MARKUP
EU-EAC MARKET ACCESS UPGRADE PROGRAMME

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THE FUNDAMENTALS OF QUALITY

ROUTE TO MARKET ACCESS AND COMMERCIAL SUCCESS: A COURSE BOOK FOR QUALITY CHchampions

International Trade Centre

About the Book

This book supports the Basic Quality Professional Certificate of the Global Quality Program on behalf of the World Alliance for Quality (WAQ) for the Global Platform for Quality (GPQ) of the International Trade Centre (ITC) which is implemented under a multi-party Memorandum of Understanding between the ITC and the individual members of the World Alliance for Quality (WAQ): the American Society for Quality (ASQ), the European Organization for Quality (EOQ), the International Academy for Quality (IAQ), the Union of Japanese Scientists and Engineers (JUSE)

The Global Platform for Quality (GPQ) seeks to develop quality competence in SMEs of the least developed and developing nations by creating a cadre of quality professionals who are able to help these organizations go beyond market access to achieve commercial market success. It aims to boost the quality capacity of Small-to-Medium Enterprises (SME) to gain market access for trade and establish success in their competitive practices by delivering quality products that prove to be attractive in international markets.

The program of studies was developed to create a core of national experts who are enabled to work with local SMEs to establish a sound quality practices that lead to qualifying market certifications as well as efficient and effective operations that permit profitable growth through trade.

The fundamentals program contains six courses that provide core content of quality management programs. This book provides supplementary reading material for participants in the Basic Quality Professional Certification program of the ITC GPQ.

Upon completion of the six courses, a practical project and the certification examination, quality practitioners are designed by WAQ as Certified Quality Professionals at a basic level. Afterwards it is possible for those designated with this credential to pursue the Certified Quality Professional program at the Advanced Level of proficiency.

Acknowledgements

This book was developed with the financial support of the European Union in the context of the Market Access Upgrade Programme (MARKUP), a regional development initiative that aims to contribute to the economic growth of the East African Community (EAC). More specifically, MARKUP aims to support increased exports of agribusiness and horticultural products, promote regional integration and access to the European market. MARKUP assists small and medium-sized enterprises (SMEs) in Burundi, Kenya, Rwanda, Tanzania and Uganda by targeting specific agricultural commodities (i.e. avocado, cocoa, coffee, spices, tea and horticulture).

At the regional level, ITC supports EAC's efforts to improve regional trade and the business environment for selected commodities. This includes advocating for the removal of sectoral trade barriers, as well as strengthening SME export competitiveness and business development, including in quality management. In each of the countries, teams of Qualified Champions - national expert trainers and advisers - are developed and qualified while implementing quality improvement in enterprises projects under the supervision of international experts. This book will directly support their work.

Dr. Gregory H. Watson EUR Ing is the author of this book and has been the principal designer and developer of the programs of studies that ITC offers in through its Global Quality Platform. Dr. Watson represents all of the member organizations of the World Alliance for Quality in this capacity. His work in developing this program of studies has been performed on a pro bono basis.

Dr. Watson delivers these training courses in collaboration with student members who are qualified as instructors in Green Belt training for the European Students of Industrial Engineering and Management (ESTIEM). These students work with the national Quality Champions to teach and coach in the methods of Lean Six Sigma at the Green Belt level. ESTIEM has been conducting this training in many of its participating universities across Europe for the past three years. This youth-enabled program will help to build a global community of quality professionals who are linked through the ITC Global Quality Platform.

Disclaimer

Originally released as an e-Quality Open Source electronic book for distribution by the International Trade Centre under the Global Platform for Quality program.

Contents

FOREWORD – THE NATURE OF QUALITY AND THE ART OF MANAGING FOR QUALITY

Abstract

This electronic book supports the deployment of the Basic Quality Professional curriculum of the International Trade Centre's (ITC) Global Platform for Quality (GPQ). The GPQ focuses on the development of the competence of local "Quality Champions" who have the capacity to train and consult in their local culture based on an understanding of quality that is "state-of-the-art" and integrated with national quality policy for advancing the economic and educational capacity of these nations. This foreword to the e-Book is presenting key concepts about quality and standardization in order to establish a common background in quality-related theory and concepts for people who participate in training as "Quality Champions" in least developed and developing nations in support of advancing the quality capacity of Small-to-Medium-sized organizations.

Introduction

This foreword describes the progression of the development of quality as a discipline since the founding of civilizations up through the modern digital age. It sets the stage for the series of six courses that whose training material is presented in this electronic book. The purpose of the foreword is to help students understand the course content better. These courses present a systematic approach to the modern state of quality which is fundamental knowledge of core concepts that are essential for implementing quality today.

Historical Roots of Ancient Quality (Pre-1900)

The earliest recorded human writings are Sumerian and the first recorded word that relates to quality is "*amagi*" which means "a return to mother." This idea expresses the "freedom" that is found from the protection of mother –avoidance of badness from the external environment. It is the freedom from negative experiences that improves the quality of life. Freedom from basic human concerns: hunger, thirst, fear, abuse, bigotry. The concept of quality developed in the Western world in ancient Greece where "*poiotēs"* was translated into Latin as "*qualitas*." This term referred to a particular property or feature – a characteristic of quality that would be able to separate good from bad. Thus, today the Oxford Dictionary defines the term "quality" as "the standard of something as measured against other things of a similar kind" and amplifies this definition by describing quality as "the degree of excellence of something." This definition of quality in the Oxford Dictionary does not address the question regarding the person who is making this judgment – from a perspective of the business (e.g., shareholder or financial point of view) or the perspective of the customer (e.g., market or user point of view). While both of these views ultimately became important, the tension between these perspectives survives the development of quality thinking over the coming centuries.

Throughout the Middle Ages the idea of quality was coupled with the profession of craftsmen who operated in a guild or association of a group of craftsmen from a particular profession (e.g., a guild of bakers, candlemakers, armorers, etc.). The guilds established the performance standards and defined levels of excellence as well as setting the requirements for development of workers in the trade through apprenticeship programs. These programs supported career growth and passed judgment on the ability of workers to perform to a structure of levels of capability from apprentice through journeyman to craftsman to master. This program remained in place until the industrial revolution evolved in the early to mid-1800s.

The industrial revolution issued in a new perspective on work. No longer would a specialist be in charge of the end-to-end process of production as in the guild system. Now specialization of labor assigned work to a series of individuals with distinct tasks, each requiring less skill than the guild system required. This transformation of

work had two consequences: first, it made the labor content of work less by diminishing the pay to individuals, and second, it diminished the skills required of workers and eventually created a new class of job: an inspector who evaluates the quality of work performed to assure that it meets the "standard" required in production of "interchangeable parts" which was a core differentiator of this new way of production.

Modern Foundations of Quality (1900-1950)

The dawn of the 20th century brought a multitude of innovation that would have its application in the world of production: Albert Einstein's theory of relativity, John Maynard Keynes theory of probability, Werner Heisenberg's principle of uncertainty, Percy Bridgeman's use of operational definitions and probability boundaries, and Ludwig Wittgenstein's theory of incompleteness all set the stage for a quarter century of intellectual revolution that centered on making the work of production more productive and efficient. Three individuals delivered the mainstream of the intellectual revolution of this age: Frederick W. Taylor, Henri Fayol, and Walter A. Shewhart.

Taylor popularized the idea of applying quantitative methods to inspect the way that work was performed, and he focused on developing standard work processes that applied the "one best way" to do a job and providing workers with job aids to make them become more productive. This birth of standardization of work and inspection by a third party became a cornerstone of quality management systems. The industrial revolution had already standardized the parts for production to enable "interchangeability" in the production process. Thus, standards became a cornerstone of the industrial revolution – standards for parts and the products that they build and standards for the processes by which these parts are assembled into the final product. In addition, production testing and inspection became recognized as essential ingredients of the production process to assure that the output shipped to customers met the specification that was established for its function. Taylor's emphasis was on improving the quality of work within the work domain of the factory. He is considered the "father of industrial engineering" for his contributions to workplace efficiency development.

Fayol wrote the first modern book on industrial management and introduced the concept of "continual improvement" into the vocabulary of business. His definition of management as the set of activities for planning, organizing, coordinating, commanding, and controlling" endures as an accepted definition today. Fayol's drive for continual improvement was a core aspect of his theory of management. Fayol believed that the act of managing requires "a constant search for improvements that can be introduced into every sphere of activity." He observed that: "the search for improvement should be pursued unceasingly at all levels and throughout all parts of the business. The executive in charge should have an active, unrelenting intention to effect this improvement." The foundation for the Japanese system of quality that developed in the second half of the 20th century was firmly based on this principle as a means to build the organizational capacity to survive and prosper in a competitive market – improve faster than competitors.

Shewhart provided the theory of control and a methodology for implementing it by applying a statistical approach to Bridgeman's description of quality as a probability of performance within a bounded set of conditions. Shewhart's superiors wished to develop an economic way to gain high quality from their mass production operations. Shewhart demonstrated that this was only possible when that system could be brought into a state of statistical control and monitored in a way that assured it would remain operating in that state.

Development of Modern Quality (1950-1990)

Kaoru Ishikawa, Joseph M. Juran, and Noriaki Kano developed enduring concepts that advanced quality thinking during the second half of this century. While there are many so-called "gurus" of quality the thinking of these gentlemen made an indelible mark on the current generation of quality management. Together they elevated quality from a structured approach to managing standards and driving their control, which summarizes the level of thinking form the first half of the century, to become a driving strategic force for assuring enduring competitiveness of the enterprise as it pursues "*kaizen*" – improving for the better. Ishikawa,

Juran, and Kano set up a framework for quality which was realized in 1987. What were their individual contributions?

Ishikawa guided the development of the modern quality system in Japan (along with Shigeru Mizuno and Tetsuichi Asaka). Ishikawa was the “Western face” of the evolving Japanese quality movement as he was able to speak English. He was the principal thought leader among these Japanese quality experts and was a strong promoter of the ideas behind the Japanese quality methods: customer satisfaction, continual improvement, working in teams, using a structured approach to problem-solving based on statistical methods, applying quality methods across the entire organization, and assuring quality through a long-term process dedicated to improving where the executive-in-charge is responsible for assuring that the system is operating and the workers also accept responsibility for the quality of their work. These principles became key cornerstones of Japanese Total Quality Control (TQC) which Ishikawa brought to the West by his consulting efforts and his introduction of quality teachers from Japan to leading industries in both America and Europe. Less well known is Ishikawa’s role in promoting the development of international standards through long-term involvement with both the International Standards Organization (ISO) and the British Standards Institute (BSI). His quality efforts focused on both continual improvement of work through team-based activities and the compliance to standards for control of product and processes.

Juran is well-known for “the Juran Trilogy” – quality planning, quality improvement, and quality control.” To these elements Juan also emphasized incremental improvement and breakthrough improvements and the need for adherence to standards. These concepts define infrastructure for quality. Juran commented: “Without a standard there can be no basis for improvement.” Defining a customer-focused standard and assuring compliance to that standard are the basis for executing Juran’s trilogy. Juran’s concepts have provided the framework for this first ITC GPQ course on the Basics of Quality. The quality management system begins with standards and making provisions for their assurance; moves on to controlling this quality performance during the operational processes of production or service delivery; then improving on these control parameters by improving in the daily work and planning either incremental gains or defining breakthrough projects that will take the organization to a new level of performance. Both incremental and breakthrough gains come from projects that drive these gains. Juran also commented: “All improvement comes one project at a time and in no other way.” Thus, he built upon Ishikawa’s idea of team-based improvement by assigning them projects to derive gains.

Kano made a significant contribution in the form of his “Theory of Attractive Quality” which can be used to understand how to develop products and services to meet the needs of customers. The theory is expressed in a model which is usually called the “Kano Model” and it defines how quality functions can be differentiated according to their assessment by customers. Kano has identified three functions that describe the way customers characteristically perceive quality requirements. The first is “must-be” quality: a set of features that are commodity-like and their performance is considered to be essential to the nature of the product by customers. These are the “standard features or functions” of the product. The customer requirement for these features is strong compliance with defined requirements. Any shortfall in performance would result in customer complaints. The second quality characteristic is called “one-dimensional” quality: a set of features that are used as a basis for performance comparison by customers as they are distinguishing between alternative products in their assessment of their performance for value. The customer requirement for this set of features or functions is “bigger is better” or more functionality for the value invested. Any shortfall in this comparative performance would result in a loss of business to the competition. This dimension of quality encourages organizations to be better than their competition. The third quality characteristic in the Kano model is called “attractive” quality: which identifies “latent” or unspecified features or functions that a customer finds attractive but were not in the specification for product or service requirements. It is this set of requirements that creates “strategic quality” and “breakthrough performance” by an organization as they will differentiate the product and service offerings from competitors and may result in a “killer ap” or a “hot product” as the customers are motivated to purchase as a result of the presence of the feature, no matter how well it is designed. So, Kano’s model has blended the ideas of standard performance, continual improvement, and innovation into a way of working that builds upon the developments of his predecessors.

The year 1987 was a watershed year in the history of modern quality development. During that year four advances occurred which have helped to focus quality into an integrated system for driving competitive performance. In this year the initial release of the ISO9001 standard by ISO occurred; the Malcolm Baldrige National Quality Award was launched to provide an operational definition of business excellence from a managerial perspective; Motorola made public its Six Sigma methodology for structured continual improvement and problem-solving; and the Profit Impact of Market Strategy (PIMS) study was made public and it demonstrated that performing to customer perceived quality standards influences market share and drives profitability for new product development. While these four advanced appeared to create the "Holy Grail" of quality, in fact they caused a decade-long "dark age" as quality professionals debated the relative merits of each program against the others and sides were drawn based on perceptions of superiority of the individual elements. However, as the lessons were evolving none of these innovations could deliver the final solution and a comprehensive, integrated approach to achieving quality needed to be developed.

Quality Embraces the Digital Age (Post-1990)

Parallel to these developments of quality thinking which follow the incremental development of knowledge as pursued in all the sciences, there has been significant advances in quality in this period of modern quality (1950 onwards). From the development of the transistor at the Bell Laboratories (the same place that Shewhart worked) in 1947 to the growth of digital technology into ubiquitous computing and global communication through the Internet, information was to transition into an economic entity that had value of its own. This was particularly true in quality considerations. Information intensity and rapidity of communication permitted the old barriers of communication boundaries to be broken and instantaneous understanding of the quality performance of materials, assemblies, products, and people could be observed in real-time. It is this "digitization" and sharing of data that is causing the current acceleration of analytics and its ability to develop predictive outcomes that are highly accurate. However, there is still a need for the human side of quality – teams work: to design and build products; to interpret results of the work that is done; to define new directions that will appeal to customers; and to conduct a structured approach to solving problems that evolve. The future of quality will balance both the technical dimension and the human dimension to produce value for the customer.

Concluding Comments

Quality is a never-ending journey. Methods evolve and techniques are developed to extend the practice of quality and enable new levels of maturity in the way that professionals apply their skills. The Fundamentals of Quality expands upon the Juran Trilogy and defines six levels for the way quality thinking may be applied by industry to support the delivery of excellence to their customers. The six sections of this book address this structure from the basic level of quality that is delivered by protecting customers from defects and risks – Quality Assurance (QA) through the levels of Quality Control (QC), Quality Improvement (QI), Quality Planning (QP), Quality Management (QM) to obtain the final level of maturity: Managing for Quality. At this highest level an organization is applying quality as a strategy to achieve market success and to extend its productivity and profitability.

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CHAPTER 2 – Q102 – QUALITY CONTROL

Abstract

The second quality capability is called Quality Control (QC) and it is such a strong supplement to Quality Assurance (QA) activities that the two are typically combined as QA/QC. While QA is aimed at preventing loss of capability below the minimum level, QC is directed toward assuring the consistency of performance at a targeted level of performance which has been specified in the process control plan. QC implements process behavior charts (e.g., statistical process control charts), applies corrective action (CA) whenever performance limits identified on QC plans are threatened, and takes preventive action (PA) to assure that these detected "fires" are extinguished permanently in the product, service, or process where the deviation was detected.

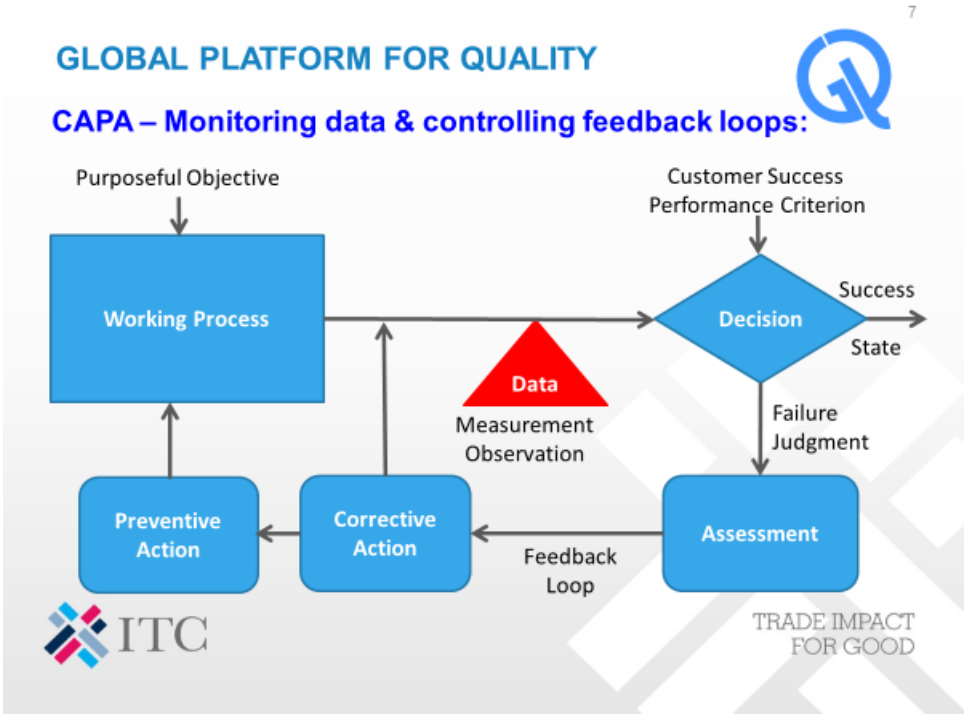
Introduction

While Quality Assurance (QA) maintains performance above standard and manages outcomes to achieve a minimal level of results as defined by customers for a competitive market, Quality Control (QC) ratchets performance to a level higher in order to consistently deliver at an acceptable quality level within boundary conditions set by the process capability. QC assures consistency of outcomes at a level of results that has been targeted based on market conditions to assure competitiveness in markets. Combining a mastery of QA and consistent performance within the band of QC should lead an organization to an ability to obtain certification to ISO9001:2015. QC introduces new elements that are added to the QA program including statistical methods for work, process analysis and reporting, as well as development of in-process feedback and activities that correct performance during the operational processes (whether the productive system creates products or services) through intervention of the people in the process. QC is the necessary, but not sufficient, quality activity for entry into global competitive markets. As Juran commented: "Quality Control prevents things from getting worse – this includes putting out fires."

Understanding the Meaning of Control

QC monitors performance of products during the production process to: assure integrity of the production process; procedures followed standards; and that results meet the quality criteria. QC operates by careful operational planning, use of proper equipment and inspection procedures, and application of corrective and preventive action to maintain compliance to defined requirements. QC tests completed products to specifications. QC integrates the CAPA process to manage its performance data monitoring and assessment process as illustrated in Figure 1.

Figure 1: CAPA Monitoring and Control Feedback Loops



Corrective action (CA) is the process that applies QC methods to remove unwanted, undesired, or wasteful quality conditions that are considered defects of production. The purpose of CA is to inhibit the transfer of such conditions as problems from the company to the customer and to begin the process of eliminating the recurrence of such conditions. CA includes three tasks:

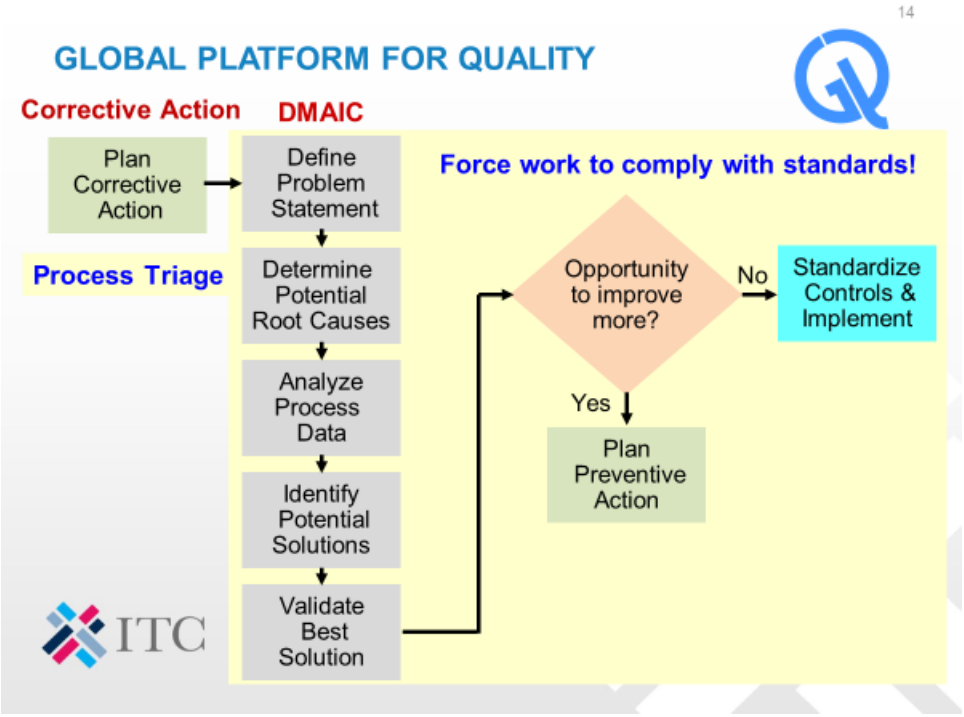
- **Preliminary tasks include**: testing or measurement, sorting, and quarantine. The benefit of this set of tasks is that they interrupt the stream of defective products from reaching the external customer and isolate the failure costs internally.

- **Subsequent tasks include**: rework or repair and scrapping or salvaging remaining defective items. The benefit from these tasks is that the residual value that is lost in the defective products is retrieved for inclusion in the product flow. Additionally, the reclamations that are negotiated with suppliers for defective parts help to decrease the losses from repair and service of the defectives.

- **Inhibit problem recurrence**: identifying the root cause of a problem and remedial actions that fix, rectify, or eliminate the cause of the non-conformance.

The process for performing CA uses the DMAIC (Define-Measure-Analyze-Improve-Control) way of conducing structured problem-solving. This process is illustrated in Figure 2.

Figure 2: The Corrective Action Process Applying the DMAIC Model

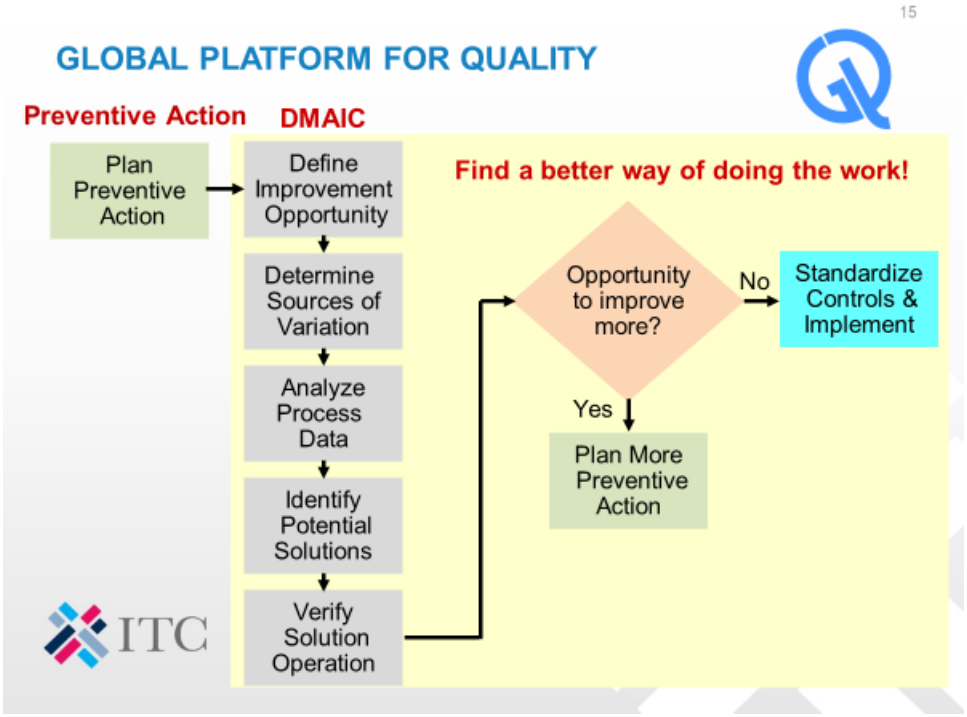


Preventive action (PA) is the follow-on step in the CAPA process which seeks to eliminate ability of the process to create potential future problems. PA makes changes to address management system flaws or weaknesses that are not yet responsible for producing failures or causing any conditions of nonconformity in delivered products or services. PA actions may derive from the process of mistake-proofing to safeguard production processes or as follow-ups to suggestions that are made regarding opportunities for improvement by employees or from customers. PA actions address technical requirements of methods in the productive process and may focus on preventing non-conformities or in improving process efficiency. PA contains two tasks.

- **Prevent Non-Conformities**: Whenever a change is made in product design or in its process of production, plans for corrective action should be initiated to reduce risks due to the change.
- **Improve Process Efficiency**: production maintenance activities are conducted to assure continuity of production and increase efficiency by eliminating the risk of loss from production interruptions.

The PA process is similar to the CA process and is illustrated in Figure 3.

Figure 3: The Preventive Action Process Applying the DMAIC Model



How is this CAPA process established? An effective CAPA process requires a meaningful set of measurements that relate to customer requirements that are critical to satisfaction (CTS) for their deliverable. Once this CTS outcome is known then the measure must be translated into internal measures of actions that deliver this performance and can be managed within the work environment: these critical to quality (CTQ) factors must be measured and monitored to assure consistent, stable, deliverable CTS outcomes to customers. Those measures that are meaningful for the daily management of the work process become the basis for routine QC management of the daily work activities. It is essential that the measurement system integrity for these factors be established and that these measures are operationally defined. Some key questions to ask in self-examination of the measurement system are:

- Are key measurement systems capable of detecting process changes that are important to customers as the CTS factors?
- Are standard service levels or boundary levels of acceptable performance agreed with the external customers for these key process output variables (KPOV) performance measures?
- Have sensitivity studies been performed to understand the degree of impact from variation in key input measures (CTQ – these factors are key process input variables (KPIV) and are called X measures) on critical to satisfaction (CTS) measures of performance outcomes (these KPOV factors are called Y measures); and
- Have business controls been put in place to manage the performance variation in feedback loops that can be normally expected based on the inherent process capability?

CAPA activities occur when stimulated by either customer feedback or process monitoring that indicates a statistically out-of-control (OOC) condition in a CTQ factor.

Bands of Tolerance for Levels of Control

Walter A. Shewhart introduced the idea of controlling quality within limits. There are four types of limits that may be considered for exercising managed control:

- **Natural Process Limits**: the total range of performance that is measured and observed for a performance indicator without any external intervention. These limits identify maximum and minimum performance boundaries of the process as compared to specification limits which reflect the band of performance that is acceptable to customers

- **Specification Limits**: the range in performance boundary conditions within which customers will tolerate deviations in performance but outside of which the customer is no longer able to tolerate delivered results as acceptable performance. The limits are imposed externally.

- **Process Control Limits**: the band of performance around the average (mean) value of the process performance as measured over a sufficient period of time where all the significant factors influencing performance have an opportunity to act on the process. The width of this band is typically accepted as +/- three standard deviations of the process measurement. Within this band the process is considered to be acting normally and not exhibiting external influences of variation.

- **Process Alert/Action Limits**: these are performance limits that, when exceeded, the process operator may be advised of the condition (e.g., alerted to the situation) and which may then be sufficient to cause the operator to intervene and adjust the process to maintain control.

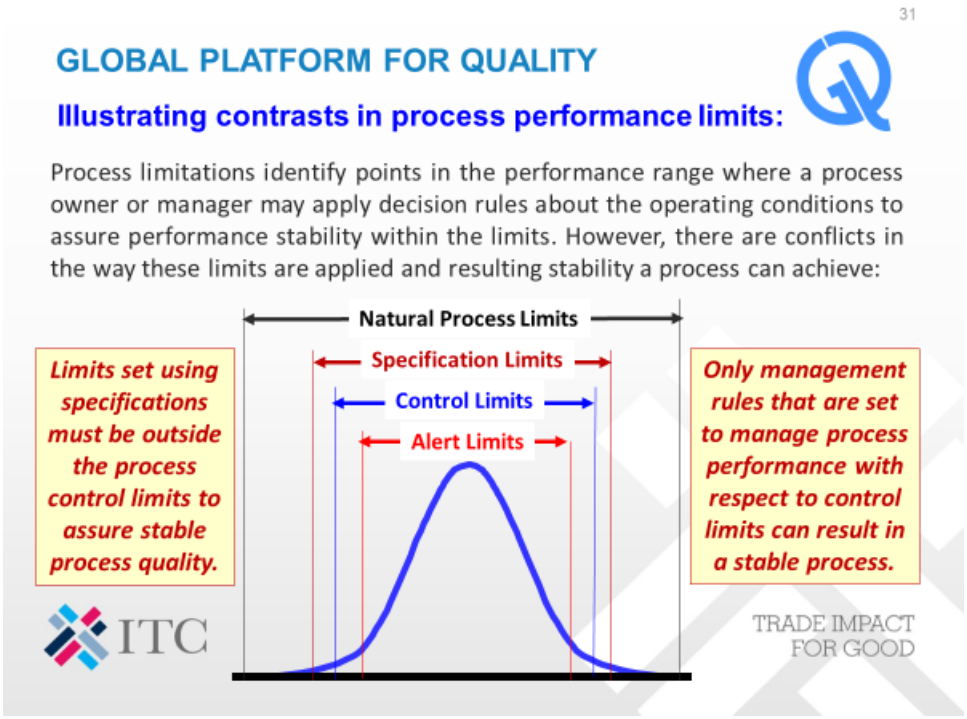
Perhaps of these limits the most important to understand how to manage are the specification limits as they are assigned to the quality characteristics of a product or a process in an attempt to reduce the distribution of performance characteristics to a useful range. However, these limits are not part of the natural variation of the process but are arbitrary limits of performance set according to personal opinion and are typically based on negotiations with the customers. When interpreting performance relative to these limits, there is no particular implied gradation of performance relative to the limits so that any performance inside these limits is considered equally good and everything outside the limits is bad or defective. There are several different ways to establish these limits and the follow list presents these approaches in the order of preference for application.

