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IA-Quality - General Concepts and Definitions

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1. Introduction

The Meanings of "Quality." Of the many meanings of the word "quality," two are of critical importance to managing for quality:

- "Quality" means those *features of products* which meet customer needs and thereby provide customer satisfaction. In this sense, the meaning of quality is oriented to income. The purpose of such higher quality is to provide greater customer satisfaction and, one hopes, to increase income.

  However, providing more and/or better quality features usually requires an investment and hence usually involves increases in costs. Higher quality in this sense usually "costs more."

- "Quality" means *freedom from deficiencies*—freedom from errors that require doing work over again (rework) or that result in field failures, customer dissatisfaction, customer claims, and so on. In this sense, the meaning of quality is oriented to costs, and higher quality usually "costs less."

Satisfaction and Dissatisfaction Are Not Opposites. Customer *satisfaction* comes from those features which induce customers to buy the product. *Dissatisfaction* has its origin in deficiencies and is why customers complain. Some products give little or no dissatisfaction; they do what the producer said they would do. Yet they are not salable because some competing product has features that provide greater customer satisfaction. The early automated telephone exchanges employed electromagnetic analog switching methods. Recently, there was a shift to digital switching methods, owing to their superior product features. As a result, analog switching systems, even if absolutely free from product deficiencies, were no longer salable.

Thus Quality can evolve several definitions such as:

- customer satisfaction and loyalty ;
- Do right things right.
- providing a product which is 'fit for the purpose';
- providing an acceptable product at an acceptable cost;
- a standard which can be accepted by both the supplier and the customer.
- the totality of features or characteristics of a product that bear on its ability to satisfy a given need.
- Fitness for use.

Big Q And Little Q. Definitions of words do not remain static. Sometimes they undergo extensive change. Such a change emerged during the 1980s. It originated in the growing quality crisis and is called the concept of "Big Q."

Table 1 shows how the quality "umbrella" has been broadening dramatically. In turn, this broadening has changed the meanings of some key words. Adoption of Big Q grew during the 1980s, and the trend is probably irreversible. Those most willing to accept the concept of Big Q have been the quality managers and the upper managers. Those most reluctant have been managers in the technological areas and in certain staff functions.

Topic	Content of little Q	Content of big Q
Products	Manufactured goods	All products, goods, and services, whether for sale or not
Processes	Processes directly related to manufacture of goods	All process manufacturing support; business, etc.
Industries	Manufacturing	All industries, manufacturing, service, government, etc., whether for profit or not
Quality is viewed as:	A technological problem	A business problem
Customer	Clients who buy the products	All who are affected, external and internal
How to think about quality	Based on culture of functional departments	Based on the universal trilogy
Quality goals are included:	Among factory goals	In company business plan
Cost of poor quality	Costs associated with deficient manufactured goods	All costs that would disappear if everything were perfect
Evaluation of quality is based mainly on:	Conformance to factory specifications, procedures, standards	Responsiveness to customer needs
Improvement is directed at:	Departmental performance	Company performance
Training in managing for quality is:	Concentrated in the quality department	Companywide
Coordination is by:	The quality manager	A quality council of upper managers

Source: *Planning for Quality,* 2d ed. (1990). Juran Institute, Inc., Wilton, CT, pp. 1–12.

Table 1. Contrast, Big Q and Little Q.

2. Quality: the financial effects

The Effect on Income. Income may consist of sales of an industrial company, taxes collected by a government body, appropriations received by a government agency, tuitions received by a school, and donations received by a charity. Whatever the source, the amount of the income relates in varying degrees to the features of the product produced by the recipient. In many markets, products with superior features are able to secure superior income, whether through higher share of market or through premium prices. Products that are not competitive in features often must be sold at below-market prices.

Product deficiencies also can have an effect on income. The customer who encounters a deficiency may take action of a cost-related nature: file a complaint, return the product, make a claim, or file a lawsuit. The customer also may elect instead (or in addition) to stop buying from the guilty producer, as well as to publicize the deficiency and its source. Such actions by multiple customers can do serious damage to a producer's income.

