OBTAINING APPROVAL AND SUPPORT FOR BIOMEDICAL QUALITY ASSURANCE STRATEGIES

A Thesis
Presented to the
Faculty of
San Diego State University

In Partial Fulfillment
of the Requirements for the Degree
Master of Science
in
Biomedical Quality Systems

by
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Spring 2011
SAN DIEGO STATE UNIVERSITY

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December 15, 2010
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DEDICATION

This thesis is dedicated to my family who has given me much needed support. It is also dedicated to those many biomedical quality professionals, who nobly seek to help their industry through the application of sound, proven quality strategies, but who quietly and desperately struggle while at a loss for how to gain the needed approval and support.
To lead people, walk behind them …
As for the best leaders, the people do not notice their existence.
   The next best, the people honor and praise.
      The next, the people fear.
         The last, the people hate.
Go to the people. Live with them. Learn from them. Love them.
   Start with what they know. Build with what they have.
But, of the best leaders, when the job is done, the task accomplished,
   the people will say,
"We have done it ourselves!"
       - Lao Tzu
ABSTRACT OF THE THESIS

Obtaining Approval and Support for Biomedical Quality Assurance Strategies by
Christopher Bales Hartle
Master of Science in Biomedical Quality Systems
San Diego State University, 2011

Quality professionals often struggle to get their ideas accepted and strategies adopted within the organizations they serve. Quality professionals are well versed in the tools, philosophies, and activities that they own; however, when it comes to getting management and others to approve them, they seem to lack the skills to gain the needed support. Consequently quality projects and initiatives frequently never make it off the ground, and if they do, they are frequently dropped as support is not sustained. This thesis proposes a research survey study and interview of biomedical industry professionals to explore what may be the possible conditions and factors influencing people’s receptiveness, willingness, and decisions to approve and support a quality change recommendation. On the whole, attitudes, values, and opinions were generally positive both toward the work environment and toward QA; however, QA’s experience of the work environment was not quite as positive. Results revealed a number of trends and demographic factors that clearly influence the variables in different ways. Multiple instances of interconnected, positive, progressive relationships among the variables were also identified. In the end, factors influencing the conditions for gaining approval and support were identified. The key influencing contributors were perceptions of QA credibility, effectiveness, and trust. Other factors such as one’s familiarity with QA concepts, experience with QA, and one’s general attitude toward quality also played a dominant role. Comments in response to open-ended survey questions confirmed the conclusions and revealed high expectations for QA. Both the comments and results from the survey analysis suggest that the QA professional will best gain support (1) when he/she focuses on establishing credibility through improved experience and education, (2) when he/she leads by example, and (3) when he/she communicates collaboratively and diplomatically to develop trust and better understandings of QA’s role, so that there are no misperceptions of QA’s effectiveness and role fulfillment. Existing social psychology and behavior literature with respect to strategies of influence and persuasion were explored. Trust emerged as the key factor influencing support decisions. A summary of quality-relevant leadership skills was presented as a guideline framework to consider for continuous self-improvement. The final study report to this research is electronically available on CD ROM. The CD ROM, an appendix to the thesis, is available for viewing at the Media Center of Love Library.
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ACKNOWLEDGEMENTS

First and foremost, I thank my wife and love, Sophie. This thesis would exist, at best, as only a passing thought in my mind if it had not been for her. With great love and compassion, she supported the completion of this work from the very start and has sacrificed much. “Daddy’s busy!” became her mantra as she kept our two small boys, Benjamin and Nicolas, occupied so I could write. As wonderful as these boys are, I recognize that this was no small feat. Frankly, I do not know how she was able to do it for as long as she did, but I am forever grateful that she did. She and our sons have been the source of my strength and motivation. Love, support, encouragement, and sacrifice; I cannot thank my family enough.

I also thank my brother and parents, who have continuously encouraged me from afar. They have always been my foundation and model for true personal character. I have counted on them and they have never failed me. I have appreciated their frequent words of support during my writing. I extend the same gratitude to Anny and Nicolas, my parents-in-law, who also wished me well all along the way. I am truly fortunate to be blessed with such a family.

I would also like to thank Dr. Dale Sevier for his ideas, enthusiasm, and support, which has inspired me to do my very best to conduct a meaningful research study and to write a practical thesis, which I hope will provide helpful insight to all my industry colleagues.

I thank Irvin Kluth for his unending support, encouragement, and patience, as I toiled these many months over the details and countless implications of the study data.

Both Dale and Irvin have given me a great understanding and respect for the quality profession, and I am extremely grateful for the new skills and knowledge that they have imparted to me over these past years.

I would also like to thank my friend and former boss, Jessie Elchico. Jessie has shown me what it means to be a leader and an example in the quality field, what it takes to make the hard decisions, and how to “sell” quality at all levels of an organization. Over the past few years, Jessie has given me valuable advice and support. She has trusted my opinion
and has believed in me when others might not. I have admired her fortitude to weather political storms as she has shown how, with patience, the just and correct message will always overcome weak, manipulations from the self-serving. As for gratitude and respect, she most certainly has mine.

I wish also to thank Commander Jeff Yuen. I have been fortunate to know and work with Jeff since 2003. In the quality field, he is a seasoned, ex-FDA expert, and in the industry, he is, by all definitions and on all levels, a true leader of leaders. It is my great honor to work with him as one of his associates and to call him my friend. I am thankful not only for the support and encouragement he has given me as I finalized this thesis, but also for serving as a role-model for my writing on quality leadership.

Special recognition and gratitude is in order for my colleagues and friends Fred Mayer, Tammy Lucik, and Don Lucik: they gave me the daily support and encouragement I needed during these final weeks of non-stop writing.

Lastly, I would like to collectively thank the many QA colleagues and consultants that I have worked with over the years who have supported and befriended me in my career. They have made life at work both memorable and pleasurable, and I often had them in mind while imagining the variety of work scenarios about which I was writing. Thank you all.
CHAPTER 1

INTRODUCTION

“The CEO has asked that you retract your audit report.” These words from my boss just baffled me. What?! I’m sorry, but I simply couldn’t believe my ears. At that time, we had just worked the past month on one of the most enlightening audits and had revealed some truly critical problems that needed immediate attention, of which our company was truly unaware. In my previous experiences as a quality professional, we would have been thanked for having brought such issues to light and for allowing the company the opportunity to correct and protect itself. I was new to this company and thought we would have been equally as recognized. I was wrong.

Apparently, the statements as they were written in the audit report were considered too alarming and appeared incriminating to upper-management, and the decision to retract was based on fear of possible legal ramifications. In all fairness, it is true that a few of the statements could have been re-worded to soften the message; however, that would not have changed the content of the message at all. As much as I tried, I still couldn’t understand how the company could respond in this way. The whole affair centered on only one or two “mistake-decisions” identified in the audit that could have easily been addressed and corrected, but instead it was met with an even worse decision: to deny. “Don’t they know this is an internal audit for their benefit only?” I wondered. “Don’t they understand these are only the auditors’ comments, and the company can respond by correcting the problem or by formally justifying its decisions?” “Don’t they understand that the legal ramifications of ignoring the unveiled problems are even worse?” “Why wasn’t the basic quality audit process understood?” “If understood, why wasn’t it at least respected?” “Had they stripped QA of its authority?” These were the questions that circled in my head for weeks following the event.

Unfortunately, this was just one of many tests I encountered at this company. The company simply did not “get” the quality Assurance function, at least not initially. Quality projects and initiatives were challenged at every level; even the implementation of the most
basic, proven quality practices met with resistance. It made me wonder, “How in the world can we get through to these people?” As a quality professional, I was frustrated knowing that even some simple fixes could vastly improve life at the company, but there was no clear path to acceptance. “How could QA go about gaining approval and support?” This became the number one question I would ponder for the next several years. Since then, I have come to learn that it is among the top concerns for most quality professionals. Naturally, it was one of the most motivating topics for me to explore in my professional studies, and has therefore become the focus of this thesis.

A Lack of Support

From classic deviation management systems to the more modern six-sigma quality improvement techniques, there are a multitude of excellent tools and strategies in the quality field that have been developed, tested, and proven effective for improving the health and wealth of companies. Despite their potential benefits, quality departments have repeatedly struggled and failed to fully implement them, and companies have not experienced their promised rewards as frequently as expected. In the spirit of continuous improvement, quality professionals have re-visited, re-created, and re-worked their tools and strategies to improve their chances for success. In the end, all is for naught as quality professionals find themselves with a bag full of even better solutions that, ultimately, are incompletely implemented, rarely applied, or not even tried at all. But, why is this?

As statistician and quality consultant Davis Balestracci (2003, p. 40) remarks, “a history of failed [quality] programs has shown, focusing just on the tools is not enough.” So we ask, “What is happening that keeps well-established quality tools and strategies from being fully exploited?” To begin, quality departments cannot force people to blindly adopt its tools and strategies; people must first choose to accept them. Once approved, success can only be achieved when people embrace and respect the appropriate implementation of the quality tool or strategy. The system will only be as good as those who apply and maintain it. In short, approval and support are required for quality strategies to be launched and to succeed. Unfortunately, approval and support do not seem as readily available as a quality professional might imagine.

[Quality professionals] see low hanging fruit so ripe even quality skeptics could pick it, but their CEO ignores it. They uncover a gap wide enough to cause a strategic detour,
but senior management applies a temporary patch and plunges ahead. They present
detailed analysis of a surefire opportunity, but the top executives snub it. They are the
voices of common sense in a chaotic and disorganized world, and nobody—at least
nobody important—gets it. (George, 2003, p. 30)

**MANAGEMENT’S ROLE**

As the above published remarks by quality consultant Stephen George imply,
management, senior management in particular, is considered a major part of the reason why
quality lacks the approval and support it needs. In fact, W. Edwards Deming and Joseph M.
Juran, the two principal pioneers of quality philosophy in the 20th century, both identified the
management role as vital to the success of quality within organizations (Tortorella, 1995).
Today, this notion appears to have become a commonly accepted understanding among
quality professionals. For example, author and quality consultant Russell T. Westcott (2009,
p. 26) claims, “Management commitment to quality is an oft-mentioned essential
requirement for the success of a sustainable quality initiative in any organization. Intuitively,
everyone knows it is needed.”

Unfortunately, as chief operating officer and entrepreneur Scott Dalgleish (2003)
points out, “top management, in most companies, is not supportive of the quality
department.” However, Dalgleish is not so quick to place all the blame on senior
management. Instead, he believes the lack of faith and support for quality departments, in
many cases, is justified when quality professionals get lost in busy work and fail to deliver
valuable results. N. Dean Meyer and Associates (NDMA, n.d.) goes further by suggesting
that if quality departments have to ask for support, then they don’t deserve it. The idea here
is that if a quality department feels they need it, then something deeper is fundamentally
wrong. NDMA (n.d.) explains how seeking support from the top can be dangerous:

> Generally, the cry for top management support means that someone is trying to
> implement some change—to be specific, trying to get others to change—and is running
> into resistance. …Once people are set against a change, top management cannot
> command them to modify what is in their hearts. …When people resist change, bringing
> top management support down on them only solidifies the antagonism and drives
> resistance underground. And of course the change agent ultimately gets blamed when
> somehow the change doesn’t come off as well as you promised.

This is a very sound and truthful argument regarding company politics and the work
experience. Nonetheless, both Dalgleish and NDMA side with Deming and Juran in
recognizing that management support is required for the successful realization of a quality
plan, and that management opposition would mean the failure of essentially any quality initiative.

**THE HUMAN ELEMENT**

For those quality departments that encounter not only a frequent lack of support, resistance, or worse, blatant opposition within their company, answers are still desperately sought as to why. Whether from up at the top or down at the operator level, why such resistance? Why such venomous disapproval? For some quality professionals, the resistance and opposition can be felt so strongly that morale radically drops and negative personal effects, such as the loss of self-esteem, are common. “The situation exacts a high cost. It lowers morale, lowers employees’ regard for management, causes problems to continue, and thwarts improvements that would profoundly benefit organizations” (Palmer, 2006, p. 27).

To effectively explore the opposition to quality, we must consider an often overlooked and little understood organizational system, the human system. Personal and organizational development leader John R. Grinnell, Jr. (1994) considers the human system as the source of energy for the “engine” of change and quality production within an organization. He believes it is the quality management tools and strategies that allow this human energy to be transformed into “fuel” for the engine. In the spirit of optimizing systems, Grinnell proposes that, in order to improve the engine’s “performance,” (i.e., the extent that change is embraced and sustained within an organization), the human system and its relationship to other systems needs to be improved, but to do so it must first be understood. For the quality professional, this equates to an absolute necessity to better understand the human side of the business so that, at the end of the day, he/she can succeed at creating and fueling suitable conditions for the approval of change and its sustained support.

So, what do we already know about the human system in our organizations and in our industry? What have our experiences with others been? What have been some of the problems? Organizational consultant Geoffrey M. Bellman (1993) reminds us of some inherent relational dilemmas that support functions, such as Quality Assurance, must face:

> Your most important customers (or users or clients) are people who do not understand what your function is about—and often do not care to learn. To make things even harder, the users of your services often see you as less important, subordinate, ancillary, part of the overhead, or a cost center to be at best tolerated and at worst abused or eliminated. (p. 4)
In addition, we are at a disadvantage since we must interact with industry colleagues, who are regularly influenced by business trends of the day that advocate leadership and innovation philosophies, which, to the untrained, seem to conflict directly with established quality strategies. When company leaders adhere to such trends and whole-heartedly believe in the benefits of “breaking all the rules,” thriving on chaos, or being “action fanatics” who are willing to make “the big mistakes,” then the conservative voice of quality will carry very little weight in their minds. In his guidebook on leadership for example, Tom Peters, author and national “über-guru” for business leaders, cited retired General Bill Creech who declared, “There’s a war on…between the people who are trying to do something and the people who are trying to keep them from doing something wrong” (as cited in Peters, 2005, p. 31). Peters (2005) goes on to further advocate the following:

The “bad guys,” …who are trying to keep the [“action fanatics”] from doing something wrong, … use “due process” and “compliance” to gum up the works, to slow things down, and stifle innovation. All innovation = Breaking today’s rules. In fact, there must always be Total War (right term!) between the Vital Forces of Action and the Necessary Forces of Control (p.31).

Insofar as quality professionals understand that compliance in production and freedoms in innovation can co-exist, communicating this notion and interacting with the colleague who has adopted attitudes similar to Peters will be an uphill battle at best.

**Resistance**

When the quality professional begins to consider the human side of the equation, the hope for change seems perhaps even darker, especially when confronted with thoughts similar to those of Bellman and Peters. What is it that can make the resistance to quality so intensely negative? Balestracci (2003) gives us a clue:

Much of what quality professionals perceive and espouse as routine parts of their jobs (including the need for new quality processes) is seen by others as threatening information contrary to the things they consciously believe—the very things that have made these same people successful in the past both at work and at home. …When quality professionals experience what seems to be puzzling defensive behavior, lack of gratitude or blatant disregard of seminar material in reaction to their efforts, it is most probably unintentional. …Strong reactions virtually never happen for the reasons people think. An unrelated, deep-seated issue—and someone’s strong attachment to it—often unwittingly sabotages communication. It is fruitless to either argue or redouble your effort with logical explanations to convince a person in this mode—his or her energy is totally committed to the status quo. (pp. 41-42)
Grinnell (1994) also underscores the fact that the process of resistance to change and maintenance of the status quo is not rational. He suggests that effective leadership by the quality professional and improvements to the human system, for better quality “fuel,” will require “more of an emotional process that is based in the psycho-logic of mindsets, perceptions, and relationships” (Grinnell, 1994). Balestracci (2003) also echoed this plea.

We can no longer naively approach the fuel elements of quality in an ad hoc fashion by relying on logical arguments to convince people to accept change. For the pace of change needed in today’s organizational climate, it is going to become necessary for all to be prepared to, at times, confront and alter their individual mind-sets to accomplish a task or human interaction. (p. 41)

**Selling Quality**

So what exactly is the quality professional to do? Management consultant John Guaspari (1998) recommends that the emotional, relational human element, to which Grinnell and Balestracci refer, must be accommodated as much, if not more, than the logical, intellectual elements in order to gain approval and support. Guaspari (1998) equates the business of seeking approval and support to that of a sales campaign and points to our common experiences as customers to guide us in our approach.

The challenge is to position quality in a way that resonates with people, and that means appealing to them both intellectually and viscerally. It needs to make sense as well as feel right to them. The intellectual part is usually pretty well covered by the quality orthodoxy, those standard technologies and methodologies. It’s the visceral part that gets left out. How do you get to people viscerally? You talk in terms that they can relate to personally. You seek out shared experiences. Look for a common denominator. That’s easier to do than you might think. Because we’ve all had a lifetime’s experience at being a customer. We know what that is, and what that means, and what that feels like. …It’s that shared experience as customers that can help people understand and feel why quality is so important. …Our common experience as customers makes it easier to ‘sell’ the concepts of quality.

Quality consultant Brien Palmer (2006) also encourages quality professionals to adopt a mind-set for selling quality. Palmer advocates a sales approach that engages the company’s internal partners from the beginning, and he recommends that quality professionals do their necessary homework in preparation to sell the quality idea and mitigate any resistance.