1. Set specification limits using mathematical transfer functions and margin analysis.
2. Set specification limits based on analysis of the output factor statistical distributions.
3. Set tolerances based on a worst-case margin analysis.
4. Set tolerances based on a percentage of the mean (e.g., ± 10% or ± 20%).
5. Guess at tolerances and set arbitrary limits.
6. Set no tolerances or targets: quality requirements are vague or undefined.

On the other hand, process control limits are based upon the analysis of a substantial sample of process output (e.g., 100 or more observations). These limits are typically set at a distance that is located at ± 3 standard deviations of the mean or process average for this measured data. This performance band will include at least 95% of the data when the performance measure is operating in a state of statistical control. Process capability is considered to be the “voice of the process” (VOP) while the specification limits are considered to be the “voice of the customer” (VOC). The ratio of the VOC divided by the VOP is referred to as a process capability index. The higher this index the more capable a process is considered to be performing.

The relationship of these various types of limits with respect to a nominal process (e.g., having a normal probability distribution) is shown in Figure 4.

Figure 4: Illustration of the Relative Structure of the Various Types of Performance Limits



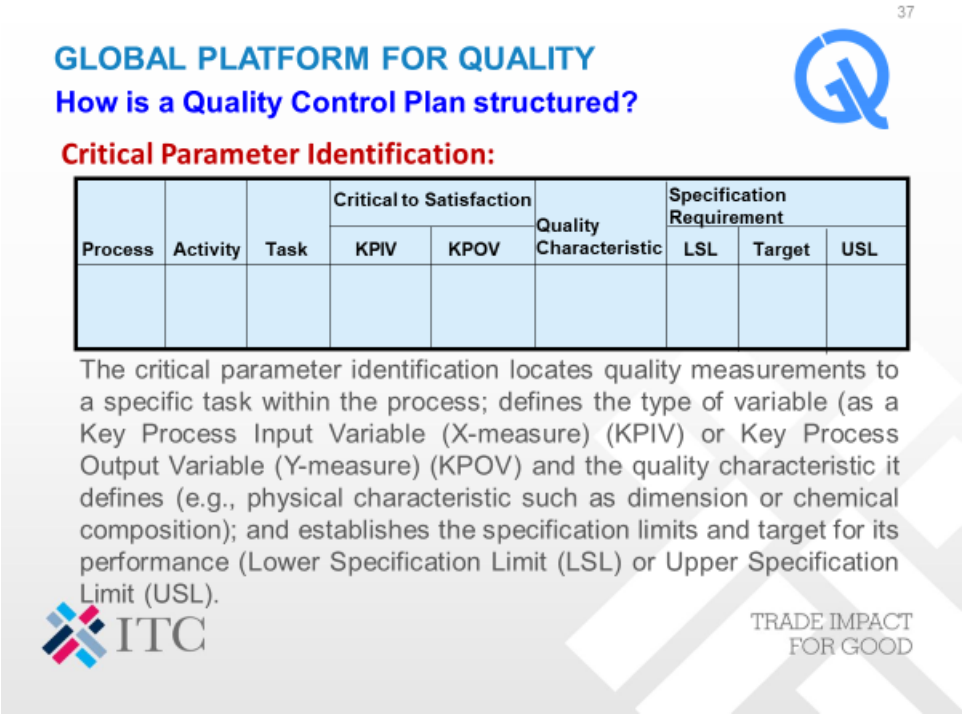
Quality Control Plans

A Quality Control Plan (QCP) specifies desired quality characteristics for the KPOV of a process, defines he measures for that quality characteristics and the sampling plan by which the factor is monitored (sample size and sampling frequency) and identifies the rules which operators apply whenever performance is not conforming to the specification limits. QCPs govern how process monitoring is managed and is considered a controlled document in any Quality Management System (QMS).

There are three elements in a QCP: critical parameter identification for quality monitoring; the specification of the quality measurement system; and the description of the response that the operators should apply whenever an out-of-control (OOC) condition is detected.

Figure 5 presents the first of the QCP elements: critical parameter identification.

Figure 5: QCP Critical Parameter Identification Matrix



Several of the items in Figure 5 require definition as they have not been mentioned before:

- **Upper Specification Limit (USL)**: The upper boundary condition of acceptable performance according to the performance agreement with a customer.
- ***Lower Specification Limit (LSL)***: The lower boundary condition of acceptable performance according to the performance agreement with a customer.
- ***Standard Operating Procedure (SOP)***: A standard operating procedure is a set of step-by-step instructions compiled by an organization to help workers carry out complex routine operations. SOPs aim to achieve efficiency, quality output and uniformity of performance, while reducing miscommunication and failure to comply with industry regulations. It should also include the sampling method and analytical procedures for managing all of the process performance data. Figure 6 illustrates the information recorded for the QCP measurement system specification and Figure 7 shows how response characterization is performed.

Figure 6: QCP Measurement System Specification Matrix

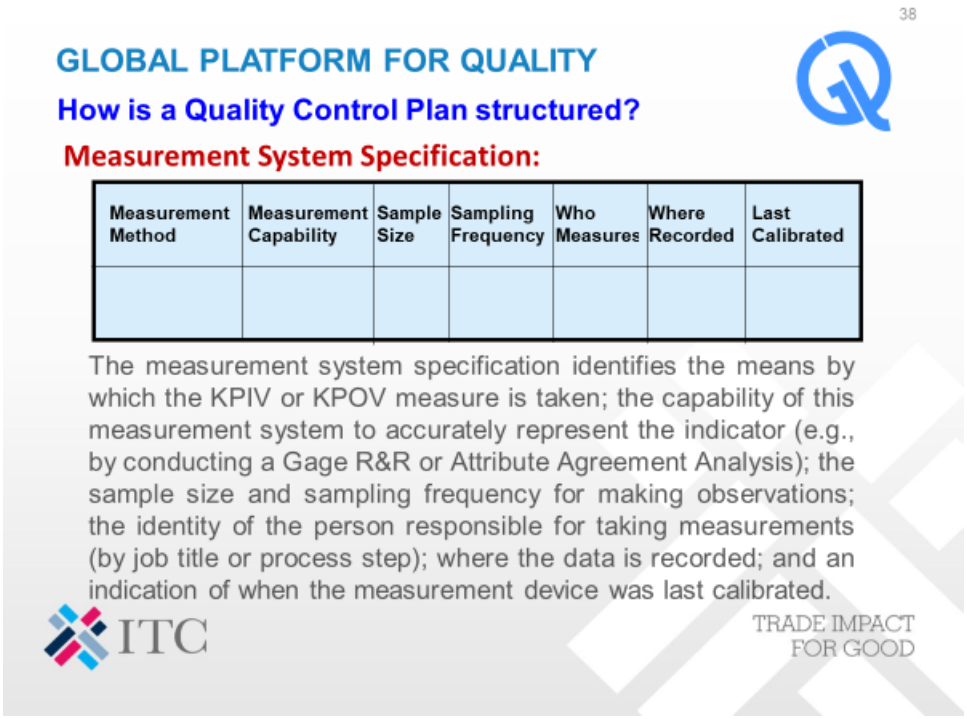
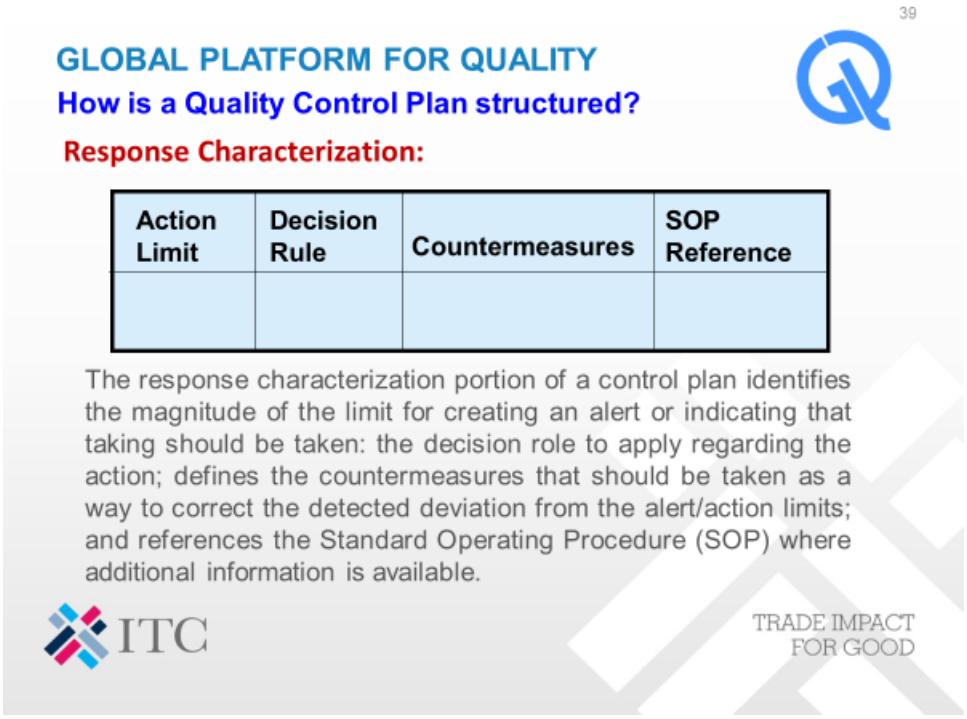


Figure 7: QCP Response Characterization Matrix



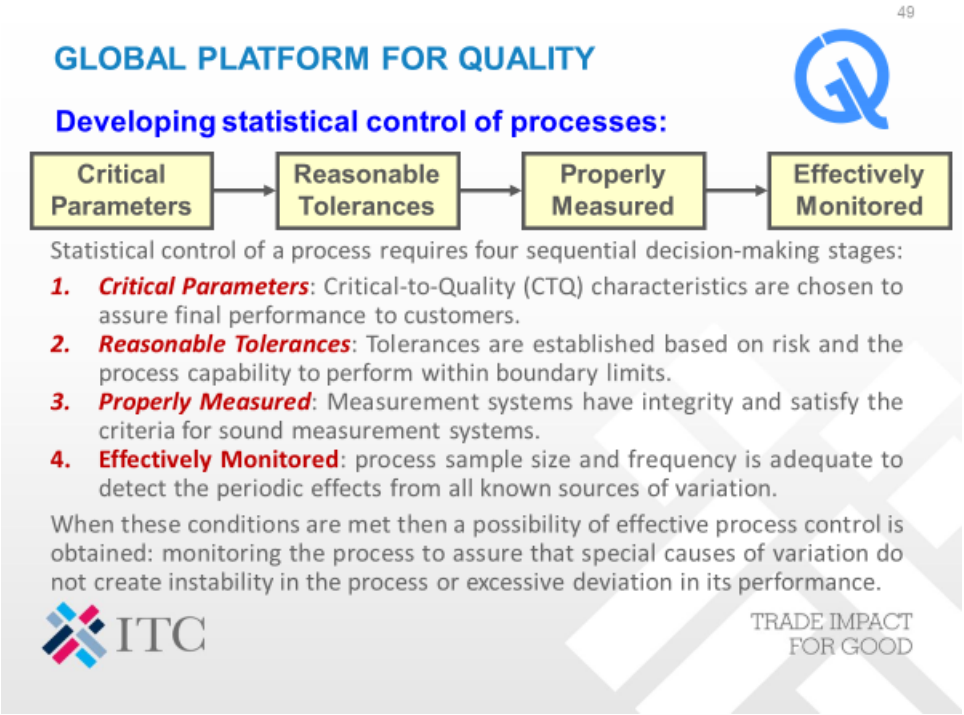
Statistical Process Management

Statistical Process Management (SPM) applies statistical methods to determine quality and the process performance capability at critical "touchpoints" in a process – those locations where the performance can be observed (e.g., check point) or observed and modified (e.g., control point). Process quality is evaluated by analyzing how a product changes across the steps of its production process as it transitions from raw material to final deliverable for customers. Statistics must be used at each process step to assure quality and SPM describes the set of methodologies used for process control that:

- Identify the most critical factors to be managed;
- Assure the measurement system is able to detect significant deviations;
- Calculate tolerances based on the statistical performance of the process;
- Monitor process performance to assure that the process is predictable (producing common cause variation that is within the desired limits); and
- Evaluate performance using customer criteria to assure acceptable results.

Figure 8 describes the four elements that compose SPM.

Figure 8: Phases of Statistical Process Monitoring

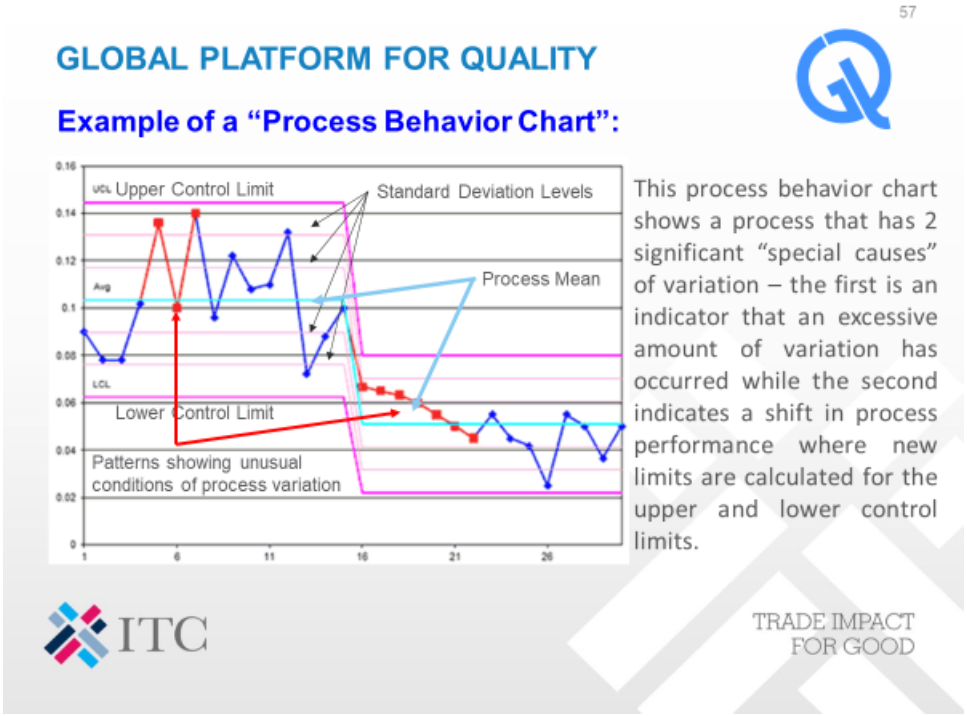


The way that process data performs over time is described as process behavior. This is the actual performance of a process is observed through objective measurement of CTQ factors over a period of time using a capable measurement process. This measurement perspective provides an analytical viewpoint of performance in its historical time domain. If there are any unusual patterns in these measured data observations, then this indicate presence of a "*special cause*" of variation which may be analyzed and

assigned to a specific cause to correct the OOC condition. When there are no unusual patterns detected in the historical data then the result is a process that is in “statistical control” and subject to “common cause” variation that is not assignable to a specific cause. Common cause variation is the natural variation that exists in a process that is not subject to any external special causes.

The control that is developed through using a process behavior chart is called Statistical Process Control (SPC). SPC charts were developed in the 1920s by Walter A. Shewhart to monitor the performance of Critical-to-Quality indicators and assure economic control of production so results may become predictable within the natural control limits. Tests for process deviation of performance evaluate any unusual patterns in the data were developed to indicate conditions when process performance is not behaving within its natural performance conditions but has an external influence or internal inconsistency that needs to be corrected so that the process can operate consistently within these limits. Figure 9 illustrates an SPC chart – also called a process behavior chart.

Figure 9: SPC Chart of Process Behavior

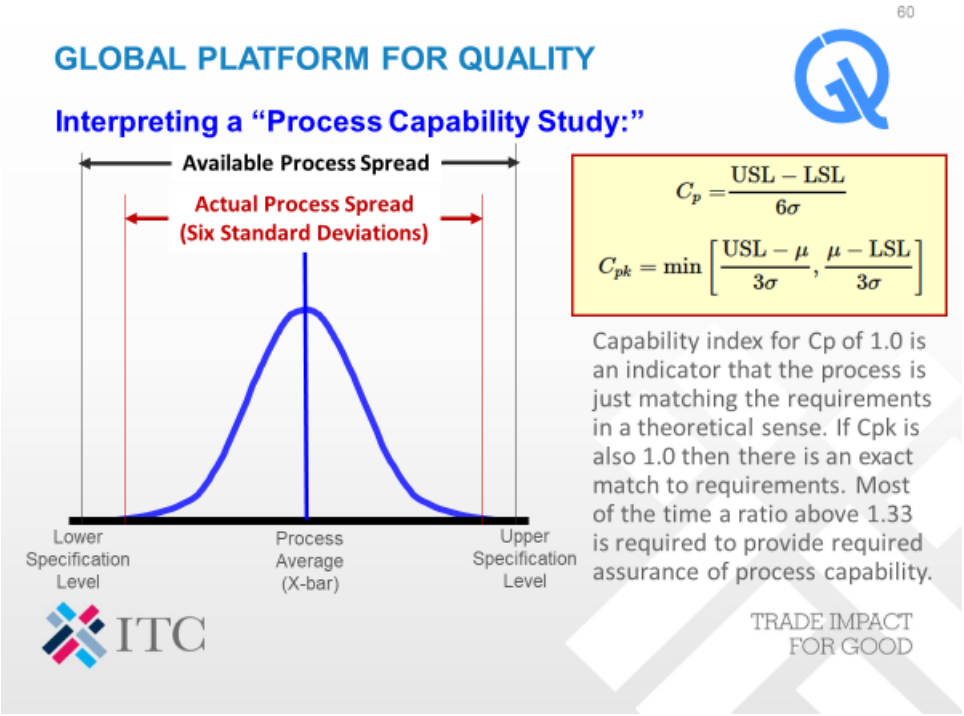


SPC charts are used to manage a control function that is based on observed performance of quality characteristics measured over a period of time. Control is maintained with a target conditions as set using the central tendency of observed performance measures and Upper Control Limit (UCL) and Lower Control Limit (LCL) that reflect +/- 3 standard deviations of the measure. The graph of a process behavior chart has a horizontal scale that is in the time order of data observations (also called run order) and a vertical scale represents the measurement scale of the data. Each observation is plotted as a dot using paired data of time order and measurement magnitude. The dots are then connected between sequential points to illustrate the time history. If the individual data point observations are used, then the chart is called an “Individuals chart” (I-Chart) and if sampled data is first averaged and then plotted then this chart is called an “X-bar” chart with a second letter indicating sample size. Typically, two charts are illustrated – one chart illustrates trends in the central tendency while the other illustrates trends in the dispersion around the mean. For real-time data

observations an I-Chart is strongly recommended as the control chart of choice as it is the most sensitive to displaying variation.

Process Capability is the ability of a process to perform consistently within valid specification limits agreed upon with customers. This measurement provides an enumerative viewpoint of the performance distribution function – in other words, it describes the total history of process performance over the entire observation period. It depicts cumulative risk of non-performance to requirements and is the ratio between the specification limits and natural process variation. Figure 10 illustrates how process capability is measured.

Figure 10: Process Capability Analysis Summary



The use of process capability charts provides an ability to understand the state of control of process performance for customer specifications and to establish expectations for long-term performance based on past history. Process capability studies are conducted to define the design capability (maximum process performance potential as indicated by the observed data) under ideal performance conditions (described as the or ratio of the range that is between the upper and lower specification limits [for the same CTQ characteristic as used in the process behavior chart] divided by the natural process variation (which is estimated as six standard deviations over the observed historical period). This ideal or design capability is labeled Cp defines process potential and should be the target for stable operation of a production process. Actual process performance is shown by a ratio labeled Cpk where the numerator is compared to the average of the process performance. (e.g., upper specification limit minus the mean and lower specification subtracted from the mean). Cpk is also the process capability of the process behavior chart over the same period of time.

Concluding Comments

The combination of process behavior charts and process capability studies allow workers to use the control plan to manage the process flow and determine conditions that require either CA or PA activities. Thus, the first two elements of a quality management system provide assurance to customers that the process will

reliably deliver the performance they desire while delivering a tool for process workers to manage their work throughput in a way that maintains a stable and predictable outcome. However, customer performance requirements do not stay fixed for a long time, so it is important to add another ingredient to these two capabilities – the ability to improve the performance over time. This will be the subject of the next chapter.

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Review Questions

After reading this chapter and reviewing the related presentation in volume two, take the following quiz to review your knowledge and understanding about Quality Control processes and their contribution to maintaining consistent process quality.

1. Appropriate quality control activities include:

a. Preventive and corrective action.

b. Applying feedback for managing process control measures.

c. Using Quality Control Plans to assure that critical quality characteristics are maintained.

d. All of the above.

2. Quality Control prevents things from getting worse – this includes putting out fires.

a. True

b. False

3. Preventive actions differ from corrective actions in the following way:

a. Preventive actions are implemented in response to customer complaints.

b. Preventive actions are implemented in response to identification of potential quality issues.

c. Requirements for preventive actions are identified through product testing and audits.

d. Preventive actions are implemented immediately to halt the flow of defective products to customers.

4. Observation of data from production processes permits comparison of performance against criteria for success that are agreed in specifications. Decisions about failure result in the following:

a. Assessment of the failure condition.

b. Corrective action to halt flow of non-conformities to customers.

c. Preventive actions to eliminate potential failure conditions from reaching customers.

d. All of the above.

5. Tasks included in corrective action include:

a. Mistake-proofing opportunities for failure or safety hazards.

b. Testing or measurement, sorting and quarantine.

c. Inquiring from customers and employees about suggestions for improvement.

d. Redesigning product specifications to assure ease of future compliance.

6. Tasks included in preventive action include:

a. Interrupting the stream of defective results to customers.

b. Taking legal action against suppliers for their role in producing bad outcomes

c. Prevention of non-conformities and improvement of process efficiency.

d. Rework or repair and scrapping or salvaging defective items.

7. Quality assurance and quality control work together to deliver quality to customers.

a. True

b. False

8. The least important band for tolerance and control is:

a. Product Specification Limits.

b. Process Control Limits.

c. Action or Alert Limits

d. Tolerance Limits.

9. The most important band for tolerance and control is:

a. Product Specification Limits

b. Process Control Limits

c. Both (a) and (b)

d. Neither (a) nor (b)

10. Which are least important for quality control:

a. Natural Process Limits and Action/Alert Limits.

b. Product Specification Limits and Process Control Limits

c. Both (a) and (b)

d. Neither (a) nor (b)

11. Control within limits is an essential or fundamental principle in quality control.

a. True

b. False

12. Which is the most preferred method for setting specification limits?

a. Set specification limits based on statistical distributions and analysis.

b. Set specification limits using transfer functions and margin analysis.

c. Set tolerances based on a percentage of the average.

d. Guess at tolerances and set arbitrary limits.

13. Quality Control Plans include:

a. Identification of an objective measure for the Critical-to-Quality characteristic.

b. Description of the sampling plan and sampling frequency.

c. Identification of countermeasures to implement when the process falls Out-of-Control,

d. All of the above.

14. Statistical Quality Management (SQM) describes a set of methodologies for process control that:

a. Identify the most critical factors to be managed.

b. Calculate tolerance based on the statistical performance of the process.

c. Evaluate performance using customer criteria to assure acceptable results or outcomes.

d. All of the above.

15. Both process behavior charts and process capability charts are required to implement an effective quality control system.

a. True

b. False

CHAPTER 3 – Q103 – QUALITY IMPROVEMENT

Abstract

Quality Improvement (QI) is a systematic, formal approach for the management of change. In Japanese the word kaizen (change for the better) embodies this concept. According to Joseph M. Juran, the purpose of QI is to "achieve levels of performance which are unprecedented" and lie beyond normal experiences of processes that just operate in a state of statistical control. QI is an essential activity to develop and maintain market success as there are two trends which must be managed at the same time: customers tend to want higher performance while processes tend to degrade over time producing a natural decline in process capability. Thus, management must steadfastly follow the advice of Henri Fayol and maintain "a constant search for improvements that can be introduced into every sphere of activity…. the search for improvement should be pursued unceasingly at all levels and throughout all parts of the business. The executive in charge should have an active, unrelenting intention to effect this improvement." This chapter focuses on a continual improvement journey and it was written as a supplement to the ITC/GPQ Basic Quality Professional course "Q-103 – Continual Improvement."

Introduction

Quality Improvement (QI) extends performance beyond QC and eliminates risks that inhibit getting better results. QI elevates process performance to the highest level of stable design capability that is achievable using the resources invested in the process or by extending these resources through investment. Every process design has a limit to its performance based on the requirements that were targeted during its design process (e.g., a hotel designed for three stars needs work before it can qualify for five stars, but it can still be exceptional hotel at the three-star level). Thus, QI increases performance capability to maximize results within the constraints of the resources dedicated in the initial investment. If more performance is required beyond this level, then investment will be required, and this need requires taking an entrepreneurial approach to develop business plans that deliver this capability. This will become the focus area of the next course: Q104 – Quality Planning.

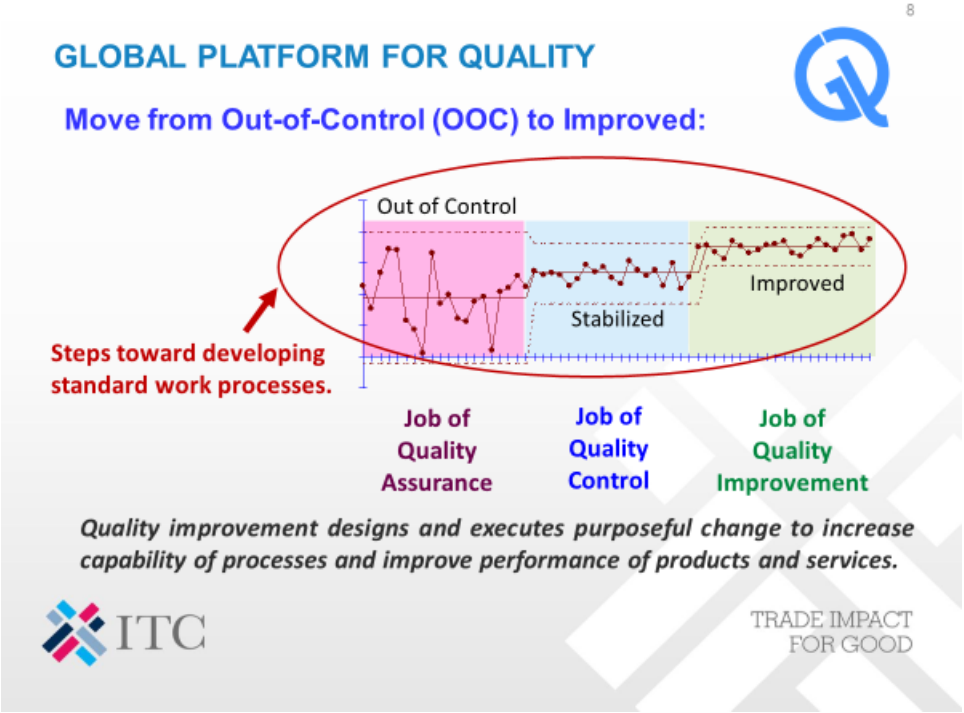
Understanding the Quality Improvement

QI builds upon the QA and QC activities of the organization. This relationship can be expressed using a process behavior chart as indicated below in Figure 1. The objective is to identify and execute purposeful change in the way an organization does its routine work.

Thus, implementing QI activites is a natural follow-on approach to QA and QC. Opportunities for Improvement (OFI) can be found at any level of an organization. It requires a team of people or a motivated individual to reflect on the way that past work activities have been performed and continually seeks opportunities to improve their operation by the identification and consider new ways to increase efficiency, effectiveness and economy in the performance of their work. The objective should be to deliver enhanced outcomes to its customers and thereby create value for the organization and society. Anything that creates a beneficial increase in quality performance is quality Improvement. Some of the factors that encourage a QI culture include:

- QI requires the "art and science" of process management.
- QI requires statistics – data-driven and managed by facts.
- QI requires managing the end-to-end working system.
- QI requires real-time, real-world information access.
- QI requires engaged people and a culture of adaptation.

Figure 1: The Relationship Between Performance Improvement sof Quality Actions

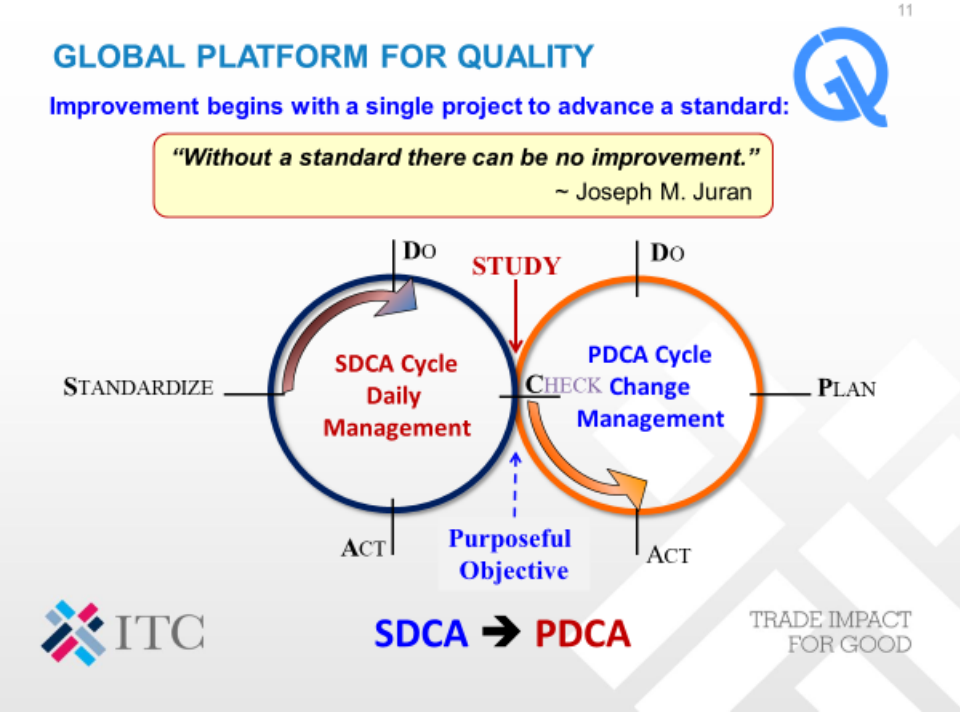


QI begins after a standard has been established and implemented. It is the responsibility of the business leaders in the management ranks (we will call this “Gemba 2” business leaders) to find how to apply resources in the best way to increase productivity that drives profitability. It is the responsibility of supervisory leaders in oprational ranks (we will call these people “Gemba 1” business leaders) to discover how to root out waste, loss, and inefficiency in the work processes of the organization. Figure 2 illustrates how the daily management system is influenced by the reflective practices of the Gemba 1 leaders in the Check step of the Standardize-Do-Check-Act (SDCA) cycle of daily management. It also shows how Gemba 2 executive conducts oversight of the daily management work to identify opportunities to “flow resources” to the most significant point of pain where improvement is most desperately needed. Management operates this step in conjunction with the supervisory function in the reflective learning process step that is called “Study” where current performance is evaluated with respect to the organization’s purposeful objectives. This planned change management or transformation process is managed using the PDCA (Plan-Do-Check-Act) cycle.

