

# The Benefits to Proficiently Establish the Quality Management System (QMS).

Why QMS Replaced the Old and Inefficient Business Management Model?

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## Summary

QMS is known in the business world as a new management philosophy that successfully replaced the traditional business management model. This philosophy is universal and applicable to all aspects of our existence as human beings. After 60 years of proven history, QMS is still not established worldwide as a widespread practice among all industries. Fortunately, its popularity is growing because its risk management nature makes it indispensable to master such kinds of crises as Covid-19. QMS became the ground for regulatory materials across the globe. Its good understanding, adoption and application will enormously improve the quality of life on our planet. The large variety of benefits to the societies and industries are tangible, such as improvement in health, an increase of productivity, sales and profit, reduction of costs and employee turnover and intangible, creating an inspired, secure, and stress-free environment, improving the quality of products and services, corporate culture and social responsibilities. The main question arises: "If QMS is so vital, why is it still not popular enough to grasp the attention of everybody capable of making changes for the common good?" My short answer is that people who are well familiar with this philosophy must join efforts and translate it into easily understandable language. Once we create the needed social environment worldwide, this will allow communicating more efficiently with a good comprehension of how to prevent or deal with crises, including pandemics, such as Covid-19. Only if the QMS's full potential is mastered, then can it be fully implemented. And only then can companies and their staff enjoy incredible results. This article emphasizes the benefits of adopting QMS because it is broadly misunderstood, therefore the traditional management model was compared to QMS to highlight the difference. In addition, key concepts and examples illustrate how QMS's results are achievable.

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## Introduction.

For centuries, the empirical "rule-of-thumb" management models have had a dominant role. In the early twentieth century, Frederick Taylor's principles of scientific management were the first successful attempt to massively move traditional perceptions in the direction in which scientific laws play a crucial role in management practice. However, the main vulnerability of his viewpoint is that he underestimated the role of the workforce in problem-solving. Between the mid-1950s and the mid-1970s, QMS was nationwide established in Japan. The remarkable results, known as the Japanese economic miracle, have led to its further global development. As the QMS principles also apply to personal and social events, their importance has an enormous impact on businesses, people, and society. If the world appreciated and adopted QMS correctly, the Covid-19 would go away like a flu epidemic in a season.

QMS is popular with different names among the various industries, that includes Quality by Design (QbD) in healthcare and life sciences, Design of Experiments (DoE) in Research and Development, Agile in IT and Financial Industry, Total Quality Control (TQC), Total Quality Management System (TQMS) and Six Sigma in car's, aircraft's and building's construction and manufacturing, to name a few. This diversity of terms is one of the reasons why QMS sounds complicated and burdensome to make it more popular and understandable for adoption. The other reason is that its dissemination is impossible if the appropriate social environment is not created where everybody will talk about its benefits and specificity. Regardless of the diversity between the various quality management schools, they all share the same principles described in the ISO 9001 Quality Management documents, and they are listed and discussed below in the article.

The regulatory materials in the healthcare industry adopt the International Council for Harmonization (ICH) guidelines, and they are coherent with the International Organization for Standardization (ISO) management system standards. As yet, the healthcare industry falls behind many other sectors regarding the adoption of QMS. It is encouraging that the interest in QMS has been increasing in recent years. Hopefully, the world pandemic provokes people to search for proven approaches from different sectors to make healthcare more successful.

A company's destiny is determined by QMS principles, where quality improvement relates not only to products but also to the entire process. As Edwards Deming had illustrated (Figure 1.), working in a QMS environment is a chain reaction. Productivity improves, products and services reach the market

*This is a radically different approach to business processes than to traditional one. It is a tremendous optimistic point of view about the people that work in a company. They will improve the processes if there's a mechanism for it. That optimistic humanism I find very appealing and we have countless examples that it works.*

Steve Jobs

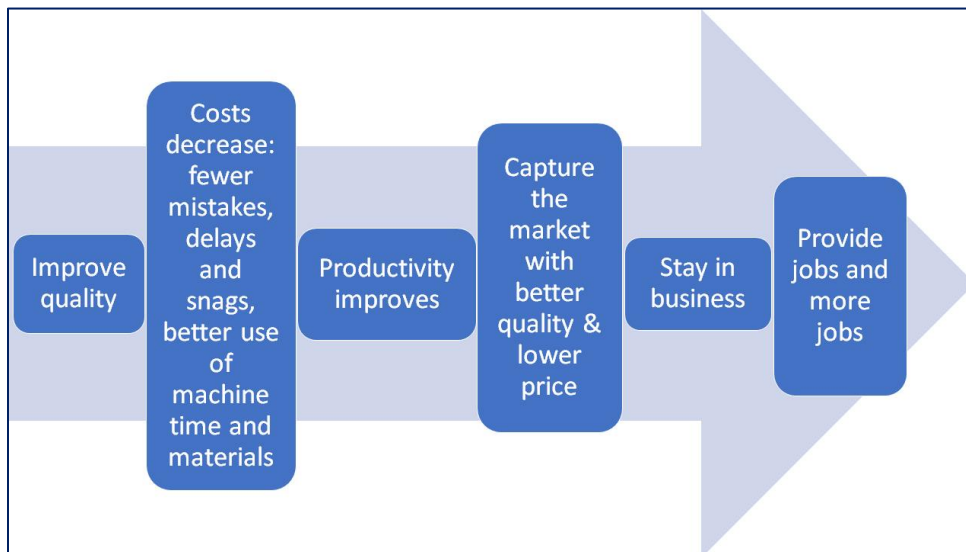


Figure 1. The Chain Reaction by Edwards Deming.

*Now, things swing back to the “good old days” when the quality belonged to the quality department. That is like thinking that financial management belongs to the financial department.*

Philip Crosby

with better quality at lower prices. Costs decrease due to fewer mistakes and better use of resources. All of that allows companies to stay in business and provide more jobs.

