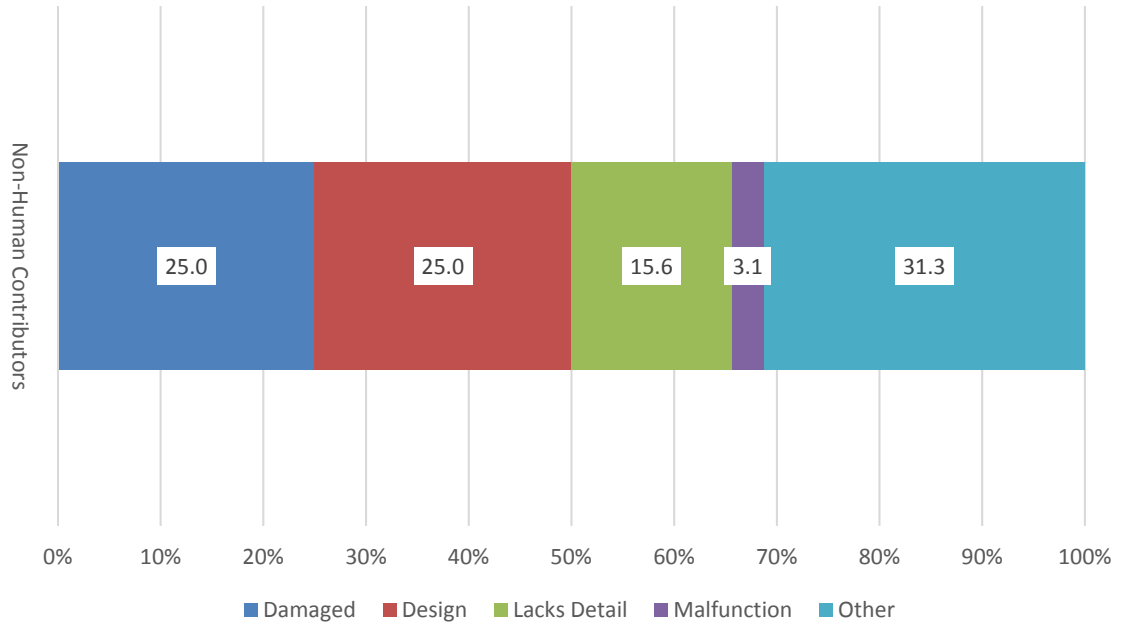
4.2 Post-*Kaizen* Results

Figure 4.4 shows the frequency distribution of the post-*Kaizen* errors from the different error categories as previously seen in the pre-*Kaizen* period results. Human error was still the largest category of errors, accounting for 34% of all errors. Errors related to Procedure/Method accounts for 29%, Equipment/System Failure 18%, and Process Variability accounted for 14%. There were no deviations listed in the other category in the post-*Kaizen* period.

Figure 4.4: Frequency Distribution of Error Categories in the Post-*Kaizen* Period

Raw Material/Component 5% · Other 0% · Equipment/System Failure 18% · Process Variability 14% · Procedure/Method 29% · Human Error 34%
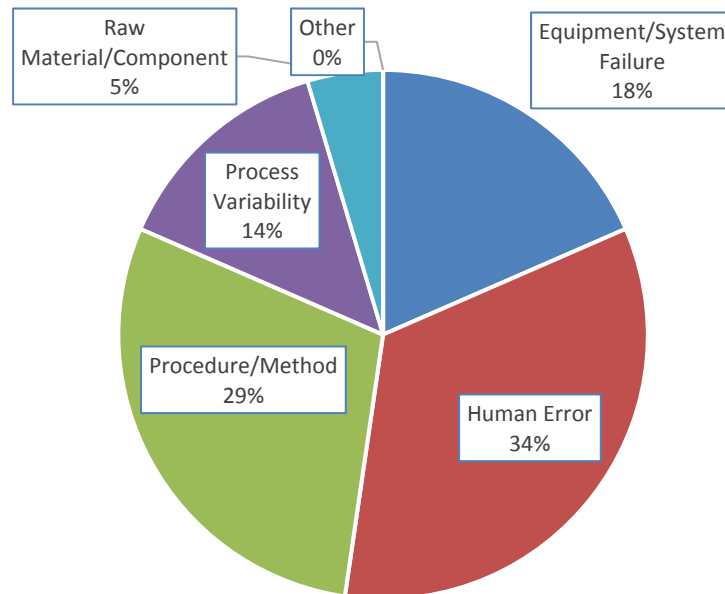
Figure 4.5 shows the distribution of the human error subcategories. Once again, failure to follow procedure accounts for 64% of human errors, similar to what was found in the pre-*Kaizen* period. Communication issues lead to 14% of the human errors, while training, set-up or assembly, and sample error collection combined make up an additional 13% of the human errors. The category listed as "other" is responsible for 9% of human errors. Although the main issue "failure to follow procedure" kept constant at nearly the same rate, the other categories shifted in order.

