

CHAPTER 1

Understanding Quality and Quality Requirements

As a teenager growing up in the seventies, I, like my fellow teens, had a deep fascination with all things technical. This post-Apollo era heralded the beginning of the technological revolution we take for granted today. It was a time when new and exciting toys were coming to the marketplace—toys that only a few years before would have seemed like science fiction. By today's standards, those new toys would appear primitive, but during that time, anything that was a byproduct of the space-age was a must-have.

I had such a toy. It was the very first digital watch. When I saw it at the jewelry store I knew I had to have it. Despite the \$150 price tag, a lot of money in the seventies, I knew I must score the coolest watch I had ever seen. Every day as I walked home from school I would stop by the window and admire the gold case with the thick gold band and the dark, blank eye that was its screen. This watch used the red LED display and showed you the time when you pressed a button. Press it twice and you saw the date as well!

I worked hard and saved my allowance and the day came to make my purchase. I was the coolest kid in town, in my own mind, as I raced home. I was very proud of owning such a technological wonder and made sure I introduced everyone I met to the latest in timepieces.

About two weeks into my adventure in coolness, I pressed the button and nothing happened. I was mortified. How could this be? It had been only *two weeks*. “It must be the battery,” I thought, and raced off to the jewelry store to make things right again. The jeweler replaced my battery and we pressed the button. Nothing happened. Then I heard those awful words: “Looks like you’ll have to send it back to the factory. We cannot fix it here.”

Deeply disappointed, I set about contacting the company, boxing up my prize possession and giving it to the mailman. Time seemed to drag on and I heard nothing. Finally, after a couple of weeks, I phoned the watch company to inquire about when I might get my toy back. They could not give me a definitive answer. Six weeks later I had my watch back—*six weeks!* The company had now officially possessed my watch three times longer than I had. At least I had it back and I was happy.

Two weeks later, the same thing happened again. I sent it back and waited another six weeks. Then, when the watch died its third and final time, I gave up. I clearly remember as I tossed the carcass in the trash how tired and worn-out it looked with the gold case now tarnished and the shiny face scratched. I remember what a piece of junk I thought it was.

Obviously, the watch company had not clearly defined the quality requirements to build such an advanced product. Neither did they have sufficient quality control procedures in place to prevent defective products from entering the marketplace, nor were they prepared to provide fast customer service. It was their systems that were defective. My watch was only a symptom of those inadequate systems.

Today, the same company that made my watch is still in business and doing well, selling very-high-quality products. The quality of today’s products is the direct result of past mistakes and improved control systems.

This chapter gives you a basic outline and definitions for quality system elements. The remaining chapters will delve into more detail about how to structure these elements, how to optimize your productivity, and how to ensure your customers will never have an experience like mine.

The fields of *quality*, *quality control*, *quality assurance*, and *quality requirements* are standalone fields. Discussions and theories about all aspects of quality have filled volumes of books. My intention in this discussion is not to write the next book on quality but rather to focus on rules, ideas, techniques, methods, and philosophies that work and come from the real world of manufacturing. While some techniques I discuss are based on well-documented and -established quality plans, other suggestions for best practices come from an experienced application of common sense.

THE END RESULT

It may seem strange to start off a chapter with a section called “The End Result.” However, this is where we must start in order to understand and properly set up our quality systems. The perceived quality of your final product, how well it performs in the field, and customer satisfaction are ultimately the sum total of all your efforts. Everything you do, from equipment selection to hiring, training, education, raw materials, testing, and so on, directly affects the final quality of what ships out the back door. Each choice we make affects the pedigree of the products we produce and creates the customer experience of ownership. In light of this understanding we are compelled to embrace the *best practices approach* in every facet of our operations. This goal of high quality and mindset-of-excellence must be established, therefore, in the very beginning. Our company’s philosophies and decisions are indeed guided by these end-point objectives and quality therefore becomes the core of the entire organization’s mission.