Most key decision-makers are not familiar with QMS, and they assign its adoption to quality departments, staying isolated from QMS companywide perception. This phenomenon is widespread among industries and leads to much pain, dissatisfaction, and disappointment from the new management model. This article focuses on the benefits of adequately adopting the QMS philosophy to make it easier to understand and fully master it. Some of the most valuable concepts illustrate the advantages of the QMS over the traditional management model.

As the article's primary purpose is to focus on healthcare, the provided concepts mainly illustrate the benefits in this sector. The examples support them to indicate how these results are achievable in real-life practice.

## 1. Financial Support.

Companies that adopt the QMS philosophy can rely on financial support from governments, banks and venture capital in various forms. Financing training programs by government funds and integrating business with academia are the best ways to achieve institutional goals and social recognition. These awards complement the benefit of receiving financial support from banks and attracting venture capital.

Whether companies rely on government or private investor finance, they must demonstrate reliable business with a good enough return on investment (ROI).

Mature QMS is the most convincing way for a sustainable and growing business. High ROI is possible when the human potential is fully utilized, multiplying people's engagement in the business process. That means that the QMS principles are well understood and followed by all employees and stakeholders. Below are listed the seven principles of QMS. They are not ordered in priority order as all they are equally important:

- Process approach
- Evidence-based decision making
- Continuous improvement
- Leadership at all levels
- Customer focus
- Relationship management
- People engagement

The QMS principles must be well understood and applied companywide to impact every aspect of the operations. To this end, a series of education and training with the proper use of relevant concepts are valuable tools to establish a mature QMS in place. The results are considerable increases in employees' engagement, creating a culture of clear accountability, increasing productivity and ROI, building trust and dialogue with people inside and outside the organization. Both tangible and intangible benefits are discussed in the following paragraphs.

## 2. Problem-solving.

Businesses deal with a wide variety of visible and hidden unresolved issues on a daily basis. Most of the time, the management team tries to solve the problem with limited resources and engagement of the employees. Often though, the same problem comes back again and again. The main reason for this is that the symptoms show up later due to many hidden causes. The diagnostic process to solve the problem requires specialized skills, which are beneficial if developed in-house.

The Quality Control Cycle, first proposed by Walter Shewhart and later developed by Edwards Deming, is a famous concept that explains how companies must organize their practice to ensure high-quality products and services (Figure 2). People cooperate reliably in problem-solving programs when the focus is quality. Thus, the reduction of defects becomes a natural consequence of well-defined programs. Education, training, and applying statistics are essential parts of the programs. As discussed in the following pages, these allow identifying needs and priorities and recording data, sources, and deviation levels. The most profound difference between the traditional management model (Fig. 3A) and QMS (Fig. 3B) is the degree to which employees are involved in the process's design and execution. According to the traditional model, scientists establish procedures that the employees must follow. A lack of efficient communication between employees, departments and external partners still exists, and this phenomenon creates a premise for errors and defects that accumulate down the road.

*There are many reasons why quality/productivity (they go hand in hand) have not kept ahead. A few of the major ones are: the educational system that turns out math ignoramuses and emphasizes the MBA (which teaches managers how to take over companies, but not how to run them); the short-term goals of corporate heads (this year's profit for a bonus or a better job elsewhere); the practice of moving about the country, and finally out of it, for cheaper labour (even though direct labour is a small minority of costs); the change from honest leadership and work ethic to "get yours" and "everyone does it" at all levels.*

Edwards Deming

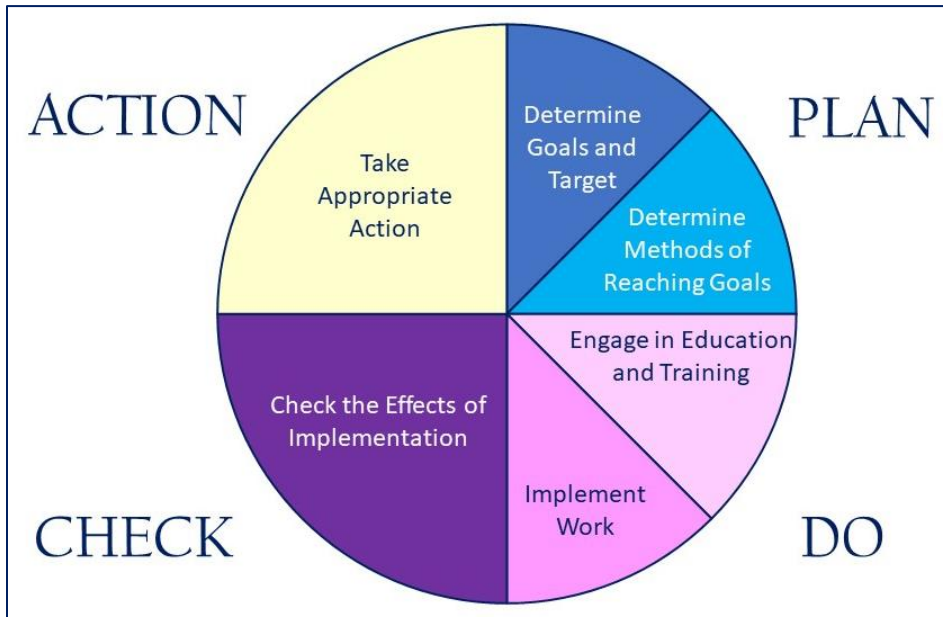


Figure 2. The Plan-Do-Check-Act (PDCA) cycle by Walter Shewhart and Edwards Deming.

The problems are permanently solved when a companywide QMS practice is well established. On average, about half of defects may come from external sources such as raw materials and services. If employees are trained to become familiar with the nature of potential causes of errors, they actively participate in problem-solving and prevention. The investment of time and effort to set up such an educational program gives an extremely high return over time.