Figure 4.5: Distribution of Human Errors in the Post-*Kaizen* Period (N = 65)
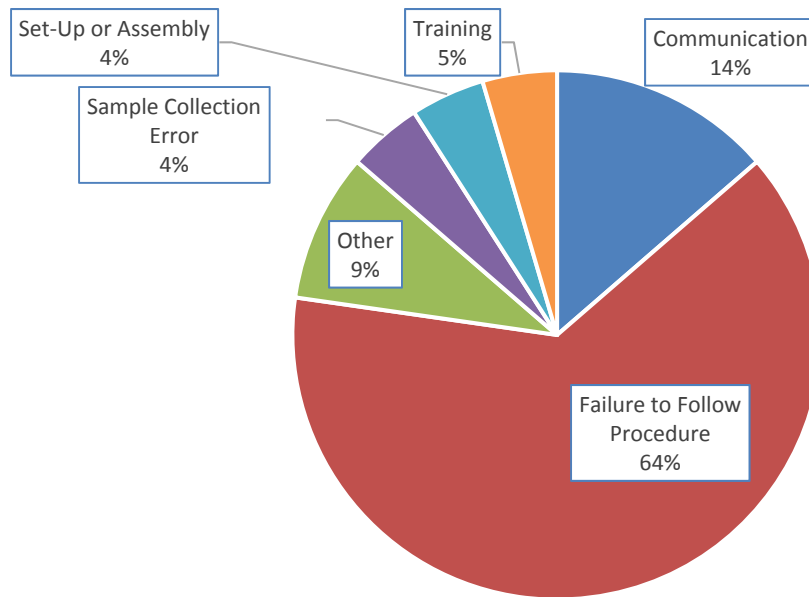
Figure 4.6 exhibits the sources of errors for the remaining errors not captured in the

human error category. During the post-*Kaizen* data collection phase, design contained the

largest majority of the non-human errors at 25%. Damaged materials and issues listed as

other each composed the graph at 21% each. Lacks detail accounted for 14% of the errors,

conflicting documents 9%, and finally outdated contained 5% of the non-human errors. As

we will discuss in the following chapter, these allocations have all changed modestly, most

notably the category listed as "lacks detail".

Figure 4.6: Distribution of Sub-Categories of Non-Human Errors in Post-*Kaizen* Period
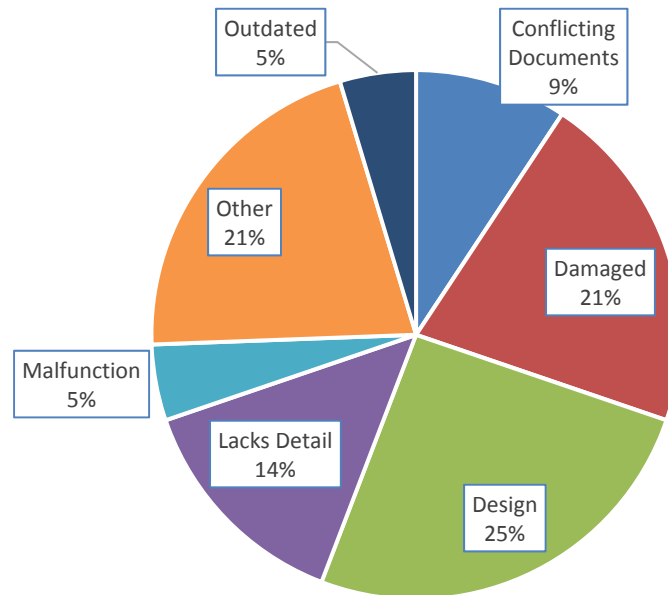
4.3 Comparing the Pre- and Post-*Kaizen* Periods