In fact, people do not so much resist change as resist being changed. Our job is to involve affected managers from the beginning. New ideas fare much better if people believe they have some control and understand the change has a good purpose: Either their lives will be made easier, or the business as a whole will benefit. Since resistance is inevitable, acknowledge it openly. Seek out doubts and criticisms, and don’t try to negate
them. It is far healthier to discuss professional concerns in the open rather than drive the discussions underground. (p. 31)

In the context of seeking support for quality strategies, Guaspari and Palmer’s notion of selling or engaging the customer through participation is perfectly supported by Paul Hersey and Ken Blanchard’s Situational Leadership Theory (changingminds.org, 2010), popular in the study of organizational behavior. The Hersey-Blanchard theory proposes that leaders, in this case quality professionals, assume a selling/coaching or participating/supporting style when the “situation” includes followers that vary in commitment, competence, willingness, and motivation. The theory recommends, however, that quality professionals can assume a delegating/observing style only when commitment, competence, willingness, and motivation are high. On the other hand, when they are all low, the Situational Leadership Theory suggests that the quality leader must revert to a telling/directing style. What is interesting about the Hersey-Blanchard model is that it creates identifiable situational boundaries such that different leadership styles do not fare well when applied to the wrong situation. It is therefore believed that some quality professionals shoot themselves in the foot and blow any chances for support when they assume a directing, dictatorial, or delegating style yet the situation is rarely appropriate for such behavior. If such an inappropriate approach were dared to be practiced on senior management, they would be quickly put in their place or handed their hat. In most cases, the quality professional must assume the selling/coaching or participating/supporting leadership styles in order to gain continued approval and support.

**SEEKING TO UNDERSTAND**

Based on the discussion thus far, it can be agreed that quality professionals must go beyond the benefits, logic, and practicality of their strategies and appeal to the emotional human side of a quality change. In order for quality professionals to learn how to sell their strategies, they must have a strong understanding of their “clients,” upper management and fellow colleagues. There must be a deeper understanding of that “human system” referred to by Grinnell and Balestracci. What are the mind-sets, the values, the behaviors, and relationships? What are the opinions, the attitudes, and beliefs? What are the factors that might influence perceptions, attitudes, and willingness to change? In short, the quality professional will need to know what those factors that influence approval and support for
quality are, and how those factors themselves can be influenced or modified so as to increase the probability of approval and support.

**Review of Existing Literature**

Unfortunately, the answer to these questions remains relatively elusive. “One key condition is vital for initiating, implementing, and sustaining a viable quality initiative: There must be management support. Surprisingly, very few articles and books on quality even mention this need, let alone what to do if support isn’t there” (Westcott, 2009, p. 25). A review of existing literature reveals only a few references (many of which have been already cited in this chapter) that discuss the current state of the human system within organizations, the need to sell quality philosophies, and/or strategies for approval and support. These articles present educated guesses based on experience and demonstrated common sense; however, few if any of them actually point to the analysis of real data gathered from the field.

**Study of the Problem**

To better understand of the specific relationships within the human system and confirm the currently speculated causes and effects, actual data from the field needs to be collected and evaluated. The research study that was proposed and performed for the purposes of this thesis set out to address this need. The focus of the study was specifically aimed at the biomedical product manufacturing industry and was developed to survey its current attitudes, values, opinions, beliefs, perceptions, and behaviors with respect to quality management roles and concepts. In addition, the study was intended to examine the different possible relationships among these human mind-sets (and a variety of demographic factors that were surveyed) in order to identify and understand any possible cause and effects that may exist. The hypothesis was that observations, patterns, or trends would be observed such that representative truths regarding the human system, as it is actually behaving in the field, could be unveiled. The second hypothesis was that these “truths” would reveal not only which factors exert the strongest influence on conditions needed for gaining approval and support for quality strategies, but also which factors do not. It is strongly believed that the conclusions derived from the data will significantly benefit quality professionals because, should the information allow their quality strategies to obtain the needed approval and
support, it then has the potential to improve life at work, the efficiency of the company, and consequently, the lives of the company’s customers: the patients.

**THEORETICAL BASIS AND STUDY ORGANIZATION**

To tap into the actual mind-set within the biomedical industry’s human system and collect actual data, a set of survey and interview questions were developed for the research in this study. Organized as an anonymous on-line survey and a brief phone interview of only a select few, specific demographic data was collected along with data of each study participant’s opinions, values, perceptions, beliefs, behaviors, and attitudes with respect to quality and change. The design of the questions had its roots in social psychology theories related to the science of influence. In particular, the work of social psychologist Robert Cialdini (2001) greatly inspired decisions regarding which variables could be of principal interest to study. Cialdini has proposed a number of distinct behaviors or factors that can trigger compliance, acceptance, and “buy-in” among individuals, which he has coined quite appropriately the “weapons of influence.” Elements of these suspected “weapons” as they pertain to the biomedical industry helped to color and to shape a number of the study questions. However, because the study was principally exploratory in nature, many of the questions were actually inspired by professional experience and investigational curiosity.

**LIMITATIONS OF THE STUDY**

As a survey, the study had to be somewhat limited in length such that potential participants would be motivated to complete it. Many possible questions, introducing multiple scenarios and possible relationships to explore could have been introduced; however, only those questions that examined what seemed, at the time, to be the most relevant factors and variables of interest were considered. Retrospective analysis allows one to identify further questions that would have been additionally beneficial to ask, but of course, such insight was not available during the original study design.

Another limitation one must consider relates to the nature of the data sought. Inquiring about such subjective topics as personal perceptions, attitudes, opinions, etc. does not easily lend to measurable data of any precision. Much of this “soft” data was collected using two forms of Likert rating scales (e.g., scales from 1 to 10, and agreement level ratings
from strongly disagree to strongly agree). Likert-scale instruments are very common in the field of psychology for survey research; however, there are some drawbacks. One deficiency is that there is frequently a tendency for respondents to provide responses that are socially or personally desirable but do not represent the “true reality.” In addition, survey respondents will interpret possible responses or scores of a scale differently, so the data lack consistency and precision, the distribution lacks symmetry, and scores carry no mathematical value (e.g., a score of 4 is not twice the value of a 2). The fact that the Likert response scales have actual upper and lower limits occasionally results in a phenomenon called “end-piling,” where many respondents gravitate to the limit of one end of a scale. The reverse of that is also possible, in which respondents avoid extreme responses and gravitate to a more central or neutral position. Statisticians refer to this type of data as non-parametric, as it is not normally distributed, and the more well-known descriptive statistics, such as mean and standard deviation, and other typical analytical assumptions are not applicable. As a result, non-parametric statistical data analysis tools had to be applied for the data in this study. This was not a limitation per se since non-parametric statistical analysis of a sample population and its central tendencies can lead to reliable conclusions and does expose possible trends of a sample group; however, interpretation of the results would never be quite as cut and dry as it can be with normally distributed datasets.

Lastly, the collected data allowed for so many feasible relationships to be considered that study analysis had to be limited to only those most relevant and potentially meaningful relationships. Calculated test statistics between factors and test variables helped to direct when further relationship analysis was warranted or might be of interest. In such cases, the data was often explored and evaluated from many different angles and relationships. In the end, it is believed that the entirety of the analyses performed generates sufficient confidence that the most common and significant messages and conclusions had been satisfactorily obtained.

**DEFINITION OF TERMS**

To conclude this introductory chapter before further elaboration on the study, it will be useful to establish a few common definitions. The following abbreviations, terms, and phrases were frequently used not only in this thesis but also in the final study report, which is
published as the appendix to this thesis. The appendix has been recorded on CD ROM, and the CD ROM is available for viewing at the Media Center of Love Library.

**IRB** is the abbreviation for *institutional review board*. Defined in Title 21 of the United States Code of Federal Regulations Part 50 (Protection of Human Subjects, 2010), an IRB is “any board, committee, or other group formally designated by an institution to review biomedical research involving humans as subjects, to approve the initiation of and conduct periodic review of such research.” Essentially their role is to serve as an independent monitor of research with the objective to protect the rights and welfare of humans in research. As the research for this thesis required the involvement of human subjects, a study protocol and all materials to which potential study participants were exposed (including the informed consent instruments) were submitted and approved by the IRB designated by San Diego State University.

**QA** is the abbreviation for *quality assurance* used in the text interchangeably as either the concept or the organizational function (i.e., the department, unit, or group).

**Variables of interest** is the phrase frequently used in reference to the different types of data values representing each study participant’s opinions, values, perceptions, beliefs, behaviors, and attitudes with respect to quality and the quality function. These values were suspected to vary depending on the influence of different conditions or factors to which they were subjected. As these were of primary interest to the purposes of this research, *variables of interest* became the best phrase to use because it provided a very succinct and descriptively exact way to refer to them.

**Demographic factors** refer in this text to those data values that were collected during the study to help define the sample population. Many of the values were truly demographic, such as an individual’s years of industry experience, his/her functional area, or his/her organizational role; however, a few datasets were also considered *demographic factors* but were more subjective in nature, such as the individual’s perception of office politics in his/her current company. Collectively, these datasets helped to describe the sample population; individually, they were used as relationship test treatments applied to determine whether or not they acted as factors of influence on the *variables of interest*.

**Non-parametric data**, as mentioned previously, are data that are not normally distributed and cannot follow the statistical analysis assumptions that normal distributions
follow. Such data must be evaluated using a different set of statistical analysis tools. The test most frequently employed for the non-parametric data found in this study was the Kruskal-Wallis test of variance, commonly used in the evaluation of Likert-scale survey data.

Likert scales, often used in psychological surveys, are response instruments that allow individuals to qualify or rank the strength, intensity, or level of their personal opinions, attitudes, beliefs, or attitudes by assigning a representative label or data value from ranges within a defined scale. The Likert scales used in this study appeared either as intensity rating scales ranging from 1 to 10, or as agreement strength level scales ranging from “strongly disagree” to “strongly agree.”

The Kruskal-Wallis test is the statistical test of choice that was used for the majority of scaled-response relationship analyses in this study. It is often referred to as a One-way Analysis of Variance by Ranking and is one of the more commonly used tests for evaluating Likert scale data (Lowry, 2010). The Kruskal-Wallis Test is “a non-parametric alternative to the usual analysis of variance,” and its primary purpose is to test the null-hypothesis that different study treatments (or factors) generate identical observations, as compared to the opposite hypothesis that they do indeed generate observations of a statistically accepted variance (Montgomery, 2005, pp. 110-111). To do this, responses are ranked (“rank transformation”), and the means of the response rankings for each factor or treatment group under evaluation are calculated and used to analyze variance among them. “Because the procedure is designed to be sensitive for testing differences in means, it is sometimes convenient to think of the Kruskal-Wallis test as a test for equality of treatment means” (Montgomery, 2005, pp. 110-111).

P-values are calculated statistical test results that express the probability that the null hypothesis (i.e., the hypothesis that there are no changes, no effects, no relationships, or no differences between two or more variables being compared) is correct. When the p value is low, the probability is low that the results being observed would occur if the null hypothesis were correct. A low p-value allows one to more readily accept the alternative hypothesis that the observed changes, effects, relationships, or differences may indeed be correct. P-values range from 0 to 1 (or 0% to 100%). A p-value of 0.05 represents a 95% confidence level that the alternative hypothesis may be the more correct description of reality. P-values of 0.05
and smaller (or confidence levels of 95% and higher) are commonly considered an indicator of statistical significance for the alternative hypothesis.

**Box-plots, or box-and-whiskers charts,** are the frequently preferred graphic display of distributions for responses to Likert scale questions used in this study. These charts depict the entire response population divided into percent distribution quartiles from one end to the other. Whiskers, lines drawn on opposite ends of the box, represent the 1\textsuperscript{st} and 4\textsuperscript{th} quartiles (the “tail-end” quartiles) of a population distribution. The box represents the middle 2\textsuperscript{nd} and 3\textsuperscript{rd} quartiles with a central dividing line or symbol identifying the median of the entire distribution. Statistical outliers are depicted in the charts of this report by simple asterisk symbols. Box-and-whiskers allow a visual view of an entire distribution as well as a general understanding of the distribution’s central tendency through the given median value, represented by a line or symbol in the middle of the box. An example box-and-whiskers chart is provided in Figure 1.

![Box-and-whiskers chart](chart.png)

**Figure 1.** Example of a box-and-whiskers chart for results to survey question #15 regarding the extent of participants’ experience working with Quality Assurance and organized by functional group.

In Figure 1, the results to survey question #15 are organized by functional group. As can be seen in the results for Manufacturing, Quality, and Regulatory Affairs, some
distributions do not have whiskers on both sides of their representative box. This is because the missing whisker shares the same part of the distribution as the box. The results for quality also give the example where 1\textsuperscript{st}, 2\textsuperscript{nd}, 3\textsuperscript{rd}, and 4\textsuperscript{th} quartiles as well as the median all fall on the same scale value, 10. Statistical exceptions, outliers to this distribution, are represented by the asterisk symbols, also evident in the quality distribution example.
CHAPTER 2

METHODOLOGY

In this chapter, the survey, interview, and the methods implemented in the execution of this research study are described in greater detail. A final study report with complete details can be found in the appendix to this thesis, and the actual IRB-approved study protocol and screenshots of the survey questions as they originally appeared on-line are also available in the appendix as final study report attachments A and B respectively. The appendix has been recorded on CD ROM, and the CD ROM is available for viewing at the Media Center of Love Library.

STUDY DESIGN

The scope of this study was limited to the biomedical product manufacturing industry, referred to in this text as the biomedical industry. The study was conducted on subjects characterized as biomedical industry professionals. This includes employees working for pharmaceutical, biologic, and medical device companies as well as contractors or consultants for such companies.

The study was conducted as an on-line survey with the principal objective to survey and expose the predominant attitudes, values, opinions, behaviors, and assumptions that may exist in the biomedical industry with respect to quality and the quality assurance function. Analysis of the survey data collected in the study had an ultimate objective: to explore possible factors causing the formed attitudes, values, opinions, and other conditions that might influence behavior and decisions such that potential solutions and approaches might be identified that allow the QA professional to be more readily heard and ultimately supported by both management and peers.

All data collected in this study fell into one of three categories: (1) demographic factors, (2) variables of interest, and (3) open-ended response comments.

**Demographic factors:** The rationale for collecting data classified globally as the *demographic factors* was two-fold: The first was to identify, classify, define, and better
understand the population of the participating survey respondents. In so doing, insight may be gained with respect to the existing attitudes, values, and behaviors among biomedical industry professionals. The second purpose was to establish a series of personal background factors that might potentially show a trend or relationship with the collected study variables of interest (i.e. behavior, attitude, values, etc. directly with respect to the QA function).

These demographic data were additionally broken-down into two principal areas of interest: (1) data pertaining to each participant’s professional background and work environment and (2) data pertaining to each participant’s quality background.

The first area of interest, the professional background and work environment of each participant, collected the following sets of personal data:

1. Functional area of work
2. Organizational role
3. Self-perception of one’s working role
4. Years of industry work experience
5. Industry sector (pharmaceutical, biologic, medical device, etc.) where one has worked
6. Average size of company where one has worked
7. Geographic region
8. Applicable regulatory controls
9. Professional title
10. Highest level of education
11. Level of experience working with QA
12. Highest level of representation held by a QA professional within one’s company
13. Political environment experience and expectation at one’s company
14. Frequency of negative experiences with QA

The second area of interest for population demographics included data from two different sets of quality background questions. The first set of questions was aimed at exposing the general degree of each participant’s familiarity, understandings, and assumptions with respect to the QA function through a series of several basic questions regarding QA roles and general quality management concepts. The other set focused on exposing personal attitudes that were considered instrumental for acceptance, implementation, and/or management of quality initiatives. Both sets of quality background
questions were designed with the intent of tracking factors that were believed to possibly influence, impact, or otherwise express correlation with the variables of interest in this study.

Variables of interest: The data identified as variables of interest were collected for two reasons: The first was to identify, classify, define, and better understand the study population’s opinions, values, perceptions, beliefs, behaviors, and attitudes with respect to quality and the quality function. The second reason was to establish a second series of possible factors (in addition to the demographic factors) that, when compared against each other, might be used to find dependencies, interdependencies, and other relationship trends among the variables of interest. Of particular interest were those relationships in which a variable is found to exhibit influence on attitudes of receptiveness and willingness to follow change recommendations from QA.

These variables of interest could be organized into three principal categories: (1) data pertaining to each participant’s working perceptions relative to the QA function, (2) data pertaining to each participant’s general attitude with respect to quality, and (3) data pertaining to each participant’s attitude of receptiveness and willingness to follow change recommendations from QA.