However, any mission without a leader or a compass is a mission doomed to failure. Strong top-down leadership guidance, using quality as its compass, is an absolute best practice. Leadership whose philosophy is primarily customer focused: leadership that empowers and encourages everyone to embrace an attitude of quality first; leadership that understands that perfection is only an *ideal*, whereas excellence is an idea that is attainable. Producing a quality final product, therefore, does not start on the design bench or in R&D. A *quality* product begins in the corner office.

Within this quality-focused mindset, there are three terms that are typically confused with one another and often used interchangeably. These are *quality*, *quality control (QC)*, and *quality assurance (QA)*. These terms are distinctly different, but they do share a common ancestry. So to better understand and subsequently utilize them, let’s explore each term in a bit more detail.

QUALITY

We cannot begin to discuss QC or QA until we can identify what *quality* means. The quality of a product is an accumulation of its

attributes. For most of us, as consumers, the first kneejerk response defines quality as a matter of degree or grade of excellence. In a more practical sense, quality means how *good* something is at satisfying the need for which we obtained it.

From the consumer's viewpoint, as long as the item does what it is supposed to do, and does it for a reasonable amount of time, and at a fair price, it is of *good* quality. This definition is based solely on the emotional experience of product purchase, ownership, and expectations. When a product far exceeds the consumer's expectations, then the product would be considered of *very high* quality. This is a valid definition.

From the standpoint of a quality control engineer, however, quality means that all the defined characteristics, parameters, and specifications are within the documented limits. Is each unit produced exactly like the last and consistent with the others? The engineer is more concerned with the cold hard facts of how well the item meets design constraints and performance requirements and not so much with the experience of ownership. This, too, is a valid definition.

Design engineers, on the other hand, look to both the aesthetics *and* functionality. Does the product look like it was designed? Does it appeal to the targeted consumer? Does it solve the problem it was designed to solve? Was the cost of production in line with estimates or better than estimated? The designer is concerned about how closely the final product meets the original vision of its design and whether it does so at targeted cost of manufacture. Again, this is a valid definition.

The people on the shop floor making your product have their own set of process criteria—parameters, tolerances, and machine settings that contribute to the overall build and final quality of the product but are not necessarily a part of the final specifications. A *good run* for a machine operator means little or no rejects or rework; this is considered a good quality run. That is another valid definition.

By now I think it should be clear to you that *quality*, like *beauty*, is in the eye of the beholder. Your relationship to the product determines, for you, what quality means. Note that when I use the term *quality*, I am indeed talking about the positive aspect of the word. *Good quality*, *first quality*, and *high quality* are all expressions

of the same positive attribute. So our discussions of quality shall cover practices that will yield the best quality possible.

QUALITY CONTROL

By definition, *quality control* is a system of checks and balances, testing, verification, and reactions that monitor product attributes and process conditions to ensure compliance to design expectations and internal and/or external specifications.

Our leaders have set a course and made provisions and given permissions necessary to produce the products we desire. What is needed now is a captain to ensure the ship is always headed in the right direction. Someone must be given autonomous authority to monitor and correct course, or to stop the ship altogether if we are about to run aground. This independent body is charged with the responsibility and authority to keep all the manufacturing processes aligned with the company's stated objectives. The *quality control group* becomes our police force. And having spent most of my career in QC, I can tell you there are times when you fill both roles of good cop and bad cop.

I cannot overstate the need for the QC group to remain autonomous. Your organizational charts should show no direct reporting of any QC area, or individual, to anyone associated with the actual product manufacture. For instance, the QC lab technician testing product quality should never directly report to the production line manager. This is a direct conflict of interest and simply not a good business practice. The lack of QC autonomy or independence from manufacturing may lead to internal conflict or, worse, coercion from manufacturing to overlook or bypass QC requirements so as to facilitate manufacturing throughput. So we must insulate our QC group from direct influence of other areas as much as possible.