Table 4.1 displays the pre- and post-*Kaizen* frequency distribution of error categories in a side by side comparison. One of the objectives of the *Kaizen* event was to reduce human error in the production process and achieve a higher RFT percentage. The table shows that the number of human errors was reduced by about 33.3%, i.e., from 33 to 22 when the number of periods for the pre- and post-*Kaizen* are balanced. Raw material/components were reduced as well as the category classified as "other". Equipment/system failure showed an increase of about 71.4% while procedure/methods and process variability increased by 90.0% and 80.0% respectively.

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Table 4.1: Frequency Distribution of Error Categories in Pre-versus Post-*Kaizen* Period (N = 130)

Cause Category	Pre-*Kaizen*	Post-*Kaizen*	Total	Difference
Equipment/System Failure	7	12	19	71.4%
Human Error	33	22	55	-33.3%
Procedure/Method	10	19	29	90.0%
Process Variability	5	9	14	80.0%
Raw Material/Component	6	3	9	-50.0%
Other	4	0	4	-100.0%
Total	65	65	130	

Table 4.2 displays the subcategories of human error for the pre- and post-*Kaizen* event. The largest category in both periods was failure to follow procedure. However, it was reduced by 30% between the two periods. With the exception of communication errors, which increased by 200% and other which doubled, all other subcategories of human error experienced declines after the *Kaizen* event.

Table 4.2: Distribution of Sub-Categories of Human Errors in Pre- and Post-*Kaizen* Periods

Cause Sub-category	Pre-*Kaizen*	Post-*Kaizen*	Total	Percent Change
Communication	1	3	4	200.0%
Failure to Follow Procedure	20	14	34	-30.0%
Sample Collection Error	2	1	3	-50.0%
Set-Up or Assembly	6	1	7	-83.3%
Training	0	1	1	
Document-Related	1	0	1	-100.0%
Weighing Error	1	0	1	-100.0%
Work Environment	1	0	1	-100.0%
Other	1	2	3	100.0%

What are the odds that the *Kaizen* event would reduce the human errors? This question is the third objective of this thesis. To address this, we explored the probability of a human error occurring in the post-*Kaizen* period compared to the probability of a human error occurring in the pre-*Kaizen* period. We did this by estimating the following logit model:

$$y \begin{cases} = 1 \; if \;\; \text{Human Error} \\ = 0 \; if \;\; \text{Non-Human Error} \end{cases} = f(K) \qquad (4.1)$$

where K is a dummy variable capturing pre-*Kaizen* period (K=0) and post-*Kaizen* period (K=1). The left-hand side of Equation (4.1) is defined as the odds ratio of having human error instead of non-human error. We hypothesized that the odds ratio of human error occurring with the implementation of the *Kaizen* events will be lower and statistically significant than the odds ratio of human error without the *Kaizen* events. That is:

$$H_o : \beta_K < 1$$
$$H_1 : \beta_K \geq 1 \qquad (4.2)$$

where β_K is the estimated logit regression coefficient presented as odds ratio and H_0 and H_1 are the hypothesis and the alternative hypothesis. Table 4.3 presents the estimated logit regression results. The number of observations used in the estimation was 130 and the log likelihood Chi-square was 3.83. Although the pseudo-R^2 as expected was very low, at about 2.2%, the model was statistically significant at the 5% level. The important outcome is that the *Kaizen* event did contribute a statistically significant explanation to the reduction in human error. It is also important to note that the model was not misspecified because running the Linktest routine in Stata showed that the predicted variable was the only statistically significant variable. The intercept was not statistically significant.

The estimated odds ratio was 49.6%, suggesting that the odds of a human error occurring in the post-*Kaizen* period was about 49.6% of the odds of a non-human error in the pre-*Kaizen* period. This estimate was statistically significant at the 5% level. The results also showed that the 95% confidence interval of the odds ratio for human error occurring ranged from a low of about 24.4% to a high of 100%. That is, within a 95% confidence, the odds of a human error occurring with a *Kaizen* event could be as low as a

quarter of the odds of non-human error occurring with the *Kaizen* event on the lower bound

and no higher than the odds of non-human error occurring on the upper bound.