The first category of variables, those working perceptions relative to the QA function, included the following sets of data:

1. Perceptions of QA’s likeability
2. Perceptions of QA’s credibility
3. Perceptions of QA’s forcefulness
4. Perceptions of QA’s effectiveness
5. Perceptions of QA’s criticality to the company
6. Perceptions of trust for QA

The second category of variables pertained to data obtained from a specific series of questions, which, individually, revealed the many different attitudes, opinions, or behavior held by each participant with respect to QA professionals, the QA function, and various aspects of QA tools and strategies. An individual’s responses to the entirety of all these questions embodied his/her general attitude with respect to QA. This data was collected and summarized into one representative attitude statistic (i.e., the quality attitude survey index) for each participant, which itself was also considered a variable of interest.
The third and final category of variables pertained to data for each participant’s attitude of receptiveness and willingness to follow change recommendations from QA. This data originated from only three specific survey questions: (1) a question regarding the participant’s receptiveness to QA’s explanations, (2) a question regarding the participant’s willingness to follow QA’s recommendation for change, and (3) a question regarding the participant’s willingness to follow QA’s recommendation for change despite mixed opinions from peers. These receptiveness and willingness attitude data were considered the ultimate variables of interest. This is because the personal attitude information collected in this portion of the survey was believed to serve as a type of data signal indicating the likelihood of whether or not a QA recommended change might actually obtain approval and support.

**Open-ended response comments:** The last category of study data collected covered all study responses of an open-ended nature. Naturally, these included all responses to the interview questions, but they also included a participant’s written comments and explanations provided in response to five open-ended questions imbedded into the on-line survey. The data could be considered an extension of the variables of interest because the focus of the question topics is very much aligned with them. In particular, many of the survey and interview questions focus on views for how best to gain approval and support for quality strategies. The intent of these questions was to allow respondents additional opportunity to more liberally communicate their opinions and beliefs anonymously. They were also meant to provide uninhibited insight regarding QA pitfalls and other concerns, as well as to be a source of advice regarding approval and support for quality strategies and how both might be obtained.

**STUDY CONDUCT**

In order for the study survey to be conducted and data to be collected, study subjects first needed to be identified, consented, and screened. Once an eligible study subject had been appropriately vetted, he/she could participate in the survey and, if interested, a brief interview. These study conduct methods are described in this section.
Identifying Study Subjects

Potential participants for this study were identified through the use of available professional databases used in the biomedical industry for networking. These were individuals who had provided their names and Email addresses in an effort to be contacted by other industry professionals interested in their experience and possible input. Following the protocol for this study, the individuals were contacted by an Email message inviting him/her to visit the research website to learn more and to participate. Those individuals who were contacted were also requested to forward the invitation they received to anyone else they believed might offer valuable input to the study. The invitational Email “blast” was sent to a total of 6,475 unique Email addresses.

In addition to the above, an IRB-approved modification was made to the protocol. It provided for the use of an internet “pay-per-click advertising” service to bring interested persons to the on-line survey anonymously. Basically, this service allowed internet surfers who entered relevant keywords (such as “FDA,” “GMP,” “QA,” etc.) into their internet search engine (e.g., google.com) to be presented with a direct link to the survey website under a link entitled: “Biomed Professionals Experience: Your input needed for this industry study survey.” When the person clicked on the link, he or she was then transferred directly to the survey’s informed consent webpage. The approach was successful in that, over the course of only six days, it resulted in 699,882 impressions posted, of which service metrics records show that 559 persons subsequently clicked to the study survey site. In order to curtail the associated financial burden, this “pay-per-click” service was terminated after six days, having run live from May 20 to May 25, 2008.

In total, 706,357 invitations were presented to the public (6,475 via Email and 699,882 via pay-per-click advertisement).

Consenting Subjects

Once a potential participant arrived at the home page of the survey website, he/she could immediately read pertinent information concerning the study. The bottom of the home page offered the visitor the option to give his/her consent to participate in the study. Once consent was obtained, the individual would move forward to the next page where the survey
questions began, starting with the initial participant screening. This is the extent of the informed consent process that initially took place on the website.

Survey Question #1 was the question regarding consent to participate in the on-line portion of the study. The respondent could answer either “yes” or “no.” Responses collected for this question showed a total of 295 respondents, with 275 that agreed to participate. In comparison with the “no’s,” the total number of “yes” is not surprising when you consider the means of recruitment: A degree of motivation to participate had already been evidenced by the effort to actually arrive and respond to the consent question. A higher, yet unknown, number of “no’s” is believed to have actually occurred since many were lost for calculation simply because they would have clicked away from the consent webpage without taking the time to click and thus register a “no” response.

**Screening Subjects**

Following consent the participant would then move to the next webpage where screening began. Participants to be included in the study were professionals that work in functional areas that require them to be exposed to quality and compliance principles such as good manufacturing practice, good laboratory practice, and good clinical practice.

- This **included** staff members in: Senior/Upper Management, Quality Assurance, Regulatory Compliance, Regulatory Affairs, Training, Document Control, IT (Information Technologies), Manufacturing Process Development, Analytical Development, Purchasing, Facilities and Engineering, Production/Manufacturing, Materials Management, Shipping and Receiving, Warehouse and Distribution, Quality Control, Validation, Calibration, Clinical Data Management, Clinical Development and Trial Management, Medical Affairs, Medical Writing, Biostatistics, and Non-Clinical/Preclinical Development.

- This **excluded** personnel in: Security, Environmental Health and Safety, Sales, Marketing, Business Development, Public Relations, Accounting and Finance (not Purchasing), Legal/Contracts, Human Resources, and Research/Product Discovery.

- This also excluded secretaries and administrative assistants despite the functional area they were in.

**Surveying Subjects**

The survey website maintained anonymity, so no contact information of participants was retained. To track participants, automatically generated sequential numbers were assigned to each unique series of survey responses as a means to maintain a record in the
database per participant. The web service utilized for hosting this study was surveymonkey.com. The private study survey webpage was opened to the public beginning the evening of May 20, 2008 and data was collected up until October 15, 2008, the last data collection day.

**Interviewing Subjects**

Following completion of the survey, participants had the option to volunteer for a follow-up interview. Volunteers provided their contact information, which was deleted/destroyed following the interview. Volunteers were contacted and sent (via email or fax) a copy of an informed consent form to read and sign for the interview portion of the survey study (see Appendix: Attachment C). Once signed consent was received, a 20-minute telephone interview was conducted to ask the volunteer a series of follow-up interview questions. The list of specific interview questions can be found in Table 4.5 (p. 318) of the Appendix.

**DATA MANAGEMENT**

In the study database, each survey question had its own unique data collection field. For proper tracking, both questions and data-fields were assigned a sequential number from 1 to 100, with question/field #1 as the participant’s response regarding his/her consent. Additionally, a unique database record identifier (ID number) was used to associate the series of responses provided by each survey participant. In basic spreadsheet format, each column (1-100) represented a data-field used to house responses for one specific survey question, and each row represented a record of all responses provided by one specific study participant. The original raw data and calculated/derived data are presented in such described database format and can be found in Attachment D to the study report (see Appendix: Attachment D).

Raw study data (survey responses) were originally stored directly into a database secured and owned by Surveymonkey.com with password-protected access granted only to the principal investigator, (author of this thesis). After closure of the survey website to the public, the data were transferred from Surveymonkey.com into an electronic data spreadsheet for management and analysis by the principal investigator.
All derived values resulting from data sorting and analysis can be linked and confirmed to their original raw data.

Often, for more clarity, it was necessary to group results into categories. For example, study subjects provided the specific functional area in which they worked. There was a wide range of responses that, separately were too small and too many to be of any use for identifying trends or signals coming from specific areas. Consequently, the subjects were regrouped into six classic functional groups: quality, regulatory affairs, manufacturing, GCP/GLP, GXP support, and senior management. This allowed for greater clarity and visibility for understanding the sample population as well as for identifying any trends or signals emerging from a particular functional group. Another common grouping worth mention that was used at times in this study was the categorization of different Likert scale ratings. In this case, ratings were placed in the following buckets: rating scores of 1-3 were categorized as low, 4-6 as moderate, 7-8 as high, and 9-10 as very high.

Another approach used for managing the data for analysis was a method of compiling of several responses into one statistic. The survey had questions, for example, that probed many attitudes, opinions, behaviors, and beliefs regarding quality. An assessment of each individual attitude or belief was treated individually; however, it was considered of little value to seek factors of influence that might impact each and every attitude or belief. Instead, an index score that represented the global attribute being considered for that person was calculated based on all responses he/she provided for that same attribute. In this study, this compiling method was used especially for the attributes of an individual’s general attitude toward quality and also of his/her familiarity with quality roles and concepts. In the case of attitude, for example, a participant’s responses to specific attitude, opinion, and behavior-related questions were combined and calculated into one overall score or index by following a process very much similar to the way one calculates a final grade or score from responses to the variety of questions in a quiz or test.

Other indexes were calculated based on compilation calculations of a much smaller scale. For example, experience or disparity indexes were frequently used when an individual’s rating of a perception of a particular QA characteristic was compared to his/her expectation for that characteristic. In this case, the expectation score was subtracted from the perception score to yield one common index score. For such an example, index scores that
were zero represented a perception that met the individual’s expectation for a particular characteristic. Positive index scores meant the individual’s perception exceeded his/her expectations, and negative scores meant the perception was deficient relative to expectations.

Although not always necessary, this compiling of data into a single index score statistic was an extremely useful method for filtering survey responses into a single, representative, meaningful, and evaluable response statistic. Exact specifics for each index employed (as well as all other data management methods) are discussed in full detail in the final study report (see Appendix).

**DATA ANALYSIS**

Analysis of the study data (both survey and interview data) was entirely dependent upon the nature of data itself. Detailed descriptions of every study question and the method of analysis applied to each can be found in the final study report (see Appendix). In general terms however, analysis consisted principally of a statistical analysis of the study data followed by a review of associated charts for trends, patterns, or other visually observable messages. When such findings were observed, further analysis and exploration was attempted followed by a similar approach to interpreting the results.

Since survey results were predominantly non-parametric, the most frequently used statistical analysis test was the Kruskal-Wallis test, previously defined and described at the end of the introduction to this thesis. The Kruskal-Wallis test yields a probability ratio known as the H statistic. The H statistic represents a probability function that very much resembles a chi-squared probability distribution. When H values are low, probability of rejecting the null-hypothesis is also low.

A calculated p-value, a subsequent function of the H statistic, can equally be derived from the Kruskal-Wallis tests. The use and interpretation of p-values are more widely understood, and, consequently, p-values have been the main statistic of interest for evaluation when Kruskal-Wallis tests were used in this study. A table of all pertinent Kruskal-Wallis derived p-values calculated (using Minitab 14.0 statistical software) for the relationships examined in this study can be found in attachment E of the final study report (see Appendix: Attachment E).
Since much of the study data has been non-parametric, p-values at the 80% or greater confidence level were explored closer for possible observable patterns. Most of the observable trends of interest exhibited confidence levels of 90% or greater. The truly strong and clear-cut relationship trends showed very high confidence levels and statistical significance frequently at levels as high as 99% or greater. In addition, some trends or patterns were occasionally identified despite the fact that the relationship being evaluated might actually have had a quite insignificant p-value. In such cases, the trend and exceptions to that trend (which minimized the p-value’s significance) could often be explained by quite logical and justifiable hypotheses. In fact, some very interesting messages were revealed when the relationship exhibited no statistically significant p-values.

For visual review, the most frequently used charts were bar-charts, histograms, and box-plots (also known as box-and-whiskers charts as described at the end of the introduction to this thesis). Another chart was the scatter-plot; however, Likert-scales limited available response selections which rendered scatter-plots less meaningful so they were seldom used.

For the analysis of the responses to open-ended survey questions, no measurable or calculable statistics were created. Instead, common themes and messages were identified and the responses were grouped according to their common message. The collection of all common messages represented the final conclusion to the exploratory survey. Responses to interview questions were treated in a similar vein: Common themes to the questions were identified in the interview analysis discussions.

For complete details on the analytical methods and procedures implemented for this research study, please refer to the discussions and accompanying charts found in the appendix.
CHAPTER 3

RESULTS AND DISCUSSION

As one of the primary study objectives was to expose the predominant attitudes, values, opinions, and behaviors that may exist in the biomedical industry with respect to Quality Assurance, results and conclusions regarding such data and subsequent analyses will be reviewed in this chapter. However, a summary and discussion of findings in the demographic data shall first be presented to better understand the representative sample population and to reveal any pertinent information that may not have previously been expected or known. Complete details, discussions, tables, and figures can be found in the final study report, the appendix to this thesis. The appendix has been recorded on CD ROM, and the CD ROM is available for viewing at the Media Center of Love Library.

DEMOGRAPHIC FACTORS

The professional background, work environment, and quality background survey exposed many qualities of the survey sample population that were later tested as possible factors of influence on their attitudes, perceptions, values, opinions, etc. toward Quality Assurance. These factors included:

• Professional background survey
  o Functional group
  o Organizational role
  o Self-perception of work role
  o Years of industry experience
  o Industry sector experience
  o Company size experience
  o Region of the world
  o Highest level of education attained
  o Amount of experience working with QA
  o Frequency of negative experiences working with QA
• **Work environment survey**
  o Regulations applied in his/her work
  o Experience of company politics
  o The highest level of QA representation within his/her company

• **Quality background**
  o Familiarity with Quality roles and concepts
  o Personal work values/priorities (people vs. results)
  o Receptiveness to Explanations
  o Willingness to Change

  Each of these factors were individually evaluated for trends and tested for signals of relationships with every surveyed attitude, perception, opinion, and behavior variable of interest using the Kruskal-Wallis statistical test. Resulting p-values for each of these tests can be found in attachment E of the final study report (see Appendix: Attachment E).

**Professional Background and Work Environment**

With respect to the demographic survey of the sample population, depending on the question, the participating population for each survey question (to the end) remained on average between N=95 and N=125 respondents depending on the question. As the study was rather involved with 100 questions total, the number of volunteers completing the survey was very fortunate for the study. In addition, approximately two-thirds of the responding population also wrote answers to all open-ended questions; this is also considered very fortunate as written discussions not only help to confirm the data but also provide additional insight that might otherwise be overlooked. All in all, it can be said that this population was relatively committed to completing the survey and providing responses. There are many possible reasons for this, but one possibility is that, for some of the industry professionals, the survey may have provided a forum to voice frustrations or possibly an outlet to communicate thoughts and recommendations for future improvement in the industry. In any case, participation was remarkably high, results showed a population that was responding with credible reflection, and the data proved to be rather meaningful.

**Demographic Landscape:** A birds-eye view of the population landscape can be had by a review of various graphics for those demographic factors discussed in this paragraph.
(see Figures 2 through 7). For the most part, the sample population consisted of very healthy representations for the demographic categories most wanted. For example, of six functional groups (Quality Assurance, Regulatory Affairs, Manufacturing, GCP/GLP functions, GXP support functions, and Senior Management), five were made up of between 24 to 31 persons, the exception was the GXP support function, which had a respectable total of 16 persons and was of lesser interest for this study (see Figure 2). Likewise, when separated by organizational role (see Figure 3), the population breakdown was close to equal thirds: 32.7% Upper Management, 38.2% Middle Management, and 29.1% Operational Talent.

Additionally, the population had a balance of experience working in different company sizes (see Figure 4) and industry sectors (see Figure 5), as well as a balanced exposure to the wide variety of applicable industry regulations. The population also represented respectable cross-sections of different possible years of industry experience (see Figure 6); however, the population was not terribly representative when it came to representing regional differences (see Figure 7). Although a number of participants from around the globe did participate, the vast majority of responses came from North America. While the population may be predominantly North American, it is otherwise a very well-represented sample of the biomedical industry.

**Figure 2.** Sample population by functional group.
Figure 3. Sample population by organizational role.

Figure 4. Size of companies where sample population has worked.
Figure 5. Industry sectors in which sample population has worked.

Figure 6. Sample population by number of years of industry experience.
Self-perception: As a representative sample population of the industry, the demographic background data did expose some interesting information. For example, industry professionals more frequently view themselves either as scientists/scientific experts or as business professionals much more frequently than they would view themselves as operators or technicians, even among actual operational staff. On the whole, quality professionals perceive themselves much more frequently as business professionals (almost 70%). Senior Managers, on the other hand, associate themselves more frequently with scientists/scientific experts (60%). Self-perception later showed to play little impact on the variables of interest to this study; however, it was initially suspected as a possible source of disrespect for quality professionals. As respondent #33 stated, in response to an open-ended question (Question #47), “Sometimes the opinion of my colleagues isn’t respected because they are not scientists.” While there are certainly examples that people may point to with similar experiences of disrespect or scientific arrogance, results in the study showed generally favorable results for Quality Assurance from the scientists. A general conservatism in responses was noted when compared to the business professional; however, on average,
there were no special messages particular to those who perceived themselves as scientists. Interestingly enough however, people who viewed themselves as operational staff were those who showed the strongest tendencies for skepticism, poor attitude, and distrust of the quality function. Figure 8 provides a summary of the working self-perceptions for the sample population grouped by functional group.

![Self-perception by Functional Group](image)

**Figure 8.** Sample population by functional group and sorted by self-perception of role.

**Education:** As may be expected, the sample population showed that this is an industry of educated professionals. The large majority have Bachelor and Master degrees, followed next by Doctorate degrees. The majority of quality professionals have only a Bachelors degree, whereas the majority of Senior Management has Master and Doctorate degrees. This information is of great interest as many of the frustrations people have with QA, as cited frequently in response to open-ended survey question #45, referred to a lack of experience, education, and expertise. Figure 9 presents a summary of the highest level of education attained by the study population and separated by functional group.
Figure 9. Summary of the sample population’s highest level of education separated by functional group.