Figure 3. Traditional Management V/S Modern (QMS) Models.©

Joseph Juran described the new role of the Senior Managers, which is to address the Big Questions to the organization. An example of a Big Question is that quality is viewed as a business problem, not a technological problem. According to the traditional management model, quality is considered a technical problem related to the products, not the process.

Taylor's management model does underestimate employee training and involvement in problem-solving practice. It separates planning from operations because most employees did not have enough education several decades ago. Today, employees are much better educated and can contribute successfully to problem-solving and preventative action. This support becomes possible when they are fully engaged and are vigilant to the whole process.

## 2.1. Scalability and Manufacturability.

Among the most common challenges in the industry are the failure to reproduce the results from R&D on a large scale, i.e. scalability and manufacturability. There are multiple reasons for this, and they are all complex. As I mentioned before, half of the reasons may be due to external factors. Therefore, it is imperative to create an efficient and effective network of contacts between the companies that provide raw materials, consumables and services with those who consume them. This cooperation is good to take the form of a consortium. Still, the critical point is to exchange valuable information about services and raw materials: what exactly needs to be adjusted in existing productions and platforms to reproduce the desired results.

The challenges that may come from internal organization gaps can be solved through staff education and training by respective internal and external professionals and consultants. Thus, the businesses will avoid future inconsistencies in the process. It is crucial to coordinate changes to make all stakeholders aware of them. This coordination ensures the robustness of efficient operations.

Let's illustrate it with the following example. A drug discovery company developed a protein-based product, say antibody. Their initial analytical studies gave them promising results. However, the results were completely different after manufacturing, and the product was unstable. This scenario happens often. To avoid such problems, companies must establish connections with the suppliers and the manufacturing company. In advance, they need to discuss the manufacturer's limitations and opportunities to work with specific materials and their whole manufacturing flow process. This information will guide the drug discovery company to work with the same raw, disposable or packaging materials, chemicals, and other consumables suppliers. Also, they need to keep a detailed record of all the steps of the R&D process and coordinate them in advance with the manufacturing team. Thus, any discrepancy will be avoided. The process coordination between the stakeholders must be organized carefully with all the employees who work on the product, including those who characterize it in the analytical laboratories. Only then the reproducibility of the results will become possible and robust.

*Employees cost money to acquire and maintain, and they should provide a return on that outlay; their value increases as they become more effective in their jobs and capable of taking on greater responsibility.*

Michael Armstrong

*Variations in the objective functions of products (or technologies) are primarily due to three sources: environmental effects, deteriorative effects, and manufacturing imperfections. The purpose of robust design is to make the products and the process less sensitive to these effects.*

Genichi Taguchi

## 2.2. Salability.

*Our brains are hardwired to critique others. But to inspire exceptional performance, managers have to lead with meaningful feedback based on what each person naturally does best. This is the starting point to build trust, which increases the likelihood that the critical feedback will result in growth and development.*

Jim Clifton

Products and services are salable when they meet the needs of the end-users. It is essential to differentiate end-consumers from customers because this distinction is a preposition to develop high-quality products and services. When creating a product or service, we involve a chain of people who participate in the process. Each of them can play the role of a customer at some point when they take over intermediates and processes them to pass on to the next in the chain. These internal customers for the company are interested in the quality of the intermediates, and their opinion is crucial for the quality of the final product. The well-established practice for exchanging critical information between the employees in the business leads to continuous improvement and permanent growth of the companies. The described scenario works perfectly in a mature QMS environment, and it is described in more detail in the next section.

Suppose the concept for internal customers is developed correctly. In that case, the quality of products and services will be high, but their price will compete with similar products with lower quality. These kinds of products and services are the most attractive for the end-user: high-quality at affordable prices. That is how businesses prosper.

An appropriate illustration of the ability of companies to offer salable products is the successful development of vaccines for the Covid-19 virus. Currently (as of January 2022), out of 140 candidates in clinical trials (194 candidates are currently in pre-clinical trials), only ten vaccines have been approved by the WHO. They are as follows: Oxford/AstraZeneca (AZD1222), approved in 134 countries, Pfizer/BioNTech (BNT162b2), approved in 132 countries, Janssen (Johnson & Johnson, Ad26.COVS.S), approved in 101 countries, Moderna (mRNA-1273), approved in 85 countries, Sinopharm, Beijing (BBIBP-CorV, Vero Cells), approved in 85, Sinovac (CoronaVac), approved in 51 countries, Serum Institute of India (Covishield, Oxford/AstraZeneca formulation), approved in 47 countries, Novavax (NVX-CoV2373), approved in 31 countries, Bharat Biotech (Covaxin), approved in 13 countries, and Serum Institute of India (COVOVAX, Novavax formulation), approved in 3 countries. These data indicate the maturity of QMS among companies that have a proven record in drug discovery.

## 3. Errors and Defects Reduction.

A common acceptance among industries is that products may tolerate 10-30% errors that lead to defects. Do we want to buy defective raw materials from a supplier? In our daily practice, this happens all the time. Sometimes errors or defects would be fatal, vital in healthcare practice. The custom to tolerate them leads to accumulation of errors and deviations down the chain of operations. According to Genichi Taguchi,



more than 80% of the products are defective without quality planning with varying percentages of deviations, Figure 4.