Ultimately, however, the senior QC manager will report to a C-level executive, like the company president, who possesses the ultimate authority within the company. The president has responsibility for all areas and departments, including manufacturing and QC. If we have established the top-down quality approach, as we discussed earlier, then we minimize any conflict-of-interest problems at this level. Another must-have criterion for all senior-level managers is

status equality. The senior QC manager must be on the same organizational level as all other senior managers.

Quality control is the central clearinghouse for all information related to the product. From specification review to process control, to final product testing and disposition, QC is ever present. Just like a cop, QC is there at our request to keep us honest in our practices. QC has the final and ultimate authority to determine if we are in compliance with our stated objectives and accepted specifications. There are times when we miss our mark, and it is the QC group who must then make the judgment about what happens next. Without QC to watch over all we do, we have no guarantees or control whatsoever of the products we put into the marketplace. Although no one likes being evaluated on the quality of his or her workmanship or performance, QC's role is vital to the continued financial success of our business. Bad quality costs money. The costs of rework, returns, missed schedules and shipments, and dissatisfied customers are all reflected in the bottom-line profitability of the business. So the question is not whether we can afford to have a strong QC group, but rather, *can we afford not to?*

QUALITY ASSURANCE

The *quality assurance group*, while a separate body from QC, performs a similar function but on a much broader level. The QA group is less concerned about specific details of an individual product and more focused on monitoring to ensure that every major subsystem is working to support the overall quality efforts. The QA group acts as overseer to our best practices systems, such as document control, process control, calibration, training, and corrective action. QA is responsible for auditing these systems and ensuring compliance to such standards as ISO 9000 or TS16949 as necessary. QA is the watch-dog of our *entire* quality effort.

THE QUALITY SYSTEM

These three aspects of quality, when working together, create a *quality system (QS)* that contains within itself all of the best practices. The

quality system is, therefore, the master system, the backbone of our manufacturing operations, and creates our quality philosophy.



Now that we have created this *culture of quality* within our organization, we must begin to feed it with more detailed information regarding our customer's needs, what the customer finds of value, the customer's expectations, and our ability to produce that product. Foundational to this task is the extraction, translation, and implementation of our customer's quality requirements into our manufacturing processes. Defining quality requirements is accomplished through the process of specification review.

QUALITY REQUIREMENTS AND SPECIFICATION REVIEW

Manufacturing doesn't just happen. Clearly we must have guidelines and detailed information to create the products we sell. These specifications come from either internal or external sources. Specifications are documents, printed or electronic, that must be reviewed and approved before use in the manufacturing facility. Specification review and approval is handled by QC and is used to establish *key product characteristics* as well as *key process variables (KPVs)*. We shall examine KPVs in depth in Chapter 7.

Specification review and approval *must* be completed before any order for product is taken from your customer. Understanding this sequence is crucial. When an order is accepted, we are then committed to manufacture and deliver. Realizing when we are ready to ship that we had missed a step or cannot comply in some way may cost us enormous amounts of money, dissatisfied customers, and lost business at the very least. Or worse, we may have to face legal issues for not being able to supply as promised. So, as you create the quality culture we discussed, make sure everyone is in agreement on this point. The specification review and approval *must* be the very first step in manufacturing.

Specification review begins with the creation of some system for logging in and tracking every specification document received. This database becomes even more necessary when the number of documents received is large. We want this best practice to create a central repository of all the work we do during the review step. The database also serves as a reference source to remind us that a document has

already been reviewed. At a minimum, the review database should contain:

- Document name, revision, revision date
- Date received
- Document owner/customer
- Internal contact within our organization (the individual who owns the specification)
- Product or process description, if applicable
- Review due date
- The members of the review team and their approve/reject status as well as any comments
- Final QC approval/reject date and any comments
- Final distribution status

We normally think of specifications as only the requirements for the actual product itself—requirements like dimensional and performance characteristics plus tolerances. In fact, specifications also contain requirements that are not related directly to the build or creation of the product. These include items such as packaging, packing, and labeling. Delivery schedules, payment terms, testing, and inspection procedures or references to other specifications may be found.