Table 4.3: Logit Regression Results Showing the Odds Ratio of Human Error with
***Kaizen* Events**

Cause	Odds Ratio	S.E.	z	P>z	[95% CI]	
					Lower	Upper
Kaizen	0.496	0.179	1.940	0.052	0.245	1.006
Intercept	1.031	0.256	0.120	0.901	0.634	1.677

CHAPTER V: SUMMARY AND CONCLUSIONS

This chapter presents the summary and conclusions from the study. The first section of the chapter summarizes the objective and the main results. The second section presents the lessons learned and the effectiveness of the *Kaizen* events in achieving the results. The third section discusses the challenges confronted in collecting data, organizing data for analyses between the two periods and suggestions for future research.

5.1 Summary

The purpose of this thesis was to assess the effectiveness of the *Kaizen* process in achieving a reduction in human errors in the biologics production unit. Identifying areas of waste is crucial to the animal health biologics industry if companies want to remain cost efficient and competitive within the market. This case study incorporated data collected from ZAHC to determine the frequency distribution of error categories and the distribution of sources of error for the identified human errors for the pre- and post- *Kaizen* periods in order to determine if the odds of human errors occurring were less after the *Kaizen* event than before the event occurred.

Drawing attention to the success or lack of success to the *Kaizen* event holds great value within ZAHC. This specific type of a continuous improvement method is readily available due to a designated support group within the facility. By taking the time to identify where the highest risks and wastes occur, it sets a pathway to create ways to error-proof processes and setting a long-term path to success in order to remain cost effective and competitive within the market. Once the process of *Kaizen* has been identified as a success, the footprint has been set for future groups and endeavors and the process of working through a Kaizen can streamlined to the maximum potential.

The three specific objectives of this case study were: (1) Analyze human error contribution to the company's inability to meet its RFT goals prior to the implementation of the *Kaizen* event; (2) Evaluate the human error contribution to the company's RFT performance after the *Kaizen* event ; and (3) Assess the effectiveness of the *Kaizen* event in influencing the RFT performance.

5.2 Conclusions

The study revealed that the *Kaizen* was successful in reducing human errors by 33.3% using a balanced dataset that included 65 pre-*Kaizen* and 65 post-*Kaizen* observations. The model was statistically significant at the 5% level. The pseudo-R^2 as expected was very low at about 4.2%. The estimated odds ratio shows that the odds of a human error occurring was about 49.6% of the odds of a non-human error with the *Kaizen* event. This estimate was statistically significant at the 5% level. Simply put, the *Kaizen* event was effective in contributing to the reduction in the probability of human error occurring. It is, therefore, recommended for future use in other departments within ZAHC.

5.3 Suggestions for Future Research

Although the research established the effectiveness of the *Kaizen* event in reducing the probability of human error, additional data on the effect of human error on RFT performance measures and their effect on economic outcomes would have provided more depth to the results. The inability to do this resulted from changes in how data were collected at ZAHC, preventing direct comparisons between the pre- and post-*Kaizen* periods.

Future research could explore the relationship between changes in established performance metrics and human error and between human error and the clarity index of production protocols, *c*, the openness of the production, *P*, given the organization's

training, *T*, that allow them to successfully implement specified protocols, and employees'

motivation to ensure quality, M. The foregoing may be expressed as follows:

$$\partial \hat{w} = f(e)$$
$$e = g(c, P \mid T, M)$$

(5.1)

where $\partial \hat{w}$ is the deviation from the established performance metric and *e* is human error.

The foregoing suggests that human error has two dimensions: the clarity with which people

understand the work they do and their contributions to it, i.e., why what they do matters as

much as how they do them; and the ability of employees to get the support they need to

perform their work in an open production environment. The ability of employees to

transform these into errors is premised on their skills and training they have as employees

and their internal motivations. Employees who are internally motivated to care about their

work because they find themselves in what they do would behave differently from those

who are not self-motivated to achieve quality. Such future research would help direct how

employee training and motivation could be organized, and how *Kaizen* events may be

organized to enhance their overall effectiveness in achieving the desired objective.

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