In the old model, a separation exists between departments, leading to the fragmentation of information and processes. In the QMS model, efficient communication between employees and departments is crucial for the business

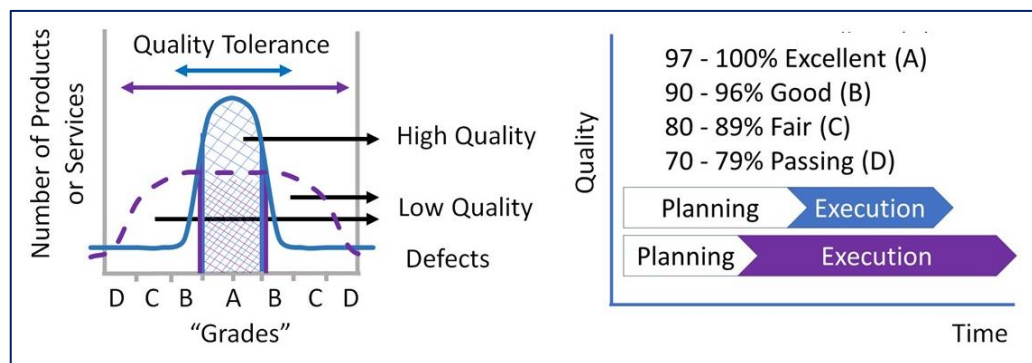


Figure 4. Quality Characteristics by Genichi Taguchi.

success. It opens space for creativity, exchanging critical information for solving problems and process improvement. Establishing a collaborative environment between external and internal departments is crucial. Three players (suppliers, processors, and customers) are the basic units, Figure 5. Everybody can play one of these three roles under given circumstances. Suppliers could be external or internal products or service providers. Customers are not only those who pay for products or services Customers are all those people in the chain who receive products or services from others and are impacted by them. So, the “processors” must request specific quality from their “suppliers” as well they must deliver quality to the “customers” according to the requirements of the latter. When applying this notion to all other units of an organization, identifying and reducing defects becomes easy to understand and practice. Such groups can work as quality circles that replace quality control and quality assurance departments. Let me illustrate it with the following example. The purchasing department (PD), which plays the role of a "processor" at the beginning of this example, must know the needs of the internal users (customers) for specific raw materials or other consumables, say plastic containers. When purchasing, the PD should require the sellers (suppliers) to meet specific quality criteria, such as the contaminations from plasticizers that may harm the solutes that will be stored in these containers. The PD becomes a supplier when the materials are purchased, whereas the "customers" become "processors" because they will use the plastic containers to perform their job. The last must inform the next on the chain "customers", who will use their processed goods on how the job was performed with the necessary details. If the "customers" have requirements, they must be followed.

*A basic key to creating new business opportunities is to increase product and service value for customers while simultaneously eliminating obstacles. This means measuring disconnects and backward creep as costs of failures and lost opportunities and working to reduce those costs.*

Armand  
Feigenbaum

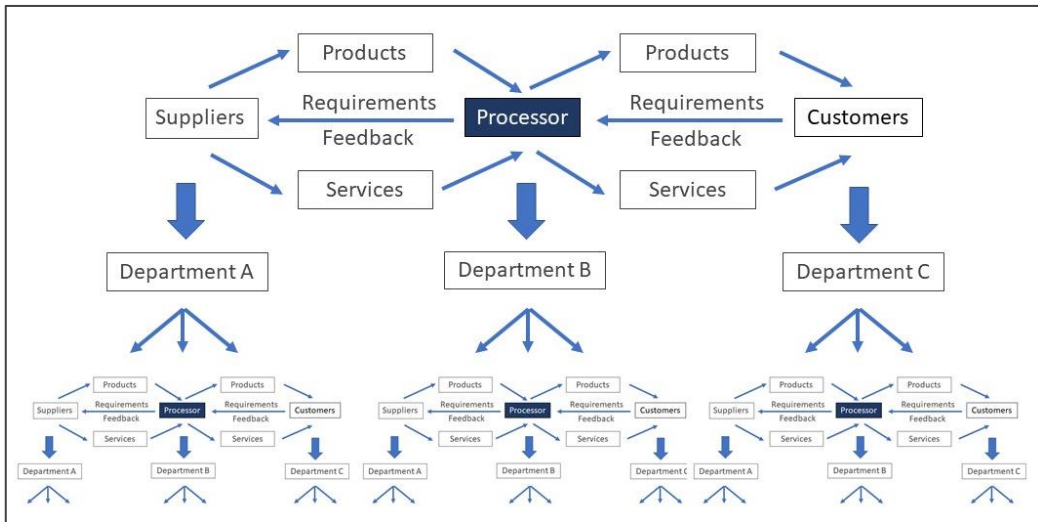


Figure 5. The Concept “Who is the Customer?” by Joseph Juran.

**Classification of Customers: Useful Many:**

*Each of the useful many customers is of limited importance to the supplier.*

*However, collectively the useful many should be regarded as a member of the vital few. There are several categories of the useful many customers:*

*consumers, the workers, and the public.*

Joseph Juran

Thus, when everyone in the chain is well informed about the requirements of each member of the chain to provide quality materials and sub-products or services, then everyone takes responsibility for the quality of their work. The end results are more than fantastic because they are the consequence not of mechanistic activity but of highly conscious actions, where not only the hands and the brain but also the heart and the soul take part.

### 4. Cost Reduction.

A general belief is that improving quality is an expensive process. Contrary, by reducing errors and deviations, the operating costs can decrease from 20% - to much more than 100%. Chronic variations and a considerable margin of mistakes usually result in massive failures. This time is when companies find the need for management model breakthrough. One of the relevant concepts, known as the rule of 10s, compares the two management models in terms of savings or financial losses over time. The QMS proper adoption leads to an exponential reduction of the costs (Figure 6, the grey curve). Whereas in the traditional management model, if we spend one dollar at the very beginning of our business practice for concept development, the next step, R&D, for example, will cost ten times more (\$10), the following step - another ten times more (\$100), manufacturing - another ten times more (\$1000, Figure 6, the blue curve).

A Pareto chart (Figure 7.) is a valuable tool for assessing the cost of defects and savings after improvement. It allows identifying priority issues and putting them on the focus for consideration. Once they are solved, other priorities will replace the previous ones. The Pareto chart is also well known as a Pareto principle 80/20. It means that 20% of the causes of errors may considerably contribute (80%) to the main problem. This rule is also widely applicable to other business, social and personal life events.