Experience with QA: This sample population mostly has had much experience working with Quality Assurance; however, there were a number of respondents that admitted to low exposure to QA. The lowest appears to be among GCP and GLP professionals, and the greatest amount of experience with QA (outside of QA, of course) was claimed by Manufacturing. This stands to reason as GCP and GLP functions are known to typically interact with Quality Assurance only in the context of audits and inspections, while Manufacturing relies heavily on the Quality Assurance Unit to regularly review and approve production records and activities. Figure 1, found on page 13 at the end of the introductory chapter to this thesis (presented initially as an example of a box-plot), provides a visual summary of the sample population’s experience with QA.

Limit of QA Representation: It was also interesting to learn that a good number of companies (13/123) have QA representation at the Chief Quality Officer level. The vast majority (59/123) have the vice-president/senior manager as the highest ranking QA position; however, many companies rely on a Director or Manager to be the highest ranking voice.
representing QA. Figure 10 presents a summary of the different highest limits of QA representation at companies of the sample population.

![Bar chart showing the highest levels of QA representation within organizations.](chart.png)

**Figure 10. Summary of the highest limits of QA representation at the different companies of the sample population.**

Having QA represented at the senior management level did prove to have a positive effect for qualities such as QA credibility and trust; however, it was surprising to learn that a similar effect was occurring when the highest QA rank was manager. In this case, it was suspected that QA managers influence trust and credibility at the grass-roots, operational level. The least influential was the Director, who is perhaps too far removed to influence operational staff as effectively and consistently as a manager, who is possibly not considered a leader since he/she reports to senior management, and who may not be sufficiently acknowledged at the senior management level and therefore has few opportunities to influence company leadership.

**Negative QA Experiences:** Another statistic of interest is the frequency of negative experiences this sample population has had as a result of QA projects and initiatives.
Largely, most people (63/106) have had a few bad experiences. The next largest grouping (24/106) was for people who felt such bad experiences occurred about half of the time. Its relationship to trust for QA following bad experiences yielded a p-value of 0.000: As bad QA experiences decrease in frequency, trust for QA naturally improves. Figure 11 provides the frequencies of negative QA experiences that the sample population has had.

![Frequency of Negative Experiences with QA](image)

**Figure 11. Frequencies of negative experiences with QA projects and initiatives.**

**Company Politics:** Company politics experienced by the survey population proved to be extremely interesting with several messages. For Quality Assurance, company politics is perceived worse than it is for any of the other functions. In contrast, Senior Management is relatively content with company politics rating it as an environment that meets their expectations as to what it should be. In fact, when sorted by organizational roles, one’s experience of the company political environment appears to improve as one climbs the corporate ladder from operational talent to upper management. Another finding was that small and start-up businesses rated generally with a better political climate than for people who experience politics at large to mid-size companies. When broken down by functional
group, this trend also held true for both Quality Assurance and Regulatory Affairs, but not for Senior Management. It is suspected that Quality Assurance meets less resistance and obstacles at smaller companies because it is forced to wear many more hats and interact internally more frequently, leading to more exposure, better mutual understandings, and therefore less political tensions. This notion that more frequent interaction may lead to improved relations is one that often emerged within the messages of this study. The benefits of communication and collaborative interactions were certainly cited often in response to many of the open-ended questions. Figure 12 provides a box-plot summary of the different company politics experience index scores grouped by functional group for the sample population.

![Organizational Politics Experience Index by Functional Group](image)

**Figure 12.** Summary of different company politics experience index scores grouped by functional group for the sample population.

**Quality Background**

**Quality Familiarity:** Within the quality background portion of the survey, there was a battery of questions that, when considered collectively as a sort of quiz, represented one’s
general familiarity with quality roles and quality management concepts. Nonetheless, responses to each of these familiarity questions were considered one by one, and in so doing, a few messages were learned that might have otherwise gone unnoticed if only the combined score was considered. A few of these familiarity questions had response distributions that stood out as unexpected or out of trend.

The first (survey questions #56 and #57 in particular) explored the notion that it is QA’s job to be tough, difficult, and otherwise needed but unpleasant. As discussed at length in reference to these questions, it is the role and responsibility of Quality Assurance to make tough decisions and to be confident and committed to the advice and positions it provides. However, this should not be confused with an obligation to be difficult, severe, aggressive, or otherwise tough. More damage is done to the quality culture of an organization when QA is perceived as difficult, threatening, harsh, or unpleasant. In fact, it should therefore be argued that a QA professional’s job is not to be tough, but rather to strive to be diplomatic. Diplomacy is a skill of knowing when to take a stand and how to do it so as to maintain healthy relations. Toughness implies a lack of skill and tact combined perhaps with a degree of resolved stubbornness; whereas diplomacy requires an understanding of how to communicate and preserve relations. What is interesting in this story is that, repeatedly throughout the responses to the open-ended survey and interview questions, participants express frustration with QA inflexibilities and recommend a less aggressive approach that is more diplomatic, collaborative, and less dictatorial. This is in direct contrast to the notion that QA should be tough.

The second observation made among the series of familiarity questions exposed that most of the quality concepts were acceptably understood except when it came to problem management questions (survey questions #63, #64, #66, and #67, in particular). In these cases, a large percentage of the population either provided the negative response or did not know the appropriate response. What the responses revealed was that there seems to exist in this industry a frequent lack of understanding of what to do when errors occur, how to manage them, and what they mean. Consequently, there is an inclination or need to find a guilty party to place blame for errors, and often the desire is to hold QA accountable. This was further voiced in response to interview question #4 by the QA Professional who said, “[The problem] is that people are afraid to be held accountable. Organization has to
understand that folks (QA included) will make mistakes. People have been beaten up because of bad decisions, so people do everything they can to cover their backs.”

Looking at the familiarity as a whole (see Figure 13), using the familiarity index score as one statistic, a number of observations surfaced. As expected, quality performed the best (when comparing medians of final percent scores). Interestingly enough, Regulatory Affairs had the worst median score; however, its distribution was wide. In other words, the Regulatory Affairs population has some of the most but also some of the least familiar with quality roles and concepts. A quality professional may wish to be mindful of this prior to accepting a position that reports directly to Regulatory Affairs.

![Quality Familiarity Index](image)

**Figure 13.** Summary of the sample population’s familiarity with quality roles and concepts, represented by the index scores and sorted by functional group.

One of the worst p-values obtained was for a test of the relationship between the familiarity index score and one’s highest level of education (p=0.91). This failing result indicates that one’s level of education has absolutely no bearing on his/her familiarity and understanding of quality roles and concepts. Other relationships were analyzed but only two
revealed trends of progression that were noteworthy. The first observed was the relationship between quality familiarity and years of industry experience. As years of experience increased, one’s familiarity with quality roles and concepts also increased. The second relationship was between quality familiarity and negative QA experiences (see Figure 14). In this case, an inverse relationship existed as one might expect: the frequency of negative experiences perceived by the respondents appeared to be somewhat dependent on their understanding of quality roles and concepts. The more familiar one is with quality roles and concepts, the better the experiences will be with QA initiatives and vice-versa. This insight is considered key information for those who seek to improve the quality culture of an organization. In fact, this notion was further echoed in the open-ended responses in which it was recommended for quality professionals to invest their time to communicate and train to ensure everyone understands quality-related details, rationales, and logic. Responses to the last interview question suggested that communication and training of this sort would also allow QA to build trust.

![Familiarity with Quality Roles and Concepts By Frequency of Negative QA Experiences](image)

**Figure 14.** Summary of the relationship between quality familiarity (by representative index score) and negative QA experiences.
**Personal Work Values:** Another quality background demographic of interest in this study related to the respondents personal work values. The importance of maintaining personal relationships and the importance of obtaining results were queried in this survey. These had been selected for review as they are considered and have proven to be the most basic values in determining working interactions and decision making. Of particular interest was the difference in priorities between the two values, as this is especially interesting when the two values come in conflict. For example, a person who has a greater preference for people as opposed to for results would be less inclined to and perhaps decide not to burn a relational bridge in order to obtain a work objective. On the other hand, the person who places more importance on results would more easily burn the bridge even though he or she may highly value personal relationships.

What the results revealed was that the industry, on the whole, is predominantly results-oriented. Most of the functional groups were distributed relatively equally among the two value preferences such that “no preference” (personal value index score = 0) was their median; however, both Quality Assurance and Senior Management had the more frequent and strongest preference for obtaining results than for maintaining relationships. The differences between the groups were confirmed as statistically significant, and this is not surprising when considering the nature of their functions. This discovery is of particular interest when considering the call for diplomacy and collaborative approaches to work recommended for QA in the open-ended responses to the survey and interview questions. The sample population’s personal value priorities are summarized in Figure 15.

Consequently, it was very much of interest to further discover that the stronger QA’s proclivity for obtaining results, the worse its experience of office politics became. In fact, the political experience appears to improve for the quality professional as his/her preference for results becomes more equal to his/her preference for people. As the results revealed, however, there seems to be a breaking point at which further preference for people begins to work against QA. The conclusion drawn from this relates back to one of earlier the messages that emerged from the survey: namely, there is an industry expectation for the QA professional to be assertive, to make the difficult decisions, and to stand his/her ground. If he/she is perceived as a “push-over” or “nice-guy” who would sacrifice compliance and quality results to ensure relations and reputations remain intact, then not only does he/she
lose respect and credibility but everything else suffers. Naturally, the office politics for such people-oriented QA professionals declines. This observation is perhaps more damaging than the political climate for results-oriented QA professionals as the political climate becomes one in which the individual or the entire quality team may consequently be viewed as ineffective. It is therefore no surprise perhaps that the quality group has more of a results-oriented preference.

According to the data, the condition that is optimum for Quality Assurance is when both results and people are esteemed with equal importance. As unbalanced value preferences appear to lead quality professionals to undesirable experiences with company politics, which in all cases is very damaging to their functional objectives, it is in their best interest to seek a balanced diplomatic approach and/or mindset to their work. This may actually be a very fine political line to walk and would require sustained training with respect to quality roles and concepts to combat continuous misperceptions of intent despite sound diplomatic approaches. For success, this calls for quality professionals to be leaders and behave in a well-balanced, diplomatic fashion. As mentioned previously, this call for
diplomatic communication and collaborative, team-oriented interactions also corresponds to the open-ended comments recorded in the survey and interview. A summary of the relationship between company politics and personal value priorities is found in Figure 16.

![Company Politics Experiences and Personal Value Priorities](image)

**Figure 16. Summary of the relationship between personal value priorities (represented by the personal values index) and company politics experiences (represented by the politics experience index), sorted by functional group.**

**Receptiveness and Willingness to Change:** Another quality background demographic topic evaluated relates to one’s receptiveness to explanations and one’s willingness to follow change recommendations. Clearly these are characteristics of great interest for this study when the explanation or change recommendation is coming from Quality Assurance. Consequently, receptiveness to QA recommendations is data that was collected and analyzed later as variables of interest; however, a series of similar data were also gathered as quality background demographics. In this case, survey questions were the same except that the source of the explanation or change recommendation was not from QA (i.e. recommendation comes from upper management, contractors, peers, competitors,
sycophants, etc.). The intent of these questions was to establish statistics for later comparison to similar results for when the explanation or recommendation did come from Quality Assurance. Figure 17 provides the willingness results for a variety of conditions.

Figure 17. Summary of conditionally-dependent, willingness-to-change attitudes.

Results showed a general willingness by the population to accept change recommendations; however, they did not show any significant difference depending on the source of the recommendation, whether it was from QA or other. There were a few exceptions that did emerge: change recommendations from persons who may have some self-serving benefit to gain by the change (i.e. a sycophant or a competitive colleague) appear to flatten and/or shift the willingness distribution slightly down the scale. In addition, change that comes with a cost (i.e. time, effort, money) also showed a downward shift in willingness although it seemingly did not flatten the curve. Manufacturing, for example, showed the greatest reluctance to change that involves time, effort, or cost sacrifices. Another interesting observation is that the quality group appears slightly hesitant to accept changes recommended or otherwise supported by Senior Management than most of the other
functional groups. Senior Management seems most sensitive and reluctant to follow changes from persons perceived as competition. The GCP/GLP and Regulatory Affairs groups appear, on the whole, to possibly be the most flexible for accepting change; however, they do appear to have their guard up slightly for Senior Management, self-serving change advocates, and change with costs. For the quality professional who is interested in gaining approval and support, this information on how the different groups may respond to change recommendations is quite helpful to keep in mind when preparing to “sell” a QA strategy.

**Variables of Interest**

The variables of interest, as they have been called for this study, relate to personal perceptions, behaviors, attitudes, and opinions regarding the Quality Assurance function. These personal characteristics are of interest especially with regard to what causes them to vary and whether or not they can influence receptiveness and willingness to follow QA recommendations, which are also variables of interest for this study. Receptiveness and willingness attitudes are the “buy-in” indicator variables in this study as they are considered the precursor signal for determining whether or not QA recommendations will actually be approved and supported. As one of the primary purposes of the study was to survey and expose the personal values, perceptions, behaviors, attitudes, and opinions regarding QA, this chapter section summarizes the significant information revealed and any other relevant observations regarding the survey of these variables.

**Likeability:** One of the first variables surveyed was the perception of QA’s likeability. It is a work characteristic that people regularly monitor in an attempt to evaluate the working relationship that one would have with another individual. It was also suspected to have potential influence on behavior as well; therefore, it was of interest to this study. A summary of the results can be found in the top third of the box-plot chart in Figure 18.

What the trends revealed was that likeability of QA was the weakest perceived characteristic because it fell short of meeting expectations more than any other surveyed variable (when comparing medians of expectations against current likeability scores). When separated out by functional group (see Figure 19), it was interesting to note that Senior Management perceived the quality function to be meeting expectations for likeability more frequently than did any other group. On the other hand, QA’s self-assessment demonstrated
Figure 18. Summary of perceptions and expectations for three different characteristics of QA: likeability, credibility, and forcefulness.

Figure 19. Summary separated by functional group for disparities between perceptions of QA’s likeability and expectations.
great disappointment with respect to its expectations for likeability. Quality’s self-assessment mirrors almost exactly the perceptions held by Manufacturing. As quality traditionally works very closely with Manufacturing, it’s possible that quality’s self-assessment may be influenced to a large extent by its perception of how receptive Manufacturing is to Quality and its messages. Although other groups found QA did not meet likeability expectations, none rated their likeability as consistently negatively as QA itself. This was probably the most obvious observation from the survey and begs one to wonder if it is possible that Quality’s own negative self-image is a self-fulfilling belief that influences conduct, ultimately attracting others to believe similarly. One of the interviewed study participants (an ex-FDA consultant), in response to interview question #4, additionally believed that a poor self-image was also the cause of frustration for everyone: “It affects [QA’s] motivation for their job, which may not be positive, can then lead to a kind-of ‘gotcha’/cop mentality, an adversary role as seen by themselves and the industry.”

**Credibility:** Perhaps one of the most critical of variables surveyed was the perception of QA’s credibility. Credibility assessments are perceptions that people regularly make and rely upon in a working relationship to decide whether one can trust the claims of an individual; an evaluation of whether what they say is true or will come true. One’s perception of QA’s credibility was strongly believed to influence his/her behavior; therefore, it was of interest to this study. Results showed that QA’s credibility was rated relatively high in general by the sample population (see middle portion of the box-plot in Figure 18). The median for the population’s rating for credibility was 8 on a scale of 1 to 10. In comparison to its expectations, this was only one off, as the median expectation rating was 9. However, a closer look at the distribution for credibility revealed that the spread was quite large in comparison to other variables; perception scores of QA credibility covered a large range.

When the disparity between assessment and expectation was calculated for credibility (see Figure 20), it yielded more significant deficiencies than did similar calculations for QA likeability. While QA’s scores showed great frequency of deficiencies, so did many of the other functional groups. This is believed to be due to the fact that the expectation for credibility of Quality is a bit higher in the industry than are expectations one might have for likeability of QA (This observation regarding QA likeability expectations is in line with the
general tone of the industry, which, as discussed previously, is more focused on results than they might be for concerns of relationships).

**Forcefulness:** QA’s forcefulness characteristic was another variable of interest as perceptions of forcefulness also help to evaluate what a working relationship might be. As with all the other variables of interest, it too was suspected to have potential influence on behavior. Ratings of forcefulness showed that the population found QA relatively strong but not overly imposing (see bottom third of box-plot chart in Figure 18, page 44). When evaluated closely, QA appeared to be meeting forcefulness expectations for approximately a third of the population. Another third seemed to find QA not forceful enough, while the final third found QA overly demanding. When separated by functional group (see Figure 21), Senior Management appeared to find QA more frequently meeting expectations; whereas it was rare for QA to believe it was meeting expectations. What is interesting here is that there were almost as many QA professionals who felt QA was not forceful enough as there were those who found it overly forceful; both expose QA’s negative self-image once again.
Effectiveness and Criticality: Perceptions of QA’s effectiveness and its perceived criticality to the business are two additional variables of interest for the study. Ratings provided were not compared to an expectation, so no disparity statistic was created or evaluated. The scaled results for both of these characteristics were fairly typical and relatively strong (medians 8 and 9 respectively); however, the population distributions for each variable did cover a long range, particularly for the effectiveness rating. When evaluated by functional group, the data do not reveal any significant or further trend; with perhaps the exception that Manufacturing seems to have the largest distribution spread as well as the lowest median for its perception of QA’s effectiveness.