The Effect on Costs. The cost of poor quality consists of all costs that would disappear if there were no deficiencies—no errors, no rework, no field failures, and so on. This cost of poor quality is shockingly high. In the early 1980s, it was estimated that within the U.S. manufacturing industries, about a third of the work done consisted of redoing what had already been done. Since then, estimates from a sample of service industries suggest that a similar situation prevails in service industries generally.

Deficiencies that occur prior to sale obviously add to producers' costs. Deficiencies that occur after sale add to customers' costs as well as to producers' costs. In addition, they reduce producers' repeat sales.

3. How to manage for quality: the Juran trilogy

To attain quality, it is well to begin by establishing the "vision" for the organization, along with policies and goals. Conversion of goals into results (making quality happen) is then done through managerial processes—sequences of activities that produce the intended results. Managing for quality makes extensive use of three such managerial processes:
1.   1- Quality planning
-      2- Quality control
-      3- Quality improvement
These processes are now known as the "**Juran trilogy**."
A summery for the 3 process is illustrated in table 2.

Fig. 1. Juran Triology.

Quality planning	Quality control	Quality improvement
Establish quality goals	Evaluate actual performance	Prove the need
Identify who the customers are	Compare actual performance with quality goals	Establish the infrastructure
Determine the needs of the customers	Act on the difference	Identify the improvement projects
Develop product features that respond to customers' needs		Establish project teams
Develop processes able to produce the product features		Provide the teams with resources, training, and motivation to: Diagnose the causes Stimulate remedies
Establish process controls; transfer the plans to the operating forces		Establish controls to hold the gains

Table 2. The three universal processes of managing for quality. [*Adapted from Juran, J.M. (1989). The Quality Trilogy: A Universal Approach to Managing for Quality. Juran Institute, Inc., Wilton, CT.*]

Inspection and Inspectors. The concepts of inspection and inspectors are of ancient origin. Wall and jewelry paintings in Egyptian tombs show the inspections used during stone construction projects. The measuring instruments included the square, level, and plumb bob for alignment control. Surface flatness of stones was checked by "boning rods" and by threads stretched across the faces of the stone blocks.

Safety and Health of the Citizens. Early forms of protection of safety and health were after-the fact measures. The Code of Hammurabi (c. 2000 B.C.) prescribed the death penalty for any builder of a house that later collapsed and killed the owner. In medieval times, the same fate awaited the baker who inadvertently had mixed rat poison with the flour.

The Industrial Revolution. The Industrial Revolution began in Europe during the mid eighteenth century. Its origin was the simultaneous development of power-driven machinery and sources of mechanical power. It gave birth to factories that soon outperformed the artisans and small shops and made them largely obsolete.

The Twentieth Century and Quality. The twentieth century witnessed the emergence of some massive new forces that required responsive action. These forces included an explosive growth in science and technology, threats to human safety and health and to the environment, the rise of the consumerism movement, and intensified international competition in quality.

An Explosive Growth in Science and Technology. This growth made possible an outpouring of numerous benefits to human societies: longer life spans, superior communication and transport, reduced household drudgery, new forms of education and entertainment, and so on. Huge new industries emerged to translate the new technology into these benefits. Nations that accepted industrialization found it possible to improve their economies and the well-being of their citizenry.

The new technologies required complex designs and precise execution. The empirical methods of earlier centuries were unable to provide appropriate product and process designs, so process yields were low and field failures were high. Companies tried to deal with low yields by adding inspections to separate the good from the bad. They tried to deal with field failures through warranties and customer service. These solutions were costly, and they did not reduce customer dissatisfaction. The need was to prevent defects and field failures from happening in the first place.

Threats to Human Safety and Health and to the Environment. With benefits from technology came uninvited guests. To accept the benefits required changes in lifestyle, which, in turn, made quality of life dependent on continuity of service. However, many products were failure-prone, resulting in many service interruptions. Most of these were minor, but some were serious and even frightening—threats to human safety and health, as well as to the environment.