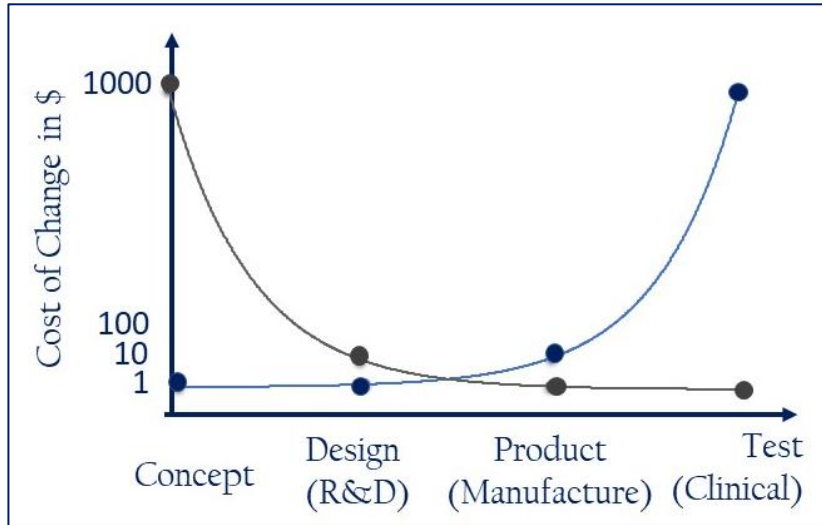


Figure 6. The Rule of 10 by David Anderson.

Operations within mature QMS result in significant cost savings over time. For example, reducing defects from 30% to 3% in a shorter period can lead to long-term savings of millions to billions of dollars. Vice versa, if companies fail to adopt QMS, they suffer million to billion dollars losses for unknown reasons most of the time. Let me illustrate it with an example. A biotech company invited me to solve a problem they could not solve for over eighteen years. It costs the company over \$120M. Mistakes in the calculations of the scaling-up product were the primary issue. Almost every batch of 1000L product has given them precipitates immediately after production or later gradually precipitates occurred. It was not only about the financial losses, but

*Leadership—at every level—is the critical factor in whether a team succeeds or fails.*

Jocko Willink

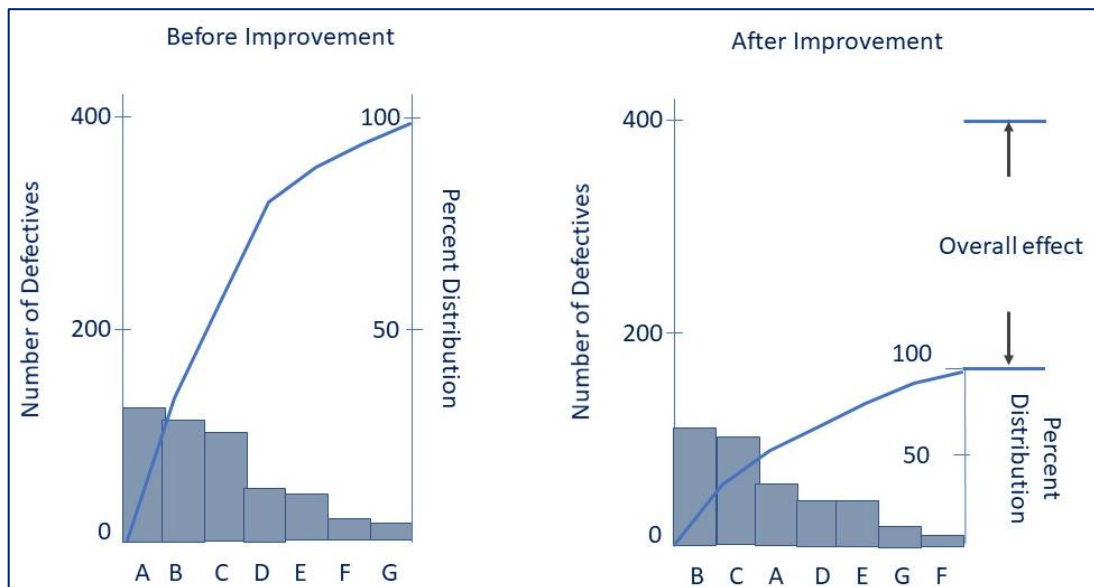


Figure 7. Pareto Chart for Root Cause Analyses.

there was a lot of frustration and a lack of confidence in how they sold the product. I can't describe how happy the whole team was that the problem was finally solved after so many years of difficulties in overcoming it.

*If we have found a way of doing our job that does not entail any risk, then the organization probably does not need us. A vision is a preferred future, and acts of courage in the creation of that future give meaning to our work.*

Peter Block

## 5. Risk Management.

The reduction of the risks in the enterprise is possible throughout a process where identification, analysis, and evaluation of the hazards have been considered. The quality risk management process facilitates decision-making when problems arise. It applies to the whole range of aspects, from raw materials - to packaging, labelling, distribution etc. Typically, an interdisciplinary team embarks on quality risk management activities. It consists of experts from different areas of operations, including external providers of services and materials, Figure 8. Thus, the whole process favours all parties' better use of resources. The reduction of the risk to an acceptable level is a step towards control, focusing on the procedures, consequences, and balance between benefits, risk, and resources.

Let's look at the global pandemic landscape. There is quite a big difference in the morbidity and mortality rates between North America, Europe and the Far East, Japan, South Korea, China and other countries in the region. How can we explain this fact? Can we link it with the global expansion of QMS? My answer to the second question is yes! Surrounding Japan countries have had over sixty years of opportunities to learn from the country, which became the world quality



Figure 8. Risk Quality Management Diagram. Adopted from ICH Q9.

leader, on how the nationwide establishment of QMS benefits the whole society, including the healthcare system. Let me go back to the first question. There are multiple reasons why the Asia-Pacific region dealt with the Covid-19 crises much better than North America and Europe. I want to emphasize three of them. First, the Asia-Pacific region was at the forefront of the battle against SARS in 2003 and mobilized in the H1N1 (2009) and MERS (2012) crises. In other words, people there have a historical experience to fight these kinds of infections. The second main reason is the social support of all government and non-government initiatives in the region. A famous Japanese consultant, Kaoru Ishikawa said: "Developing a national quality management system is impossible in a social vacuum." Both support directions were developed in the Asia-Pacific region: top-down, where governments set strong control policies and bottom-up, where the public supports governments and adheres to government-led public health measures and actions. These measures gave excellent results with the lowest prevalence of infection and mortality. The third reason is that people in these countries have experience surviving in a stressful environment, both climatic and health-related. Many typhoons and earthquakes often disrupt the life of the citizens there. Living in unpredictable health and climate environment, they are trained to manage the risks and live in a mode of protective action.