Receptiveness and Willingness: Receptiveness to QA explanations and willingness to follow change recommendations were the ultimate variables of interest. This was because the information they contain was considered the attitude signal that would determine whether or not a QA recommended change would actually be accepted, supported, and ultimately implemented. The raw survey scale results (see Figure 22) revealed that, on the whole, the population considered itself relatively receptive to listen to QA and willing to follow their
Figure 22. Scores of receptiveness and willingness attitudes when explanations and recommendations for change come from QA (sorted by functional group).

change recommendations (medians for all functional groups were between 7 and 8 on a Likert scale from 1 to 10). In the planned comparison test, results for conditions when change recommendations come from people outside of QA were essentially the same. This suggested that, when it came to explanations and change recommendations, QA was no better or worse off than any consultant, peer, or other neutral person trying to persuade and advocate change. This further suggested that industry receptiveness attitudes may be influenced by factors unrelated to the realization that a QA professional is the person recommending the change.

**Trust:** Trust in QA was a key variable to evaluate for this study essentially because trust is considered the foundational cornerstone to any working relationship and would therefore be expected to influence one’s behavior. A box-plot summary of the different distributions of trust for QA from each functional group is presented in Figure 23.
The variable for trust in QA was collected under the context that the respondent had already had a negative experience with QA. The variable could be named “trust in QA despite any negative experiences with quality initiatives or projects.” Despite the context in which the data was collected, the information gathered was an expression of the respondent’s degree of trust in QA, and the context built into the survey question regarding trust may have only strengthened the meaningfulness and reliability of such expression.

The survey results exposed and confirmed that the frequency of negative experiences with QA had a direct and obvious negative impact on trust for QA (see Figure 24). Likewise, the less frequent the instances of negative QA experiences were, the greater trust was for QA; however, it was noted in this latter case that the distribution spread for trust ratings covered a larger range. This suggested that perhaps other factors impacting trust were also at play.
Quality Attitude: Similar to the index statistic for quality concepts familiarity, the measure of a survey respondent’s quality attitude was also an index statistic that was derived from a battery of 24 questions that exposed one’s thoughts, beliefs, and behavior relative to multiple quality-related topics. Combined, the collection of responses represented the individual’s general attitude with respect to quality concepts, roles, philosophy, and practices. On the whole, the general attitude of the sample population was relatively positive, although there were several cases that were toward the lower end of the curve.

When separated into functional groups (see Figure 25), median scores were relatively similar. Quality exhibited an attitude score that was neither exceptional nor poor (index score = approx. 33%). It was, however, among the higher scores with a higher and tighter distribution spread in comparison to the other functional groups. Manufacturing had the lowest quality attitude (approx. 20%), but at the same time, it also had a very large distribution ranging over much of the possible index percent scores.
Before closing this discussion on the quality attitude survey results, it is important to discuss the results to three of the attitude-related questions (survey questions #61, #62, and #73). Responses to these three questions stood out because of the convincing numbers of respondents that essentially expressed one unexpectedly strong message. The common message resonating emphatically from responses to all three questions is that QA professionals need to stand up, speak up, communicate, and interact with others more. It is a call from industry for QA professionals to learn how to make decisions, take a stance, and communicate their position all while educating and interacting much more frequently with teams external to QA. This was the first appearance noted for such a message; however, variations of the same theme were further repeated multiple times in response to the open-ended questions.

**OPEN-ENDED RESPONSES**

There were numerous messages relevant to the variables of interest and the objectives of this study that can be found in the open-ended responses to the survey and interview.
questions. As part of the study analysis, common themes were grouped together in order to understand its messages. These categories of common responses to the open-ended questions have been abbreviated and collected for presentation and ease of review.

- **Survey Question #45/Interview Questions #3 and #4:** Study participants have felt frustrated when working with QA, because:
  - They do not feel respected, heard, understood, and/or validated by QA professionals due to QA’s imbalanced judgment, stubborn approach and/or inflexible interpretation of regulations, situations, or facts.
  - QA does not possess sufficient expertise or appropriate mastery of their profession.
  - QA does not possess the necessary foundational knowledge and does not seek to understand the broader context of issues.
  - Improper priorities and motivations lead QA to behave inappropriately.
  - QA has poorly developed and managed quality processes and systems.
  - QA has poor communication and insufficient team interaction.
  - Forms of poor communication result in inadequate QA performance.
  - QA lacks sufficient numbers of human resources.

- **Survey Question #46/Interview Question #5:** To be more effective in their company, QA professionals should:
  - Seek credibility by improving their applicable industry knowledge, understanding, and experience.
  - Avoid adversarial approaches and strive to work together more as a team involving other departments as partners.
  - Set the example for the company and gain respect as a leader who acts in an assertive, diplomatic fashion.
  - Improve their listening and communication skills.
  - Implement well-balanced interpretations and methods of approach.
  - Be open to listen, learn, and improve.
  - Seek to be included in upper management decision making.
  - Hire more trained QA professionals.

- **Question #47/Interview Question #6:** To gain approval/support, QA professionals should:
  - Collaboratively communicate purpose, logic, and full rationale to reach creative solutions that are well-balanced and that consider benefits and risks.
o First seek to listen and understand, and then collaboratively communicate purpose, logic, and full rationale to reach creative solutions that are well-balanced and that consider benefits and risks.

o Seek team-oriented interaction and improved collaboration with company departments to identify creative solutions together.

o Improve its professional education, experience, and expertise.

o Consistently demonstrate its decisions and actions are effective, logical, compliant, factual, and data-driven.

o Demonstrate true leadership.

o Seek upper management/company support.

• **Question #48/Interview Question #7:** QA has been most successful at gaining support when:

  o QA explanations are balanced, knowledgeable, logical, and based on experience.
  
  o QA seeks solutions collaboratively with trust and understanding.
  
  o QA seeks first to understand before proposing solutions.
  
  o QA leads by example being consistent, assertive, and diplomatic.
  
  o QA demonstrates experience and expertise.
  
  o QA can emphasize the value of regulatory compliance to provide direction.
  
  o QA attains upper management support.
  
  o Some form of a threat is perceived.

• **Interview Question #8:** In order to earn trust and gain support, QA professionals should improve or focus on:

  o The importance of developing stronger education and experience
  
  o The importance of interacting and communicating in a collaborative manner to build trust and understanding.
  
  o The importance of reducing any potential fear by convincing people that QA is not looking to point fingers and will not turn an issue on people.

  Combined with the responses to the interview questions, analysis of all open-ended comments ultimately reveals the following basic underlying messages. Essentially, the industry is emphatically calling on QA professionals to adopt the skills of a leader. First, the industry absolutely requires QA to be experts in their field with proper experience and education. It then expects QA to lead by setting the example and by frequently and actively interacting and communicating in a diplomatic, assertive manner, and most certainly not in a dictatorial or otherwise adversarial fashion. The industry needs QA to clearly explain details,
logic, and rationale behind compliance requirements and QA recommendations, but perhaps most importantly, the industry desperately desires QA to be open to listen and learn in order to collaboratively work with its internal partners to find solutions together under a more team-oriented spirit.
CHAPTER 4

STUDY CONCLUSIONS

Given the conclusions from the open-ended comments along with consideration of the variables of interest selected for this research, one may surmise that the studied characteristics of most concern to the industry would be QA’s credibility, effectiveness, and trustworthiness. It may be assumed that improvements in these characteristics would lead to improvements in understandings with respect to quality, which, in turn, might then be expected to influence one’s attitude toward quality and even help to improve QA’s likeability. Based on the underlying messages in the survey for how best to gain support, improvements in each of these characteristics would therefore be expected to increase acceptance and approval of quality strategies. QA’s forcefulness may be less of a preoccupation for the industry, but it is suspected to have an impact on one’s quality attitude as well as perceptions of QA’s trustworthiness and likeability. Perceptions of QA’s criticality are not suspected to play much of a role; however, it is suspected to be influenced by the other variables of interest.

INFLUENCE OF THE FACTORS

The intent of this section is to summarize and reveal the significant conclusions derived from the analyses of the different relationships between the variety of demographic factors and the variables of interest. As the variables of interest are also suspected to be factors of influence, conclusions from the study of these relationships will also be reviewed. An understanding of the conclusions and messages revealed from the relationship analyses will allow final conclusions to be drawn with respect to this study’s ultimate purpose: to better understand the conditions that might influence whether or not quality strategies are heard, accepted, and supported.

Study of the relationships between the multiple factors and the variables of interest was extensive and many trends were observed. Table 1 summarizes the trends and effects of the study factors on the variables of interest that were observed.
Table 1. Summary of the Effects of Different Demographic Factors on Study Variables

<table>
<thead>
<tr>
<th>LIKEABILITY</th>
<th></th>
<th>Effect/Trend/Observation</th>
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<tbody>
<tr>
<td>Influencing Factor</td>
<td></td>
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<tr>
<td>Organizational role</td>
<td>Perceptions of QA’s likeability progressively improve as one moves up the organizational ladder (perceptions remain relatively low, however).</td>
<td></td>
</tr>
<tr>
<td>Years of industry experience</td>
<td>Perceptions of QA’s likeability progressively improve as one’s industry experience increases over time.</td>
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<tr>
<td></td>
<td>• Note: Industry freshmen (1-2 years experience) initially perceive QA as likeable. This sharply declines after the second year.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Note: Industry seniors (over 20 years experience) show a slight decline and do not continue the incremental progression of increasingly positive perceptions.</td>
<td></td>
</tr>
<tr>
<td>Personal values</td>
<td>When the importance of obtaining results is balanced with the importance of maintaining relationships, perceptions of QA’s likeability is at its peak.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Perceptions of QA’s likeability progressively decline the more one personal value (results or people) increases in priority over the other.</td>
<td></td>
</tr>
<tr>
<td>Negative QA Experiences</td>
<td>Perceptions of QA’s likeability progressively improve as the frequency of negative QA experiences decreases.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CREDIBILITY</th>
<th></th>
<th>Effect/Trend/Observation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influencing Factor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Organizational role</td>
<td>Perceptions of QA’s credibility progressively improve as one moves up the organizational ladder.</td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td>Perceptions of QA’s credibility are increased for those who have a higher education (in particular a graduate degree level: Master or Ph.D.).</td>
<td></td>
</tr>
<tr>
<td>Highest level of Quality representation within an organization</td>
<td>As the highest level of QA representation within an organization climbs from Director to Chief Quality Officer, QA’s credibility progressively improves. Credibility is also strong when Manager is the highest held QA position. Credibility is the weakest when the highest held QA position is Director.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Note: This observation is only very slight with respect to the credibility variable; however, it is noted here because the pattern observed may be some form of an “echo” signal from the same trend found much stronger for the variable of trust.</td>
<td></td>
</tr>
<tr>
<td>Company Politics</td>
<td>Perceptions of QA’s credibility progressively improve as a company’s political environment improves.</td>
<td></td>
</tr>
<tr>
<td>Negative QA Experiences</td>
<td>Perceptions of QA’s credibility progressively improve as the frequency of negative QA experiences decreases.</td>
<td></td>
</tr>
</tbody>
</table>

(table continues)
### Table 1. (continued)

#### FORCEFULNESS

<table>
<thead>
<tr>
<th>Influencing Factor</th>
<th>Effect/Trend/Observation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Highest level of Quality representation</td>
<td>Perceptions of QA’s forcefulness progressively improve as the highest level of QA representation within an organization climbs from Manager to Chief Quality Officer.</td>
</tr>
</tbody>
</table>

#### EFFECTIVENESS

<table>
<thead>
<tr>
<th>Influencing Factor</th>
<th>Effect/Trend/Observation</th>
</tr>
</thead>
</table>
| Organizational role   | Upper Management holds a strong, positive opinion of QA’s effectiveness.  
  *Note: Operational Talent and Middle Management hold a generally positive opinion of QA’s effectiveness.* |
| Personal values       | Results-oriented people hold a strong, positive opinion of QA’s effectiveness.  
  Relationship-oriented people hold a weaker opinion of QA’s effectiveness. |
| Education             | Perceptions of QA’s effectiveness progressively improve the more one’s level of education advances.                                                       |
| Company Politics      | Perceptions of QA’s effectiveness progressively improve as a company’s political environment improves.                                                |
| Negative QA Experiences | Perceptions of QA’s effectiveness progressively improve as the frequency of negative QA experiences decreases.                                     |

#### CRITICALITY

<table>
<thead>
<tr>
<th>Influencing Factor</th>
<th>Effect/Trend/Observation</th>
</tr>
</thead>
</table>
| Organizational role   | Upper Management holds a highly positive belief in the criticality of QA’s role/function.  
  *Note: Operational Talent and Middle Management hold a positive belief in QA’s criticality.* |
| Personal values       | Results-oriented people hold a strong, positive belief in QA’s criticality.  
  Relationship-oriented people hold a weaker belief in QA’s criticality.                      |
| Education             | Belief in the criticality of QA’s role/function progressively strengthens the more one’s level of education advances.                              |
| Company Politics      | Belief in QA’s criticality progressively strengthens as a company’s political environment improves.                                                 |
Table 1. (continued)

<table>
<thead>
<tr>
<th>Influencing Factor</th>
<th>Effect/Trend/Observation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organizational role</td>
<td>Upper Management trusts QA very highly (despite any negative experiences). Note: Operational Talent and Middle Management show moderate trust levels for QA.</td>
</tr>
<tr>
<td>Years of industry experience</td>
<td>Trust for QA progressively improves as one’s industry experience increases over time. Note: The trend caused by this factor is repeated for several other variables; however, the trust variable had one obvious, unexplained exception to the trend in the category for participants with 11-15 years experience. Note: Industry freshmen (1-2 years experience) initially trust QA relatively highly. This sharply declines after the second year. Note: Industry seniors (over 20 years experience) show a slight decline in trust and do not continue the increasingly positive progression.</td>
</tr>
<tr>
<td>Company size</td>
<td>Trust for QA is high in small and start-up companies. Trust is slightly less high (more moderate) in mid-size and large companies.</td>
</tr>
<tr>
<td>Region</td>
<td>Industry professionals in Europe trust QA the least. Industry professionals in South/Central America trust QA the most. Note: Sample populations outside North America were low and may not actually be representative.</td>
</tr>
<tr>
<td>Education</td>
<td>Trust for QA progressively increases the more one’s level of education advances.</td>
</tr>
<tr>
<td>Highest level of Quality representation within an organization</td>
<td>As the highest level of QA representation within an organization climbs from Director to Chief Quality Officer, trust for QA progressively improves. Trust for QA is also very strong when Manager is the highest held QA position. Trust for QA is the weakest when the highest held QA position is Director.</td>
</tr>
<tr>
<td>Company politics</td>
<td>When a company’s political environment corresponds to ones expectations, trust for QA is at its peak. Trust progressively declines not only as the political environment declines, but it also declines as the environment becomes better than expected.</td>
</tr>
<tr>
<td>Familiarity with Quality</td>
<td>Trust for QA progressively increases as one’s familiarity with quality roles and concepts improves.</td>
</tr>
<tr>
<td><strong>Influencing Factor</strong></td>
<td><strong>Effect/Trend/Observation</strong></td>
</tr>
<tr>
<td>-----------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>Organizational role</td>
<td>One’s general attitude toward quality progressively improves as one moves up the organizational ladder.</td>
</tr>
<tr>
<td>Self-perception of working role</td>
<td>Those who view themselves as an operator or technician have a poorest general attitude toward quality.</td>
</tr>
</tbody>
</table>
| Years of industry experience | One’s general attitude toward quality progressively improves as one’s industry experience increases over time.  
  - *Note: Industry freshmen (1-2 years experience) initially demonstrate a strong attitude. This sharply declines after the second year*  
  - *Note: Industry seniors (over 20 years experience) show a slight decline in attitude and do not continue the positive improvement progression.* |
| Applicable Regulations | The more heavily regulated one’s work is, the poorer one’s general attitude toward quality is. Professionals working in GMP disciplines exhibited the worst attitude; GCP professionals exhibited the best attitude; and GLP professionals were in between the two. |
| Experience working with QA | When one has little to no experience working with QA, one’s general attitude toward quality is also low.  
  When the experience increases to at least a moderate level and above, the attitude rises and stays high regardless of further experience acquired. |
| Highest level of Quality representation within an organization | Quality attitudes are strong when the highest held QA position is part of upper management. Quality attitudes are also strong when Manager is the highest held QA position. Quality attitudes are the weakest when the highest held QA position is Director.  
  *Note: This trend was found much stronger for the trust variable previously discussed, and it appeared to be slightly echoed by the credibility variable as well. The same observation is made here since a similar pattern was identified with the quality attitude variable.* |
| Negative QA Experiences | One’s general attitude toward quality progressively improves as the frequency of negative QA experiences decreases. |
| Familiarity with quality roles and concepts | One’s general attitude toward quality progressively improves as one’s familiarity with quality roles and concepts improves. |

Please note that evaluated relationships that showed “no effect” or other observation are not listed in Table 1.
Although a number of the relationships observed are perhaps not terribly surprising (such as the trend that one’s quality attitude improves as negative QA experiences decrease), most of them are of great interest to learn for the quality professional who is seeking to understand the environment in which he/she works. For greater detail, a complete discussion including related data analysis charts can be found in the final study report (see Appendix).