These two cycles are managed through the execution of the “Check” step that occurs in both of these cycles. The “Check” step not only evaluates quality performance, understands deviations from expected results, and conducts improvement projects that increase the capability of the daily management system, it also acts as a forum for exchange of improvement ideas that may be initiated as strategic change projects using the PDCA approach. These cycles of improvement must be implemented cross-functionally as well as within functional operating areas. These two approaches to improvement may also address different categories of improvement. Work level improvement activities tend to focus on the maintenance and improvement of the Critical-to-Quality (CTQ) characteristics of processes, products or services as this control performance and assure delivery of quality to customers. These activities are typically embedded within the daily management practices of Gemba 1 and are a normal function of the organization’s QA and QC activities. Critical-to-Satisfaction (CTS) characteristics of a product or services represents the set of factors that deliver marketing features and are desirable to external customers. They are also very important to the business as they tend to distinguish in performance between competing organizations for the customer’s business and are linked to the

decision criteria for purchasing or choices to continue in business relationships. Managing CTS factors should always be an area where CI activity is pursued.

Figure 2: The SDCA and PDCA Cycles of Improvement



Categories of Improvement

One of the beliefs of modern quality management is that everyone is responsible for improving their work and, in this way, engages everyone in the organization. Specifically, observations of particular quality responsibilities may be defined:

- Workers are responsible for improving the quality of their own work.
- Supervisors are responsible for improving the quality of end-to-end workflows and also for supporting workers in the improvement of their specific work contributions to the end-to-end process flow.
- Cross-functional integration is the responsibility of the functional managers who ensure the collaborative work across functional boundaries so that harmony occurs. This process needs to be comprehensive – all business processes involved in supporting the productive money machine of operations.
- Executives are responsible for formulating strategy based on critical insights into the need for change and then for assuring that the allocation of resources appropriately supports all priority improvement projects. The executive in charge must have an unrelenting pursuit of improvement.

While corrective action activities tend to investigate "backward quality" – elimination of defects that occurred in the past as observed in the recorded process data, preventive action activities tend to develop a proactive or "forward quality" approach to improving the future state that will be realized as CTS factors are made more and more competitive. Both of these ways of perceiving quality improvement rely on statistical methods to develop

profound knowledge of what can be done to effect the changes required. In the case of “backward quality” there are clear objectives for shifting the mean or reducing the variation of the key process variables to achieve stability and control In the case of “forward quality” there is a clear objective to achieve increased capability based on predictive analytics about how well the process can be designed to perform for CTS functions that motivate customers to increase their business relationships or expand the scope of their current engagement. This creates new value and expands capability of processes and performance of products or services.

Juran observed that there are two types of improvement: continual, incremental improvement types of projects and breakthrough, step-function change types of projects. While incremental projects tend to be initiated at the working level (Gemba 1) of organizations that encourage the evolutionary change in working ways, breakthrough improvement projects tend to be initiated by management in Gemba 2 and seek to achieve revolutionary change. Incremental projects are most-often focused on a particular workflow while breakthrough project tend to alleviate a system-wide problem across the end-to-end business process flow. In both cases improvement work is done as a project. Juran commented about this fact regularly in the improvement part of his handbook:

- “All systems of control, no matter how well they are documented, will tend to deteriorate due to changes in the business as well as due to human nature.”
- “A project is a problem chosen for a solution; it is also a way of managerial life.”
- “A project provides a forum for converting an atmosphere of defensiveness or blame into one of constructive action.”
- “Participation in projects increases the likelihood that a participant will act on the findings.”
- “*All breakthrough is achieved project by project, and in no other way*.”

Managing Breakthrough projects will be the focus of the next course: Q104 – Quality Planning. In the meanwhile, we will focus on incremental improvement projects in the remainder of this course. It takes an unrelenting pressure to improve performance in order to overcome natural deterioration of process performance.

Incremental improvements, also called *kaizen* projects (for “improvement for the better”) are the way that much improvement occurs. The objective of these projects is to continually seek new ways of working that will increase efficiency, effectiveness, and the economic performance of an organization by improving work at the “atomic level” of the front-line working teams.

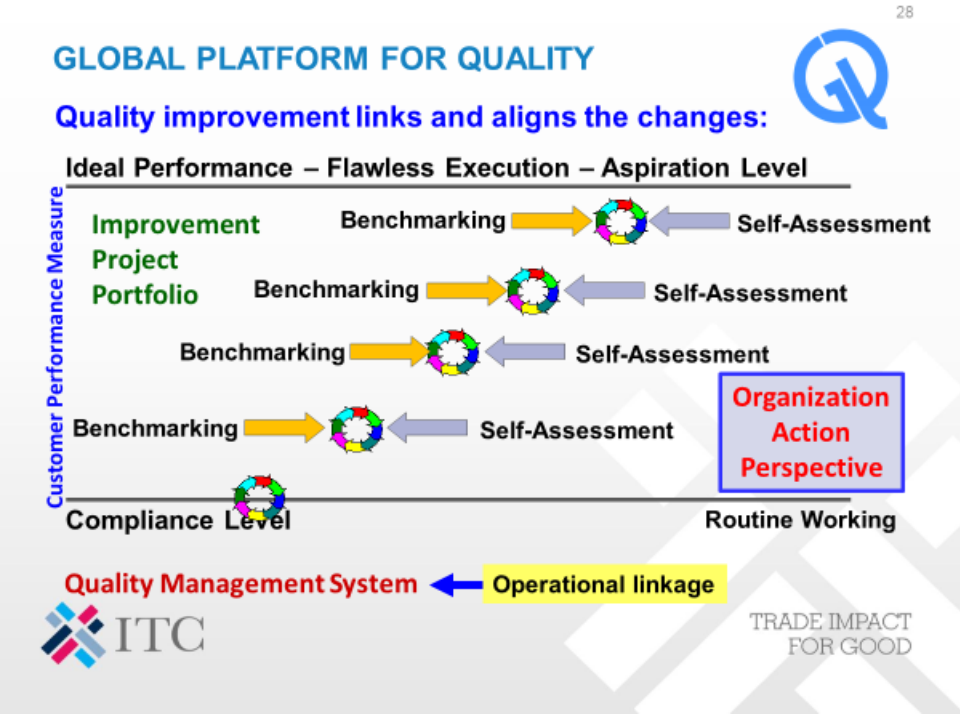
This type of improvement focuses on how to change standard work or process designs that are already implemented so they are performing better than they have in the past. These projects are led from the organization’s bottom by supervisors or work process owners

Continual, incremental, evolutionary improvement seeks to:

- Stabilize process performance,
- Remove waste and defects,
- Eliminate safety hazards, and
- Maximize process capability, and thereby reduce the costs of operations.

Figure 3 illustrates how large organizations have taken a systematic approach to integrating the incremental and breakthrough improvement projects.

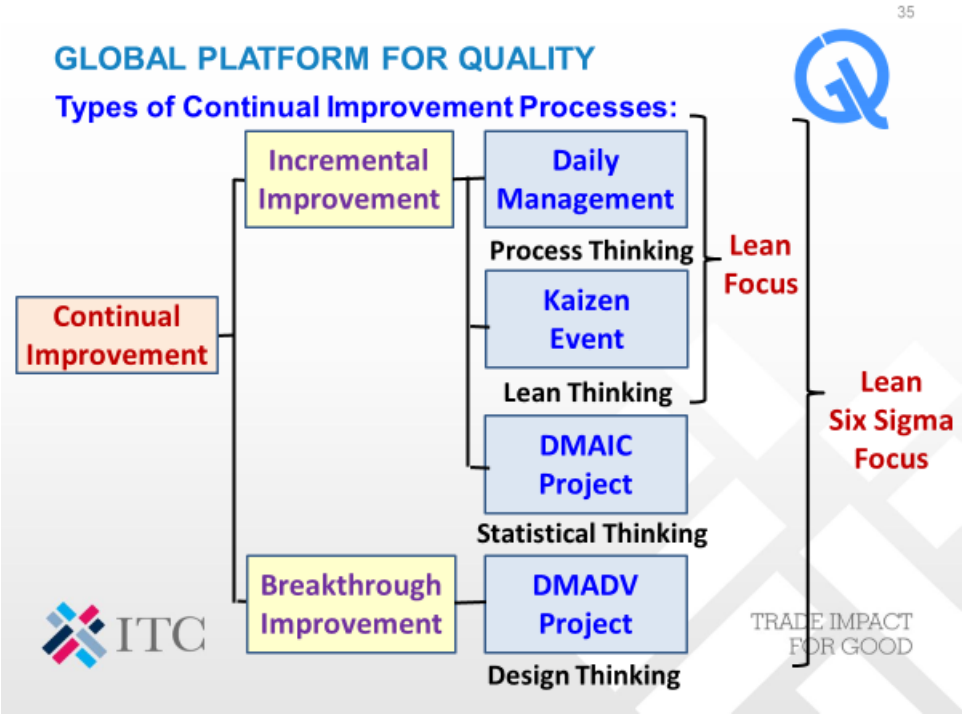
Figure 3: Systematic Approach to Driving Company-wide Continual Improvement



This figure illustrates that organizations transition in maturity from a "compliance level" of their quality management capability toward an "excellence level" of performance. This journey (or as it should be called "*safari*" in Swahili), is composed of a sequence of improvement projects that are driven by managerial actions occurring in the "Study-Check" step of the SDCA-PDCA cycle. As management observes performance in Gemba 1 and determines how to apply its resources to effect improvements it builds a portfolio of improvement projects (coordinating incremental and breakthrough projects) to advance the organization's process maturity toward the level of performance that it aspires to attain. The portfolio of these two types of projects are linked and aligned during the strategy formulation stage of planning as the Gemba 2 business assessment process conducts internal self-assessments of OFI's as compared to external benchmarks that offer a "reality check" for targeted performance levels as well as introductions of "best practice lessons learned" from other organizations that perform better. Each project builds upon former projects and as time passes the organization makes a "step-by-step" approach toward driving a coordinated, company-wide improvement effort.

It now becomes clear that there must be some form of architecture for improvement projects to permit them to become coordinated into a portfolio that provides "linked and aligned" gains without duplicating effort or wasting resources. Again, this is the domain of "Quality Planning" however, profound insight can be gained by examining the various types of CI projects that an organization can pursue. Figure 4 shows a breakdown of CI into incremental and breakthrough projects and a further breakdown into the operating models for conducting improvements.

Figure 4: Decomposition of Continual Improvement into Methodological Elements



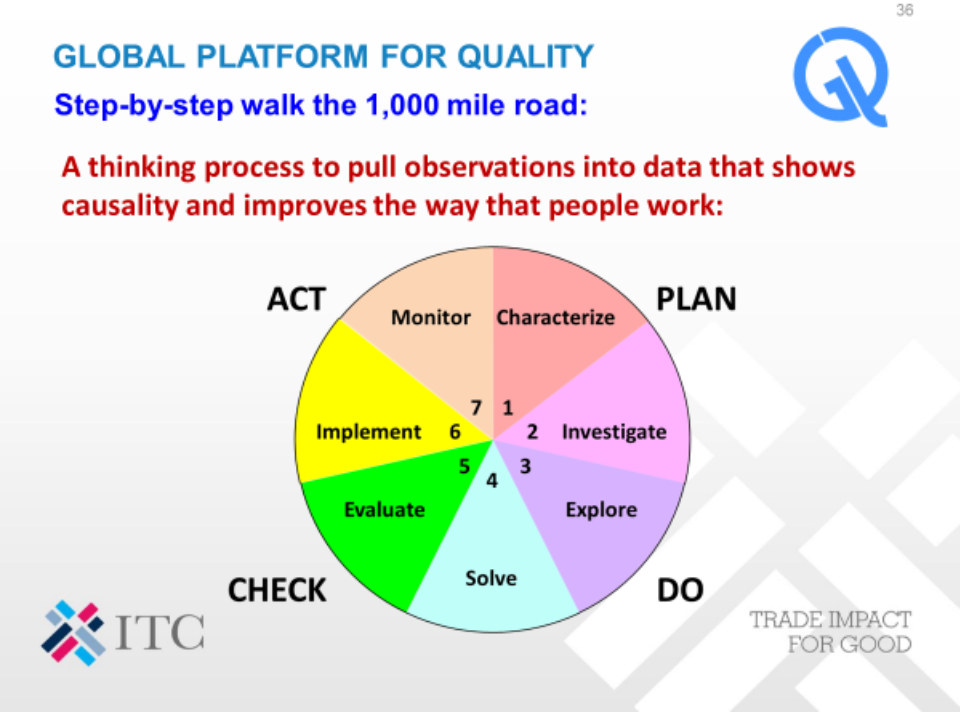
The CI process breaks down into incremental improvement which are focused projects that are applied at the Gemba 1 level to products, services, and process as a way to drive improvement. There are three ways of thinking that are applied in incremental improvement: process thinking that is focused on understanding and characterizing the flow of work; lean thinking that has the focus of eliminating waste and increasing efficiency of the working process; and then statistical thinking which characterizes the flow sequence to assure balance, productivity, and optimize all important performance factors. These thinking processes occur in different methods that have been applied for incremental improvement: daily management conducts the routine, standard work of the operating system and creates value as the work flows through is sequence of work processes. Kaizen events are dedicated team improvement activities that are concentrated on a specific OFI in a targeted work process. These events concentrate short-term bursts of team-based improvement work to generate a rapid improvement in basic operational processes or tasks. Both daily management and kaizen events are generally described in business literature as “lean” methods. A deeper level of process knowledge can be gained by supplementing these into an integrated form using the DMAIC model for conducting improvement projects. This is the basic improvement approach applied in Lean Six Sigma (LSS) methods and it encapsulates both the lean and kaizen types of improvement activities. LSS also has a breakthrough method for implementing design thinking: a Design for Six Sigma (DFSS) approach applies the DMADV model for designing new changes to products, services, or their processes to increase the way that they perform as a “step function” above their historical or legacy work processes. This will typically involve significant resources and technology changes.

While the preceding paragraph appears to present a banquet table or smorgasbord of different ways to improve performance of organizations, it becomes clear when examining each of them at a detailed working level that many of these are applied in the different models are actually very similar and they employ the same tools sequenced in similar ways. This means that their processes can be reduced to a generic description of CI. In 2014 the International Academy for Quality’s Designed Improvement Think Tank initiated the development of such a generic model of CI. A final report to the Academy was presented in 2017 and a high-level perspective of this Continual Improvement Process (CIP) is presented in the next section of this chapter.

The Continual Improvement Process

What common elements do all continual improvement models contain that are available to be integrated into a generic model that satisfies the needs of all functional disciplines? A seven step model was constructed based on the comonalities among all the improvement models the team investigated it is illustrated in Figure 5 and described below.

Figure 5: The IAQ Continual Improvement Process (CIP) Model



The seven steps in the CIP model roughly track the PDCA model in the Japanese quality method and the SDCA step is fully embedded within the seventh step – Monitor. Here is a description of these seven steps:

- **Characterize**: Identify an opportunity then define, specify and scope the project.
- **Investigate**: Evaluate facts to find boundary constraints that limit an opportunity.
- **Explore**: Identify the essential nature of the opportunity to improve.
- **Solve**: Determine alternatives for improving outcome performance.
- **Evaluate**: Demonstrate the efficacy of the proposed solution(s).
- **Implement**: Develop plans for implementation and benefit capture.
- **Monitor**: Monitor the process to ensure sustained, consistent performance.

The Monitor step is particularly important as it embeds the complete routine operational work system and all of the SDCA activities for daily management.

This CIP model extends the LSS DMAIC model one step in both pre-DMAIC and the post-DMAIC directions. The initial step of Characterize provides a link to the strategy formulation process in which management sorts business issues according to criticality in order to determine which of the issues are a priority given the constraints of available human and financial resources. This is a step that enables the linkage of the organization's strategic intent for improvement. Likewise, the Monitor step extends beyond the Control step in DMAIC to fully transition improvements to operational control including determination of functionality and

acceptance by the workforce as their new operational methods. Monitor also embeds the standardization and improvement cycle of SDCA which operates within the organization's daily management system. In another important aspect of the model, "clear roles" were developed to assure that the improvement team could function appropriately within all constraints of a process management organization. The final section of this chapter discusses the role of team activities in CI.

Team Activities in Continual Improvement

There are three roles specified in the CIP model for improvement: process doers, improvement facilitators, and system designers. Each of these roles describes a different competence level in the application of the CIP model. These roles in implanting continual improvement using the CIP model may be summarized as follows:

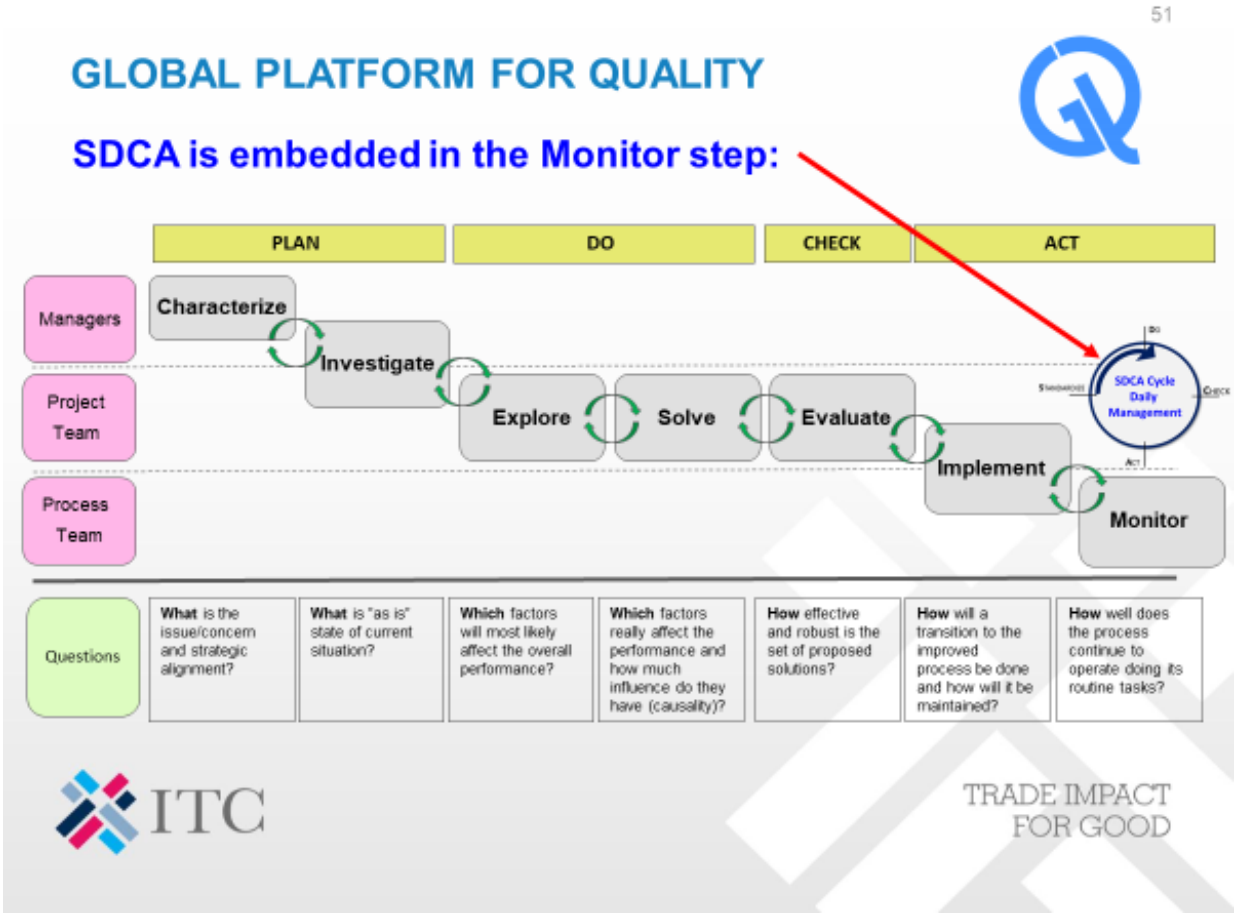
- **Process Doer**: individuals whose activity is executing, maintaining, and improving standard work and has a need for process management, problem-solving, teamwork, collaboration skills, and quality improvement capacity.

- **Improvement Facilitator**: individuals who serve as team leaders and project analysts for the CIP project activity. They guide improvement teams through the application of the CIP steps and work on solution of complex problems that operate across the flow of multiple work or business processes.

- **System Designer**: individuals who act as system architects to design the flow of the socio-technical systems of an organization which deliver productivity through the integration of a web of cross-functional workflows and who manage the most advanced problem-solving or improvement efforts. System designers also provide coaching and executive-level consulting regarding the selection of strategic improvement projects and act as facilitators of the end-to-end strategic planning process.

The CIP model measures work processes using standard indicators that flow through all of the processes: throughput yield of quality (right-the-first time (RFT), consistency of flow to demand, work safety hazard reduction, economy of operations, and motivation of workers. The team-based improvement projects are trained by the specially trained improvement facilitator. The relationship of the CIP model to the PDCA change management process and the way actions are delegated to various teams is illustrated in Figure 6.

Figure 6: Structure of Improvmeent Team Efforts in Implementing CIP



Each of the seven steps in the CIP model focuses on the work of distinct organizational teams and each step addresses a particular question that must be resolved. The work across these seven steps is characterized as follows:

- **Characterize** (Managers and System Architects): What is the priority issue or concern and how is it aligned with the organization's strategic objectives and business goals?
- **Investigate** (Managers, System Architects and Project Facilitator with Project Team): What is the "as is" state of the situation and how much improvement of the current process can be made without further investments?
- **Explore** (Project Facilitator with Project Team): Which performance factors will most likely affect the overall performance the most; in what mechanism do they relate to the outcome; and how much variation do they contribution to the performance shortfall?
- **Solve** (Project Facilitator with Project Team): Which factors really affect performance and how much influence do they have as causal drivers of the poor results?
- **Evaluate** (Project Facilitator with Project Team): How effective and robust is the set of the proposed solutions – does it have any unintended consequences?

- **Implement** (Project Facilitator with Project Team and Process Owner with Process Team): In what way will a transition of the improved process be accomplished; how will all changes be implemented; and has the change been demonstrated to operate in an effective, efficient, and economic manner?

- **Monitor** (Process Owner with Process Team): How well does the change operate once it has been integrated into the routine operations of the process – are there any further areas for improvement that should be worked upon?

Concluding Comments

Continual Improvement (CI) has two distinct stages: incremental improvement as addressed by the daily management system in the operational activities of Gemba 1, and the breakthrough activity which is managed by Gemba 2 in order to create strategic change. While the first type of CI process is managed within the Juran Trilogy it maximizes at the limit of the upper bound of the process performance potential to reach higher levels of improvement typically requires additional resources and more complex planning. This will be the topic of the next chapter.

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Review Questions

After reading this chapter and reviewing the related presentation in volume two, take the following quiz to review your knowledge and understanding about Quality Improvement processes and their contribution to developing continuing success in market results.

1. Quality improvement can be described using all the following words **EXCEPT FOR**:

a. Systematic

b. Random

c. Deliberate

d. Formal

2. Quality improvement aims to achieve levels of performance which are unprecedented – levels which are significantly better than any past level. The methodology consists of a process.

a. True

b. False

3. Quality assurance requires all but:

a. The “art and science” of process management.

b. Solid financial accounting records.

c. Managing the end-to-end working system.

d. Real-time, real-world information access.

4. Quality improvement should begin after:

a. The work process is standardized.

b. Out-of-Control (OOC) conditions have been eliminated.

c. The work process has been stabilized.

d. All of the above.

5. After the preliminary study step in a process that precedes standardization, effort must be placed on the SDCA process by:

a. Understanding the process flow.

b. Determining how value is produced as the process operates.

c. Eliminating waste and loss from the work system.

d. All of the above.

6. The proper order of activities should be:

a. First identify the waste and eliminate its obvious causes then standardize the process.

b. First standardize the process then identify the waste and eliminate its obvious causes.

c. Both (a) and (b).

d. Neither (a) nor (b)B

7. Quality improvement seeks to close the gap between routine process performance and the natural process limit in order to maximize quality delivered.

a. True

b. False

8. Continual improvement applies the following methods to achieve results:

a. PDCA/SDCA, benchmarking and self-assessment.

b. Targets compliance level quality improvement.

c. Assures that the routine way of working is managed consistently.

d. Applies only evolutionary change to obtain results.

9. Teamwork required to improve processes engages:

a. Process doers.

b. Process facilitators.

c. Process designers.

d. All of the above.

10. The Continual Improvement Process (CIP) is related to SDCA in the following way:

a. SDCA is a prerequisite for CIP and also embedded into the Monitor Step of CIP.

b. SDCA is not related to CIP in any way; it is a separate activity.

c. CIP is a prerequisite for SDCA.

d. SDCA is embedded into the Monitor Step of CIP.

11. Managing Critical-to-Quality items is a role of QA/QC while managing Critical-to-Satisfaction is the role of Quality Improvement.

a. True

b. False

12. The most advanced capability for “managing by process” is found in the:

a. Chief Executive Officer (CEO).

b. Process Designer.

c. Process Facilitator.

d. Process Doer.

13. An organization believes in a “synergy of experts” but does not require them to collaborate as long as they are working on common goals using their own best practices. Management sets objectives to be achieved by the collective unit and requires each person to apply their expertise toward the achievement of these objectives.

a. This is a “group,” not a “team.”

b. This is a “team,” not a “group.”

c. This is neither a “team,” nor a “group.”

d. Cannot tell from this description.

14. Teams that cooperate for Quality Improvement include all the following **BUT**:

a. Work Group Teams.

b. Tiger Teams.

c. Project Teams.

d. Steering Committee

15. The Continual Improvement Process is a more detailed version of the basic PDCA model.

a. True

b. False

CHAPTER 4 – Q104 – QUALITY PLANNING

Abstract

Quality Planning (QP) operates at various process levels within an organization. QP is contained in the QI process at the daily level of managing change in routine work activities. This type of planning is managed by the supervisory function and is closely aligned with production scheduling and control activities which assure that a smooth flow of work progresses through the operational activities of the organization. This type of planning supports small-scale improvement activities and kaizen events. When broader scale improvement projects are conducted then planning specialists become involved in steering these projects. In this chapter QP emphasis will be placed on such projects that achieve either an incremental or breakthrough improvement to processes, services, or products. Breakthrough improvement to business systems and product development typically require a more strategic emphasis and their consideration will be postponed to chapter six where emphasis will be placed on “quality as a strategy” to achieve the breakthrough improvement of organizational performance.

Introduction

Quality Planning (QP) develops plans for improving the performance of work to increase the quality, efficiency, and cost-effectiveness of productive work. There are two ways to plan how quality improvement is accomplished: improving the quality of the daily work processes and the products and services that they deliver to customers using incremental improvement activities and improving quality using breakthrough improvement activities. Use of incremental activities and projects is managed through QI actions in a Quality Management System. The achievement of breakthrough activities occurs by engaging the PDCA change management process in support of the SDCA daily management process when front-line process workers have not been granted decision rights to make changes or where investment in resources is required beyond those budgeted for the normal operating expenses. The QI emphasis in daily management focuses on evolutionary gains in the way standard work is performed and includes kaizen events where teams of workers act to create better flow and waste elimination in their activities. As broader scale improvements are required, then the organization applies QP to improve performance.

Understanding Quality Planning

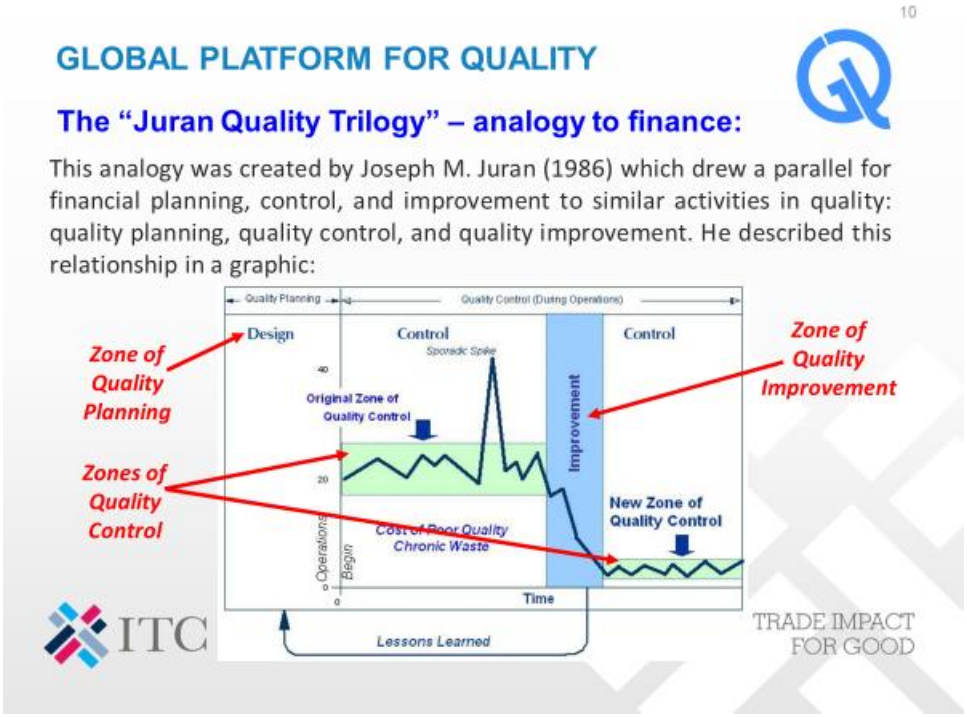
To better understand how QP operates it is necessary to establish a few definitions that will allow us to distinguish among its core elements. The first two definitions apply to the entire structure that an organization develops as its framework for quality:

Quality Policy*:* A documented statement of organizational commitment or intent that needs to be implemented across all levels and by all participants in the organization to achieve quality. A quality policy is a guide to action – a statement of principles and values. It differs from all other quality management system elements by stating “what” is to be accomplished; not answering the “why” or “how” questions that are required for these results is to be delivered.