## 6. Quality Improvement.

When talking about quality, usually, people link the word with the quality of products. In the context of the QMS philosophy, we look at quality as a category that relates to the processes in the first place and afterward to the products, which are the result of the process. Some of the critical ingredients of the QMS are depicted in Figure 9. that includes self-management, formation of consortiums, quality circles, and councils, efficient communication with a unified language, training and education, extensive use of statistics and data integrity, continuous improvement and problem-solving to keep the business practice in a prevention action mode of operation.

Quality is a vague term, and it often refers to luxury and expensive goods. As a subjective term for us, the most common definition of quality is "fit for purpose". The quality of the final product is a result of many steps that must focus on this quality. The term "data integrity" describes the business practice as a "living organism". As an illustration, the human body consists of eleven systems: integumentary, skeletal, lymphatic, respiratory, digestive, nervous, endocrine, cardiovascular, urinary, and reproductive. They work in a tightly synchronized way. Similarly, departments and external parties must work in harmony in a business. Recording, organizing, and analyzing all data help identify interactions between factors and communicate them, presenting them

*Habits of diligent work and self-criticism, respect for humanity and treating each worker as a whole person contributes to the improvement of corporate health and character. Normally, in companies that do not have Quality programs, there are ten times more potential complaints than actual complaints. These actual complaints are nothing but the tip of the iceberg.*

Kaoru Ishikawa

*Innovation is the lifeblood of an organization. There is nothing so stultifying to a company – or the people in it – as a belief that the old ways must be the best ways. An organization that tries to stand still will not survive.*

Michael Armstrong

*Leaders can send messages about new expectations, model new behavior, introduce methods for learning and practicing new disciplines. They must ensure that measurements ultimately empower rather than punish people.*

Rosabeth Kanter



Figure 9. Critical Ingredients of QMS<sup>®</sup>.

to the stakeholders. Proper communication helps to spot errors and fix problems. Removing errors and improving the quality of processes and products becomes a part of the business practice. To this end, education and training must be conducted regularly.

The interrelationships between factors, such as product improvement, instrument operation, meeting design or others, help quickly move to the next step, the prevention mode of action. These actions inspire people to unlock their potential for quality work. Objectives must be established in such a way as to ensure cooperation from all subdivisions. In this way, we can achieve productivity gains, given that human nature encourages us to be proud of our overall achievements in the workplace.

The traditional management model misinterprets employees' engagement in improving the process. Thus, the unlimited human potential remains hidden, underestimated, and unused.

## 7. Increase in Productivity, Sales, ROI and Profit.

Improving productivity is a significant concern for managers and employers, both technical and psychological. It can be easier overcome if we study psychology and read more books about human resource management and self-development. Gallup surveys show that about a third of employees in most United States companies are engaged in the workplace, whereas over 70% of employees are engaged in the best-practice organizations. For comparison, statistics show that about 15-20% of the employees are engaged in the workplace globally. The most decline in engagement

in 2021 compared to that before pandemic included healthcare workers and managers. Specifically, healthcare workers saw the most significant decreases in feeling that someone at work cares about them, someone encourages their development. They have an opportunity to do what they do best, they have clear expectations and equipment that they need to do the right job, and their opinions are counted. Managers have noted the sharpest decline in the feeling that they have clear expectations and someone who encourages their development. Gallup found that people's commitment is highly dependent on managerial talents to motivate, have confidence in results, build a culture of accountability, build relationships and make decisions based on productivity rather than policies, Figure 10. These criteria align with the QMS principles defined in ISO 9001 materials and are listed on page 5.

*Economic advantages may be created by any person who surrounds himself or herself with the advice, counsel, and personal cooperation of a group of people who are willing to lend wholehearted aid, in a spirit of perfect harmony.*

Napoleon Hill

Diving into the QMS basics and building a team is a must. Napoleon Hill defines it as “The Power of the Master Mind,” the driving force - organized and intelligently directed knowledge. This approach is fundamentally different from the traditional management model where employees must follow written operational procedures, and the only motivation in the workplace is the salary. In the QMS philosophy, people are the essential resource in the company who take responsibility for improving productivity, profit, and sales. Accordingly, the company ROI may increase by folds with a significant improvement in the corporate culture. The intangible benefits from the QMS adoption are discussed in the following sections.



Figure 10. Gallup Criteria for Great Managers Talents.

## 8. Personal and Professional Development.

It is a common perception that education ends with college or university. There is a wide range of professional development programs, but employees’ interest is mainly to find a better-paid job. This is because little training exists at the

*One of the most profound learnings of my life is this : if you want to achieve your highest aspirations and overcome your greatest challenges, identify and apply the principle or natural law that governs the results you seek.*

Stephen Covey

*Participation in the breakthrough process is a form of management development. It provides the opportunity to advance new ideas, reconcile conflicts and find ways to optimize overall company performance.*

Joseph Juran

workplaces, intensifying defective work rather than improving the operations and solving problems. Therefore, most of the workforce is demotivated to put effort and dedicate time and financial resources for self-education personal and professional growth. Opposite, on-site personal and professional development is a routine practice in the QMS environment, Figure 11. Education and training direct employees to creativity and empathy at the workplace. Thus, their productivity and effectiveness exponentially increase.