**Years of industry experience:** There were, however, a few observations that were curious and merit further discussion here. For instance, the repeating pattern revealed for relationships between the variables and the sample population’s years of industry experience was particularly interesting. While a definite progression was observed, industry freshmen displayed non-conforming (perhaps “naïve”) traits: They had a better quality attitude, found QA more likeable, and were also more trusting of QA. After two years, this positive attitude sadly drops and appears to require a career to progressively return to similar levels. In addition, professionals with over 20 years of experience (which, for this study population, was principally the upper management), regressed slightly and did not continue the pattern of increasing positive improvement. Whenever a signal was detected for the “years of industry experience” factor, this pattern consistently appeared. An example is provided in Figure 26.

![Quality Attitudes by Years of Industry Experience](image)

**Figure 26.** Relationship between quality attitudes (percent scores) and the number of years of work experience in the biomedical industry.
**Personal values:** Another trend that merits discussion relates to the fact that Quality Assurance is a predominantly results-oriented group of professionals whose role is to ensure the tough decisions are made. Consequently, the study results show that this nature of QA is apparently not always well received by people-oriented professionals (see Figure 27). As a result, QA was perceived as less likeable and less effective for those who find maintaining relationships of greater importance than obtaining results. Although results-oriented people also found QA less likeable (for different reasons perhaps, such as for being a nuisance or an obstacle as they seek their own personal results), they did, however, respect QA as effective. It is believed this phenomenon also generated the results found in the politics vs. trust relationship (see Figure 28). In this case, when the company political environment is better than expected, trust in QA seems to drop. When one considers for such a political environment to exist, the company must highly value relationships. It is therefore not surprising that the QA group, whose role is to place results (for compliance) first, may be skeptically viewed in such companies. Although it may of course be tempting, QA professionals should seek a good balance and perhaps avoid accepting positions at companies that are overly relationship-oriented.

![Personal Values Priorities and QA Likeability](image)

*Figure 27. Relationship between personal values priorities and QA’s likeability.*
Limit of QA representation: The last unusual pattern worth discussion emerged with respect to the highest level of QA representation within an organization. Progressive improvement for QA variables was originally suspected to occur as quality leadership could interact at higher levels of the company and influence other company leaders for a trickle-down effect to improve a company’s quality culture. For the most part, this is what was observed. What was not expected was the seemingly high impact that companies had with only a Manager as their highest ranking QA representative. In this case, it was hypothesized that QA managers had a recognizable impact because they can influence trust and credibility at the grass-roots, operational level. Nonetheless, the observed trend resulted in making the Director the least influential level. Perhaps this was the underlying message. A Director may be too far removed to influence operational staff as effectively and consistently as a manager. In addition, the Director is possibly not considered an empowered leader since he/she reports to senior management and therefore may not be recognized from below nor sufficiently acknowledged from above. As a consequence, the Director may find few opportunities to
improve a company’s familiarity with quality and influence its quality culture and attitude. A visual example of this phenomenon is presented in the box-plot chart in Figure 29.

**Figure 29. Relationship between the highest level of QA representation within an organization and trust for QA.**

**Little or no impact:** There were also some factors that were originally believed to have an impact; however, results did not always yield any clear relationships. Evaluated relationships that showed “no effect” or other observation were not listed in Table 1.

There were almost no factors, for example, that had an observable impact on one’s perception of QA’s forcefulness. Instead, QA’s forcefulness proved later to be more of a factor of influence.

Familiarity with quality concepts showed little impact on perceptions of QA’s likeability, credibility, or effectiveness. It did however play a role in one’s trust for QA and one’s attitude. This is important to know since one’s quality attitude played a frequent role of influence when considered as a study factor.
Receptiveness and willingness attitudes: The effects of demographic study factors on those variables, which may ultimately affect whether or not one approves or supports QA strategies, was of great interest to this research. Those variables of interest reviewed here are one’s receptiveness to QA and willingness to follow QA’s advice. A summary of the relationships between the factors and these variables is presented in Table 2.

Table 2. Summary of the Effects of Different Factors on Receptiveness and Willingness Variables

<table>
<thead>
<tr>
<th>Influencing Factor</th>
<th>Effect/Trend/Observation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organizational role</td>
<td>Upper Management is very highly receptive to QA explanations. Note: Operational Talent and Middle Management are relatively highly receptive as well.</td>
</tr>
<tr>
<td>Self-perception of working role</td>
<td>Those who view themselves as an operator or technician are the least receptive to QA explanations.</td>
</tr>
<tr>
<td>Years of industry experience</td>
<td>Receptiveness to QA explanations progressively improves as one’s industry experience increases over time.</td>
</tr>
<tr>
<td></td>
<td>• Note: Industry freshmen (1-2 years experience) initially are quite receptive. This sharply declines after the second year.</td>
</tr>
<tr>
<td></td>
<td>• Note: Industry seniors (over 20 years experience) show a slight decline in receptiveness and do not continue the incremental improvement progression.</td>
</tr>
<tr>
<td>Region</td>
<td>• Asia/Pacific industry professionals are the least receptive to QA explanations.</td>
</tr>
<tr>
<td></td>
<td>• South/Central American industry professionals are the most receptive.</td>
</tr>
<tr>
<td></td>
<td>• European and North American industry professionals are similarly quite receptive.</td>
</tr>
<tr>
<td></td>
<td>Note: Sample populations outside North America were low and may not actually be representative.</td>
</tr>
<tr>
<td>Experience working with QA</td>
<td>When one has little to no experience working with QA, receptiveness to QA explanations is also low.</td>
</tr>
<tr>
<td></td>
<td>When the experience increases to at least a moderate level and above, receptiveness rises and stays high regardless of further experience acquired.</td>
</tr>
<tr>
<td>Negative QA Experiences</td>
<td>Receptiveness to QA explanations progressively improves as the frequency of negative QA experiences decreases.</td>
</tr>
</tbody>
</table>

(table continues)
Table 2. (continued)

<table>
<thead>
<tr>
<th>RECEPTIVENESS (to QA explanations)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Familiarity with quality roles and concepts</td>
<td>When one’s familiarity with quality roles and concepts is low, receptiveness to QA explanations is also low. When the familiarity level improves to at least a moderate level and above, receptiveness rises and stays high regardless of further improvements to one’s familiarity.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>WILLINGNESS (to follow QA change recommendations)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Influencing Factor</strong></td>
<td><strong>Effect/Trend/Observation</strong></td>
</tr>
</tbody>
</table>
| Region                                           | - Asia/Pacific industry professionals are the least willing to follow QA change recommendations.  
|                                                  | - South/Central American industry professionals are the most willing.  
|                                                  | - European and North American industry professionals are similarly quite willing. Note: Sample populations outside North America were low and may not actually be representative. |
| Negative QA Experiences                         | Willingness to follow QA change recommendations progressively improves as the frequency of negative QA experiences decreases. |
| Familiarity with quality roles and concepts      | Willingness to follow QA change recommendations progressively increases as one’s familiarity with quality roles and concepts improves. |

<table>
<thead>
<tr>
<th>WILLINGNESS (to follow QA change recommendations despite mixed support)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Influencing Factor</strong></td>
<td><strong>Effect/Trend/Observation</strong></td>
</tr>
<tr>
<td>Self-perception of working role</td>
<td>Those who view themselves as an operator or technician are the least willing to follow QA change recommendations when support and opinions are mixed (possibly more influenced by peer opinions).</td>
</tr>
<tr>
<td>Years of industry experience</td>
<td>Willingness to follow QA change recommendations despite mixed support progressively improves as one’s industry experience increases over time. Industry freshmen (1-2 years experience) appear to be the most influenced by the noise created by different peer opinions. Note: Industry seniors (over 20 years experience) show a slight decline in willingness and do not continue the improvement progression.</td>
</tr>
</tbody>
</table>
Table 2. (continued)

<table>
<thead>
<tr>
<th>WILLINGNESS (to follow QA change recommendations despite mixed support)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Region</strong></td>
</tr>
<tr>
<td>- Asia/Pacific industry professionals are the least willing to follow QA change recommendations despite mixed support.</td>
</tr>
<tr>
<td>- South/Central American industry professionals are the most willing.</td>
</tr>
<tr>
<td>- European and North American industry professionals are similarly quite willing.</td>
</tr>
</tbody>
</table>

*Note: Sample populations outside North America were low and may not actually be representative.*

<table>
<thead>
<tr>
<th><strong>Experience working with QA</strong></th>
<th>When one has little to no experience working with QA, willingness to follow QA change recommendations despite mixed support is also low.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>When the experience increases to at least a moderate level and above, willingness rises and stays high regardless of further experience acquired.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Negative QA Experiences</strong></th>
<th>Willingness to follow QA change recommendations despite mixed support progressively improves as the frequency of negative QA experiences decreases.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>Familiarity with quality roles and concepts</strong></th>
<th>Willingness to follow QA change recommendations despite mixed progressively increases as one’s familiarity with quality roles and concepts improves.</th>
</tr>
</thead>
</table>

In review of those factors that have yielded a trend or some observable effect on one’s receptiveness and willingness attitudes, it is evident that the most common key factor relates to one’s experience with quality. Whether it be experience working directly with QA, years of industry experience in general, the frequency of negative QA experiences, or experience in the form of improved familiarity, one’s receptiveness and willingness attitude is, perhaps not surprisingly, influenced by the information the individual has absorbed from different work experiences. Interestingly enough, the freshmen to the industry proved their lack of experience when a drop in their willingness to follow QA advice was detected because the support for QA’s recommendation to change was mixed. This was the only time the positive quality attitude pattern that had been previously and consistently exhibited by the industry freshmen was not present (refer example of this pattern as observed in Figure 26, page 60). Apparently, they are susceptible to a variety of influences and may not have enough industry experience to ignore the noise of peer opinions (Note: It is important to introduce caution with respect to the interpretation of this last statement. Peer arguments may actually be sufficient and appropriate to justify why one ultimately decides not to follow
a QA recommendation; however, they should never be a determining factor influencing one’s willingness from the start).

One observation of interest made with respect to one’s receptiveness and willingness attitude relates to the quality familiarity factor. Although familiarity with quality roles and concepts did not always have an impact on other variables of interest, it did, however, play a role here. What was particularly interesting was that it takes only a minimal amount of familiarity for people to be receptive to QA explanations; however, results showed that familiarity must progressively increase for willingness to improve. This means that, when only a little foundational understanding of quality concepts is attained, QA has the listeners ear and can get itself closer to support if it would take advantage of the opportunity to further explain, teach, and improve one’s familiarity with quality concepts. Apparently, this would then increase chances for one’s willingness to improve, which could lead ultimately to a decision to support a QA strategy. Responses to the open-ended questions indicate that the industry most definitely expresses the need for QA to communicate more frequently, explain, and help others better understand quality topics.

**Influence of Study Variables as Factors**

To better understand any influence the variables of interest might potentially have on each other, evaluations of each possible relationship were performed (see Appendix: Attachment E for corresponding Kruskal-Wallis calculated p-values). Survey data confirmed very strong statistically significant relationships among them that also showed obvious trends when graphed. When a trend was present, it was typically a positive progressive relationship. For example, as one perception improved, so did the other. Although relationships were clearly observed, it was not always evident whether one variable was the cause of the relationship, or whether they were mutually interacting. In any case, awareness of the relationships is important for this study and for quality professionals who desire to understand their working environment.

Since so many messages resulted from the analyses, it is not useful to spell each of them out in this discussion. However, Tables 3 and 4 have been prepared to expose, at a glance, all of the relationships that were studied.
Table 3. Summary of Relationships between the Study Variables

<table>
<thead>
<tr>
<th>Factors:</th>
<th>Variables:</th>
<th>Likeable</th>
<th>Credible</th>
<th>Forceful</th>
<th>Effective</th>
<th>Critical</th>
<th>Trust</th>
<th>Attitude</th>
</tr>
</thead>
<tbody>
<tr>
<td>Likeability</td>
<td>None</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Credibility</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Forcefulness</td>
<td>None</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>Jump</td>
<td>Jump</td>
<td></td>
</tr>
<tr>
<td>Effectiveness</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Criticality</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>Jump</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Trust</td>
<td>✓</td>
<td>✓</td>
<td>None</td>
<td>✓</td>
<td>✓</td>
<td>Jump</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Attitude</td>
<td>✓</td>
<td>✓</td>
<td>None</td>
<td>✓</td>
<td>None</td>
<td>✓</td>
<td>None</td>
<td></td>
</tr>
</tbody>
</table>

Table 4. Summary of Effects of the Study Variables on Receptiveness and Willingness Attitudes

<table>
<thead>
<tr>
<th>Factors:</th>
<th>Variables:</th>
<th>Receptive</th>
<th>Willing</th>
<th>Willing despite mixed support</th>
</tr>
</thead>
<tbody>
<tr>
<td>Likeability</td>
<td>Jump</td>
<td>Slight</td>
<td>Slight</td>
<td></td>
</tr>
<tr>
<td>Credibility</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Forcefulness</td>
<td>Jump</td>
<td>Jump</td>
<td>Slight</td>
<td></td>
</tr>
<tr>
<td>Effectiveness</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Criticality</td>
<td>✓</td>
<td>None</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Trust</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Attitude</td>
<td>Jump</td>
<td>Jump</td>
<td>Jump</td>
<td></td>
</tr>
</tbody>
</table>

- Checkmarks represent the positive progressive improvement relationships that were typical (i.e. as factor of influence improved, the variable of interest also improved).
- “Slight” described those cases in which only a very slight positive progressive improvement trend was observed.
- “None” was used when no trend or other meaningful message could be discerned.
- “Jump” described those cases in which negative, low, or absent results for a factor yielded negative or low results for a variable; however, when the influencing factor improved just a little, results for the variable were observed to jump to a higher level and sustain itself at that level despite any further improvements by the influencing factors.
These were relationships that essentially showed no effect unless the factor of influence was low or absent, as if the signal was either “on” or “off” (similar relationships were often seen between quality experiences and willingness attitudes).

Figure 30 presents a series of box-plot charts that correspond specifically to the relationships described in the last column of Table 3. It is provided in this text to illustrate, as an example, the positive progressive improvement trends that were typical. These are identified by checkmarks in Table 3 (for QA likeability, credibility, effectiveness, and trust).

Figure 30 also includes an example of the “jump” phenomenon described. In this case, the jump occurs for the QA forcefulness and quality attitude relationship. Quality attitudes jump and stay high when at least a moderate degree of forcefulness is perceived.

Lastly, Figure 30 also presents an example of no trend observed (“none”). This has been observed for the relationship between criticality and quality attitude.

Table 3 allows us to realize how interconnected these characteristic variables can be. For example, low trust may be due to low credibility which certainly cannot be good for one’s perception of effectiveness. A poor general attitude may affect one’s belief in QA’s effectiveness, credibility, or even likeability. The studied relationships in both Tables 3 and 4 are numerous and, for the most part, are very significant and very strong, so it is important for quality professionals to identify and focus on those variable characteristics that will benefit them the most, the others may improve as a resulting consequence.

The ultimate purpose of this research was to uncover those factors that may influence whether or not quality strategies are accepted and supported; therefore, this last Table 4 is perhaps most helpful to the quality professional and, at the same time, most meaningful for the entire study because it provides insight as to what the quality professional should seek to improve versus what may be wasted effort. Review of the table allows the QA professional to realize, for example, that improvement in one’s likeability may allow them to be heard, but it has only slight influence on whether or not the person will be willing to follow any advice he/she may have.

As the visual overview that the tables provide is valuable, a similar summary was prepared in Table 5 for those trend effects that the demographic factors had on the receptiveness and willingness attitudes (patterns/trends only; relationship observations were not included).
Figure 30. Relationships between different QA perception assessment variables (e.g., QA’s likeability, credibility, etc.) and the quality attitude (percent scores).
Table 5. Summary of Trend Effects of Demographic Factors on Receptiveness and Willingness Attitudes

<table>
<thead>
<tr>
<th>Factors:</th>
<th>Variables:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Receptive</td>
</tr>
<tr>
<td>Years of industry experience</td>
<td>✔</td>
</tr>
<tr>
<td>Experience working with QA</td>
<td>Jump</td>
</tr>
<tr>
<td>Negative QA Experiences</td>
<td>✔</td>
</tr>
<tr>
<td>Quality Concept Familiarity</td>
<td>Jump</td>
</tr>
</tbody>
</table>

The “years of experience” factor is the one factor in Table 5 that cannot be controlled. One may consider that the trends observed for the “years of industry experience” factor are actually an expression of the effects of being exposed, over the years, to the quality function. If this is the case, then those same trends can be attained by working to improve the other three factors. This essentially makes all of the demographic factors, which impact receptiveness and willingness attitudes, controllable attributes that can be worked on, corrected, and improved. Attention by QA to improve these quality experiences will allow it ultimately to better control those conditions that influence acceptance and support for its advice.