Quality Plan: Documented information that defines the activities, methods, and schedule for implementation to be taken to achieve quality objectives and meet specified requirements.

Of all the early quality thought leaders, Joseph M. Juran had the greatest influence on defining how quality management operates. He defined the approach based on his fundamental way of defining how operational quality exists using an analogy to financial management which he has called a Quality Trilogy as illustrated in Figure 1.

Figure 1: The Juran Trilogy Illustrating the Breakthrough Planning Project Results



Juran's Quality Trilogy: There is a three-pronged approach to developing quality. As the three elements, Juran included: quality control (which he coupled with quality assurance as actions that are dedicated to meeting product, service and process goals); quality improvement (which he emphasized as actions aimed at delivering unprecedented levels of performance – beyond a level of performance that is routinely obtained); and quality planning (designing products and services along with their implementing processes that are required to meet customer needs).

Juran identified QP as "the activity of developing the products and processes required to meet customers' needs." While he placed QP in his Trilogy as preceding both the QC (embedding the QA function) and the QI activities, it should be clear that this model confounds several related concepts that need to be clarified with respect to both timing and the organizational decision structure with respect to planning and implementation. For example, Juran's trilogy does not indicate any distinction between the concepts of continual improvement and breakthrough improvement. It does not identify what are the short-term as compared to long-term planning actions of management, nor at what levels of an organizational hierarchy these plans are either designed or implemented. However, this does not in any way diminish this contribution. It must be placed in a more comprehensive context of the entire system of "Managing for Quality."

Juran provided a proposal for quality planning that is most helpful. He identified the QP activity as containing a series of five universal steps which are equally useful for both incremental planning and breakthrough planning:

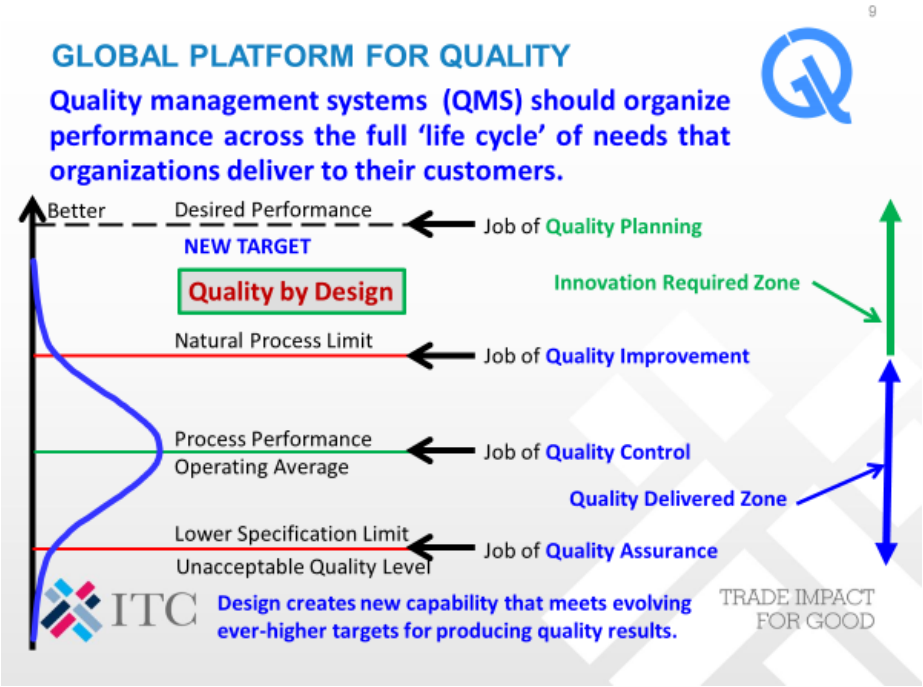
1. Determine who are the customers (internal and external).
2. Determine the needs of these customers.
3. Develop product and service features which respond to these customer needs.
4. Develop processes which are able to produce those product and service features.
5. Transfer these resulting plans to the operating units for implementation.

QP must be integrated with QA/QC and QI in an environment of inspirational leadership that actively engages workers in an effective quality culture applying teamwork to achieve harmony within the organization to thereby accomplish its shared goals obtain mutual success. The five activities identified by Juran apply equally to the design and development of operational plans to achieve evolutionary QI as well as for strategic to achieve breakthrough QI. How do these two activities differ?

Operational Quality Planning: This type of planning is directed at design and development of the organization's daily management system. It includes design, development, and commercial deployment of products as well as the same functions related to the processes by which these products are to be produced. The dividing line between the application of operational types of product and service improvement and strategic improvement is the type of investment that is required. If investments in assets or business systems are required, then these resources must be delegated by management. If improvements can be made using modifications to supplied parts or in routine maintenance activities and are covered within the operational budget that has already been approved by management, then these are considered incremental types of improvement that are managed under the rubric of operational QP. Concurrent engineering of products and processes applies in both the operational and strategic domains as it permits a rapid streamlining of waste from the overall process and the integration of quality concerns from the cross-functional stakeholders in this new product design / development process.

Strategic Quality Planning: This planning process identifies long-range customer-focused goals and determines the best approach to meet those goals. This is an integral part of the overall strategic planning process of an organization and is typically led by senior management (often referred to using Juran's concept of "***BIG Q***" – a topic to be discussed in Chapter 6). Thus, it is a quality activity of the senior management function in an organization's structure. On the other hand, operational quality planning focuses on product and process planning which engages the middle management level (which coupled with the QA and QC elements of operational quality is referred to by Juran as "***little q***"). Strategic QP emphasizes project such as business systems engineering (strategic changes to the business and its operating systems) as well as the new product development activities. Figure 2 indicates the zone of strategic quality planning using the label "innovation required" while operational quality planning focuses on quality delivered.

Figure 2: Quality by Design is Required to Reach Beyond Natural Process Limits



Those QP projects that focus on delivering strategic quality plans are typically referred to as "***Breakthrough Projects***" as they seek to develop a "step-change" function that defines the concept of revolutionary improvement. QP projects that focus on delivering operational quality plans are typically referred to as "***Continual Improvement Projects***" or as ***Kaizen Events*** (using the Japanese word which means "change for the better") as they seek to develop incremental or evolutional performance changes. Figure 2 illustrates the distinction between the two types of projects with respect to the baseline performance conditions that are addressed. In general, breakthrough projects operate in the performance domain labeled "***Quality by Design***" in this figure while continual improvement projects operate below this level of performance.

Quality by Design is a process to develop and execute business plans for improvement that will elevate quality to a higher level than available under the current constraints of resources and competence. It plans to implement a funded business plan for breakthrough change. Change management and project management provide ingredients for this approach. The conceptual framework of Design for Six Sigma (DFSS), as operationalized in its DMADV (Define-Measure-Analyze-Design-Verify) project management method and toolkit applies "Design Thinking" to integrate innovations for both products (or services) and their associated delivery processes into an engineered development program to create "attractive quality" and deliver the quality dimensions that increase competitiveness relative to alterative market choices by customers. In this case, QP will document the business case for change and develop the implementation plan to achieve the desired transformation as part of the "BIG Q" strategic quality program.

To manage systemic change planning must be accomplished on both operational and strategic levels of an organization. The structure by which organizations develop and deploy this way of working is in the in its quality management system (QMS). So, what is and how is it structured?

Quality Management System (QMS): A formal system documenting structure, processes, roles, responsibilities, and procedures needed to achieve effective quality management. Around the turn of the 21st century there were three elements contained in the more advanced designs of QMS: ISO9001, Lean Six Sigma, and Business Excellence. What is necessary to understand with respect to these systems and their roles in QP?

ISO9001 Quality Management System: This QMS addresses all of the three quality levels: QA, QC, and QI within the context of delivering commercial benefits in contracts with external (e.g., second party) customers. This standard, however, is non-prescriptive in that it does not define a particular set of methods or tools that must be applied for compliance – it says "what" must be addressed but does not provide a rationale for "why" it relates to a particular business or for "what" must be done in terms of specific methods or techniques necessary to satisfy its set of requirements. Thus, ISO9001 provides a documentation management framework that will allow organizations to define how to populate with its own content about: what it will accomplish for customers; why it will do it the way it chooses to; how it will conduct the methods, tools, and techniques to perform the necessary actions; when and where it will accomplish this set of its quality activities; and how much effort it intends to invest as well as how much benefit that it believes it will achieve.

Lean Six Sigma Breakthrough Strategy: Lean Six Sigma (LSS) is a project-management based improvement strategy that integrates a process thinking with statistical thinking by designing work systems that incorporate humanistic work methods (e.g., ergonomics, and lean process improvement tools) within the context of an end-to-end, customer-focused business system to both optimize the organizational design (DMADV projects) while also increasing the productive efficiency of its operational processes (DMAIC projects) through standardization and problem-solving so that the organization is transformed into a more competitive state of performance. LSS identifies the methods, techniques, and tools that will facilitate this transformation (this is why it is referred to as a breakthrough strategy – although not all of its projects are aimed at the target of achieving breakthroughs). However, LSS does not specify the components of the daily management system nor does it provide a structure for quality system design. It focuses on the throughput of processes in services to external customers.

Business Excellence Assessment Criteria: Business Excellence is an outgrowth of an effort in the United States to develop criteria for a national quality award. A large team of quality executives drawn from among leading American companies was convened to address this question: what must an organization do in order to create a sustainable business capability and assure that it will have success in the market? A set of criteria and managerial deployment methods was then developed as areas to address that are essential ingredients for creating business excellence. It is similar to ISO9001 in the sense that these questions and criteria are not prescriptive (e.g., tell managers exactly what to do or how to do it to succeed) and, therefore, do not define any particular tools or methods that must be employed to deliver this goal.

However, if these three are merged synergistically, then they provide the ingredients necessary to design a comprehensive system for organization-wide quality management (Figure 3).

Figure 3: The Synergy of Quality Methods: ISO9001, Lean Six Sigma and Business Excellence

Application of QP within the activities of the QMS focuses on either process-based or project-based approaches to CI planning. These two aspects of the QMS focus will be discussed with respect to their contributions to continual QI planning in the next two sections of this chapter.

Process-Based Approach to Continual Improvement Planning

Process-based improvement tends to be evolutionary, incremental change and it focuses on improving the quality of standard work, so it approaches the ideal capability that was initially designed into its work processes. Process-based improvement is conducted by individual workers or by a work team in a joint effort to collaborate on increasing their process output or quality of work. Initiation of the improvement effort typically occurs during the “Check” step of the daily work cycle – SDCA – where examination of the process performance identifies that an Opportunity for Improvement (OFI) exists. Classical OFIs include the following characteristics which identify “things going wrong” in a process:

- Reducing cycle time in process performance actions.
- Minimizing waste in scrap and associated rework time.
- Achieving increased productivity through implementing lean work efficiency methods.
- Eliminating safety hazards that are discovered in the process.
- Decreasing worker or material movement in the process activities.
- Eliminating errors that are observed to recur chronically in the process.
- Assuring tests results are provided so operations can be completed in a timely manner.
- Increasing skills of operators by cross-training so they may be work flexibly and assigned to a wider range of process activities.
- Simplifying process flow to assure more consistent throughput

Process improvements may be done rapidly using the PDCA method when a process is failing to keep up the established work standards. At other times a more detailed improvement activity will require some loss of time in production operations in order to rearrange the work. In this case is more extensive QP planning may be required to achieve the incremental improvement gains but reducing productivity losses from lost production downtime. Examples of these types of work-disrupting improvement activities are:

- Rearrangement of the layout of production equipment or production materials.
- Cross-training operators to perform new work skills or learn different work positions.
- Re-organizing the material flow or material handling systems.
- Conducting a team-based kaizen event to rapidly re-structure workflow or support tasks.

In addition to “spot projects” that are focused on a particular activity or workstations, it is also clear that sometimes incremental improvement projects may require application of a complete *Continual Improvement Process (CIP)* to arrive at the improved state of work process control. In these cases, a project-based approach to improvement may be required.

Project-Based Approach to Continual Improvement Planning

Achieving a quality culture requires, among other things, that an organization develops its own common or standard way to conduct project-based improvement. This is essential as no single project is really stand-alone – they all exist within a business system which must be allowed to flow across the end-to-end stream of activities that deliver value to customers. Quality planning starts with a review of the product design to assure that the operational processes are capable of delivering its result flawlessly to customers according to the boundary conditions of their set of deliverable requirements. Then, the emphasis moves on to review the process design so that assurance may be given that it supports an efficient, effective way to conduct required work. In evaluating the process activities, the relationship of the process steps toward delivery of the product quality characteristics must be analyzed to assure that the process flow produces the product efficiently and that steps have been taken to perform the following tasks:

- Error proof the process,
- Plan a neat and clean workplace organization,
- Validate the quality measurement processes,
- Plan for operator self-control, and
- Document the basic working procedures for the quality management system.

Throughout this planning process statistical measures should be used to guide the focal areas for improvement and to determine the “stopping point” for improvement efforts – the point where sufficient improvement has occurred. In general, the stopping point has one or more of the following characteristics:

- The process is not capable of further improvement as its capability has been maximized,
- No further effort is required to satisfy customer demand,
- Additional investment in the process are no longer cost-effective,

- New technology is available to do this work better and further gains require investments,
- Other steps in the process require improvements and this particular step is no longer the bottleneck in the process throughput, and/or
- A more comprehensive project must be initiated to address a wider aspect of the issue that is being addressed as the scope of the current project no longer contains its root cause(s).

When considering how to build a process for project-based improvement, it is good to take the perspective that was offered by Juran: “All improvement happens one project at a time and in no other way.” He commented further that “quality improvement is a process.” So, creating a process for conducting QI projects is an essential ingredient to successful efforts for making CI into a part of an organization’s improvement culture.

The original structured approach to CI was the Japanese Total Quality Management (TQM) way of applying the cycles of learning contained in their Standardize-Do-Check-Act (SDCA) and Plan-Do-Check-Act (PDCA) daily management and project-based change management cycles. This is the approach that was adapted and reformulated by LSS in America as the DMAIC, and it is also taken as the logical foundation in the thinking processes behind the IAQ CIP model, as discussed previously. Since CIP is discussed in detail in the IAQ documents and there is a long history with the Japanese SDCA/PDCA models, this chapter will describe in detail the LSS approach to doing problem diagnosis and problem remediation using the DMAIC project management process.

Define: Focuses management attention on a “vital few” major improvement activities and it consists of the following activities:

- Identify a portfolio of potential improvement projects based on customer-based issues that have been presented or on other observed OFIs.
- Evaluate the set of proposed improvement projects to determine which of them present the highest potential to obtain returns and to determine the proper sequence in which the improvement projects in this portfolio of potential actions should be conducted.
- Select a priority project for improvement based on business criteria and urgency in which it is necessary to obtain results.
- Develop a problem statement from the observed issue and create terms of reference, project charter, or mission statement for the team that will be dedicated to do the project.
- Select the team members based on the competence and/or skill requirements; identify an experienced project manager; champion or process owner to provide managerial oversight and sponsor the project; launch the project; and agree upon project schedule with key DMAIC milestones set along with the goals that should be targets for improvement and used to assess progress and evaluate outcomes.

Measure: Establish the performance baseline, missing opportunities for improvement, and then determine the measurement system integrity for the performance factors in the project goal.

- Identify key product and process characteristics that measure and describe its performance.
- Document the end-to-end flow of the process activities.
- Identify the key output process measures that are either Critical-to-Quality (CTQ) or Critical-to-Satisfaction (CTS).
- Chose meaningful control objectives and points in the process for this measure.
- Establish measurement capability of this indicator at each of the control points.
- Validate the measurement system and ability of the metrics to inform about performance of the process in all critical dimensions (productivity and cycle time as well as the reasons for losses in these factors across the process sequence of activities).
- Establish standards for output performance and boundaries that define the limits of process responsibility for the process owner.
- Collect historical data and evaluate with Exploratory Data Analysis (EDA) techniques.
- Plan for additional data collection to gain a better picture to measure actual performance.

- Compare actual performance capability (Cpk) to standard (or ideal) process capability (Cp).
- Characterize and document initial process performance baseline.
- Review progress and update the overall project objective and charter as needed.

Analyze: Evaluate the detailed process performance measures in the segment that the EDA has identified as most problematic in order to discover the sources of special cause variation.

- Breakdown results measures into process measurements.
- Collect historical process measurement data.
- Analyze data by key rational sub-groups for trends, correlations, and interaction effects.
- Determine which parameters have the greatest impact on total process performance.
- Evaluates process history and current data to diagnose and discover the causes of process performance deviations as well as the sources of variation. The following steps are applied:
- Develop and test theories about variation and cause-and-effect relationships.
- Diagnose process symptoms to identify determinants of process performance deviations and parametric variation.
- Develop hypotheses regarding the causal mechanisms that need to be improved.

Improve: Determine effective, efficient, and economical remedies. Design remedies that: eliminate the cause(s) that were discovered during prior diagnostic phases (Define-Measure-Analyze); prove the effectiveness of the remedy; and prepars an implementation plan for capture and realization of the potential benefits. The following steps are a standard approach to this phase:

- Identify any alternative remedies available to close deviation gaps or reduce the variation.
- Design experiments (statistical or operational) to optimize the process performance.
- Design the system requirements for the remedy including the control points as well as the alerting limits and countermeasures to be employed when alerts are activated.
- Test the remedy in its ultimate operational environment, using the actual people who will be performing the work to determine the limits of its correct operational performance.
- Develop changes to operating procedures, measurement systems, work instructions, test procedures, and training of operators as appropriate.
- Identify organizational factors that will cause resistance to change and correct these factors.
- Transfer the remedy into the daily management system under the supervision of the normal responsible process owner.

Control: Integrate effective remedies into operational use. This step implements all product and/or process improvements to consistently maintain the improved performance level and transfer project operations to the additional process owners in related performance areas. The steps in this phase are:

- Design controls to mistake-proof the process and safeguard the performance capability.
- Document improved processes in work instructions and / or standard operating procedures that are embedded into the QMS.
- Validate the measurement system integrity for the improved process and product to assure that the capability is sufficient for the accuracy and precision requirements.
- Implement the changes and train the workers in all operating shifts and work locations.
- Monitor the process performance controls.
- Maintain the focus on continual improvement.

Planning for Incremental Gains or Breakthrough

Senior management is responsible for change that represents planned application of resources to deliver managerial breakthrough in customer deliverables, business performance, and in the adaptation of new

technologies to increase performance capability and stimulate growth. The managers who possess decision rights about process design and have a fiduciary responsibility for work are typically the sponsors of breakthrough projects as these projects tend to require major capital investments for completion and they have the potential for major cross-functional ramifications in both project management as well as in implementation.

Breakthrough change projects implement the strategic plans for major improvements in most organizations. Japanese management systems refer to this type of project as a "hoshin kanri" project. These projects define the strategic direction of an organization, focus its investments of time and money, and create the future strength of the organization. Typically, fewer than 5-7 of these projects will be all that a major corporation manages at a single instant in time. Some of the projects will address development of future core competence of the organization such as a major shift in technology (e.g., digitization) or software (e.g., enterprise-wide management system) or new product developments that change platform architecture or transition to new or emerging technologies (e.g., nanotechnology). These projects need to have the constant attention of management and those teams that are performing this work need to be dedicated to accomplishing just that one project. Most of these projects will be performed using a Quality by Design approach (e.g., DFSS method such as DMADV). This type of breakthrough project will be discussed in Chapter 6.

Concluding Comments

This chapter merges two quality models to increase understanding of how a quality planning function delivers improvements: merging the Ishikawa model for the structure of with Juran's trilogy of quality activities. In both of these models, Quality Planning is the fourth functional ingredient that comprises the Quality Management System (QMS). Planning for incremental improvement of products, processes, and services is fully within the discipline of quality planning. Breakthrough planning for processes is also within this discipline if this does not require adding new technologies or investments. However, when a "Quality by Design" project requires investment or engagement of external partners (e.g., use of the DMADV methodology) then this activity is outside the normal realm of QMS actions and is part of the process called Managing for Quality. In the next chapter will continue the discussion of QMS and will focus on how management of the quality function occurs. The final chapter of this book will shift from the idea of developing operational strategy to manage quality to using "quality as a strategy" for managing the growth and forward-looking development of organization, including Quality by Design and DMADV processes.

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Review Questions

After reading this chapter and reviewing the related presentation in volume two, take the following quiz to review your knowledge and understanding about quality planning and how it contributes to developing continuing success in market performance.

1. Quality Planning includes:

a. Determining who are the customers.

b. Determining the needs of customers.

c. Developing product features which respond to customer needs and processes that deliver on these features.

d. All of the above.

2. Quality planning is the activity of developing the products and processes required to meet customers' needs.

a. True

b. False

3. The Juran Trilogy does **NOT** include:

a. Quality Assurance.

b. Quality Control.

c. Quality Planning.

d. Quality Improvement.

4. Operational Quality Planning is directed:

a. Toward making major improvements in quality of software.

b. Toward the design and development of the daily management system of an organization.

c. Toward product improvement through introduction of new technologies.

d. Toward cross-functional breakthrough projects that rapidly advance an organization's results.

5. The job of quality planning is:

a. Move performance to the desired level of output.

b. Deliver capability for new target levels.

c. Execute Quality by Design.

d. All of the above.

6. Steps in Juran's Trilogy Quality Planning Process include all the following **EXCEPT**:

a. Transfer to Operations.

b. Develop Process.

c. Measure Actual Performance.

d. Develop Product.

7. The Juran Trilogy operates collaboratively to improve performance and hold gains of improvement.

a. True

b. False

8. Steps in Juran's Trilogy Quality Control Process includes:

a. Measure actual performance.

b. Compare actual performance against standards.

c. Both (a) and (b)

d. Neither (a) nor (b)

9. Quality Improvement in Juran's Trilogy includes:

a. Deal with resistance to change.

b. Establish controls that will assure the improvements.

c. Organize the project improvement team.

d. All of the above.

10. Improvement projects happen one-project-at-a-time and may:

a. Involve more than one project in a sequence that executes a portfolio of projects.

b. Uses benchmarks to challenge goals and seek best practice.

c. Applies self-assessment to discover changes that are required and progress in achieving results.

d. All of the above.

11. Strategic quality planning is often referred to as a “Big Q” management activity.

a. True

b. False

12. The last generation of quality planning and management systems included:

a. ISO9000 Quality Management System.

b. Lean Six Sigma Breakthrough Strategy.

c. Business Excellence Assessment Criteria.

d. All of the above.

13. While a “quality policy” defines “what” should be accomplished, “how” improvement should be accomplished is described by:

a. Work Instructions.

b. Standard Operating Procedures.

c. Implementation Plan.

d. All of the above.

14. Improvement of productive processes:

a. Is either conducted by individual workers or by project teams.

b. Begins with SDCA and transitions to improvement at the “Check” step.

c. Both (a) and (b).

d. Neither (a) nor (b).

15. Juran’s Quality Improvement Process is essentially the same as the Lean Six Sigma DMAIC process.

a. True

b. False

CHAPTER 5 – Q105 – QUALITY MANAGEMENT

Abstract

According to Frank Gryna, assistant editor to Joseph M. Juran in *Juran's Quality Handbook*, quality management is the process of identifying and administering the activities need to achieve the quality objectives of an organization. Thus, quality management will: support the quality operations required to stabilize, control, and improve the daily management system; develop, manage, and maintain the documented ISO9001 QMS; and facilitate the strategic quality improvement projects of an organization. In this chapter the activities of the quality function are defined and a set of roles and responsibilities for quality, both within the quality function, and across the organization are specified. This chapter is focused on developing and implementing strategy for the quality function while chapter six will discuss how quality concepts and its improvement projects can be used to shape the strategy of the entire organization to achieve competitive differentiation in its marketplace.

Introduction

The task of quality management is administration and supervision of all the quality activities of an organization so that they work consistently as a smoothly operating system. The need for an independent quality function occurs at a point in an organization's growth when it transitions from an informal teamwork approach into a formalized structure with distinct set of operating functions. A quality function leader is responsible for coaching business leaders in developing a formal quality organization that is capable of managing the administrative aspects of quality and also for supporting the responsible line organizations that deliver operating performance which achieves the customer-required quality outcomes through operation of its system of daily management processes. An organization's reputation for quality is a key ingredient in establishing its "brand value" in a competitive market. Customers build confidence and trust in an organization that is able to consistently perform and, when an incident does occur, rapidly respond by acknowledging the responsibility and correcting the situation in a way that minimizes the impact on customers. Brand value is built upon many performances of quality-saving activities which increase the satisfaction of customers.

Bad quality has an opposite effect - it misses the mark that has been set by customers. The original term for this is the word hamartia (Greek: *ἁμαρτάνειν* or *hamartánein*) which means "to miss the mark" or "to err." It is associated with Greek tragedy and refers to a tragic flaw which leads to a chain reaction that results in fatality which is a culmination that reverses good fortune. The error or flaw typically results from ignorance, wrongdoing, an error in judgment, or a flaw in character. Quality management systems (QMS) must be built on a strong foundation of Quality Assurance (QA) that protects consumers by maintaining the performance "on target" for their expectations. It is this consistency in "on target" outcomes that increases the value of an organization as perceived by its customers? So, how does an organization work to manage this type of outcome consistently?

Understanding Quality Management

Quality Management conducts its role as the assurer of quality for customers by focusing on customers in three ways:

1. Developing an understanding of what actually satisfied customers in the past (as a basis for creating improvement in processes that will protect these to quality characteristics – its QI function).
2. Developing an understanding of what is currently satisfying customers relative to the set of factors that define deliverable performance to customers (as a basis to assure that these quality characteristics are safeguarded and controlled – its QA and QC functions).

3. Developing an understanding of what will satisfy customers in the future (an activity related to planning for quality target-setting and establishing improvement projects that will deliver this performance – both the QI and QP functions).

Taken collectively, this emphasis on customer focus and aligning work to their needs describes the end-to-end process of quality management. In order to achieve these outcomes, a quality management must operate by:

- Managing the organization's quality function;
- Auditing the control functions at key decision points in the business processes; and
- Delivering assurance through communications with customers of conformance to quality.

Quality Management oversees all acts and tasks that are needed to maintain the desired level of excellence in the deliverables to customers and the processes by which these deliverables are prepared. This oversight includes determining a quality policy, creating and implementing the core elements of a quality system: QA, QC, QI and QP activities. These actions assure product quality achieves requirements of specifications and that process quality yields stable production, so operations are managed consistently within acceptable boundary conditions. In doing this quality management focuses on achieving long-term goals by implementing short-term improvement initiatives.

By performing these activities, quality management enables businesses to gain a competitive edge in its industry by obtaining a better understanding of those market forces influencing it and is therefore able to align with customer expectations better by creating what could be called an "imaginative understanding of customer needs" that allows it to deliver "attractive quality" based on innovative insights and adapt observations of intimate customer concerns generated through its engagements and thereby anticipate their evolving needs even when the needs are not fully understood by customers. Such a vibrant quality interface with customers enables the highest degree of competitiveness in market performance.

Figure 1 illustrates the way a systems approach to quality accumulates by merging all of the individual quality functions into a coherent system.

Figure 1: Merging Quality Elements into Quality Management as a System

However, a casual survey of these categories indicates that there are many quality activities that are not identified in this breakdown of Quality Management. What else should be included in Quality Management? Perhaps the most important activity that has not been highlighted in this system is Quality Auditing. Auditing is a very important activity that is required to assure an independent and objective viewpoint regarding the adequacy of a quality management system. Quality audits provide useful support to the quality function of an organization. Auditing provides an independent evaluation of the degree of compliance that a QMS has with its quality requirements. Typical approaches and policies that are embedded within quality audits:

1. Verification of facts and reporting to management.
2. Discovery of causes that have resulted in major deficiencies.
3. Offering recommendations for remedies to observed issues.
4. Reporting audit findings independently to senior leaders.

When an independent auditor conducts an evaluation of organizational processes, there are several areas that normally are featured in this type of independent audit:

- Products conform to specifications.
- Product compliance with requirements and are fit for consumer use and safe for users.
- Standards and regulations defined by authorities are being followed.
- Procedures are adequate to produce quality and are being adhered to.
- Data collection and management systems are accurate and provide enough evidence to make proper judgments regarding quality for all stakeholders.
- Deficiencies are identified, and corrective action is promptly taken.
- Plans for attaining quality in products, services, and processes.
- Opportunities for improvement (OFI) are identified, the appropriate people are alerted, and preventive action is taken.

There three types of audits that are conducted: quality audit, product audit and process audit. Each of these is described below:

Quality Audit: A systematic and independent process to gather objective evidence that will determine whether audit criteria are being met. Audits are based on a sample and are independent of the productive system, the operational quality activities function, process or product being audited, unlike verification activities, which are part of the process. This type of audit may be conducted by internal auditors from a superior quality function (e.g., the highest-level quality function of a medium-to-large-sized organization) or by professionals who are external to the organization from an independent auditing firm.

Product Audit: A quality audit which reinspects product characteristics that are critical-to-quality (CTQ) as they deliver performance that is critical-to-satisfaction (CTS) of the market-base of customers. The purpose of this type of audit is to verify the adequacy of acceptance and rejection decisions made within the organization's final testing station before shipping to customers.

Process Audit: A quality audit of production activities that can be performed in two ways. An engineering process audit provides a detailed assessment of all the technical activities in production to assure that they are performing according to their designed parameters. A process monitoring audit checks the managerial conditions and documentation of processes and assures that the workers are following their work instructions and operating standards.