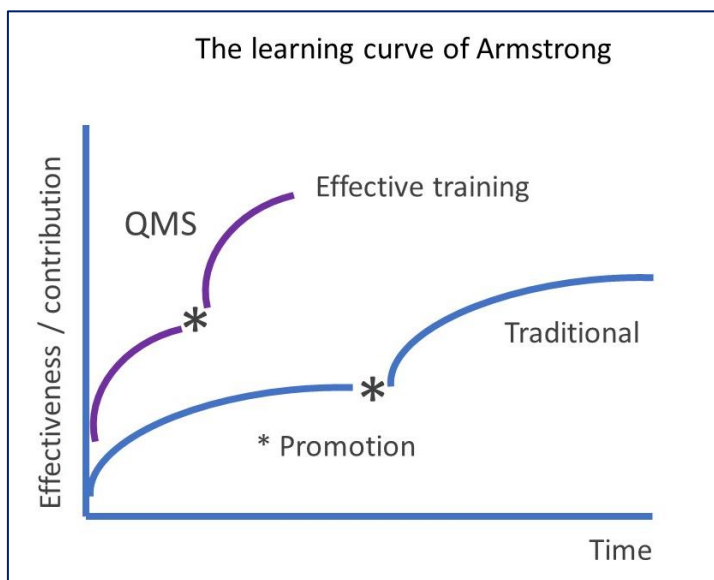


Figure 11. The Learning Curve by Michael Armstrong.

The benefits multiply as all the principles are valid for personal and professional growth. The desire for success springs from every human being, and it is the main trigger for permanent development in both personal and professional directions. Nurturing leadership behaviour at all levels is vital for building a creative and productive environment. As stated above, this new philosophy is entirely different from the old ones in focusing on people's potential as the essential factor for success. Permanent education and self-development, sharing knowledge and experience with others, and working for the common good are among the most powerful driving forces behind the QMS philosophy.

## 9. Mastering Employee Turnover.

Loyal, accountable, and hardworking employees are the dream of all employers. On the flip side of the coin, the primary factors influencing people's decisions to remain in a company are corporate culture, opportunities for growth, and financial rewards. It is a process of developing and implementing strategies, policies, and systems to



keep people in the business: inspiring motivation, engagement, creating a positive perception about the job and expectations. Reward management practices include both financial and non-financial benefits, Figure 12.

Building a highly-valued corporate culture takes time and effort, achievable when mature QMS is established. Employees appreciate the opportunities at the workplace for growth and recognition. Therefore, one of the best investments in human resources is a training and rewarding system that stimulates efforts and performance. As Gallup noted, shifting from the boss to coach mentality of the top managers helps create trusted relationships and a culture of creativity and accountability.

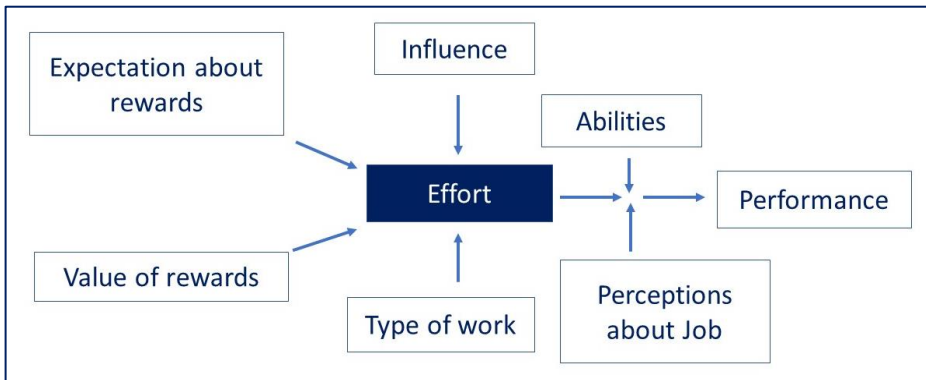


Figure 12. The Effect of Performance on Job Satisfaction by Edward Lawler and Lyman Porter.

It is possible to achieve these goals when a clear understanding of the hidden needs for professional growth is known. The improvement in employees' effectiveness at existing jobs develops an excellent potential for the company's future.

Traditionally, people are afraid to openly discuss professional goals, concerns, and opportunities at work. As Peter Drucker noted, strength, performance, values, and contribution are attributes each employee owns and must share with others. In this way, a respected and productive environment creates a healthy working climate.

## 10. Stress-free Environment and Social Recognition.

A stress-free environment is possible to achieve when focusing on data and facts rather than emotional and subjective considerations. Objective decisions based on realistic findings can establish a more predictable environment and

*“No bad teams, only bad leaders.” When leaders try to live by that mantra, it usually has a positive outcome. When a leader has a substandard individual on the team, that leader takes ownership of the individual and ensures that the individual gets the training, coaching, and mentoring needed to get up to speed. That personal investment usually pays dividends: the substandard individual improves and becomes a solid contributor to the team.*

Leif Babin

*An increasing number of companies have been moving toward a continuing emphasis on an entirely new spectrum of opportunities that are being created as New and Old Economies connect globally.*

Edward Feigenbaum

bring out the best in everyone. Falsehood disappears as data and facts guide people in the right direction. When mature QMS is established, people unlock creativity, ask quality questions, and work together for the common good. Edwards Deming used the word SECURE to explain the phenomenon; it is composed of two Latin words: SE (without) and CURE (fear), meaning not afraid to express ideas or to ask questions. Employees' satisfaction positively correlates with engagement in their jobs. The surveys show that employees' proper engagement leads them to devote themselves to advancing the institutional objectives. Moreover, high levels of employee satisfaction drive productivity improvement and their accomplishments. The most critical factors that impact employees' performance include work-life balance, autonomy, diversity, job security, health and safety risks, and social capital.