A typical specification review cycle, therefore, requires circulation of the documents through all the functional areas for comment. Each detail of every section must be carefully scrutinized. It is not a matter of simply being able to produce the product. We must also be able to package it correctly and test its attributes for compliance to our customer's requirements. Each area then must bring its own expertise and use the tools and information necessary to evaluate that particular area's ability to meet the listed requirements. For review of the actual product properties, statistical analysis is often used. Histograms, capability analysis, control charts of similar products, and historical data help us make these approval decisions.

A word of caution here: Specifications are notoriously incomplete. Many are lacking information that we, as manufacturers, know is required to turn out a first-class product. When reviewing specifica-

tions, we must be aware of vital information *that is not documented*. For instance, if we are in the widget business, then no one knows how to build widgets better than we do, right? We know that widgets can look very similar but have very different functions, and so identification labeling is a key part of widget manufacture. Labels prevent the mixing of parts. Our new specification has no requirement for any type of marking or identification. Should we simply accept this, approve the specification, and build the product as called out with no labels? Of course not—it is best practice in this case to reject the specification and offer to work with our customer to surface the missing information. After all, who is better to assist them than we are? After all, we are the experts. So when reviewing any specification or drawing, you must be vigilant to watch for what information *is not there!*

As each area completes its review, the results are funneled back to QC for inclusion in the database. QC is responsible to track and follow up on any review response that is late or whose approval is unclear. QC then examines the results of the review and works to resolve any unclear information. So specification review can take a considerable amount of time as we draw on the knowledge of all our resources and experience to be sure the review is thorough and complete. Once the review is finished, QC makes the final approval or rejection of the specification. In the case of rejection, QC will supply feedback and detailed information on the reason for rejection and any suggestions for changes that would allow subsequent approval.

If the specification is approved, QC is charged with the responsibility of dissemination of the document and its information. The specification may be copied or scanned into a central system or simply have its information loaded into a manufacturing business system. More about this distribution process will be found in Chapter 6. The end result of the review process is an all-encompassing collection of information termed *quality requirements (QRs)*.

QUALITY REQUIREMENTS

Ask almost anyone what a quality requirement is and they will most likely talk only about attributes and properties the item should have. A better question to ask is, What is required to have a quality experience?

Or, What makes an ordinary product *extraordinary*? For example, you purchase a new car. One dealer offers you not only the car but free maintenance for life, free wash, wax, and detailing, and guaranteed trade-in on your next purchase. The other dealer across town is merely willing to sell you the same car with no extras. Which would you consider the higher quality experience? Both dealers have only one chance to *get it right* when they make you the offer. Knowing what your customers expect or helping your customers to *discover* what they expect and then delivering, or exceeding, those expectations creates the perception of higher quality beyond the product's attributes.

Quality requirements are more than just the basics. Defining quality requirements probes deeper into all the areas that touch your customer. We must address the non-obvious as well as the obvious questions. There exists within each organization a *body of knowledge* that is required to produce our goods. This knowledge consists of the minimum amount of information required to *get it right* the first time. Miss one point and you risk that very same point being the crucial one. Each company that manufactures products will have its own list of these requirements. Although I cannot possibly list all the requirements for every industry, I refer you to the Appendix, which contains a sampling of generic items for some common topics. This list will guide you in making your own list.

FINAL THOUGHTS

Understanding what quality means and the roles of both QC and QA is fundamental to good manufacturer practices. Remember that quality is an attitude and the experience of quality varies depending on how someone interacts with your product or process. You must create a *culture of quality*, starting with strong top-down leadership that bestows upon the QC and QA groups the authority and autonomy to manage the quality systems. Defining quality requirements and key process characteristics must be accomplished *before* any order or commitment to manufacture can take place. You and your team, better than anyone else, know what is required to put forth your best effort. Your *final* product quality begins with these very *first* steps. Get these steps right and hopefully you will never have a disappointed customer who tosses his dream purchase in the trash.