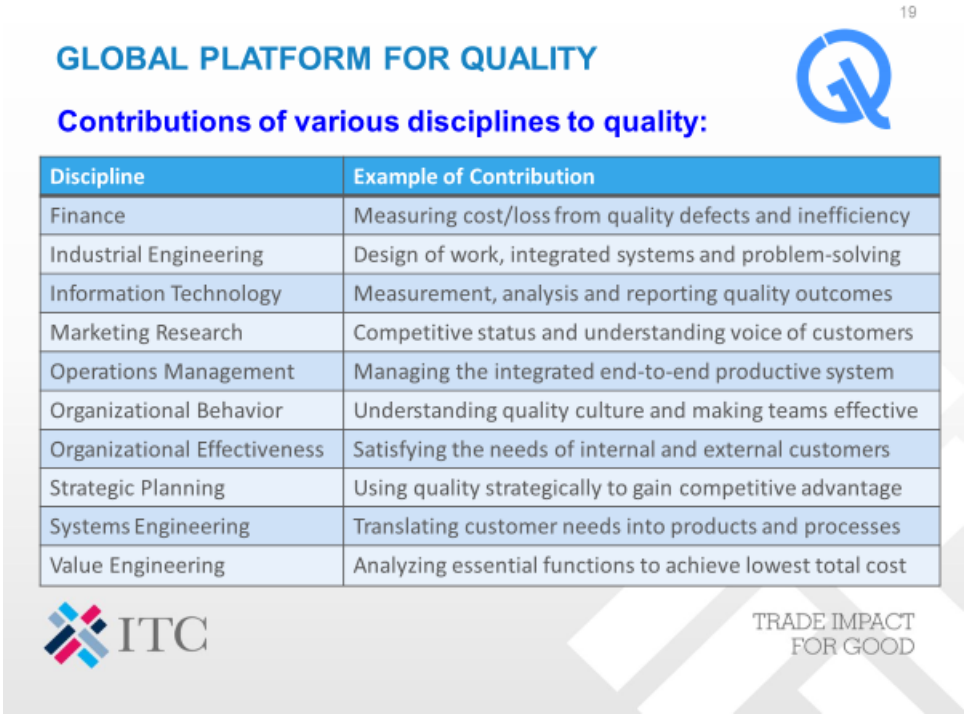
It should be noted that a Quality Audits differs significantly from a Quality Assessment. An audit focus on alarming conditions that indicate issues regarding conformance to requirements while a quality assessment surveys the entire business to identify unexpected business or operational threats as well as opportunities to improve and typically follows some performance criteria or questions that evaluate the business excellence of the management practices and its market performance. Assessments are typically conducted using a set of

criteria for business excellence such as those that are derived from the criteria used in national quality award programs.

Quality Management Manages the Organization's Quality Function

While most medium to large organizations have a formal quality function, it is important to note that many disciplines and various functions contribute in different ways to achieving a sound quality reputation among customers. Figure 2 illustrates some of these contributions.

Figure 2: Contributions to Quality from Organizational Functions



Discipline	Example of Contribution
Finance	Measuring cost/loss from quality defects and inefficiency
Industrial Engineering	Design of work, integrated systems and problem-solving
Information Technology	Measurement, analysis and reporting quality outcomes
Marketing Research	Competitive status and understanding voice of customers
Operations Management	Managing the integrated end-to-end productive system
Organizational Behavior	Understanding quality culture and making teams effective
Organizational Effectiveness	Satisfying the needs of internal and external customers
Strategic Planning	Using quality strategically to gain competitive advantage
Systems Engineering	Translating customer needs into products and processes
Value Engineering	Analyzing essential functions to achieve lowest total cost

To start this discussion about what activities should be performed in the quality function of an organization, let's first focus on when an SME needs to develop a formal quality function. It is clear than when an organization is a micro-enterprise (less than 10 people) that quality needs to be the responsibility of everyone and that there is not enough resources to warrant having full-time expertise running just a quality function. However, as an SME grows and evolves, at a certain point, it requires the development of a functional structure in order to obtain a better control over the work that is being done and to help with employee development in each of the particular core skills related to each function (typically starting with operations, finance, sales and marketing, and product development). As this functional organization evolves further there emerges a need for support functions (e.g., information systems, human resources, and quality management). This point typically happens sometime after an organization has grown up to 50 or even 100 employees. This number is flexible depending on categories of work that is being done and the complexity of the operational function. Once the decision is made to create such a function then two questions emerge: what should this function do in terms of responsibilities and how should it be staffed in terms of skills and competence?

The functions of an "ideal" state of a quality department as an organization migrates toward a medium-to-large size commercial operation could include such activities as:

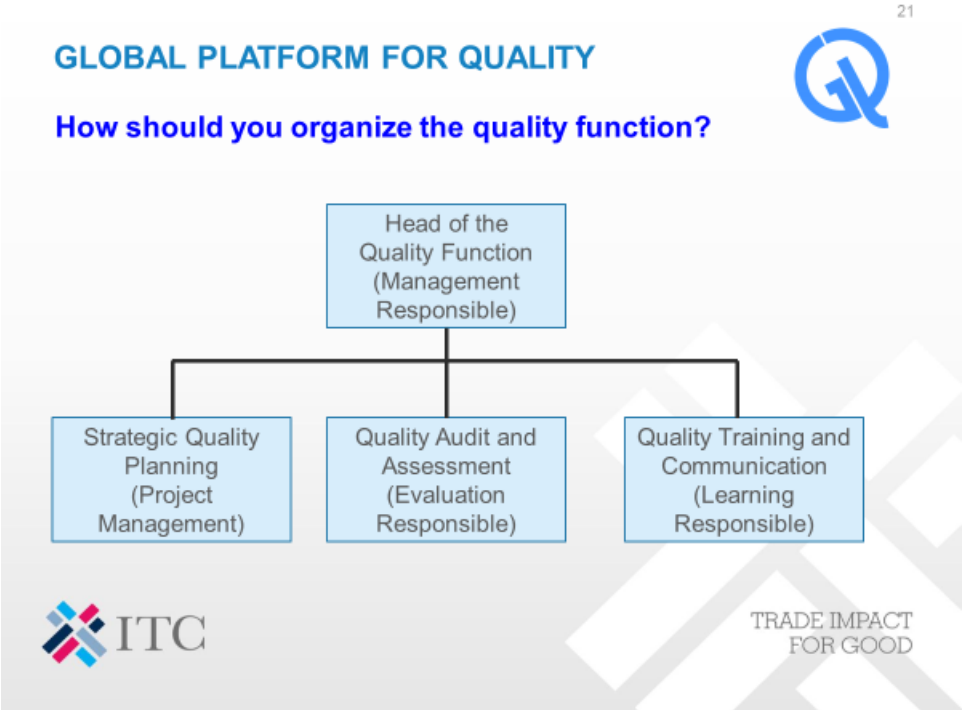
- Company-wide quality planning (operational and strategic)
- Establishing quality measurement systems (integrated bottom-to-top)
- Auditing out-going product quality
- Auditing internal process quality
- Coordinating and facilitating quality improvement projects
- Participating in supplier partnerships (auditing, assessing, and training)
- Training in quality methods and practices
- Consulting on quality applications across business functions
- Coaching business leaders on quality-related matters
- Developing and integrating new quality methodologies
- Transferring quality functions into responsible line organizations

Competence areas that need to be addressed in an embryonic quality organization when the size of the whole organization is less than 50 people? The initial competence areas that are needed include the following capabilities:

- Conducting required operational and final product inspections prior to shipment.
- Conducting required technical tests and inspections that assure product quality for markets.
- Facilitating product, service, and process-based improvements and problem-solving.
- Developing basic quality process descriptions and process structure for work instructions.
- Performing data collection, analysis, and reporting tasks of recorded quality information.

When the firm grows much larger, then the quality function needs to expand. Figure 2 illustrates the organizational structure that should be sufficient for an organization that is servicing a mid-to-large size firm (well above 100 employees).

Figure 3: Management Structure of a Sample Medium-to-Large Size Quality Function



Activities of the quality function in a more mature quality organization would include assisting senior management with strategic quality in the following ways:

- Developing quality strategies to increase revenue and decrease costs.
- Formulating actionable policies and goals.
- Delegating organizational responsibilities for quality.
- Assessing effectiveness, efficiency, and economics of the quality system.
- Reviewing progress on product and process quality improvement projects.
- Managing quality reward and recognition programs.
- Determining and coaching senior managers in personal quality roles.
- Facilitating organizational quality council or quality steering committee.
- Establishing quality agenda for senior management meetings.
- Integrating quality activities into the strategic business planning cycle.

As organizations grow into requiring this type of strategic quality function, then its needs will go beyond having an individual who is competent in managing the technical skills required for inspection, testing and certification. Some of the qualifications that are required for success as a leader (at the manager level or higher) in this type of advanced quality function include:

- Focus on customer orientation, satisfaction, and advocacy.
- Ability to establish collaborative relationships across functional boundaries.
- Goal orientation.
- Political astuteness.
- Good oral and written communications to encourage information sharing.
- Ability to analyze complex situations and generate innovative plans.
- Ability to organize activities and projects.
- Initiative, perseverance, and self-confidence to drive improvement activity.
- Ability to develop subordinates and mentor employees.
- Ability to teach complex topics to non-technical people.

As organizations mature into this type of structure, then the role of executives needs to be a little more focused than just monitoring the daily management system. What should be this evolving quality role of the senior management?

- Setting policy for strategic direction by applying quality to achieve business differentiation and competitive advantage.
- Allocating resources to eliminate systemic quality problems that have been detected in the daily management system (e.g., as “chronic issues”) and assuring that the front-line team has sufficient capability to apply timely corrective action and countermeasures to problems.
- Encouraging a constant state of alertness is maintained within the organization to detect any opportunities for improvement and act upon those that will make a material difference.
- Establishing an example for the organization by paying attention to efforts at improvement of the business through participation as a sponsor of operational and strategic projects.
- Prioritizing customer relationship information, safety results, operational process data on efficiency and effectiveness, and product quality statistics at the same level of management attention and interest as the financial measures of performance.
- Serving internally and externally as the visible purveyor of the organization’s quality culture.

If this is the role of the executive in charge of the organization, then what should be the quality role of middle managers in the organization?

- Nominating quality problems for solution within their scope of the organization.

- Serving as leaders of cross-functional quality improvement teams and also leading kaizen efforts within own functional area of responsibility.
- Participating as a member of quality teams in related areas that are in its process chain of operational activities.
- Working on task forces to assist the cross-functional quality council or quality steering committee in developing focus areas for improving the organization's quality strategy.
- Leading the quality activities in their own area, encouraging supervisors to pursue quality improvement efforts, and demonstrating a commitment to quality through supportive activities and personal communications to workers.
- Identifying customers and suppliers of their work area and meeting with them to discover their needs then pursuing activities that will meet any of their needs that are unfulfilled.

It has regularly been observed that most quality problems are either management or system controllable. It is the responsibility of management to place workers in the situation where it is possible for them to exercise self-management (or self-control) over all the work processes that they use. So, what remains as the quality role of the individual worker? Consider this list:

- Nominating quality problems for solution from within their own process area.
- Identifying elements in their own jobs that need improvement and suggesting opportunities for improvement to their supervisor.
- Serving a member of quality teams for solving problems or developing improvements.
- Becoming more knowledgeable about their jobs and also developing expertise in related activities in their work area thereby expanding their skill and competence to increase their ability to provide valuable contributions to the organization.
- Contributing innovative ideas about how improvements for safety, quality and productivity can be made in their work.

Quality Management Manges Routine Control Functions

As a quality organization matures, it takes on a broader responsibility for managing and then improving the business controls of the organization – the set of process controls that determine the current and future enduring success of the organization. So, what exactly is the set of quality activities that are related to an organization's business controls? First, we must identify what an organization's business controls are and how they operate. Business controls include those restrictions that control the financial, legal, regulatory, safety, and decision rights. Constraints may be placed upon these various subject areas to assure there is no waste, fraud, or abuse, and assure that processes will comply with laws, regulations, standards, and policies that are applicable to the industry and nation. Business controls may be:

Visual: Reminders that people can observe in the workplace and raise a flag when work processes deviate, or people fail to remember and cause people to focus on correcting the situation. Visual business controls can include checklists, dashboards, budgets, and such forms of measurements as scorecards.

Procedural: Work instructions or procedures, such as Standard Operating Procedures (SOP) must be followed to assure compliance with the rules that guide operational conduct. This typically is addressed using what is called a "two-person rule" where two unrelated parties check to assure proper actions are taken.

Embedded: These are controls that work without human intervention such as data back-ups that have been automated or financial controls that operate in the deep background of the organization's information management processes.

Business controls are often embedded into the planning systems of an organization as a means to assure the uninterrupted flow of productive processes and will attempt to optimize the productive capacity of manufacturing operations. These controls permit the proper scheduling of production equipment so that idle time and overuse are equally avoided. What planning controls are applied in the productive processes of business operation and how does quality improvement relate to the management of these control ? Some production controls include:

Safety Stock: Additional production materials that are ordered materials that are beyond the demand required for production but are maintained “just-in-case” they are needed to replace defects for quality or manage unexpected production increases.

Lead Time: The advance time required to order materials before they can be delivered.

Buffer Inventory: Excess inventory maintained between the steps of the production process.

Standardized Material: Limiting raw material of a commodity to consumption of a limited range of quality specifications.

Production System Design: A process for designing measurement control systems and their corrective action feedback mechanisms into the production process.

Production Policies: The set of policies that govern execution of the end-to-end production system for management of human workers, production materials, and the equipment used in operations and testing.

Just as an organization maintains controls over its business system elements and its production processes, it also maintains controls over the deliverables that this system produces. The set of production controls assure that product specifications are managed within limits that have been demonstrated to work properly during R&D development and testing. Quality-related product controls are typically fixed in the production process to assure incoming, in-process, and outgoing quality is achieved at the desired level of performance. What are the product controls that are operated within a quality management system? Examples of product controls include:

Preferred Supplier Qualifications: Identifying and approving suppliers of parts, materials, or services that have been demonstrated to possess the ability to meet production demands for quality, cost, and delivery responsiveness.

Control Parameters on Part Specifications: Measured test items that need to be produced exactly to requirements and whose control must be demonstrated through inspection or testing the records of which must be maintained at the source of supply, testing, inspection, or production.

Incoming Raw Material Inspections: Inspections made of critical control parameters when they are received at the production facility.

Control Points in the Productive Flow of Manufacturing Processes: Locations within a production process where control parameters are tested in order to assure compliance and to demonstrate quality progress – this occurs at check points or control points.

Process Controls assure that end-to-end productive processes have capability to deliver their specified performance. Such controls may be automated through application of sensor systems with computer-controlled feedback loops or by simple manual tests that may be executed with hand measurement devices.

What quality-related process controls are used in across a business system? Examples of process controls include:

Operator Go/No-Go Testing: Use of measurement gauges to demonstrate maximum and minimum dimensional performance boundaries for mechanical parts.

Engineering Process Control (EPC) Systems: Fixed-control mechanisms that are “hard-wired” and built into the production process for controlling settings of automated manufacturing equipment.

Computer Numerical Control (CNC) Systems: Software-control mechanisms programmed as instructions to guide repeatable machining in computer-aided manufacturing (CAM).

Design for Manufacturability and Assembly (DFMA) Methods: The smart controls that have been designed into part specifications (e.g., color-codes or the use of designs that assure the parts are only capable of assembly in single way).

Finally, people controls can be established to assure that the human aspect of production is managed in the most consistent manner. What quality-related people controls can be applied across a business system? Examples of such controls include:

Recruiting and Selection Process: The process for obtaining workers that possess the full set of required skills and knowledge.

Training and Development Process: The educational and experiential process of advancing the state of worker performance through on-the-job training or supplemental education.

Skill-based Certification or Qualification Process: A training process for specific work-based skills required on-the-job with achievements of standard levels of performance tested using demonstration tests (e.g., welding or ability to perform specific reliability tests).

Standard Operating Procedures: The documentation of the “one-best-way” to perform the work tasks of production operators which then becomes the required way to perform that job for all employees.

Mentoring Process: A personalized coaching process in which senior leaders provide one-on-one career, managerial, cultural, and technical guidance to junior workers.

Recognition and Promotion Criteria: The criteria for recognizing, promoting, and rewarding workers for producing desirable outcomes in their jobs.

All of the above control elements: business, production, product, process, and people control mechanisms are managed through operational functions, not by the quality function. It is the job of the quality function to provide assistance, consultation, and support in establishing these controls, working with the responsible organizational managers. Effectively implementing these controls will result in an organization that is able to follow-through on delivering its quality assurance marketing claims to its customers and thereby build trust and brand value.

Quality Management Delivers Assurance to Customers

Developing more intimate relationships with customers is a "secret ingredient" for sustainable success. Creating an "Imaginative understanding of customer needs" can assure that current needs, emerging needs, and "latent" or future needs can be characterized, understood, and included in the design of the products or services that are delivered to them. This "deep empathy" that is developed with customers can be purposefully created by establishing clear communication pathways with targeted customer segments to gain insights about their points of view and concerns. How does the quality function help to manage customer relationships? Examples of some mechanisms to achieve this objective includes:

Major Account Teams: Marketing teams that are assigned to create relationships with these key customers and their principal contacts; discover unexpressed needs of customers; and deliver focused service and attention to those critical customers whose purchases dominate the organization's sales.

Customer Executive Advocates: Assigning senior executives to develop close personal relationships with the executives or leaders of its major accounts so they have open access to the company for communications of both negative and positive experiences.

Customer Members Included on Design Teams: Inviting key customers to advise product development teams on requirements and performance creation and to become engaged in the testing of pre-production products.

The idea behind "customer advocacy" is that the organization has created an internal function or role in which a company representative assumes the role of a customer and interprets the company's way of doing business from that perspective. In this role the advocate monitors design, production, service, and the end-to-end process of customer relationship management to "speak for the customer" and complain about lack of responsiveness or make suggestions about how to improve the organization's processes from the customer's perspective. Often it is the senior manager in the quality function who is tasked with acting as an advocate on behalf of consumers. A few examples of actions that could be taken in assuming this role include:

Reviewing Specifications: Analyzing product specifications or guarantees of service from the customer's perspective for adequacy of performance level; appropriateness of the band for performance margins; and performance notification alerts.

Reviewing Communications: Reviewing user documentation to assure clarity in the message conveyance.

Reviewing Customer Interfaces: Assessing the way that customer touchpoints operate and assuring that the performance of information interfaces meets the customer's expectations for simplicity and ease of use.

Finally, the quality function is usually tasked with development the "customer scorecard" or "customer dashboard" as a way to to focus on the way that a company performs at "customer touchpoints" across its end-to-end customer engagement process. How must customer-related quality performance be measured? Some examples of measurements that can be taken for understanding customer-related quality performance include:

Customer Satisfaction Survey: This survey directly questions customers about their level of satisfaction with products and services. The survey should include cross-checking questions such as: willingness to repurchase; and willingness to recommend; as well as willingness to engage again, if history could be reversed and the initial procurement decision revisited. These questions only mark intent on behalf of the customer and must be compared with the customer's actual behavior – do they repurchase and recommend? Note that a popular metric is not included here: Net Promoter Score (NPS). This exclusion is purposeful as this type of satisfaction-based metric ignores the opinions of a large segment of customers but I is this segment

whose trend in satisfaction actually dominates in the future potential of the organization to maintain its customer relationships. All customers must be counted.

Customer Complaint Analysis: Complaints made by customers should be analyzed according to the type of complaint and by specific product to evaluate trends in those things that are most important to customers.

Field Failure Reports: Reports of customer returned products, product failures in the field, and warranty claims should be analyzed to determine if there are patterns or trends.

Customer Return Analysis: Analyze customer product returns to assess the reasons for returns and determine how to improve performance to assure more satisfied customers.

Lost Sales/Bid Analysis: Analyzing the performance on competitive bids and proposals should be done to determine why the company lost bids and sales and what it can do to fix these problems and increase its win-loss ratio.

Concluding Comments

This chapter has concentrated on organizing the quality function, so it supports a growing task of assuring the delivering quality characteristics in products and services to customers who are increasing in size and importance in an expanding business environment. While this is a primary responsibility of the quality function, it does not define the full context of what is required for a quality executive to move beyond the "management of a quality strategy" to driving the firm in an approach that delivers "quality as a strategy." To understand this final aspect in the modern dimensions of quality will take study of the final chapter which is titled "Managing for Quality."

References for Further Study

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Frank M. Gryna (2001), *Quality Planning and Analysis*, 4th edition (New York: McGraw-Hill).

Review Questions

After reading this chapter and reviewing the related presentation in volume two, take the following quiz to review your knowledge and understanding about quality management and how it contributes to developing continuing success in market performance.

1. The thinking foundation of quality management is based on the discipline(s) of:

a. Process Thinking

b. Statistical Thinking

c. Both (a) and (b)

d. Neither (a) nor (b)

2. Quality management is the process of identifying and administering the activities needed to achieve the objective of an organization.

a. True

b. False

3. What is the most basic foundation for a Quality Management System?

a. Quality Assurance

b. Quality Improvement

c. Quality Planning

d. Quality Strategy

4. Quality management focuses on the customer by asking three questions:

a. What did satisfy customers in the past?

b. What is currently satisfying customers?

c. What will satisfy customers in the future?

d. All of the above.

5. Quality Management operates by:

a. Managing the organization's quality function.

b. Aligning financial management methods to quality management methods.

c. Designing information technology systems to assure proper data storage.

d. All of the above.

6. Quality Management focuses on achieving:

a. Short-term goals by implementing long-term initiatives.

b. Long-term goals by implementing short-term initiatives.

c. Both (a) and (b).

d. Neither (a) nor (b).

7. Quality Management assures the delivery of a desired level of excellence to customers.

a. True

b. False

8. Quality Management takes a systems approach which includes:

a. Quality Assurance

b. Quality Control

c. Quality Improvement

d. All of the above.

9. Which of the following statements is most correct?

a. Quality Audits are on behalf of management to verify facts relating to production.

b. Quality Assessments examine work process detail for compliance to standards.

c. Quality Audits typically apply Business Excellence criteria for their checklists.

d. Quality Audit findings are reviewed by functional managers for cost-effectiveness.

10. Auditing methods included in Quality Management include:

a. Quality Audit.

b. Product Audit.

c. Process Audit.

d. All of the above.

11. Quality disciplines have been drawn from many various fields.

a. True

b. False

12. One way to organize the quality function is to have different areas of responsibility, including:

a. Strategic Quality Planning

b. Quality Audit and Assessment

c. Quality Training and Communication

d. All of the above.

13. Quality-related controls include the following categories:

a. Business Controls.

b. Product and Process Controls.

c. People Controls.

d. All of the above.

14. Measurements used for evaluating customer-related quality performance include:

a. Profit generated by customer segments.

b. Customer satisfaction and complaint analyses.

c. Analysis of market share by industry category.

d. All of the above.

15. Customer advocacy is an internal company role whereby an executive “speaks for the customer.”

a. True

b. False

CHAPTER 6 – Q106 – MANAGING FOR QUALITY

Abstract

Juran created the term “Managing for Quality” and he defined it by saying that “Managing for Quality” is accomplished by the exercise of the three quality management processes of planning, control, and improvement. However, this concept has been expanded greatly when considering the growth and maturity of quality thinking over the past half century. Today this phrase describes a much broader and higher level of quality engagement in the management processes of the organization than it did in 1988 when Juran described the process. The purpose of this final chapter is to describe a broader view of “Managing for Quality” where quality becomes the focal strategy that differentiates an organization in the marketplace and enable it to achieve not only market access for trade but enables competitive market success.

Introduction

Managing for Quality describes a system of managerial activities that are essential to assure long-term sustainable quality of an organization and achieve innovative competitive advantage in its future. By using this approach, over the long-term, quality becomes elevated from being a limited operational activity that assures consistent delivery of quality products and services to customers and is transitioned to a strategic approach to assure organizational competitiveness and provide for a successful future in its global marketplace.

This application of quality in strategic business planning crates improvement projects that are executed to achieve critical breakthroughs in business results. When an organization operates at this level of performance, it becomes highly competitive in its international market based as judged by the level and consistency of its operational performance and the quality of goods and services that it delivers to customers. When an organization adopts quality as its strategy as the means for differentiation from its competitors, then it develops an ability to sustain results as it marries its quality approach to its business requirements for successful financial performance that will permit it to endure successfully as an organization.

To achieve this type of alignment requires a blending of two perspectives of quality activities: the internal or largely operational viewpoint with the external and largely business viewpoint. These two perspectives for thinking about quality can be summarized as follows:

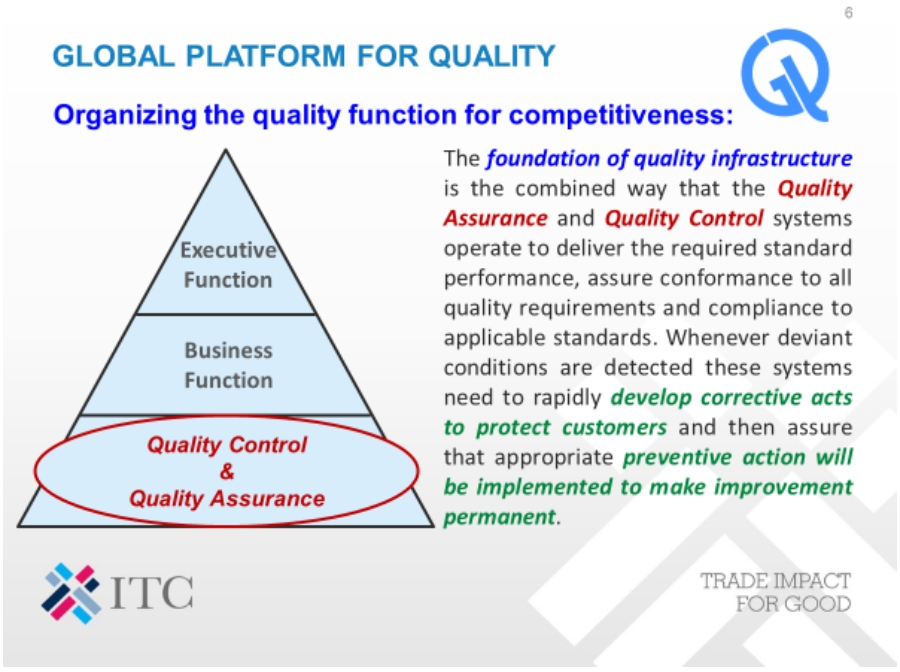
Internal Viewpoint (Operational): Operationally focused quality interprets quality with respect to company targets focusing on: performance to specifications where products are evaluated at final inspection, and defects are prevented in productive processes or during warranty periods. In this perspective emphasis is placed on manufacturing quality where the metrics of performance relate to bottom-line cost and internal indicators that drive cost. During this internal perspective quality is considered a technical issue that should be managed by a functional manager or the responsible process owner.

External Viewpoint (Business): Strategically focused business quality accommodates the perspective of external customers and competitors by comparing how the deliverables to customers rank for customer satisfaction against the best that its industry has to offer. In this approach performance of deliverables is evaluated over the full product lifetime that is experienced by customers (beyond warranty periods). Both current and latent customer need must be met or exceeded as judged by customers. To achieve this outcome, all of the organizational functions must contribute to generating quality as measured in terms responsive to customers so that quality becomes a business issue that engages significant executive energy for oversight and leadership. Figure 1 illustrates how this structure is deployed in an organization.

Figure 1: Organizational Structure of Managing for Quality

At the base of this organizational triangle, the functions of quality assurance (QA) and quality control (QC) are focused. When an organization is unable to deliver these basic functions then it violates the accepted norms of commercial engagements and encourages consumer complaints and punative legal action which may require consumer protection. Figure 2 illustrates how QA and QC engage the base of this organizational triangle. Together they form the foundation of a comprehensive quality management system.

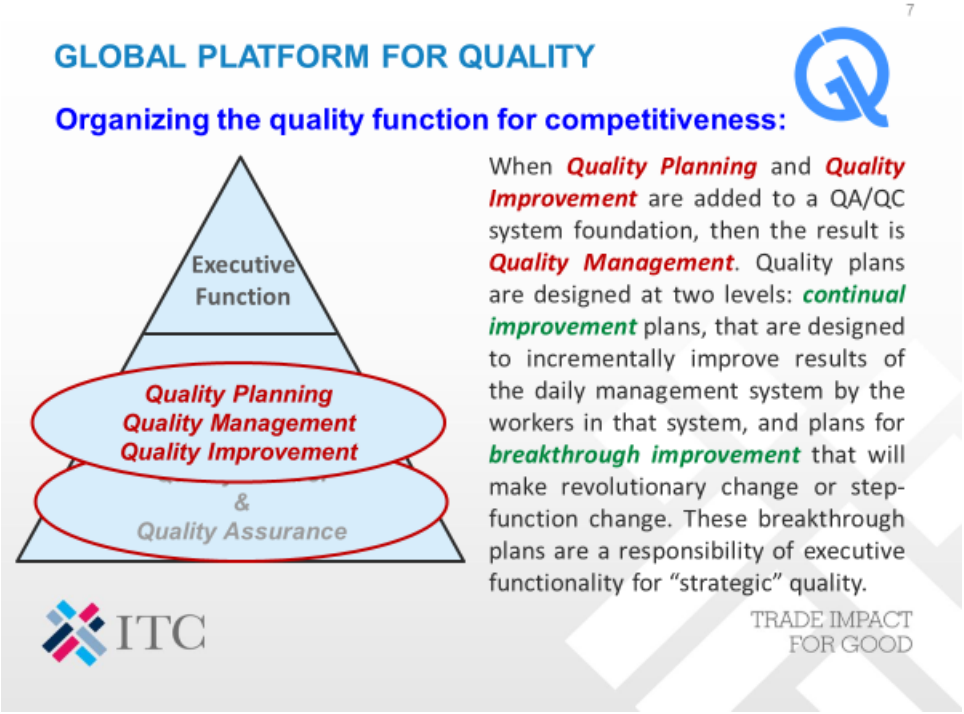
Figure 2: QA and QC are Addressed by the Operational Functions



QA and QC activities assure that customers do not experience intolerable issues in their daily experience with an organization's deliverables. They also assure that the organization has an ability to deliver stability in this performance over time so that the foundation for a reliably performing brand may be established. These activities formulate a proactive approach for the delivery of quality results to customers. If this is not possible to achieve, then this indicates that the organization's daily management system is chaotic and that it does not possess an intimate understanding of their customer's needs. The priority of an organization in this type of situation is to develop a robust and resilient quality management. This requires creating a profound level of knowledge about customers "deep empathy" that understands their experience as well as the needs that it creates for their products and services. The first steps in creating an enduring quality capacity is to gain a profound and imaginative understanding of the environment of the customer and to discover how their own products and services can work to the benefit of these customers.