**Final Study Conclusions**

With respect to Table 4, those factors that have a direct influence on one’s receptiveness and willingness to listen and follow QA, across the board, are perceptions of QA’s credibility, effectiveness, and trust. In fact, credibility, effectiveness and trust are the only factors in Table 4 that showed a steady influence even when challenged by mixed opinion. Charts of the relationships among these variables yield very clear and obvious patterns of positive progression. Figures 31, 32, and 33 are included here as a visual review of these relationships relative to QA’s credibility, effectiveness, and trust respectively.
Receptiveness and Willingness to Change When Advised by QA
As Influenced by Perceptions of QA Credibility

Figure 31. Receptiveness and willingness to change when advised by QA as influenced by perception of QA’s credibility.

Receptiveness and Willingness to Change When Advised by QA
As Influenced by Perceptions of QA Effectiveness

Figure 32. Receptiveness and willingness to change when advised by QA as influenced by perception of QA’s credibility.
Receptiveness and Willingness to Change When Advised by QA
As Influenced by Trust for QA

<table>
<thead>
<tr>
<th>Trust for QA</th>
<th>Receptive</th>
<th>Willing</th>
<th>Willing Despite Mixed Support</th>
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</thead>
<tbody>
<tr>
<td>Low (1-3)</td>
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<td></td>
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<tr>
<td></td>
<td><img src="1" alt="Bar" /></td>
<td><img src="2" alt="Bar" /></td>
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<td></td>
<td><img src="5" alt="Bar" /></td>
<td><img src="6" alt="Bar" /></td>
<td></td>
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<tr>
<td>Moderate (4-6)</td>
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<td><img src="8" alt="Bar" /></td>
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<td><img src="9" alt="Bar" /></td>
<td><img src="10" alt="Bar" /></td>
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<td></td>
<td><img src="11" alt="Bar" /></td>
<td><img src="12" alt="Bar" /></td>
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<tr>
<td>High (7-8)</td>
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<td></td>
<td><img src="13" alt="Bar" /></td>
<td><img src="14" alt="Bar" /></td>
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<td><img src="17" alt="Bar" /></td>
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<tr>
<td>Very High (9-10)</td>
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<td></td>
<td><img src="23" alt="Bar" /></td>
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</tbody>
</table>

Scale: (Skeptical/Reluctant) 1 to 10 (Readily Accepting)

Figure 33. Receptiveness and willingness to change when advised by QA as influenced by level of trust for QA.

The importance of the role of these characteristics had also been previously surmised following assessments and conclusions from the survey data and the open-ended questions as stated at the beginning of this chapter. As a result, it can be argued that perceptions of QA’s credibility, effectiveness, and trust should be considered by far the most key factors for QA to focus upon and improve if it wishes to gain needed support.

Of course, perceptions of these characteristics have always been considered significant for QA’s success. This is why they were originally selected for study as variables in this research along with a few other qualities that seemed likely to influence support for QA. What this study has provided, however, is the realization of the extent of their role, a confirmation regarding what these factors affect, an understanding of their interconnectivity, and lastly, perhaps most importantly, a wealth of knowledge regarding what other factors affect and influence them.

As this study has revealed, there are many factors impacting and influencing all the different variables to various degrees. Certainly perceptions of credibility, effectiveness, and
trust are not the only factors that play a role in one’s openness to QA advice and recommendation, and these other factors should not be ignored. However, the research has revealed much of the interconnectivity of the factors and variables, such that it is the firm belief that improvements in the key influence contributors (credibility, effectiveness, and trust) will result in improvements in many of the other factors of influence. The comments in response to the open-ended survey and interview questions embellish the sentiments and concerns the industry has with respect to QA’s credibility, effectiveness and trust. The survey population has offered much commentary that all seems to point back to the importance of these variables by focusing on changes, corrections, and other solutions to improve them.

This research survey arms the quality professional with extremely valuable information relative to what is really happening in his/her environment. More importantly, the survey provides information with respect to what is influencing the attitudes, opinions, perceptions, and ultimately the behaviors of QA’s professional colleagues. Certain demographic factors that were studied cannot be controlled by a quality professional, but being aware of their impact can help him/her to understand the environment and temper his/her approach accordingly. Table 5, for example, emphasizes the importance for QA to concentrate on creating occasion and opportunities to improve QA experiences and develop better familiarity to quality concepts, which, in turn, will improve conditions for the desired approval and support.

As factors, perceptions of QA’s credibility, effectiveness, and trust were shown in the study not only to have an influence on each other (such as one’s quality attitude and QA’s likeability), but more importantly to have a direct influence on one’s receptiveness and willingness to follow QA. As variables in the study however, factors that directly influence them were also revealed. What is interesting here is that many of the other variables (i.e., one’s quality attitude and perceptions of QA’s likeability, criticality, and even forcefulness), when acting as factors had quite direct influence on credibility, effectiveness, and trust.

When one considers the larger picture, the conclusions revealed in this research ultimately are those that are applicable to human interaction in general. For example, it was observed earlier that there was little or no difference in receptivity or willingness to follow QA’s advice as compared to advice from any other type of colleague or consultant. Quality
perceptions and attitudes exposed in this study were, on the whole, relatively positive actually, which lends some truth to the notion that QA professionals may have an incorrect self-image or self-perception related to their role. The role of QA requires it to make tough decisions and take appropriate compliant stances; however, the research also shows that the best approach is not for QA itself to be tough, but instead to seek assertive, well-balanced diplomacy. Open comments revealed that the industry has high expectations for the quality function, and expects QA professionals to behave as expert leaders. It is therefore not surprising that QA can easily fall off the mark with respect to perceptions of credibility and effectiveness, especially when the bar of expectation is not only high but also varied from one person or group to the next.

Based on the research, the QA professional will best gain support when he/she focuses on establishing credibility through improved experience and education, and when he/she leads by example, communicates, and works more closely with the company to develop trust and advocate better understandings of QA’s role, so that there are no misperceptions of QA’s effectiveness and role fulfillment. Further research could explore a wider variety of factors that influence the key factors of credibility, effectiveness, and trust in the biomedical environment; however, it is believed that existing literature for general social interaction may be sufficient to coach the quality professional for success.
CHAPTER 5

GLOBAL ASSESSMENT AND SOLUTIONS

In quality philosophy terms, the research of this thesis provided direct feedback from the biomedical industry that ultimately corresponds to internal customer requirements for quality professionals regarding their interactions with the organizational human system, (i.e., the network of human relationships within an organization). It is believed that this system has a direct and primary relationship to the success of all the other quality systems, yet it is frequently neglected, disregarded, or discounted altogether by quality professionals, consultants, and other industry professionals. The original intent behind this research was not only to allow an opportunity for discovery but also for deficiency correction analysis.

In layman’s terms, we hoped to learn how to improve ourselves.

GLOBAL ASSESSMENTS

In the end, what was it that we learned? Certainly some very interesting relationships of cause and effect were observed as well as a number of trends for the quality professional to be mindful of, such as the strong influence of a variety of past experiences for people’s willingness to follow change. Looking at the wide landscape of responses on the whole, we also realize that the industry could improve somewhat with regard to its familiarity of quality roles and concepts. However, it showed to have a relatively positive view and attitude of the function and the QA professionals; not perfect, but not as bad as the view that quality professionals rated for themselves. In addition, we discovered the extent to which so many of the variables are interconnected, one having influence over the next. Lastly, when it came to conditions that had the greatest impact on one’s willingness to follow QA, none were as consistent and as statistically strong as the perceptions of QA’s credibility, effectiveness, and trust. Although this is not necessarily a new revelation, the research provided did yield insight regarding which factors surveyed had the strongest potential to influence the perceptions of credibility, effectiveness, and trust.
Given the final results of the survey as well as the many open-ended remarks from the survey and interview, the common ultimate message emerging is that the industry so very much desires for quality professionals to perform as strong, values-driven leaders. Not only does the data point to the fact that quality professionals are more positively perceived when they assume a diplomatic, values-balanced disposition, but also that willingness attitudes change and people are more receptive to follow such a lead.

When one considers the profession, the role of a quality professional is indeed one of advocating and leading change. The final study conclusion to the research for this thesis suggested in closing that existing literature for general social interaction may be sufficient to further coach the quality professional for success. When it comes to organizational leadership, the library inventory on the topic is bursting. Two popular business leaders and co-authors James M. Kouzes and Barry Z. Posner (2003) define leadership as a relationship and describe quite nicely the importance of relationship building in the business of leading meaningful change.

Leadership is a reciprocal relationship between those who choose to lead and those who decide to follow. Any discussion of leadership must attend to the dynamics of this relationship. Strategies, tactics, skills, and practices are empty unless we understand the fundamental human aspirations that connect leaders and their constituents. …We cannot expect to renew our companies and our communities … until we understand what forms the foundation of the leader-constituent relationship. And we cannot hope to build the towering institutions of our dreams until that foundation is strong and solid. (pp. 1-2)

Best-selling management author Stephen P. Robbins (2003) contributes to this discussion by pointing us to trust as the essence and foundation of leadership, which resonates well with signals and conclusions coming from our research data.

When employees trust a leader, they’re willing to be vulnerable to the leader’s actions—confident that their rights and interests will not be abused. People are unlikely to look up to or follow someone whom they perceive as dishonest or who is likely to take advantage of them. …leadership effectiveness depends on the ability to gain the trust of followers. Why? Because in times of change and instability—which characterizes most workplaces today—people turn to personal relationships for guidance, and the quality of these relationships is largely determined by the level of trust. (p. 75)

**SOLUTIONS**

The discussion, knowledge, and awareness may be interesting, but what exactly is the quality professional to do?

It is believed that the research data and information presented in this thesis thus far is only a start—an initial awareness to the quality professional of a need to build his/her
expertise not only in the quality fundamentals, tools, and strategies, but also in the skills of building relationships, building trust, and leading change. One must first begin by understanding what is going on. The research study has given some insights, and a review of a wide variety of social behavior literature can also expand one’s understanding. But before going further, what is it we already know? For starters, we know that in order for the quality professional to succeed, he/she must be an advocate for continuous improvement. Whether it be improvements to business processes, systems, or culture, he/she must lead others to choose some sort of different path, or change. In essence, leading change is a sales job. Even if the quality professional were at the top organizational position, he/she might be able to impose a change in company method, but such dictating would never lead to company-wide approval or support, it would not win hearts, and it could certainly never lead to an improved culture change. No matter what level of the organization, the quality professional is at the mercy of a decision-maker who determines whether or not to buy into the ideas and accept the plans that the quality professional is selling. He/she must build and rely on interpersonal relationships in order to succeed at his/her role and bring about sustainable change.

**Selling**

Considering the quality profession as a technical sales profession may represent a major shift in thinking for some. For others who have learned through repeated failure and other lessons in the school of hard-knocks, it is merely a different way for stating the obvious. Either way, understanding what is going on is, as mentioned previously, the first step, but it should not be the last step. Very often, this is where the quality professional’s knowledge on the topic begins and ends: He/she is often at a loss as to what it means to truly sell and lead others to change. It is perhaps worthwhile for the corporate QA reference library to have a few books on leadership and sales strategy next to its texts on manufacturing and statistical process control.

As this thesis is committed to explore obtaining approval and support for quality strategies (or, said now another way, on selling quality), let us then continue to better understand what this means. There is a bit of reluctance to liken the quality leadership role to that of a sales role, because salespersons are more frequently associated with short-term trust-
building tactics; whereas, quality professionals should have a genuine interest in building successful, collaborative relationships with their colleagues. Nonetheless, selling a quality strategy fundamentally signifies building confidence or trust in a quality idea or plan. Selling, ultimately, is about creating enough trust in the acceptability of a decision to buy, such that the decision-maker makes a commitment. For the quality professional, obtaining approval and support from a decision-maker (i.e., senior manager, supervisor, technician, etc.) equates to building his/her confidence in the acceptability of a decision to approve and/or support the quality strategy and in the acceptability of any possible known or perceived risks associated with that strategy. In the end, the business of selling boils down to the business of building trust.

That sounds simple enough; however, the task of selling change to others is renowned for its pitfalls. The problems are not new: No less than 16th century Italian philosopher Niccolò Macchiavelli gave this warning in 1531 regarding advocates of change in his infamous book, *the Prince*:

And let it be known that there is no more delicate matter to take in hand, nor more dangerous to conduct, nor more doubtful of success, than to be set up as a leader in the introduction of changes. For he who innovates will have for his enemies all those who are well off under the existing order of things, and only lukewarm supporters in those who might be better off under the new. (as cited in Salacuse, 2006, p. 72)

To avoid the pains and costs of a massive resistance campaign, quality professionals must not advocate change blindly and without strategy. Building trust for oneself and one’s ideas must be based on a skilled, educated approach; however, before any skill is acquired, one must first be exposed to the proper education of influence and persuasion. Let us further our knowledge-base by returning to the literature and considering some vital information regarding human nature with respect to decision-making.

**Influence**

As revealed in the introductory chapter, this research had been originally influenced by the theories of social psychologist Robert Cialdini (2001) presented in his book *Influence: Science and Practice*. In it and subsequent other Cialdini publishings, he promotes the idea that in human interaction, there are six fundamental psychological principles of social influence at play that govern one’s inclination to comply with a request. By name, they are the principles of:
1. **Reciprocity** (we feel obligated to return favors performed for us),
2. **Authority** (we look to experts to show us the way),
3. **Commitment/consistency** (we want to act consistently with our commitments and values),
4. **Scarcity** (the less available the resource, the more we want it),
5. **Liking** (the more we like people, the more we want to say yes to them), and
6. **Social proof** (we look to what others do to guide our behavior).

(Goldstein, Martin, & Cialdini, 2008, p. 6)

The premise behind each is based on the notion that complying to a request can be likened to an automatic *fixed-action pattern* that occurs as a reaction to some specific stimulus, or *trigger*. Cialdini (2001) briefly summarizes the idea in this way:

> You and I exist in an extraordinarily complicated environment, easily the most rapid moving and complex that has ever existed on this planet. To deal with it, we need shortcuts. We can’t be expected to recognize and analyze all the aspects in each person, event, and situation we encounter even in one day. We haven’t the time, energy, or capacity for it. Instead, we must very often use our stereotypes, our rules of thumb, to classify things according to a few key features and then respond without thinking when one or another of these trigger-features is present. (p. 7)

Cialdini further points out, we are not animals or robots falling mindlessly prey to any person who tries to trigger a response: we do use (or try to use) our brains. However, when our guard is down, if we’re not careful, we can be vulnerable to those who seek to manipulate and mimic the trigger-features so as to benefit from such *weapons of influence*, as Cialdini refers to the six principles collectively when they are used against us.

As quality professionals, most if not all of us have applied these triggers of influence (without knowing Cialdini’s labels for them) to persuade or manipulate compliance from our decision-makers at some point in our careers. Here are a few examples: “Here you go: I just finished your report. By the way, have you had a chance to …” (reciprocity); “According to FDA warning letter,…” (authority); “Time is running out, the FDA will be here on…” (scarcity); “Company X has used this system for years and has successfully…” (social proof). Certainly, these principles have been used on us as well, “As head of QA, you certainly should…” (consistency/commitment) and “Bob wants to know if you’re coming to his party. By the way, have you reviewed his report?” (liking).

Although Cialdini’s triggers and principles are certainly influencing our behavior and decision-making at work and on a daily basis to some extent, most of us are not acting on
auto-pilot when it comes to those decisions that require much more sacrifice or commitment from us, such as the need to reconfigure the clean-room layout, to revamp a training system, or even to log our actions on a daily basis. In these cases, the principles may get us to listen and perhaps even go along with an idea to a certain extent, but in the long-run it may not lead to the sustained support that QA is typically seeking. Very often, persuasion tactics employed without established relationship trust and buy-in from the heart and mind typically results in complacency, disdain, resistance, and/or non-compliance. We must look elsewhere for a healthier, longer-lasting approach.

Instead, a team of award-winning authors, researchers, and business consultants together have proposed that to in order to truly seek long-lasting approval, support, and sustained implementation and embrace of a change, you will need to “change the way you change minds” (Patterson, Grenny, Maxfield, McMillan, & Switzler, 2008, p. 45). As most of us have learned in today’s culture and exposure to psychology and sociology theories, people change only when they decide they want to. According to Patterson et al. in order for people to change, they will need to change their thinking (2008, p.45). In addition, they point out that, “People choose their behavior based on what they think will happen to them as a result” (2008, p. 49). Many influential leaders, managers, sales people, even parents and other types of negotiators have tried to tap into this notion of consequences (cause and effect). The carrot or the stick or both used at the same time are powerful motivators and link to the psychological premise that our actions are motivated either to avoid forms of pain and displeasure or to seek benefits and other forms of pleasure.

As an example, organizational development consultants Kathleen D. Ryan and Daniel K. Oestreich (1998) consider the decision-making process and the power of cause-and-effect when one is faced with change.