To ensure a stress-free environment in the workplace, a predictable and transparent management system is a must. Ricardo Semler demonstrated to the world that such an approach is achievable. As a CEO and majority owner of Semco Partners, a Brazilian company, he established a radical industrial democracy. His employees are the primary triggers of the business initiatives and their performances. As a result, the company revenue has grown from 4 million US dollars in 1982 to 212 million US dollars in 2003. It is no coincidence that his business practice attracts worldwide attention.

Shigeo Shingo proposed a business model known as Poka-Yoke, meaning mistake-proofing, Figure 13. He puts the corporate culture and the process to play the central roles. When people are trained in the QMS principles, they are awake to identify and remove errors immediately. Their contribution to a well-established business practice makes them proud and relieved of stress.

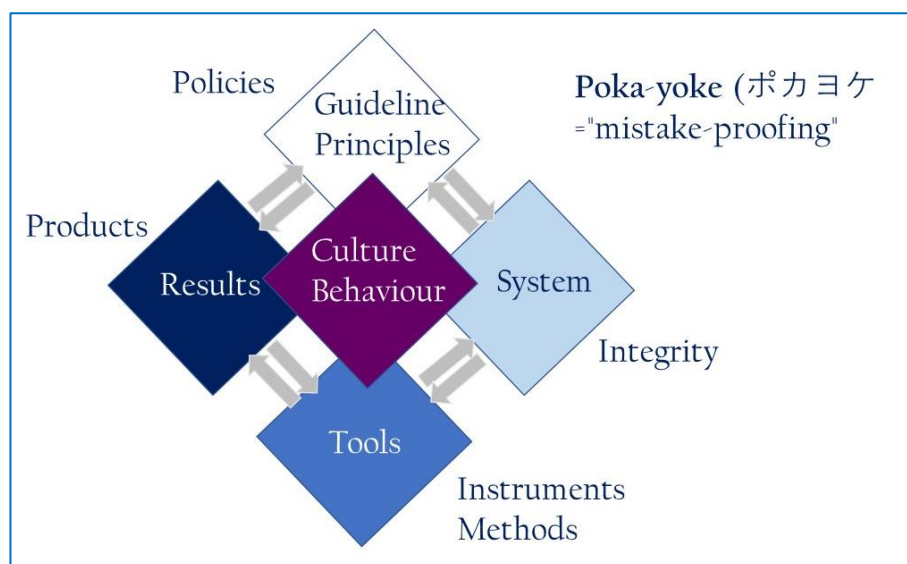


Figure 13. The Poka-Yoke Model by Shigeo Shingo.

QMS principles apply not only to businesses but also to any other social phenomenon and private human life. Preventing the re-occurrence of problems is an approach that advances the quality of one's personal and professional development. Sharing positive experiences among participants accelerates the processes towards achieving successful outcomes that make QMS particularly crucial for adaptation to healthcare institutions.

Businesses survive and grow when making money. However, their primary purpose is to provide value to people. If the impact of our business on society is high, we are appreciated and awarded, which means that we are moving on the right path. Profit and social recognition go hand in hand - if the business doesn't benefit humankind, there is no point in existing then.

## Concluding Remarks.

QMS brings companies to the next level of their business practice by adopting the new management philosophy. It reduces costs and risk, increases productivity, retains talent, expands the business with new partnerships, and receives financial support and social recognition. The most important benefit for companies is that they build a culture that makes employees happy in the workplace, makes them proud of their achievements, and stimulates them to unlock their full potential for the common good.

After the QMS nationwide adoption in Japan in the mid-1970s, it became recognized worldwide and was the basis for developing regulatory materials and international quality standards. QMS philosophy views quality improvement as activities whose objective is to satisfy all stakeholders: external customers, suppliers, management, investors, employees, and humankind. The internal stakeholders (management and investors) lead the process toward effectiveness at all possible levels. They drive total business performance where the process quality impacts the final results. The benefits are financial (decreased costs due to productivity improvement, occupying the market with better quality and lower prices, staying in business, and providing more jobs), and humanitarian (creating an environment of creativity where human potential is unlimited and make people happy at their workplace).

Several engineers and statisticians created the QMS philosophy, proven and refined over the last six decades in Japan and globally. It became the core of international guidelines and national regulatory documents for various industries. The benefits for companies who adopt QMS are both financial and humanitarian. Therefore, this philosophy becomes a strong foundation for 21st-century business practice.

With over 25 years of history, the ICH continually improves its practices to deliver more robust guidelines to the healthcare industry, where the collective

*You need to learn to like yourself and see your own uniqueness, to learn to live in the present without guilt and fear, to be able to see your strengths and use them, to realise that you can make your own choices and consequently have to take responsibility for the situation you are in. You need to be flexible and open to new ideas, to vary and change your behaviour, to perceive problems as exciting challenges and see mistakes and setbacks as part of your development process. You need to think positively and be committed.*

Claus Møller

efforts of professionals with diverse backgrounds maximize the impact on enterprises. Still, businesses should not accept the guides and regulations as perfect documents that they must follow. A thorough study of the guidelines with the related literature is a good starting point for successful business practice. The prominent authors of the philosophy recommended this approach as the best way to navigate the QMS efficiently.

*Empowering beliefs — this sense of certainty — is the force behind any great success throughout history.*

Antony Robbins

I expect my thoughts to resonate with the concerns and unmet expectations of millions of people who want to prevent future health and humanitarian crises and enjoy their professional and personal lives every single day. Hopefully, humanity will take good enough lessons from the Covid-19 pandemic. As I already stated, if the world had fully mastered QMS in all aspects of personal, professional, and public life, this pandemic would be another flu. Today, the Fourth Industrial Revolution is taking the world to a whole new level, where Internet-based and cloud-based communication unify the global processes. As a result, financial and health crises will continue to spread globally, hopefully for the common good. Already, the pandemic that shocked the world and awakened sober thinking started to create conditions for the revival of the QMS at a new higher level, where the prevention mode of the business operations and empathy play a dominant role.

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