Once this has been secured, then the organization is able to focus on developing maturity that will lift it to a more elevated quality competence as shown in Figure 3.

Figure 3: The Business Functions of Quality Drive Improvements



When quality is elevated from the operating level to the business level, then it ceases to be merely a quality function and transitions into a management system. In this area quality is not just controlling outcomes and stabilizing output, it is also seeking improvement through one of two means which are facilitated by different types of planning functions. The improvement of the organization can occur through planning for incremental improvement (e.g., kaizen events) or through planing for breakthrough or revolutionary improvement (e.g., hoshin projects). Each of these types of improvement contains a "quality planing" element.

In a kaizen event type of evolutionary improvement planning seeks to squeeze out process waste, loss and inefficiency through the use of lean methods which are steered to the most effective opportunity for improvement using statistical analysis of the value stream's process flow. This planning will be constrained to improvements within the bounds of current resources (e.g., limitations on the number of employees and the

expense budget available for funding change). Thus, this type of improvement is within the capability of the normal production planners and process owners are able to authorize the improvement without any further management review as the change is within their "terms of reference" for their function of managing the particular process.

In the breakthrough or revolutionary planning that marks the preconditions for a hoshin type of improvement project, the planning requires engagement of the senior management decision-makers as they will need to provide the financial resources to enable the change and will also be the bearers of the risk if the project fails to deliver or the organziation suffers any losses. It is therefore a requirement of such a project that it have an executive sponsor from the business area that oversees the process so they can act as a champion to assure that desired business outcomes are achieved through the change project and resource investment.

Figure 4 shows how this strategic shift in focus changes the quality concentration from the QMS type of focus to a strategic focus which will be called "Managing for Quality:"

Figure 4: Driving Strategic Quality Outcomes by "Managing for Quality"

Managing for quality seeks to steer the organization by applying the quality culture in the way a rudder is applied on a boat – to cause it to move in the desired direction. The raison d'etre of most organizations is to fulfill some external need that is presented by society. This activity is typically conducted based on the priciple of economic exchange whereby one organization trades or exchanges its beneficial outcomes (e.g., some form of output deliverable such as the goods, products, or services that result from its labors) in order to receive something of value in exchange (e.g., goods or services of equal value or monetary compensation which takes the place of bartered goods).

Thus, trade forms the bi-party seller-buyer relationship that is at the foundation of the ISO9001 Quality Management System. As organizations move from their local delivery of goods and services to national or global exchanges, the need for quality assurance of the deliverables becomes more imperative. This becomes

especially true as goods and services are exchanged across global borders where the relationship between seller and buyer becomes more complex and convoluted and therefore, the assurance of quality at the source transitions into a dominant theme in the trade relationship. How can this type of arrangement be started?

How can quality energize global trade performance? Organizations typically initiate their path to developing global trade with a quality strategy to deliver consistency in product and service performance. Thus, the starting place for energizing trade relations is with developing product and service quality that meets market minimal needs. In practical terms this means that wherever possible products must be tested to demonstrate their conformance to standards and that organizations must certify their quality management system to demonstrate that it meets minimal requirements. This is the reason why many companies start their quality journey by making investments in ISO9001 certification and buying required test equipment.

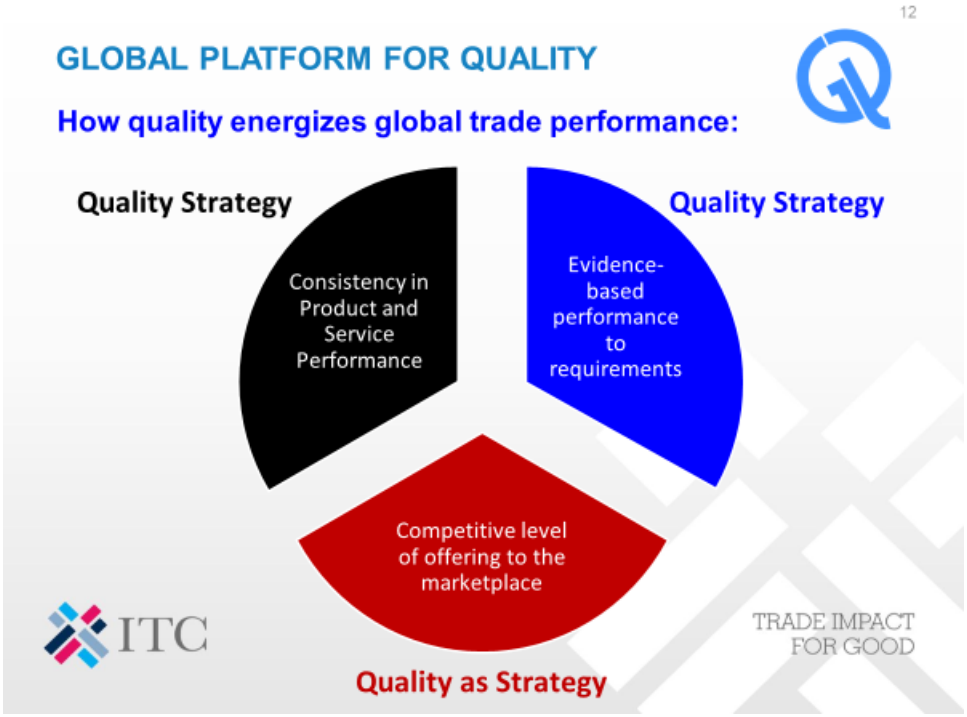
the trade expands and the organization grows and matures in its quality experince it expands its quality strategy to achieve evidence-based performance to requirements through imporved inspection and testing methods. The next phase in developing a quality strategy is to deliver objective evidence of performance to requirements that is capable of demonstrating that products are equivalent to industry global norms. This step requires investment in enterprise-wide information management systems so they can monitor sales, complaints, field failures, etc. This enterprise-wide software does not need to be expensive or complex, but it must provide the business leaders with necessary information to permit them to manage work and to improve performance.

As an organization reaches full maturity in its quality approach it shifts toward treating quality as strategy by applying customer insight to build a more competitive offering that is capable of extending its marketplace. How does this transition occur?

After the internal quality competence of a company has been established through the design and execution of QA/QC and CAPA into a functional QMS, it is essential that the company demonstrate that the output of its goods and services are competitive in those global markets where it chooses to complete. This aspect of quality requires an upgrade of goods and services in a visible manner to customers. This differentiation of an organization's deliverables must be so transparent that customers can accept the fact that the products and services it offers in the marketplace are superior to previously available competitive offerings and that these new offerings are "worth what they paid for it" with respect to their other purchasing options. Often a new market entrant will complete on price, but this can only initiate a price war. It is far more productive to compete on quality by providing "attractive" features which motivate purchasers to buy because they appreciate the "charm" of the deliverable and its price-point is not outside their tolerable region for spending (e.g., "price tolerance).

When this type of quality marketplace differentiation becomes the competitive advantage of a company, then it creates a brand reputation that stands on its own and becomes recognizable over the long term as delievering products and services that are immediatly identified as both excellent in features and performance as well as valuable with respect to price-for-benefits. Generating this nature of quality reputation ensures that a company's market position will become sustainable. Figure 5 indicates these three states in transitioning from basic quality as the consistency of outcomes of quality products produced in predictable processes to evidence- based performance to requirements and then to competitive quality that permits buisnesses to endure in expanded marketplaces where the competition is more fervent.

Figure 5: Transitions Required to Shift from Qualty Strategy to Quality as Strategy



This transition from quality strategy to strategic quality identiifes the shift in style of a quality management system as the focus expands from quality management to qualty development. As quality strategy requires implementation of a Quality Management System, likewise developing “Quality as Strategy”requires a transformation – creating a Quality Development System. What does this mean?

Quality Strategy: An organization’s quality strategy collects tasks, projects, and ideas to maintain its current state of customer-deliverable quality at its targeted performance levels and within acceptable tolerance limits. This activity defines an organization’s routine quality work.

Quality Management System: Quality management conducts routine planning, coordinating, scheduling, developing, implementing, and assurance functions that execute the organization’s quality strategy. This management function engages mid-level managers in product, process, and service quality improvement activities.

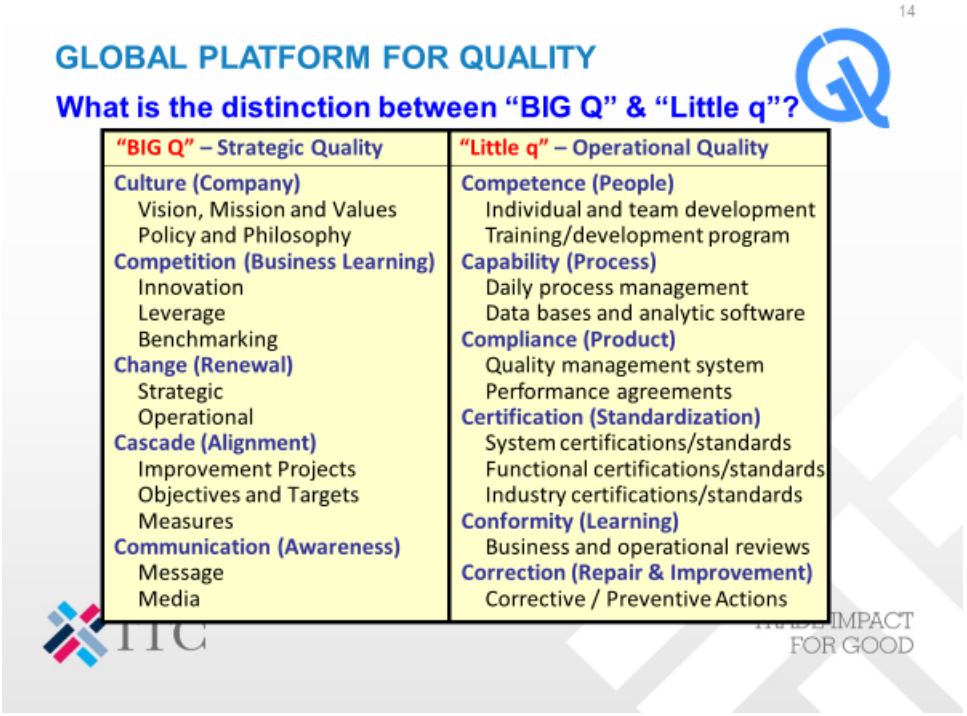
Quality as Strategy: When quality is developed as a “strategy” in organizations, it prepares an organization for a future by pursuing sustainable competitiveness. The focus is on designing quality so it will be capable of delivering the long-term expectations of customers and defining an approach to meet these goals.

Quality Development System: Quality development manages the strategic alignment of routine management resources for continual improvement of organizational performance as combined with capital investment to achieve breakthrough-type improvement as an integral part of the organization’s strategic plan. This activity is directed by senior management and executives and it aims to redesign the organizations productive systems so they can attain higher performance.

One way of understanding this expansion in the focus of an organization’s quality approach as it matures is to use the analogy established by Joseph M. Juran where he compared “BIG Q” with an alternative he called

"little q" for quality emphasis. Organizations typically commence their quality journey by concentrating on the "little q" factors that are identified in Figure 7 and then shift toward the "BIG Q" factors as they embrace "quality as strategy."

Figure 7: Characteristics of "BIG Q" and "little q" Types of Quality Emphasis



The key distinction between "BIG Q" quality activities and those of 'little q" is that 'little q" manages the operational performance of current products, services, and processes and also managing the quality function. "little q" quality should not be where executives of medium-to-large businesses should focus their efforts. On the other hand, "BIG Q"manages the quality development of the future state of the organization in order to build its market strength and create the potential for enduring success. The emphasis of "BIG Q" is placed on managing for qualty results and positioning the organization as an industry leadery by incorporating quality as its market-differentiating strategy. Delivering profitable growth in the future is the job of the executive function and this is the way to engage senior management in paying attention to quality as a developmental issue to build organizational strength. So, what are the "BIG Q" and "little q" performance elements?

The "BIG Q" strategic quality effort of management focuses on building a sound quality culture and infrastruture by concentrating on "Managing for Quality" and this includes developing the processes and programs related to the following topics:

- Purpose, mission, vision, environment, and values
- Management guiding principles, and assumptions
- Top-level structural design, and accountability
- Business system, core processes, and ownership
- Business measures, benchmarks, and targets
- Compensation structure
- Communication and education

On the other hand, “little q” conttributes to the quality program by focusing on the strategic content of quality in its application within the local operational organization where its efforts are concentrated upon:

- Deploying strategy, objectives, and strategic projects
- Development of Products and Markets
- Strategic resource allocation and alignment

However, in a mature organization both “BIG Q” and “little q” emphases must be concurrent as it is the collective strength of these in combination which delivers “strategic quality.” What is the contribution of all these efforts to “Managing for Quality”? How can this be summarized?

Quality Management: a process of identifying and administering the activities needed to achieve the quality objectives of an organization.

Quality Planning: an activity of developing products and processes required to meet customers’ needs through continual improvements or breakthroughs.

Breakthrough Improvement: improvement projects making step-function changes in major, cross-functional activities that are formally designated by management and assigned a full-time project manager to implement new generation technology in products or processes or systems.

Quality by Design: the process of designing for higher levels of performance than current capability by engineering the future products and processes of an organization to achieve “stretch” quality performance goals. The concurrent design and development of product and process capabilities to deliver market advantage over competitive offerings.

Quality Planning: an activity of developing products and processes required to meet customers’ needs through continual improvements or breakthroughs.

Collectively this system should be described as “Quality Development” as illustrated in Figure 8.

Figure 8: Elements of the Quality Development System

Understanding the Maturity of Quality Development

If improvement is not driven by senior managers, then the natural law of entropy will prevail, and systemic degradation will occur.

Development of quality maturity is an evolutionary process of management in which an initial foundation is built upon structured processes as the starting point. The next stage to advance in maturity occurs when process analytics are introduced, and full maturity occurs when the entire end-to-end organizational system has been integrated to achieve business excellence. Thus, all of the efforts at establishing a quality program begin with learning how to "manage by process." An operational definition of the ten maturity levels that organizations evolve through is shown in Figure 9. This maturity journey follows three phases: first, the process foundation phase; second, the process analytics phase; and third, the system integration phase. As each of these phases is completed the organization makes progress toward a goal of achieving business excellence.

Figure 9: Levels of Maturity in the Sequence of its Quality Development

Organizations should use this maturity scale as a guideline for advancing their quality capability; building structural capacity for process working; and implementing improvements to their quality system. Each level of this maturity scale must be completed before advancing to the next level to assure that the system is sound from the base to the apex. Failure to fully integrate these methods will create structural weaknesses within the quality system and this will inhibit the organization's abilty to create a mature program for its Quality Development.

Quality by Design

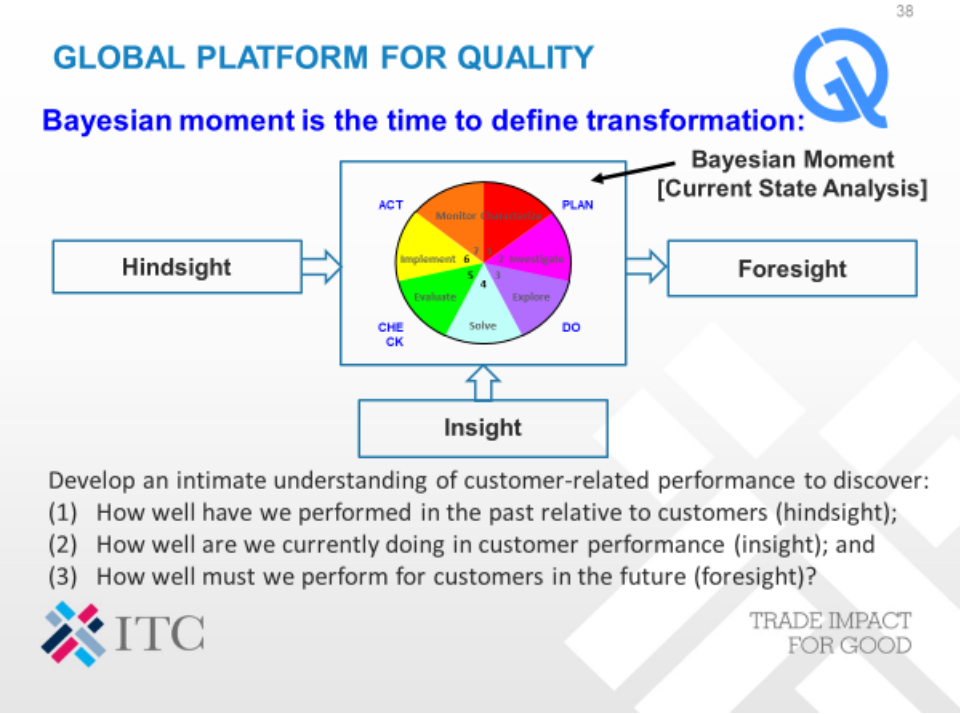
Quality by Design is a systematic approach that begins with predefined objectives for creating product and process understanding to assure process control in the follow-on production phase. Quality by Design is based on sound principles of science and quality risk management and it includes:

- Targeting the product profile so it provides a quantitative objective for the design outcome.

- Collecting relevant prior knowledge and using risk assessment to prioritize knowledge gaps for further investigation.
- Designing the product and production processes concurrently to meet the most critical of customer requirements.
- Testing products in their ultimate environment to the point of failure so that the product's weaknesses may be revealed and corrected before release to the market.
- Establishing a control strategy and plans for the entire process to anticipate increases in scale and market breadth in a manner that is guided by objective risk assessment.

Creating a sound Quality by Design capability requires a transformation in most organizations. This creative insight comes after an organization makes a serious inquiry into its past shortfalls in creating new products and services along with the processes that deliver them. From this hindsight an organization gains insight into what changes must be employed to develop a more innovative approach. The Continual Improvement Process (CIP) can be applied for analysis of this current state (which is called the Bayesian Moment in Figure 10 below). The Bayesian Moment is that current period of time in which the future performance is developed given the events in the history of the past performance of the organization. Exercising CIP as a managerial inquiry process helps to create the foresight by identifying those quality developments that must be managed (e.g., using Quality by Design) to create the desired future state.

Figure 10: Applying the Continual Improvement Process within the Bayesian Moment



Redesign of the quality system is required whenever the actual process capability of a customer requirement (called the process capability index – an idicator of the ration of the specification limits to six standard deviations of the process performace) begins to approach its design capability and yet customers are requesting increased levels of performance. At this point it is mandatory to redesign the specific product, process or service, in a way that assures customers that their performance needs and requirements will be managed consistently and delivered within the tolerance band in the future. Whenever competition advances performance beyond the level that your own products or services deliver, and customers therefore reward them with their business so you are losing sales, then it is mandatory to redesign deliverables to regain competitive advantage.

Business sustainability occurs when an orgaization delivers sustainable products from processes that are also sustainable. What does this mean? Products should be both profitable to produce and environmentally sound both during the period of use and in the disposal after the period of obsolesence. Sustainable products are*:*

- Products that last a long time – enduring value
- Products that have persistent market success – sustainable sales
- Products that contribute to the planet's environmental goodness
- Products that "do no harm" to ecosystems that sustain society

Organizations should qualify their products according to market-based requirements that mark this form of deliverable sustainability. However, processes must also be sustainable and this means they must be "lean and clean" or free from defects so they:

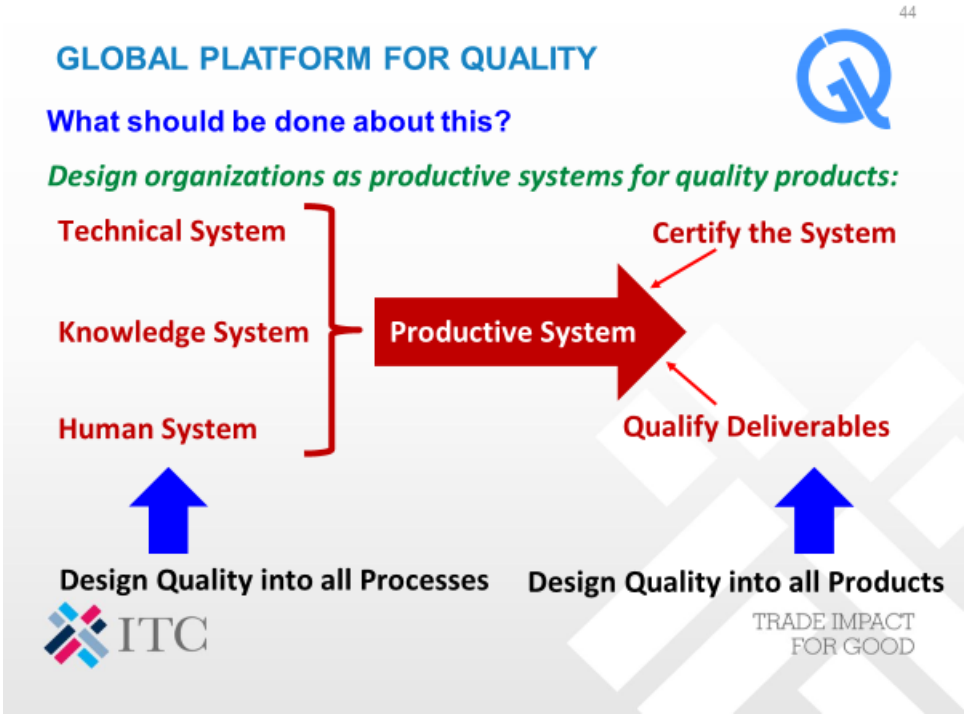
- Operate with no waste, loss, or inefficiency;
- Deliver continued profitable growth; and
- Adapt to new environments and are portable and permit agile transfer to other locations.

Organizations should embed these characteristics into their quality management system that they certify for compliance to ISO9001. This act advances the ISO9001 QMS standard from a mere market-entry condition toward a contributor to enduring sustainability of the business. Thus, business sustainability requires that two components be achieved: (1) sustainability of the global environment, and (2) sustainability of organizations that operate with quality. In order to achieve long-term sustainability, both quality management and quality development must be delivered where these two simultaneous efforts may be summarized as:

- Creating and implementing the standard is quality management
- Enhancing and advancing the system's performance is quality development

Delivering a conjoined quality management and quality development structure requires the design of quality into processes and products. This is accomplished through focused projects to improve the major three sub-systems in the productive system of the organization: technical, knowledge, and human sub-systems. Quality must be designed into the processes that apply these three aspects of the end-to-end business system into a productive system that delivers excellence to customers. In addition, quality must be designed into the products or services that are delivered through these production processes. This activity, called Design for Quality or Design for Six Sigma, requires cross-functional coordination of the entire organization in order to obtain products that flow through production processes and add value to the organization while delivering satisfaction to customers with the final deliverable experience. In order to have this type of success, it is essential that organizations certify the productive system that it is able to deliver customer requirements (e.g., an ISO9001 certified QMS that meets the fundamental requirements of a sound work management system) and also qualify the products that have been produced by this system that they meet the market requirements and customer needs (e.g., through inspection and testing to provide objective evidence or through attainment of an external quality mark or professional accreditation). This structure is illustrated in Figure 11:

Figure 11: Designing Quality into the Productive System of Processes and Products



Achieving this sort of integrated management system requires that the organization discover how to create a systematic approach toward gaining intimate knowledge of the preferences of its preferred customers – a so-called "imaginative understanding of customer needs." To gain this outcome the organization must first structure how it defines customer requirements. Surely, not all of the expressed wishes, hopes, and dreams of customers should become quality requirements that are embedded into the delivered products and services? How to choose what are the most important quality characteristics to include in this design? An operational definition of a customer requirement can be built upon three ingredients:

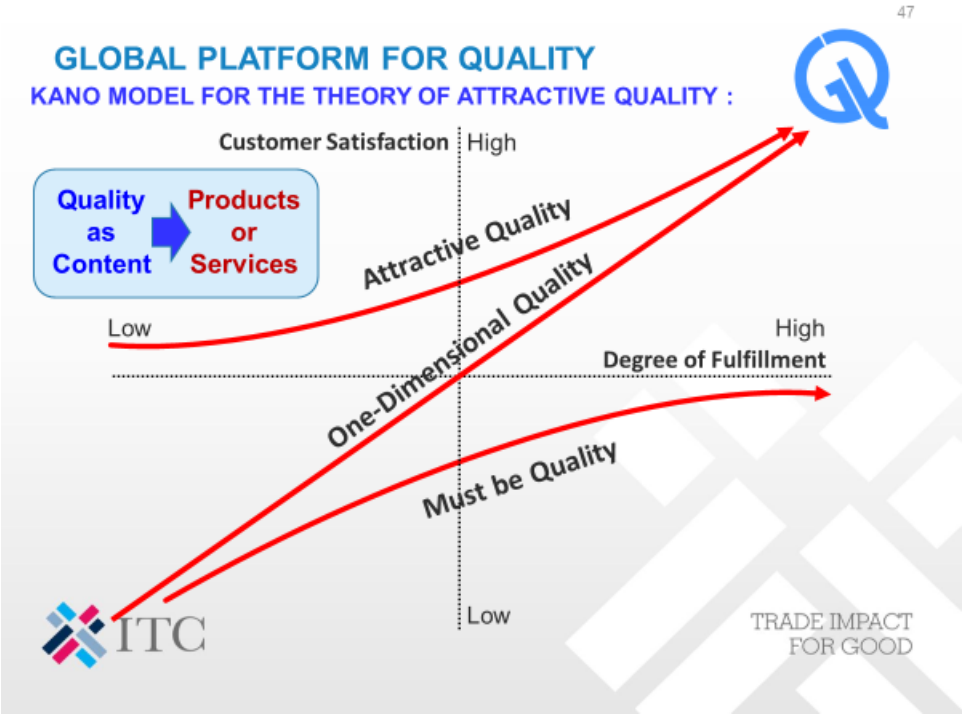
1. Identify the specific customer for whom the feature or function is satisfying a need so its efficacy may be evaluated according to its ability to meet the need of that individual as expressed from their point of view (POV) in the voice of the customer (VOC) description of the feature or function.

2. Identify the feature or function that must be engineered (best defined using a practice taken from value engineering where functions are defined as a noun-verb phrase (e.g., ship package) where a noun describes the deliverable (package) while the verb identifies the action that must be designed (the process of shipping); and

3. Describe the benefit or value that the customer obtains through this function.

An effective process of quality by desgin will generate an innovative understanding of the "voice of the customer (VOC)" as expressed from the particular customer's "Point of View (POV)" and then effectively translate this requirement into their deliverable by preserving visibility to the VOC throughout the complete qualty-by-design process. To accomplish this preservation of the VOC it is necessary to consider two models: the Kano Model that expresses the "Theory of Attractive Quality" and the "quality delivery model" that organizes production of the quality characteristics by the design process. The Kano models is shown in Figure 12:

Figure 12: The Theory of Attractive Quality as Developed by Noriaki Kano



A brief explanation of Kano's Theory of Attractive Quality cannot do justice to its deeper ability to contribute for developing competitive insights and positioning an organization within its market. However, the following simple explanation is offered to provide basic insights into how the model operates.

Kano explains how the product definition side of a quality by design process operates. He noted that not all the features that are included in a customer deliverable have the same degree of influence on customer statisfaction. Therefore, increasing capability in some of these features (e.g., expanding the degree of fullfillment of their requirements through more engineering or product capabiity) will not have the same outcome with respect to changing the customer's perseption about their satisfaction with the outcome of this effort. Kano observed that there are three classes of features that can be distinguished by the way that customers respond to them in their "satisfaction attitude" about the product or service:

Must-be Quality: This first class of quality requirement represents those features that are mandatory for meeting customer needs. In fact, if this set of features is not present then the customer will be extremely disappointed and will probably not purchase the deliverable in the first place. These features or functions require compliance or conformance with their specified performance at the risk of creating exceptional dissatisfaction and disintegration of the organization's reputation through loss of confidence in its ability to serve customers. In this dimension of quality, customers require complete fulfillment of "critical-to-quality (CTQ)" product or service quality characteristics. Without satisfying these requirements, the organization cannot be considered a viable market competitor.

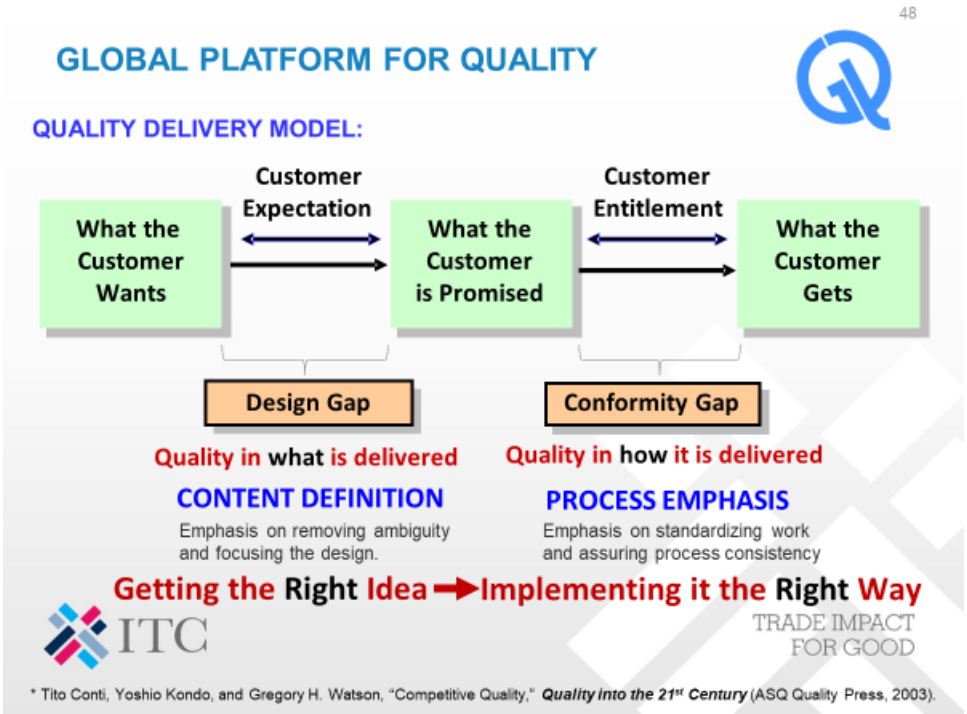
One-Dimensional Quality: The second class of features defines the competitive dimension of the deliverable – these are the features or functions upon which a customer makes their decisions regarding procurement – to buy or not to buy – the deliverable. The higher the value proposition in terms of fulfillment of requirements in this dimension, then the higher the degree of satisfaction among customers which implies that customers will consider this feature strongly in determining their procurement decision. This competitive domain of the product features and functions identifies the realm where most companies compete against their market rivals

and in which product comparisons are made on a “head-to-head” basis for their “critical to satisfaction (CTS)” product or service quality characteristics.