As you think about the change and its likely impact, if you are like most people, you will probably consider how the change will affect your reputation, and your position within the work environment. Although you might not use the actual words hopes and fears, this is the emotional terrain in which you will find yourself. Frequently unexpressed at work, these hopes and fears are almost always voiced as part of an ongoing internal and highly personal dialogue that takes place as you weigh the pros and cons of change. (pp. 280-281)

Ryan and Oestreich identify four personal variables that are possible targets to be affected either positively or negatively as a result of change: (1) personal credibility, (2) competence, (3) relationships, and (4) future security. Naturally, they are the topics of
internal hopes and fears dialogue and the focal point of concern when a decision-maker must contemplate change. Ryan and Oestereich refer to such personal concerns as undiscussables in the workplace; however, their impact for the business is real and must be considered and addressed by the change advocate.

Ultimately, Patterson et al. draw the conclusion that “if you want to change behavior, any behavior, you have to change [people’s mind] maps of cause and effect” (2008, p. 49). In the business of changing minds, they further point out that it is not necessary to change every incorrect assumption or belief; instead, they suggest that there are key factors influencing change decisions, and offer this advice:

When it comes to altering behavior, you need to help others answer only two questions. First: Is it worth it? (If not, why waste the effort?) And second: Can they do this thing? (If not, why try?) … If you want to change behavior change one or both of these expectations. (p.50)

Reflecting back on the study results to this thesis, in particular the open-ended comments received as recommendations for how best to gain support, several of the common themes could be boiled down into a call for QA to help the decision-makers determine: “Is it worth it?” Very often, the quality professional is explaining how a new tool or strategy will work and be implemented, and frequently they will also tout all its known benefits, the carrot. They may even throw in the stick and offer the consequences of what would happen if the change were not adopted; however, it is rare that the quality professional will seek to persuade the other cause and effect mind-maps associated with whether or not a change is worth it, such as Ryan and Oestreich’s undiscussables and other personal motivators relevant to the decision-maker. As a result, the quality professional is in essence only explaining why the change seems worthwhile to QA. This may also be why many of the comments in the survey pointed to the need for QA to provide “balanced” rationales or why other comments found QA to be lacking in understanding of the full landscape. It is true that QA cannot know all possible issues or concerns of the decision-maker exist, and therefore cannot be expected to address mind-maps of which he/she is unaware; however, this is where the quality professional frequently fails to take the initiative to question and discover what those other concerns may be. As a result, they are found as being either dictatorial or inexperienced, depending on the approach they choose to seek compliance from others.
Equally as rare is an attempt by QA to understand and address possible fallacies in mind-maps regarding the decision-maker’s concern: “Can it be done?” Again, QA often falls short because they don’t take the “sale” of the quality strategy seriously enough to do the necessary homework. Logistics issues, human resources issues, project conflict issues, etc. are often ignored by the quality professional in his/her pursuit to get agreement on a certain initiative. Again, QA, as a result, comes across as dictatorial and “not listening” or as inexperienced and not qualified or effective depending on their approach. QA professionals will gravitate to excuses of not enough time or other resources to devote to such investigative homework, but in all reality, this effort is not terribly time-consuming and is merely the matter of a few key conversations. In terms of cause and effect consequences, the cost of not doing the “sales” preparation homework can be entirely damaging for QA’s reputation and future success.

In addition to understanding some of the rationales behind the mind-map thinking of the decision-maker, many sales professionals, negotiators, and other business change leaders consider the personal nature of the decision-maker to temper their approach to persuasion. In the Hersey-Blanchard situational leadership model (changingminds.org, 2010) discussed in the introductory chapter, we have already been exposed to the notion of modifying our approach to gain compliance based on situational conditions. In doing their homework, successful sales professionals seek to understand their customer and the conditions of his/her character that lead him/her to buy. This way, the salesperson can adapt his/her persuasion approach. Expert negotiator Roger Dawson (2004) exposes us to a series of conditions relative to buyers (i.e., decision-makers) that help explain what motivates them to commit to a decision:

1. **Possibility versus necessity.** People are either motivated by the possibility of reward as the result of acting or by the feeling that they must take action out of necessity.

2. **Self-centered versus externally centered.** People either see the change in light of how it would affect them or how it would affect others.

3. **Pleasure versus pain.** People make decisions to either move toward pleasure or move away from pain.

4. **Field-dependent or field independent.** This is psychology-talk for questioning whether people care about what others think. Some people are very much influenced by what others think. Other people could care less. (2004, p. 149)
Dawson further elaborates on traits about people that makes them different types of buyers/decision-makers. Unlike those traits that describe what motivates them, Dawson (2004) identifies these as the characteristics that describe how they go about making decisions:

1. **[Assertive versus unassertive.]** Assertive people make decisions quickly. Unassertive people are slow decision-makers.

2. How quickly you push for a decision must be based on their level of assertiveness.

3. **[Emotional versus unemotional.]** Next, determine their emotional level. From this you develop four different persuasion appeals:
   - Emotional/Assertive: Razzle-dazzle them with how exciting the project will be, and how they have to jump on the opportunity before it passes them by.
   - Emotional/Unassertive: Warm them up slowly to the idea. Tell them how good everybody’s going to feel.
   - Unemotional/Assertive: Tell them the bottom line benefits, and push for a fast decision.
   - Unemotional/unassertive: Give them lots of precise detail, because they make a decision based on facts, but they need an overload of information.

4. **[Open-minded versus closed-minded.]** Next, determine if the buyer is open- or closed-minded. You can persuade the open-minded buyer with show and tell, but the closed-minded buyer must see and do.

5. **[Conscious thinker versus unconscious thinker.]** Next, does the buyer process information you’ve given her with conscious or unconscious thought? Conscious thinkers process the information with their five senses. Unconscious thinkers go with their intuitive feelings about your persuasion presentation. So with conscious thinkers, you must let them see, hear, and touch your product or service. With unconscious thinkers, it’s more important to romance their imaginations. (p. 165).

Those professionals who are in negotiations and sales regularly study the different possible characteristics of human behavior. They learn how to determine which type of decision maker they are trying to persuade and then tailor their entire approach to accommodate the nature of the person.

**Trust**

From Cialdini to Dawson, we hopefully have a better appreciation for the wide variety of under-the-radar influences that affect the decision making process. In the final analysis, it all goes back to a decision-maker desperately trying to ascertain trust: trust in the
information received, trust in the analysis, cause/effect conclusions, and proposed recommendations, trust in you, your motives, your competence, your integrity. There is a chain of trust that ultimately leads to whether or not the decision-maker can trust the advocate for change. I have created a graphic (see Figure 34) to describe the importance of trust in the decision making process that quality professionals (or any change advocate) must understand. A decision to commit to a change rests on the balance of so many pre-established confidences, beliefs, or trusts originating from the change advocate, that it is no wonder the industry demands leadership from QA: It is too vulnerable otherwise. For the quality professional, it is a very heavy responsibility, a true balancing act!

**Compliance**

The question then becomes, how can the quality professional succeed with what seems like such a daunting challenge to consistently meet (or circus act to continuously perform)? One must also consider another wrinkle, one very significant consideration, which has not yet been discussed that quality professionals must face: In addition to being advocates for change (a sales/marketing leadership role, so to speak), QA is also responsible for enforcing regulatory compliance (which many refer to as its policing role). These are two very different hats, and the two roles conflict with each other in such blatant ways that, for some quality professionals, it can lead them to inaction or inappropriate action, and they then fail in both roles. For example, one of the messages emerging from the survey was that QA professionals need to speak up, interact and participate more. Part of that request was for QA to become more collaborative and build trust-filled relationships. The other part of that message was that QA needs to have the courage to take a stand more often, curb the *sinners*, and lead the company on the correct path. The request for QA to collaborate and work more closely with others falls right in line with the need for QA to build trust and lead change. However, the action of standing up to colleagues or superiors, calling them out, or even simply speaking up to publicly voice a quality opinion appears to have great negative consequences to his/her reputation, the key commodity in the business of leading change. Just as decision-makers weigh the pros and cons or cause and effects of their commitments, so do many quality professionals when it comes to taking a public stance.
Figure 34. The integrity balancing act: To approve a change, they must trust you.
Ryan and Oestreich (1998) explored this phenomenon in their research and found the following:

When people told us they were afraid of speaking up because of fear of some repercussion, we asked the question, “What are you afraid will happen?” [Starting with the most frequently cited fear, as follows:] Loss of credibility or reputation includes being seen as a troublemaker, a boat-rocker, an agitator, or not a team player, or being given other labels that mark the individual as a problem to the organization; this category also includes the fear of losing influence or as being seen as not possessing good judgement or acting in an unprofessional way. …Interpersonal rejection consists of being disliked as a result of speaking up, being seen as not fitting in the organization, not having the right image, or being isolated or shunned by others. …Emarrassment or loss of self-esteem includes being embarassed or humiliated in front of others, particularly one’s peers or powerful people in the organization, and fear of looking ignorant or unskillful. (pp. 92-93)

Considering the personal, undiscussable four concerns that preoccupy the self-dialogue of decision-makers in the face of change, (i.e., personal credibility, competence, relationships, and future security, introduced by Ryan and Oestreich in our earlier discussion on the decision making process), it is understandable that the quality professional might refrain from standing up and speaking out. Not only might the fears about taking a stance as listed above fail every personal concern, they also appear detrimental to any hopes for having any future success in the world of leading change.

Let us, however, consider the choice of not speaking up, of not taking the stand. First of all, silence can be considered the same as consent; it will be misconstrued as consensus in a group-think sense. Second, by not standing up when we should, the quality professional is not fulfilling his job responsibilities. Being aware of it leads most certainly to lowered self-esteem as one is now behaving in a way that, not only is inconsistent with the values of his formal responsibilities, but also with his/her personal work ethic and integrity. It does take courage to speak up when the round-table of voices appears in agreement, albeit in the wrong direction. The quality professional is typically participating as part of a team because of the insight or information that the others may not be considering, so not speaking up means not being a team-player, by definition. In addition, there are many that, equally afraid, know what may be right but also do not have the courage. What’s more, it may not be their role to speak up so they hold their tongue, yet are terribly dismayed to find that the QA representative did not say a word. “What has happened?” “Did he not understand what was going on?” “Was she listening?” “Is he qualified?” “Is she incompetent?” “He is most definitely not a leader.” And that is just it: The main thing a quality professional should wish
to preserve above all is his/her integrity; however, the perhaps short-lived comfort of remaining uninvolved or silent costs him/her terribly. The ramifications of poor integrity are lowered trust and lowered influence. As much as the quality professional seeks to lead, he/she cannot: Leadership must be earned, and a leader does not remain silent.

The industry has seen this time and time again. Poor leadership among its ranks is not new and only continues to kindle the negative perceptions of QA. However, the personal cost for QA is the most extreme. It is believed that this phenomenon of not living up to one’s own standard, being inconsistent with one’s own messages may be what resulted in the study data showing that QA had the strongest negative opinion of itself than any of the other functional group. Too much is at stake for the quality professional to not stand up.

Let us consider the effects of when the quality professional does speak out for what is right, or speak up to redirect the group to more compliant thoughts. Without getting into different ways this can be handled just yet, let us consider the benefits of actually making sure quality is heard when it may not be the most popular message in the room. First, of all one’s personal integrity can remain intact. You have followed your values and remained consistent to them. You have performed your job as well. In fact as mentioned before, the study data showed that the industry wants QA to do its role, to be that courageous voice on their behalf. That is what leaders do. In fact, speaking up usually brings much more respect than one might imagine. The day the quality professional learns to truly follow his/her values, have the courage, and stand up for what is right is the day he/she moves from being mediocre and ineffective to a true leader in the field commanding respect. You are now in such a position that you have the power of influence to fulfill not only the compliance enforcement part of your role, but even more interestingly enough, your chances of leading change have increased dramatically as well. This is because you are now seen as more of a team-player on the larger organizational scale: You have proven yourself as someone whose motives are not self-centered, someone who is perceived to have risked much by taking a stand whose actions are based on company-centered values. The irony in all of this is that the risk is far greater it seems when the one remains silent. In fact, all those fears about speaking out are not real, yet they actually become realized when one remains silent or lays low. In the end, unless one changes his/her way, the mediocre will get more mediocrity.
Skills

With that said, the question of concern is of course, how should one go about speaking up? There are ways that work, and certainly those that fail. After all, the study has shown that many QA professionals are very strong results-oriented people and may not have any qualms about speaking up to ensure they meet objectives and enforce, or should I say, *force* compliance. Being too results-oriented and you will burn too many bridges such that you cannot be effective to later seek change or compliance on a grander scale. The data also suggested that being too people-oriented risks the chance of placing relationships above the business of compliance enforcement. In this case, negative effects similar to those when one does not speak up can result. As with many things, the proper road to follow is down the middle path: seek to be a results-oriented diplomat who places the importance of relationships on relatively equal footing with that of attaining objectives.

Actually, the business of speaking up and that of leading change require the same fundamental home work. In both cases, such leaders must start with solid quality field-related competence. In addition, the quality leader must also arm him-/herself not only with a skillset for leading change but also for constructively speaking out. Per Ryan and Oestreich (1998):

> Many people hesitate to speak up because they do not want to cause trouble for others or want to avoid the trouble that open conflict might cause for themselves. At the base of this is a competence issue: most people do not know how to constructively engage in the exploration or resolution of differences. Interpersonal conflict scares them. They believe that a disagreement over something will lead to a situation that may get “out of control.” They worry that direct or indirect repercussions will result. (p. 104)

Just as the sales person and the change advocate must prepare the ground for influence, persuasion, and ultimately the commitment decision through the building of relationships and of trust, so too must the skilled QA professional who dares to represent the voice of quality. In fact, it is believed this part of the homework exercise is by far the most important. Lastly, the quality professional should continuously verify that he/she regularly gives similar if not equal importance to compliance as to relationships, a balance between results and people.

To constructively speak out, it is always best when the quality professional has invested in relationships as part of his/her homework. Just as trust is key for gaining approval and support, it is equally important in circumstances when one needs to speak one’s mind so as to ensure intentions are not misconstrued. Just as the decision-maker is
vulnerable to effects of accepting a change, so is the quality professional vulnerable when publicly voicing the quality stance. The tables are turned somewhat, but at the core of it all is trust.

In summary, one should conclude that the principal leadership qualities that a QA professional must seek to possess in order to succeed are the following:

1. Fundamental quality education and competencies
2. A balanced sense of importance given to both results and people (compliance and relationships)
3. Diplomatic communication skills
4. Relationship building skills
5. Constructive compliance enforcement skills
6. Influence/Persuasion skills

These skills and qualities are illustrated in Figure 35.

Figure 35. Pyramid of foundational values-based leadership skills for building trust to advocate and influence quality change (based on thesis).

Qualities 1 through 6 combined make up the required leadership skills in the QA field. They are also summarized in a graphic created for illustrative purposes. Individually, qualities 1, 2, and 3 influence and direct your thoughts and behavior to become prepared for success in the remaining three qualities. Qualities 4 and 5 are built off of a solid foundation.
in qualities 1, 2, and 3. They help to build trust, reinforce perceptions of your integrity and motives, and are useful to establish your relational and personal influence necessary for quality 6. Lastly, quality 6 (influence/persuasion skills) depends largely on mastery of the other five. There are certainly multiple tactics spelled out in the latest book on sales and persuasion that can help; however, they are no replacement for doing the proper foundational homework of building long-lasting relationships and trust. They can backfire as simple manipulations if the necessary groundwork of trust has not been built.

**STRATEGIES FOR TOMORROW**

A fairly thorough discussion has been presented thus far, setting the stage for considering different strategies for leading change (and constructively enforcing compliance). As this thesis proposes, one quality or skillset builds off the next, and mastery of all skillsets make up the quality leader. It is believed this is the base solution for developing into the trusted, influential quality leader we need to become to gain approval and support for our quality initiatives at all levels. It requires that we continually review and improve our skills at each of the levels. It also emphasizes the importance of each foundational skill: If we are not having success in one area, we can look to the underlying skillsets below for areas to improve first.

As a solution, however, it offers merely a skeletal framework to be used as a guide, leaving open each leadership skill to be continuously improved through on-going education in order to learn new strategies and the latest relevant philosophies. The research for this thesis has led to the discovery of an ever-expanding variety of literature on different strategies for effective communication, trust-based relationship building, constructively standing one’s ground without fear, establishing credibility, framing a proposal, etc. The strategy for the quality professional is to regularly sharpen the saw and use this framework to make sure all the skillsets get continuous educational and, whenever possible, on-the-job nourishment.

**CLOSURE**

In closing, I would like to emphasize the key messages emerging from the research and the literature. First, the strongest message detected was the industry’s need for true leadership in quality. By leadership, this meant a need for quality professionals not only to
assume their compliance roles (i.e., do their jobs), but also to do so in a way that builds trust and builds relationships. Trust in the QA role is best displayed and accepted when the quality leader values people as much as he/she values results.

The literature on persuasion and influence points repeatedly to communicating effectively and to building mutually “safe” ground for success in working through possible future difficulties as just about the only means to truly sell ideas and gain support when it counts. Logic and rationales only go so far to sell an idea, but they do not address the human element if it has been neglected.

If one intends to sell quality, one must be a leader in the human system. The key is integrity and trust; access to it is communication and consistency; exclusion from it is fear and neglect.
REFERENCES