Attractive Quality: This final class of features relates to those unexpected innovations that contribute to the uniqueness of the product and deliver a “charm” that cannot be resisted during the product surveillance phase of a purchasing process. This attractiveness motivates consumer engagement and purchase because it provides them with an solution to a “why-didn’t-someone-think-of-that-before” type of concern that generates a motivational type of experience that “attracts” their attention and “excites” or “delights” their desires. These attractive features are “critical to motivating (CTM)” customers and they also increase the reptuation of the organization as a market-leading innovator that needs to be considered as an industry leader and the most-probable source of the next “killer ap” or “hot product.”

However, as time progresses, attractive features become less attractive as they migrate into a one-dimensional feature. This occurs because competition will not permit the existence of a stable leadership position among its rivals and will find creative ways to emulate this capability in their own products. Likewise, as customers become accustomed to the one-dimensional features they tend to become expected in future deliverables so these features will migrate toward the must-be type of quality characteristic. Thus, entropy also influences the customer excitement and motivation with products and services that are delivered. This requires that organizations create a process that is capable of generating constant, systematic innovation. Such a process is the quality delivery model depicted in Figure 13.

Figure 13: The Quality Delivery Process Developed by Gregory H. Watson

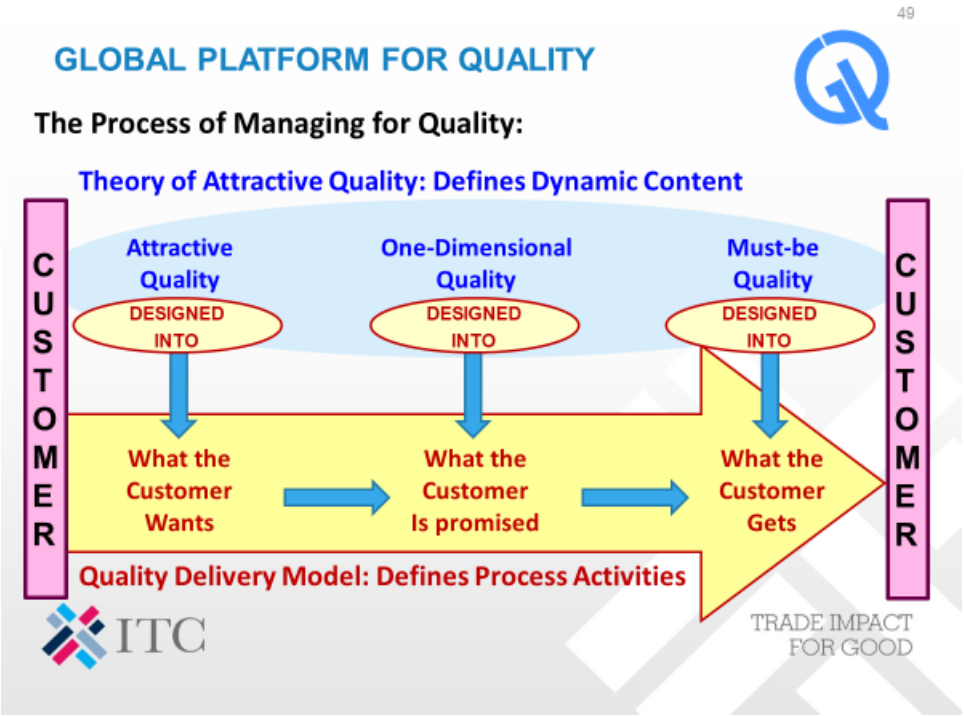


The quality delivery process consists of three steps: determining what the customer really wants, making a promise to customers as to what they will get, and, finally, determining the customer’s viewpoint regarding the quality of what they actually got. This process depicts quality delivery through two major stages – design of the deliverable and production of the deliverable design (including potentially its installation for the customer) to the point where customers can experience the final product. The first half of the process defines the content while the second half of the process concentrates on standardizing the production process and ensuring its consistency so that deliverables have predictable quality.

Design for Quality takes a systems approach to the desaign of quality in both the deliverable product as well as in the process that produced the deliverable. By merging these two models into a comprehensive product/process model it can be made clear how the team designing the outcome should shift its emphasis from understanding what comprises “attractive quality” in its consideration of “what the customer wants” to assuring competitive performance in “what the customer is promised” in the comparative “one-dimensional quality” characteristics to assuring that “what the customer gets” fullfills all of the product’s “must be” quality requirements.

The integration of the Kano Model’s three elements that define the quality perspectives of the customers with the organization’s approach to delivery of quality shows that there is a very natural way that these two models should be considered in the Qulaity by Design process which is shown in Figure 14.

Figure 14: Integration of the Theory of Attractive Quality with the Quality Delivery Model



Previously, the ideas of critical-to-qualty and critical-to-satisfaction were introduced as ways of distingushing the qualty contributions of various product functions. It should be noted that the Kano model actually identifies these three “critical-to” factors in the three quality dimensions that are represented. Characteristics of these three “critical-to” factors and their relationship to the Kano Model features are described below:

Critical to Quality (CTQ): In order to understand the requirements of the “must-be” quality dimension with its requirements for delivering a disciplined approach to feature and function characteristic compliance, an organization must pay particular attention to the drivers of both product quality as well as the process by which its deliverables are created. Failure to meet expectations and requirements in the CTQ domain undermines customer confidence in the deliverables and results in loss of business over the long term.

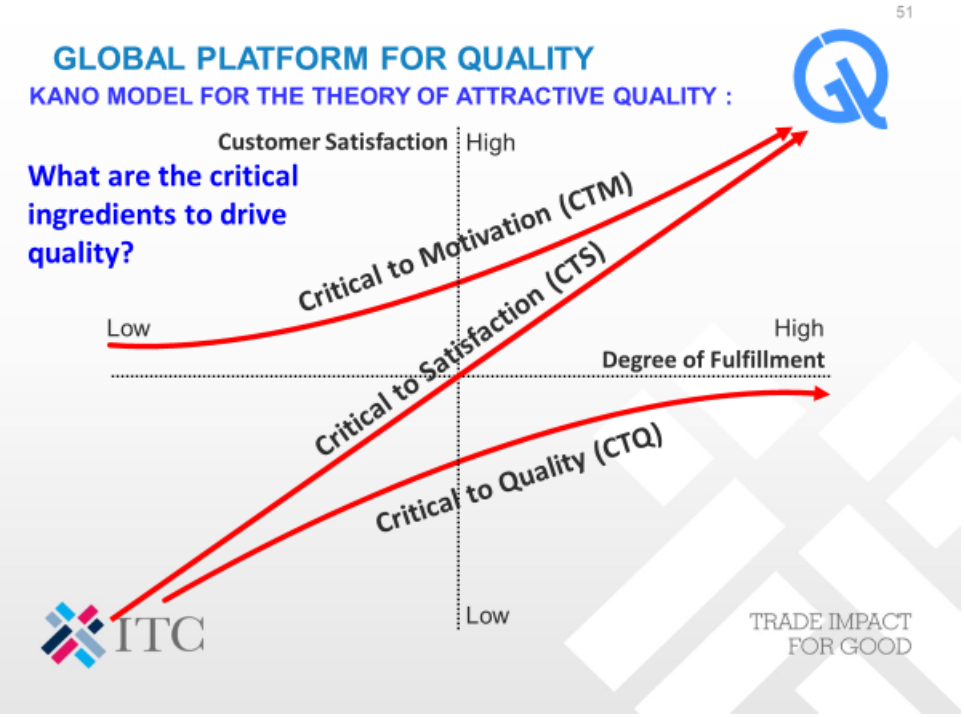
Critical to Satisfaction (CTS): CTS requirements deliver a competitive edge to the features and functions of an organization’s deliverables. The objective for a CTS quality characteristic is to take advantage of the intimate customer insight and to improve performance relative to competitive market offerings so that the CTS

performance requirements are clearly superior to alternatives and will deliver higher perceivable value to customers for all of the dominant “one-dimensional” quality characteristics.

Critical to Motivation (CTM): The CTM requirements create the “charm of a product” through differentiated innovation that triggers emotional responses to latent customer desires and thereby creates customer delight that results in a “killer product” or “hot application” which disrupts the marketplace which is the essence of the “attractive quality” features of the product.

Figure15 illustraties how these factors are superimposed on the Kano model.

Figure 15: Mapping the “Critical-to” Labels to the Kano Model Quality Dimensions



Just as there is a process maturity grid for evaluating how well an operational qualty system has progressed in its development, there is also a maturity grid for the quality by design process. Developing competence in quality by design requires that management steer their organization through four stages of development (see the full description in Figure 16).

Artisian Stage: Deliverables are one-off, unique creations that are custom-developed to suit the whims of the creator.

Craftsman Stage: Deliverables have been standardized into a design, and teamwork is used to produce products using an assembly-line like processes where the individual workers collaborate loosely with each other, and learning processes are applied to understand how to improve from mistakes that were made. This stage products resembles a production line, but lacks coordination of activities to create smooth mass production flow.

Engineer Stage: Technology is applied to create unique *categories* of materials, components and commodities and integrated with modular design *platforms* of the core technologies to manage production better. Design rules and product portfolios are used to plan and execute structured, and integrated mass production processes.

Designer Stage: Develops multi-generational plans to manage new product development risk relative to the maturing of technology and the return on investments in R&D to assure that they are aligned with business strategy, and that investments are driven equally by introduction of technical innovations and profound market insights.

Figure 16: Quality by Design Maturity Development Levels

Bringing qualty by design into a permanent state of operational execution will also require that the senior managers design a quality culture which expresses an organization-wide consistency in quality knowledge, attitude toward personal responsibility for quality, and a shared set of behavioral norms that define the expected experience that customer should come to expect from the organization and its employees.

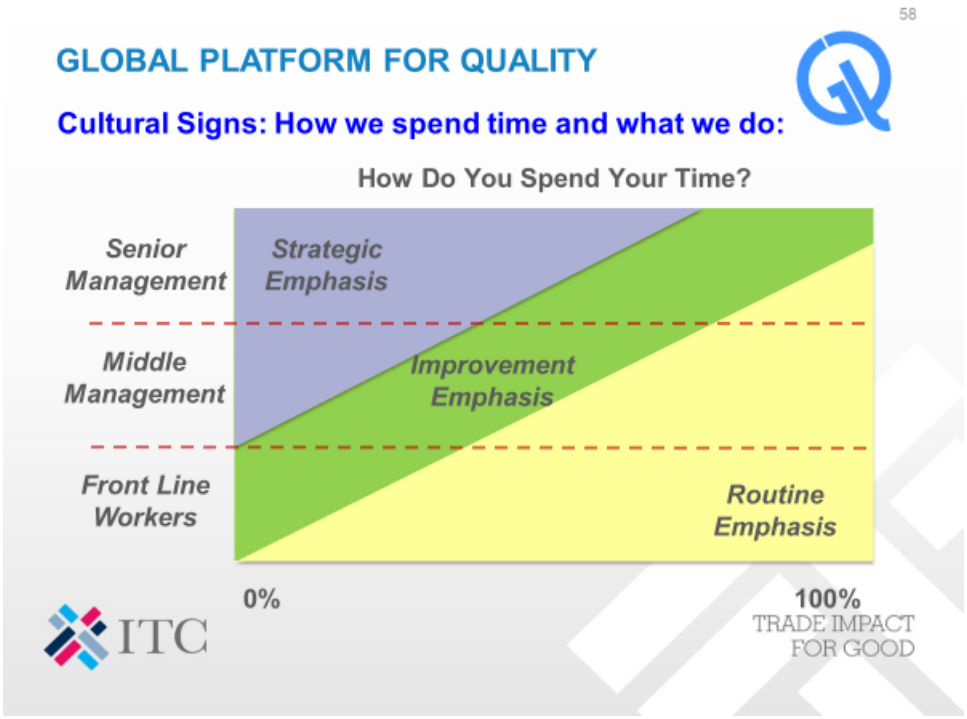
Quality Culture

The cultural awareness of quality and its importance to the business and its customer's must be led and reinforced by senior management who also has the duty to set an environment which fosters strong customer-oriented values that are demonstrated in the quality of the way that its daily routine of business and work operations are conducted.

Culture refers to beliefs, opinions, traditions, and practices which embody a code of behavior or set of mores or system of ethical values. It is possible that each individual may be influenced by multiples such codes of conduct and that some of these may be stronger or weaker – and consequently problematic. It is possible that an individual is influenced by codes with conflicting principles. A quality cultures can be negative (e.g., "hide-the-scrap-and-waste") or positive (e.g., "let's work together to delight our customers").

One way to determine how a culture operates within an organization is to seek out cultural signs such as examining how people spend their time at work. Figure 17 shows an idealized view of how organizations should budget their time investment. Improvement issues and strategic issues based on where they are located within the organizational hierarchy.

Figure 17: Investment of Personal Time Indicates Quality Culture Maturity

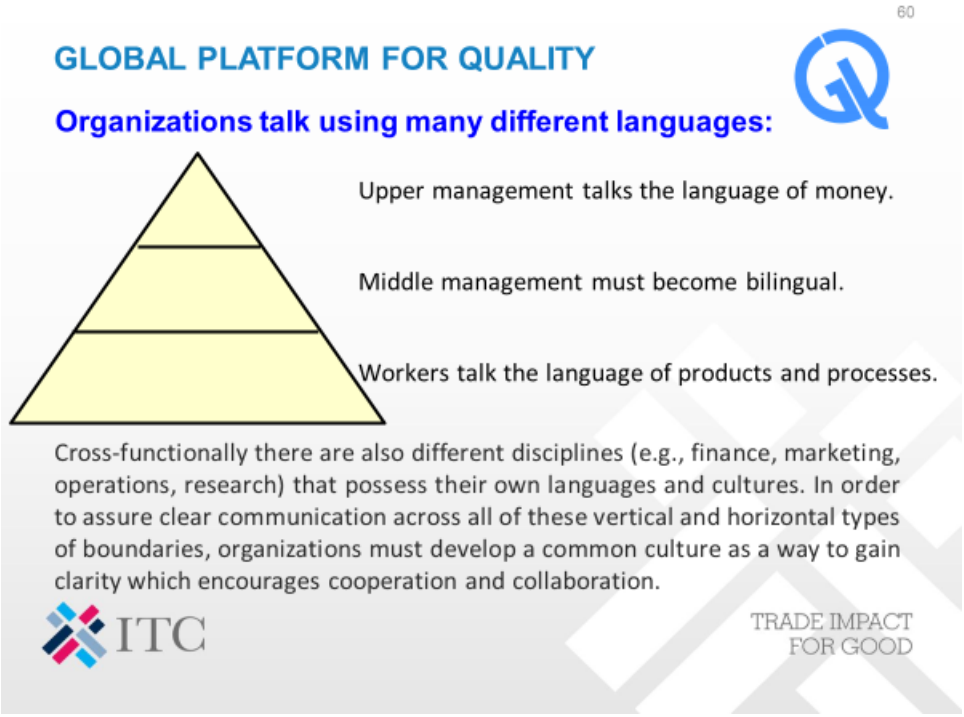


Just as organizations can assess the maturity growth that drives the quality of their processes and deliverables, they can also evaluate the quality of their culture. Here are seven questions that can be graded according to four answers (to a great extent, moderately, minimally, and not at all). This quiz provides an insight into the relative maturity of a quality culture.

1. Do you feel that you understand what good quality is?
2. To what degree are you familiar with the company's emphasis on quality?
3. To what degree do you agree with the following statement: "My manager's actions and attitude convince me that quality is important"?
4. To what degree to you understand the quality measurements in your own department?
5. Everything considered, how do you rate your department on providing high-quality service and outputs?
6. To what degree do you think your achievement of applicable quality standards affects your performance evaluation?
7. Have you worked in a quality circle, quality improvement team, or on a quality project in the past year?

One thing is clear when examining the culture of an organization: various functions and levels in the organizations talk using many different languages: finance-talk, marketing-talk, design-talk, engineering-talk, etc. Generalizing across the three major levels in an organization (that were described in Figure 1), it is clear that there there is a major distinction between the top and the bottom of this hierarchy where management talks using financial language and workers talk the language of products and processes. Thus, middle management must become "multi-lingual so it can undestand the results of the workers and translate this practical information as it learns to communicate in a meaningful manner with executives (Figure 18). Thus middle management serves a "communication pivot function" as it acts as an organizational interpreter.

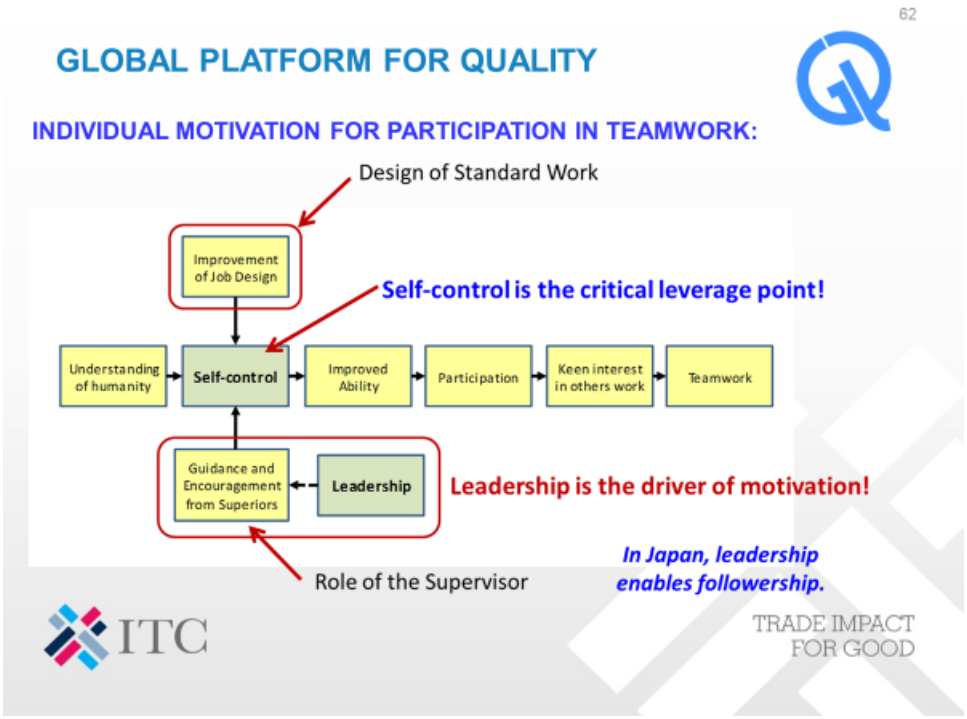
Figure 18: Communication Challenges Across the Organizational Hierarchy



Just as motivating customers with attractive quality features is important, it is also important that workers be motivated with the work that they are asked to do. Yoshio Kondo defined worker motivation as the "stimulation of people's desire to work." He observed that three conditions create the "spark" that ingites this desire: employment in a job that is well-designed based on an understanding of humanity with the strong encouragement of the worker's supervisors. Kondo believed that these conditions establish a willingness within the worker to exercise self-control. Figure 19 indicates how generating self-control within workers drives a chain of events that builds cooperative teamwork within organizations. Workers will increase their own ability to perform when taught, coached, guided, and encouraged by their supervisors. This increase in capability instills a confidence that allows them to participate in the improvement activities within their process which in turn creates curiosity and develops a keen interest in how the work of others affects their own work. This is the basis for teamwork.

The culture of quality includes many factors: putting the customer first; dedicating activities to the continual improvement of products, services, and processes: working in teams; accepting responsibility for the quality of work that one does; seeking facts to understand how processes can improve and products can be made better; trusting in colleagues to collaborate for the good of the whole organization; and managing processes using statisical insights about how to control and standardize outputs within the range of performance desired by customers. To be fully effective this system relies on an integrated system that can be called "Leadership through Quality."

Figure 19: Yoshio Kondo's Model – The Logic of Human Motivation



Leadership through Quality

In 1911 Frederick W. Taylor wrote *The Principles of Scientific Management*. It would have been better for humanity if he had discovered the content to allow him to write a book titled: *The Principles of Scientific Leadership*! Sound management can be reduced to an algorithm. One of these algorithms is shown in Figure 20 which illustrates how Hewlett-Packard defined a Process of Management (POM) in 1987. HP continues to teach this methodology today – an application of the principles of PDCA (Plan-Do-Check-Act) to management. This management process has remained constant since 1987 although the way it is applied differs according to the content of the activities that it manages.

Another approach to understanding how to develop executives is taken by the integration of the process maturity model with a five-step leadership maturity model (see Figure 21). While individuals act as manageres across levels one through four of the process maturity model, they must shift to becoming leaders in order to coach organizations to higher levels of maturity. In the first four matiurity levels the focus is concentrated on functional performance and this creates a chaotic overall structure for managing the business as a system. However, to progress beyond the fourth level, development of leadership within an organization is required.

At the fifth level of process maturity, managers become competent as they gain knowledge about how functional activities are properly integrated in the end-to-end process flow across the organization. At the sixth level, managers become capable as their experience increases with the integration of other functions participating in the process that they own. As processes are measured consistently and compared to business results, a consistency in the leadership style develops across the organization. At the seventh level managers consistently demonstrate their ability to work across the different functional activityies. Finally by the eigth level of this process maturity evolution, leaders become clairvoyant as they are now able to predict the future and relate operational activities to the organization's strategies for improvement.

Figure 20: Hewlett-Packard's Application of PDCA to the Process of Management (POM)

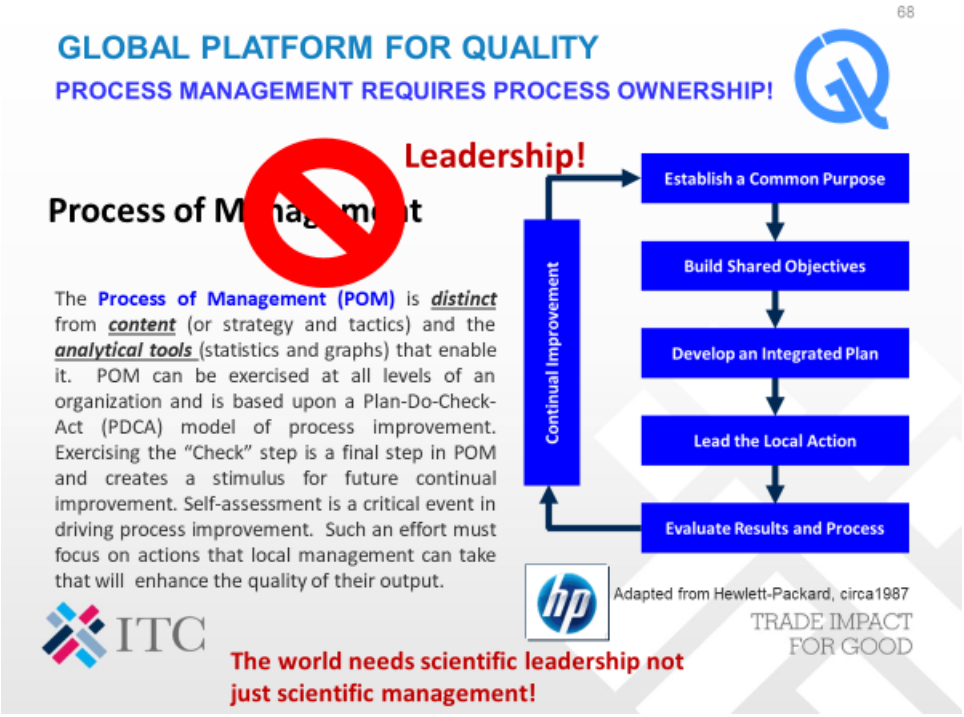
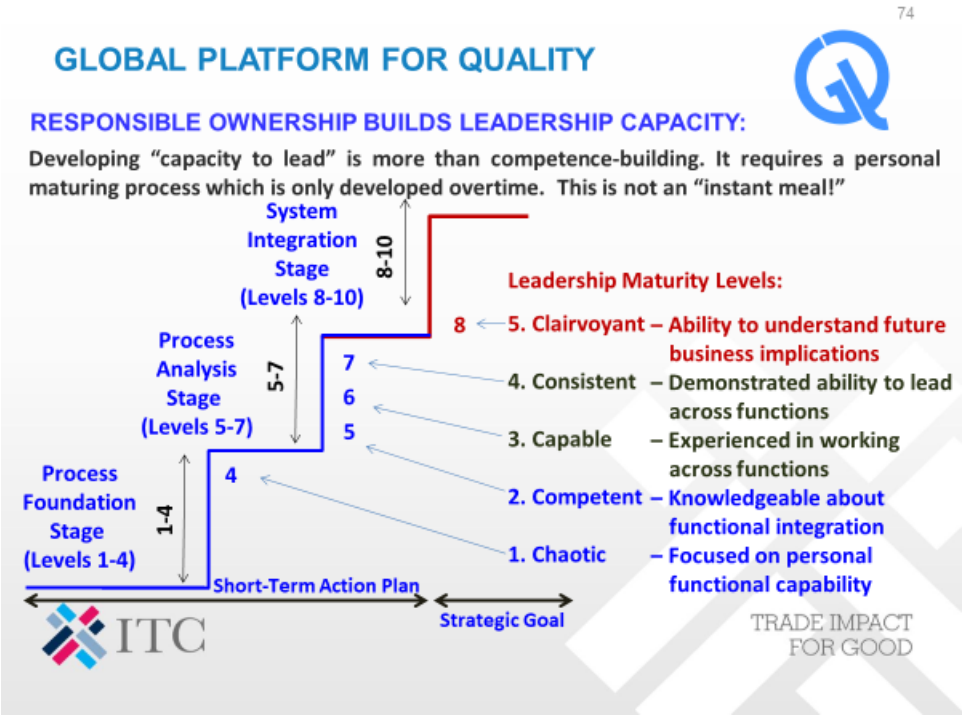
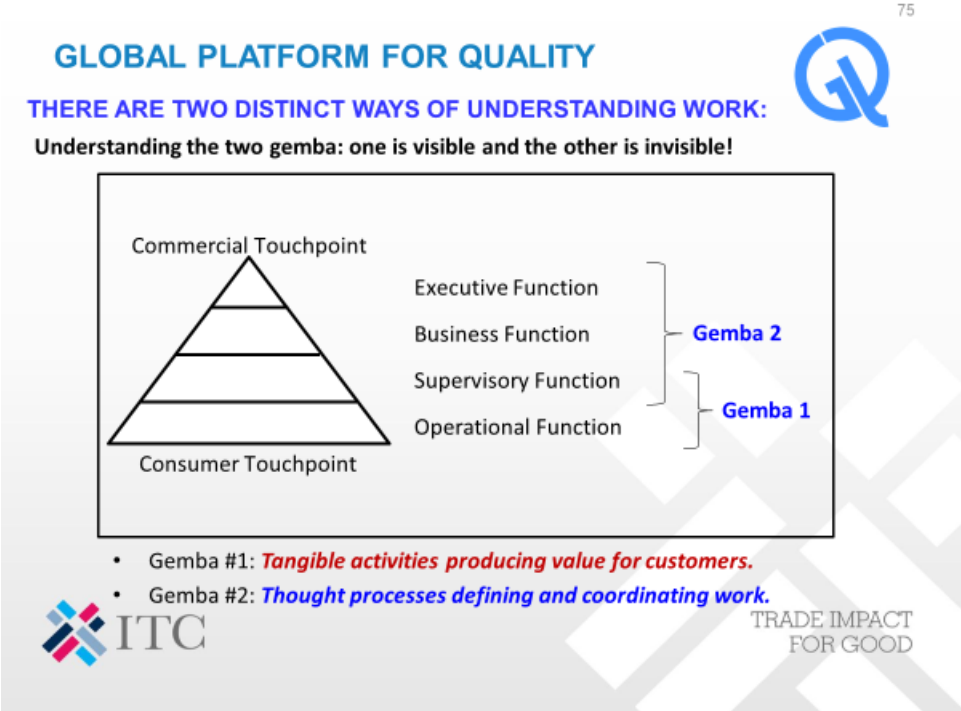


Figure 21: Mapping Leadership Development to Increasing Levels of Process Maturity



This migratory maturing of leadership tracks across the hierarchy identified in Figure 22.

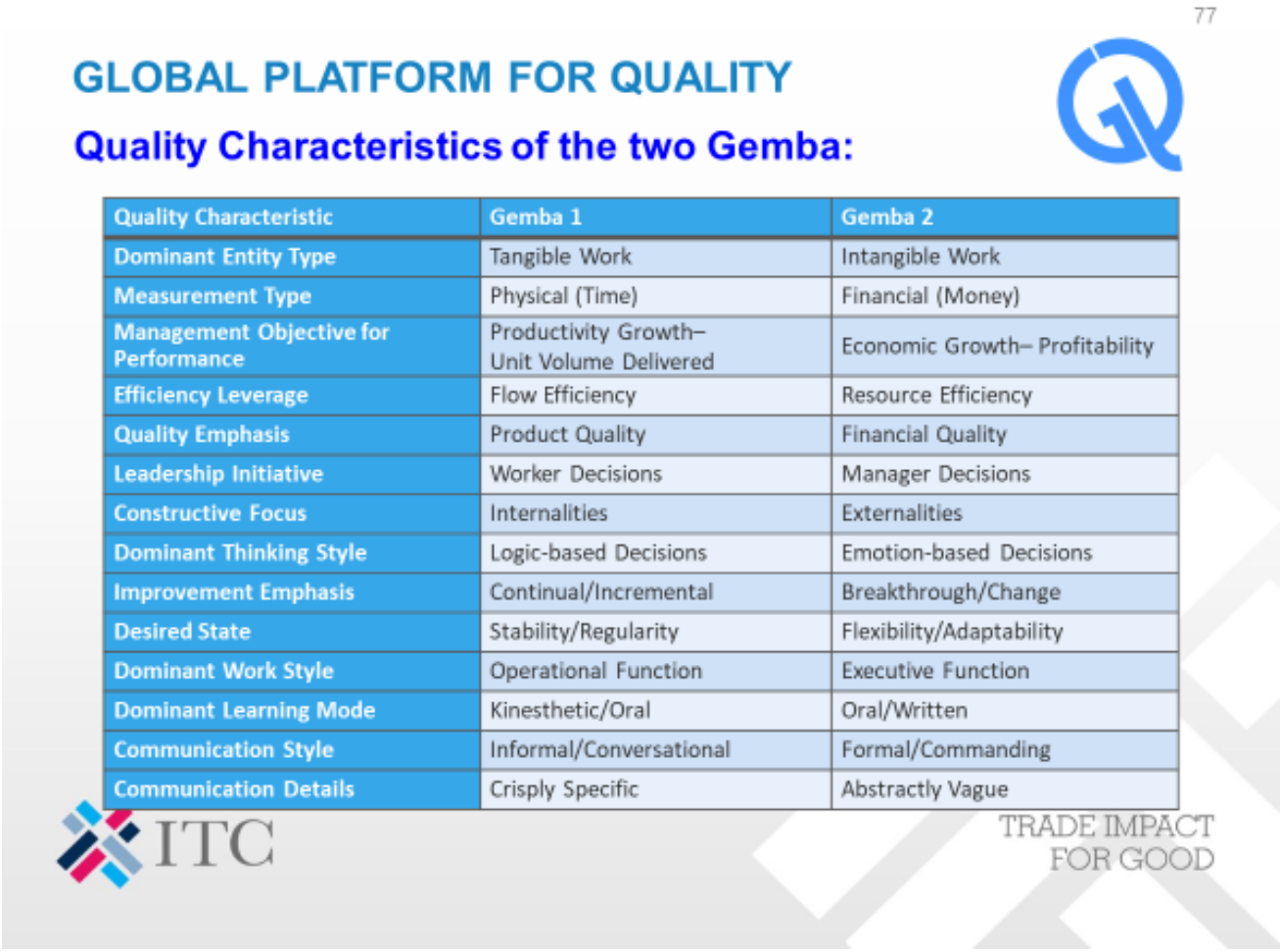
Figure 22: The Language Separation in the Organization Foretell Distinctions in Style Between Managing Leadership



As previously noted, an organizations work is divided into two workplaces called Gemba 1 (the operational environment of tangible process working) and Gemba 2 (the administrative work environment of intangible thought processes). Gemba 1 operates using language of production while Gemba 2 operates using language of finance. Other comparisions between these two gembas can be seen in the list contained in Figure 23. It is no wonder that it is so difficult to work across these organizational levels!

Gemba 1 is focused on the “where” and “how” of the daily management system and produces its output (“how much”) measured in tangible units of production. On the other hand Gemba 2 is focused on the “what” and “why” questions that generate organizational strategy and it will measure output (“how much”) using financial indicators. The characteristics of these two ways of managing show that they truly represent not only different languages or ways of working but also two totally different cultures. Since middle management provides a “bridge” between the two gemba, middle managers must become “ambidextrous” in their ways of communicating or operating when they manage downward or manage upward. One expression that has been told in management litterature for a long time is: “every manager must also be a leader and every leader must also be a manager.”

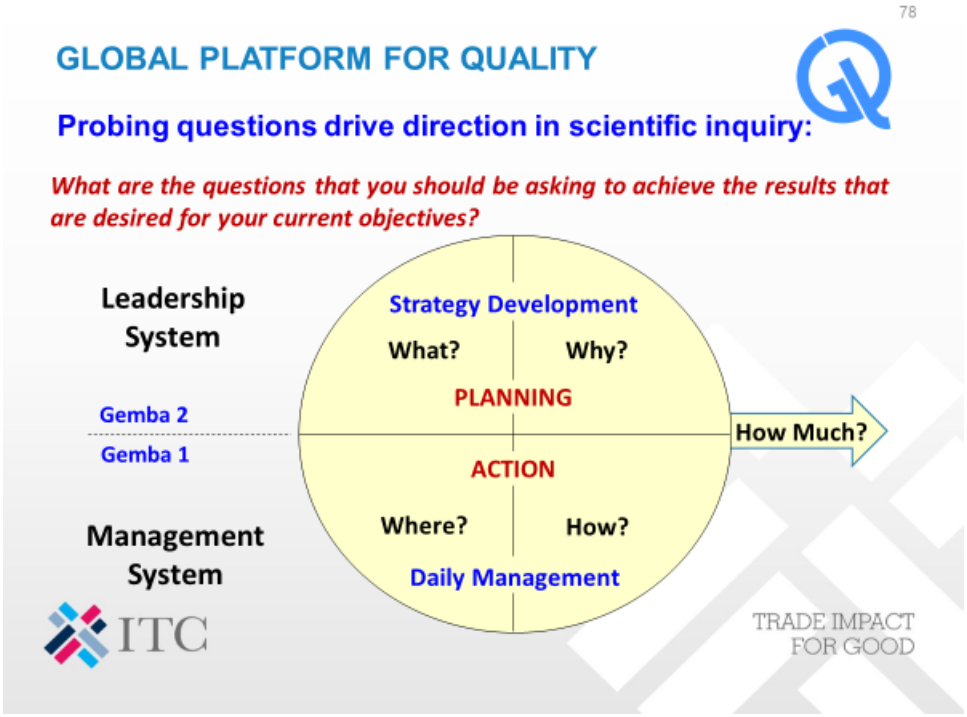
Figure 23: Distinguishing the Characteristics of Gemba 1 and Gemba 2



Quality Characteristic	Gemba 1	Gemba 2
Dominant Entity Type	Tangible Work	Intangible Work
Measurement Type	Physical (Time)	Financial (Money)
Management Objective for Performance	Productivity Growth– Unit Volume Delivered	Economic Growth– Profitability
Efficiency Leverage	Flow Efficiency	Resource Efficiency
Quality Emphasis	Product Quality	Financial Quality
Leadership Initiative	Worker Decisions	Manager Decisions
Constructive Focus	Internalities	Externalities
Dominant Thinking Style	Logic-based Decisions	Emotion-based Decisions
Improvement Emphasis	Continual/Incremental	Breakthrough/Change
Desired State	Stability/Regularity	Flexibility/Adaptability
Dominant Work Style	Operational Function	Executive Function
Dominant Learning Mode	Kinesthetic/Oral	Oral/Written
Communication Style	Informal/Conversational	Formal/Commanding
Communication Details	Crisply Specific	Abstractly Vague

Figure 24 shows that Gemba 2 focuses on determining strategy in the strategy development process while Gemba 1 focuses on managing the daily work processes in the management system. Thus, strategic change projects are targeted at driving organizational transformation or change and are generated in Gemba 2 and then executed in Gemba 1.

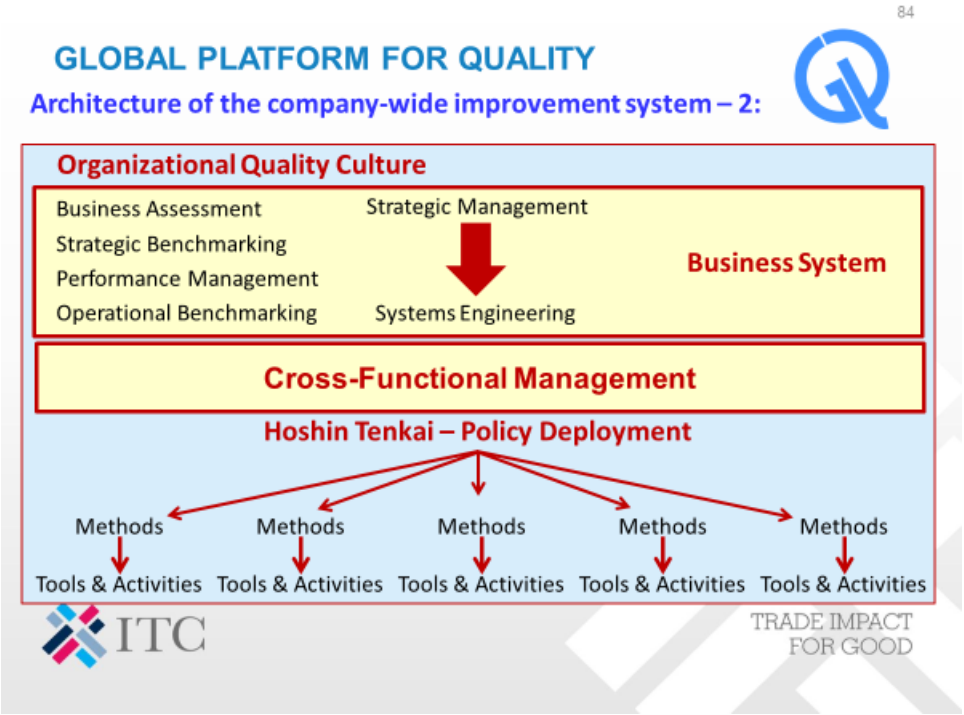
Figure 24: Observing the Difference Between Leadership and Management Focus Areas



The linkage between these two gembas occurs through a management process that translates strategic direction into operational plans and projects for driving improvement. In Japan this system is called "*hoshin kanri*." Developing of strategies and their accompanying strategic change projects occurs at the executive and cross-functional levels of Gemba 2. These plans are then deployed for implementation (this is called "*hoshin tenkai*"- literally the "rolling out" of a kimono that has been packed) through a cascading negotiation process where improvement strategies are coupled with the methods, tools, and activities which support indivdual change management projects and create the process improvement which becomes integrated through the cross-functional collaboration that is designed into this process. The *hoshin kanri* process is illustrated in Figure 25.

Hoshin kanri evolved out of developments in Japanese management during the mid-1960s. The "flag measurement system" of Bridgestone was merged with the "business review process" of Komatsu and the "cross-functional steering process" of Toyota to steer "breakthrough" projects for improvement which were introduced by Japan and greeted "like the fresh air in spring after a shower" and thereby energized the creation of a Japanese-based system of business systems management. The process of communication of strategic direction, generation of projects that manage and implement change, and alignment of these projects to achieve strategic direction all combine to enable the integration of the cultural aspects of quality with its set of practical improvement projects that create and deliver the desired future state which can deliver a result of business sustainability. This development allowed Japanese business leaders to move to the forefront of global trade over the coming two decades.

Figure 25: Managing the System of Systems – The Hoshin Kanri Management Process



Leadership through Quality (LtQ) is achieved when all of these quality-related elements become integrated into a singular management system as illustrated in Figure 26.

Figure 26: Operationally Defining the Elements of Leadership through Quality

The journey to create Leadership through Quality is not a short one: Progress must be made employing a step-by-step deliberate approach with frequent learning sessions to study and reflect upon progress and to correct the course, so the organization remains true to its vision of becoming a sustainable business. This is the challenge that all business leaders and management teams face as they adapt to the contingencies and external influences on their operations and seek to manage their work while they lead their people. Both actions require a solid foundation in quality.

Concluding Comments

This chapter concludes the text on Fundamentals of Quality. Perhaps, the readers will become intrigued and want to pursue further study. After completing the basic quality program of study an advanced level of study, coupled with practical experience, will assist these people as they attempt to navigate the quality maturity journey in all of its dimensions. There is perhaps no greater challenge for organizations and the leaders which guide them into the future.

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Review Questions

After reading this chapter and reviewing the related presentation in volume two, take the following quiz to review your knowledge and understanding about quality management and how it contributes to developing continuing success in market performance.

1. A "total quality management system" will encompass which of the following:

a. Internal viewpoints only.

b. External viewpoints only.

c. Neither internal nor external viewpoints – just conformance to standards.

d. Both internal and external viewpoints, including conformance to standards.

2. Managing for Quality is done by the use of the three management processes of planning, control and improvement.

a. True

b. False

3. The organizing principle of “Managing for Quality” requires:

a. Managing across organizational functions.

b. Developing business culture that applies a “quality strategy” for control and improvement.

c. Establishing a “strategy for quality” to assure commercial and environmental sustainability.

d. All of the above.

4. The foundational quality disciplines for a comprehensive quality management system includes:

a. Quality Assurance

b. Quality Control

c. Both (a) and (b)

d. Neither (a) nor (b)

5. Quality Management adds the following quality disciplines to the foundation:

a. Quality Improvement

b. Quality Planning for Continual Improvement

c. Both (a) and (b)

d. Neither (a) nor (b)

6. Quality energizes global trade opportunities by providing:

a. Consistency in product and service performance.

b. Evidence- based performance to requirements.

c. Competitive level of offerings to the marketplace.

d. All of the above.

7. In transitioning from a functionally-based quality strategy to an organizational way of using quality as a strategy for improvement Quality Management and Quality Development must be designed to operate synergistically.

a. True

b. False

8. The quality strategy of an organization should focus on:

a. The planning, developing, coordinating, implementing, and assuring quality in current products.

b. Engaging front-line workers, supervisors, and middle managers in doing standard work right.

c. Maintaining the current state of customer-deliverable quality at its targeted performance level.

d. All of the above.

9. Which of the following statements is most true?

a. “Big Q” Strategic Quality Focuses on developing an organization’s quality culture while “Little q” Operational Quality focuses on developing an organization’s daily management systems.

b. Strategic quality assures that all appropriate standards are maintained routinely.

c. Benchmarking is a primary management method among “Little q” quality methods.

d. Designing a company-wide measurement system is a significant “Little q” improvement project.

10. Quality Development adds what dimensions to the foundation of Quality Management?

a. Quality Planning

b. Breakthrough Improvement

c. Quality by Design

d. All of the above.

11. One outcome of developing quality maturity to level 10 is creation of business excellence.

a. True

b. False

12. Quality by Design

a. Synergistically designs the product outcome with its productive process.

b. Aims its performance achievements to capture the voice of targeted customers for their most critical requirements.

c. Establishes a control strategy and plans for adapting to market growth conditions.

d. All of the above.

13. A customer requirement will:

a. Describe the function that the customer requires (noun).

b. Describe how this function should behave (verb).

c. Describe the value or benefit that is achieved from this requirement.

d. All of the above.

14. Quality culture is developed by:

a. Focusing on customer needs and requirements as a priority over cost minimization.

b. Developing employee competence and skills to increase their pride in work.

c. Creating an attitude that sensitizes everyone on applying a common value system for good.

d. All of the above are important ingredients in an effective quality culture.

15. Sustainability refers both to the enduring operation of the business for the long-term and to the way a business operates with respect to environmental impact.

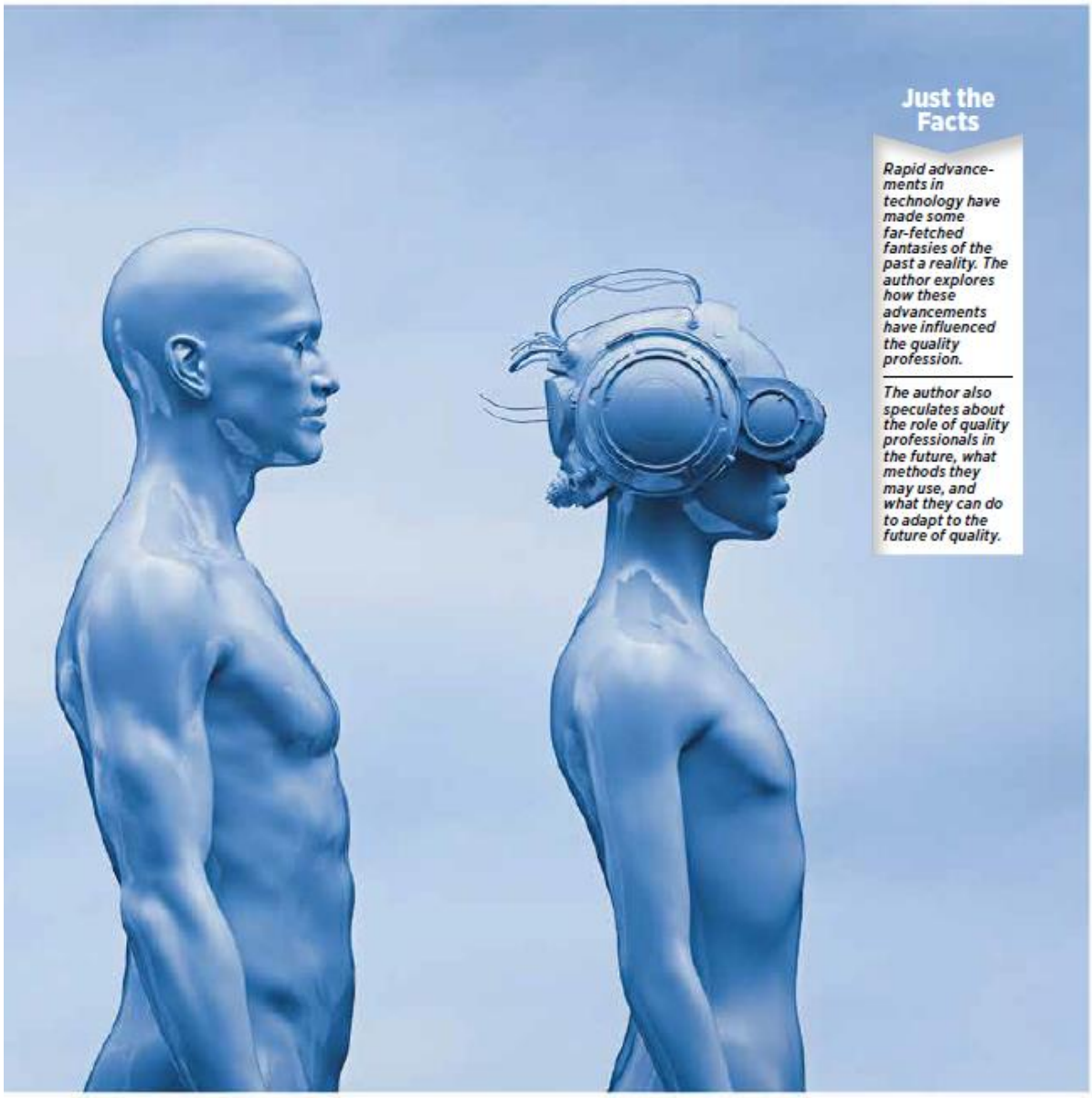
a. True

b. False

ANNEX – ARTICLE: THE ASCENT OF QUALITY 4.0 - QUALITYPROGRESS.COM

FEATURE
QUALITY 4.0

THE ASCENT OF



Just the Facts

Rapid advancements in technology have made some far-fetched fantasies of the past a reality. The author explores how these advancements have influenced the quality profession.

The author also speculates about the role of quality professionals in the future, what methods they may use, and what they can do to adapt to the future of quality.

QUALITY 4.0

How the new age of quality came to be and what it might look like in 20 years

by Gregory H. Watson

FEATURE
QUALITY 4.0

In recent years, the phrase "Quality 4.0" has come into our vocabulary. It derives from the German industrialization program called Industry 4.0 and evaluates the role of quality in an age of increasing digitization and automation of work.

In 1998, *Quality Progress* published the cover article, "Digital Hammers and Electronic Nails—Tools of the Next Generation,"[1] which forecasted how quality would evolve over the next two decades in response to the growing availability of digital technology. It predicted that quality functions and analyses would become automated and inquired, "How will the role of quality professionals change in that emerging environment?"[2]

At the time, the internet was creating new ways of doing business, and the article described a future in which information—like food and consumer electronics—would be a freely traded commodity.

That day has arrived, and those technology trends have evolved into our current realities. How can we cope with the challenges associated with this new environment, and how should we adapt to prepare for a future that will continue to evolve?

Reflecting on the past

The digital environment forecasted in "Digital Hammers and Electronic Nails" focused on two key drivers:

1. Telecommunications technology and the internet.
2. Personal computing, networks and thought machines.

These technologies did indeed drive much of the change that occurred over the past two decades. However, enterprise computing, integrated multimedia, cloud computing and artificial intelligence (AI)-enabled technology also contributed to the current state.

Today, the simple act of making an airplane flight reservation can generate many megabytes of data, which are connected to past experiences and a travel profile so that "thinking machines" can propose your next potential journey with some degree of accuracy. Purchasing a book or selecting an internet movie proposes a list of similar recommendations. Making a restaurant reservation online can result in receipt of a discount offer from another restaurant attempting to influence your choices.

The technology powerhouse firms in 1998 included Nokia Mobile Phones, Motorola and Compaq Computer—all of which have since been dismantled and their remnants restructured into different entities. Major technology players of today—such as Amazon, Google and Apple—had insignificant presences in those earlier markets. Amazon sold books online; Google had a web browser engine; and Apple produced graphical computers.

Since then, these firms reinvented themselves, taking advantage of the evolving technology trends, and they have emerged as global technical powerhouses. As a result, many organizations have scrambled to transition from analog to digital technologies, converting their predominantly human-based environments to machine-based platforms.

What happened to the work of quality professionals over these past two decades? It too has shifted substantially as we have adopted new approaches. For example:

- Improved statistical software has influenced quality analytics and supported the Six Sigma movement.
- The extensive availability of data related to customer complaints and interactions at touchpoints makes it possible to understand preference trends and react to quality issues almost in real time.
- More sophisticated statistical methods and computer software are integrated to enhance causal structure investigations to solve performance

There has been evolutionary growth in the size of computing power since the transistor was first developed in the late 1940s. Moore's Law for Technological Progression is used to describe this growth as a "doubling function" of power in computing every two years.

TABLE 1

Aligned view of changes in industry and quality approaches

Period	Summary description	Quality	Summary description
Industry 1.0—Prior to 1890	+ Humans harness water and steam power to build industrial infrastructure. + Crude machines gain productivity over independent craft work. + Increased output is achieved using mechanical advantages. + Work focuses on performing tasks faster and more consistently. + Transportation/moving goods occurs more frequently.	Quality 1.0	+ Quality is assured through measurement and inspection. + Production volume is emphasized rather than quality. + Inspection does not focus on cost reduction, eliminating wastes, or loss and inefficiency. + Work conditions are not important; maximizing worker productivity takes precedence.
Industry 2.0—1890 to 1940	+ Electricity powers industrial machines. + Performance capability gains occur through application of new mechanisms. + Scale of automation becomes broader as motor size can be varied to fit specific circumstances.	Quality 2.0	+ Maximizing productivity continues to be the primary focus. + Adherence to standards that reflect the minimally acceptable quality level is prevalent. + Financial quality is measured based on scrap and rework. + Labor performance is used to measure productivity.
Industry 3.0—1940 to 1995	+ Computer power provided to workers to increase productivity. + Use of information and communication technology drives improvements. + Human participation in workplaces declines. + Stand-alone robotic systems replace manual work.	Quality 3.0	+ Quality is a business imperative. + Meeting customer requirements (customer satisfaction) is emphasized. + Continual improvement is applied. + Gains in productivity occur by stabilizing highly efficient processes, standardizing work and involving all workers in the activities that create quality. + Standardization activities (ISO 9001) and achieving business excellence through organizationwide assessment (such as the *Baldrige Criteria for Performance Excellence*) emerge.
Anticipated changes that will occur during Industry 4.0—1995 to present	+ Integrated cyber-physical interfaces automate working environments. + Automated processes deal with end-to-end systems. + Humans serve only in positions where human judgment cannot be automated and human interactions cannot be simulated. + Machines learn to learn (artificial intelligence).	Quality 4.0	+ Digitization is used to optimize signal feedback and process adjustment, and adaptive learning supports self-induced system corrections. + Quality shifts its control-oriented focus from the process operators to the process designers. + Machines learn how to self-regulate and manage their own productivity and quality. + Human performance is essential; the emphasis shifts from production to system design and integration with the business system.

problems. By reducing reliance on professional statisticians, this development also has driven the broad acceptance of Six Sigma across all organizational functions and dimensions of society.

Understanding the effects

The current predominant technology trends related to the digitization of society are big data and AI. Big data have evolved as the world becomes more connected and software applications begin to record more user interactions as a result of "links" (LinkedIn) and "likes" (Facebook), which allow cross-referencing of individual choices regarding consumer preferences.

Amazon has been most visible in applying these methods to its online purchasing model, which has evolved from a home shopping network to a worldwide portal for goods and services. Even political elections have been influenced by the ability to access and manipulate massive databases. AI has been combined with big data to make search engines more efficient by using pattern recognition and rule-based logic derived from the choices people make, and used to gain deeper insights to derive personal preferences.

The growth of big data is not surprising. There has been evolutionary growth in the size of computing power since the transistor was developed in the late 1940s. Moore's Law for Technological Progression is used to describe this growth as a "doubling function" of power in computing every two years.[3]

This powerful computing technology now is available to almost everyone through transformational changes, such as mobile phones becoming mobile computing platforms. Access to complete information is available at our fingertips wherever we can connect to the internet, which is almost everywhere. In the first decade of this century, the transition to digital technology became so complete that it can be considered ubiquitous.

Industry 4.0 is built on the framework that internet connectivity through wireless telecommunications permits integration of diverse types of devices (such as home appliances, automobiles, industrial platforms and merchandise markets) for business or personal purposes. Digital signals now are influencing almost every aspect of our lives, as demonstrated by:

- Performing diagnostics on remote elevators.
- Restaurant food delivery by courier.
- Establishing environmental settings before arriving home.
- Starting and warming cars remotely on cold winter days.
- Doctors receiving secondary opinions on medical test data from off-site colleagues.
- Surgeons receiving advice from "master doctors," who are highly specialized in a procedure or a particular diagnostic field.

How does this affect the quality profession? One visible trend is the rise of a new related job: data scientists. Data scientists use data management tools and software to explore affinities among measurements from massive online databases (often stored in the cloud) by using predictive analytics. These evaluations support organizational decision making based on predicted outcomes, which provides insights, not possibilities, for the future. Clearly, technology has enabled the widespread application of statistical thinking.

But what is the implication of this shift in technology access for the quality profession? Generally, academic research is the primary source of new approaches to industrial engineering and statistics. Now, the curricula for those fields incorporates systems-thinking and data science for industrial engineering and statistics students, respectively. Sometimes, these areas are established as independent fields of study.

There is a growing need for organizations to divide their data analytics resources into two compartments—developing strategic insights and market positions (data science) and managing daily routine operations (quality). This arrangement challenges the perception of the value of quality management and raises questions regarding the importance of "little data analysis," which focuses on real-time, data-based investigations of problems' causalities and ensuring consistent quality is produced by a stable process.

Many of the control mechanisms in this daily management system can be enabled through robotics or other types of automation that use sensor systems, data monitors or telemetry. These systems are supported by AI systems that feed corrective action signals through an adaptive feedback mechanism for changing production system settings.

The evolution of quality

Why do we still need quality professionals? Did the quality profession become perceived as unimportant because digitized technology can replace it? What can we do to change this perception and reshape our profession in the coming two decades? How can we convince decision makers that automated little data analytics do not replace quality professionals and big data?

Joseph Juran declared in his important "Last Word" speech that the 21st century would be the "century of quality!"[4] We must act to ensure the truth of his prediction.

Collaborative analytics will give equal credence to the technological aspects of the production system and the human aspects of the administrative system.

Let's begin by clarifying the roots of how quality professionals think and work. We'll compare the histories of industry and quality to understand how our principles, methods and tools have matured over time. Quality 4.0 will be shown to be the appropriate companion to Industry 4.0. As in previous developmental periods, this relationship between industrial advances and quality developments is interactive and it operationalizes these changes using an aligned approach, which is described briefly in Table 1 (p. 27).

Here are some key considerations to bring the maturing of industry and quality into context:

- Quality 1.0 dates back thousands of years and describes the earliest roots of the quality profession.
- The idea of Quality 2.0 emerged from the Industrial Revolution. This period often is referred to as Taylorism, as described by Fredrick W. Taylor in his 1911 book, *Principles of Scientific Management*.[5]
- Quality 3.0 evolved from the time of Taylor to the end of the 20th century and was stimulated by Walter A. Shewhart's interpretation of the advancements in physics discovered during his lifetime. He pragmatically applied them to the production environment in his 1931 book, *Economic Control of Quality of Manufactured Product*,[6] which became the cornerstone of Quality 3.0. This period represents the analog equivalent of the current digital transformation.
- Quality executives now must cope with the reinvention of research and development practices. Quality thinking must be incorporated into the design of holistic business systems that support productive operations. Furthermore, the reformation of quality competence among professional staff members must prepare them for full participation in this digitally enabled management age.

Insights about the future

The emerging path forward for the quality community must extrapolate these lessons. What will be the job of the quality professional in 20 years, and what methods will be employed then? The following three conjectures are based on observations of the current state:

1. The emphasis will shift from the operationally oriented task of creating and executing a quality strategy to more holistically applying quality as a strategy across the entire organization. Quality thinking will equal financial thinking in organizations' operational management systems, as demonstrated by and documented as the Toyota Management System, which goes beyond the well-known Toyota Production System.[7]
2. The distinction between quality professionals and data scientists will be replaced by a new approach that might be called "collaborative analytics." It will merge all continual improvement activities into an integrated, cross-functional, organization-wide method driven by a structured, scientific approach to problem investigation, diagnosis and remediation.

   Additionally, collaborative analytics will give equal credence to the technological aspects of the production system and the human aspects of the administrative system. Research regarding such a system has been underway since 2014 by the International Academy for Quality.[8]
3. The tools of data analytics will mature to incorporate a new way of conducting exploratory data analysis. This will combine big data methods for identifying interesting rational subgroups (or, as W. Edwards Deming described, an enumerative approach) with little data methods for determining potential causes and detailed patterns that might exist in historical data sets—what Deming called an analytic approach.[9]

   Many new analytical methods will be associated with this change. James Duarte, for example,

has proposed seven analysis tools that can be used for data probing and other methods to use data more efficiently.[10]

Another technique might be labeled "passive design of experiments," where statistical computing systems analyze natural interrelationships among multiple factors in a large data set.

Focusing on the future

Perhaps the rate of change has been too fast for us to comprehend what will occur in the next two decades. Information storage is doubling every two years, mirroring technological advances. These two factors increase information access and processing speed, and their combined effect is multiplicative.

The quality community now faces the same circumstances. Although a specific path may not be totally predictable at this point, there are known factors that improve our forecasting ability. Most importantly, we must develop a strategic approach that organizations can implement to sustain success while we focus on enhancing our methods and toolkits.

We will thrive, rather than merely survive, if we learn how to gain greater insights from collected data and design quality systems that fit our organizations specifically, rather than copying and pasting approaches from the past. These are essential elements for us to master to embrace and leverage these turbulent times of digital transformation. QP

Many of the control mechanisms in this daily management system can be enabled through robotics or other types of automation that use sensor systems, data monitors or telemetry.

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