Thus the critical need became quality.

Expansion of Government Regulation of Quality. Government regulation of quality is of ancient origin. At the outset, it focused mainly on human safety and was conducted "after the fact"—laws provided for punishing those whose poor quality caused death or injury. Over the centuries, there emerged a trend to regulation "before the fact"—to become preventive in nature. This trend was intensified during the twentieth century. In the field of human health, laws were enacted to ensure the quality of food, pharmaceuticals, and medical devices. Licensing of practitioners was expanded. Other laws were enacted relating to product safety, highway safety, occupational safety, consumer protection, and so on.

Growth of government regulation was a response to twentieth-century forces as well as a force in its own right. The rise of technology placed complex and dangerous products in the hands of amateurs—the public. Government regulation then demanded product designs that avoided these dangers.

To the companies, this intervention then became a force to be reckoned with.

4. The rise of the consumerism movement

4.1 How to think about quality

Consumers lacked expertise in technology. Their senses were unable to judge which of the competing products to buy, and the claims of competing companies often were contradictory. When products failed in service, consumers were frustrated by vague warranties and poor service.

"The system" seemed unable to provide recourse when things failed. Individual consumers were unable to fight the system, but collectively they were numerous and hence potentially powerful, both economically and politically. During the twentieth century, a "consumerism" movement emerged to make this potential a reality and to help consumers deal more effectively with these problems. This same movement also was successful in stimulating new government legislation for consumer protection.

Intensified International Competition in Quality. Cities and countries have competed for centuries. The oldest form of such competition was probably in military weaponry. This competition then intensified during the twentieth century under the pressures of two world wars. It led to the development of new and terrible weapons of mass destruction. A further stimulus to competition came from the rise of multinational companies. Large companies had found that foreign trade barriers were obstacles to export of their products. To get

around these barriers, many set up foreign subsidiaries that then became their bases for competing in foreign markets, including competition in quality. The most spectacular twentieth-century demonstration of the power of competition in quality came from the Japanese. Following World War II, Japanese companies discovered that the West was unwilling to buy their products—Japan had acquired a reputation for making and exporting shoddy goods. The inability to sell became an alarm signal and a stimulus for launching the Japanese quality revolution during the 1950s. Within a few decades, that revolution propelled Japan into a position of world leadership in quality. This quality leadership in turn enabled Japan to become an economic superpower. It was a phenomenon without precedent in industrial history.

5. Quality to center stage

The cumulative effect of these massive forces has been to "move quality to center stage." Such a massive move logically should have stimulated a corresponding response—a revolution in managing for quality. However, it was difficult for companies to recognize the need for such a revolution—they lacked the necessary alarm signals. Technological measures of quality did exist on the shop floors, but managerial measures of quality did not exist in the boardrooms. Thus, except for Japan, the needed quality revolution did not start until very late in the twentieth century. To make this revolution effective throughout the world, economies will require many decades—the entire twenty-first century. Thus, while the twentieth century has been the "century of productivity," the twenty-first century will be known as the "century of quality." The failure of the West to respond promptly to the need for a revolution in quality led to a widespread crisis. The 1980s then witnessed quality initiatives being taken by large numbers of companies.

Most of these initiatives fell far short of their goals. However, a few were stunningly successful and produced the lessons learned and role models that will serve as guides for the West in the decades ahead.

Lessons Learned. Companies that were successful in their quality initiatives made use of numerous strategies. Analysis shows that despite differences among the companies, there was much commonality—a lengthy list of strategies was common to most of the successful companies. These common strategies included:

Customer focus: Providing customer satisfaction became the chief operating goal.

Quality has top priority: This was written into corporate policies.

Strategic quality planning: The business plan was opened up to include planning for quality.

6. IB-quality control - general concept

Quality Control Defined. "Quality control" is a universal managerial process for conducting operations so as to provide stability—to prevent adverse change and to "maintain the status quo."

To maintain stability, the quality control process evaluates actual performance, compares actual performance to goals, and takes action on the difference.

Quality control is one of the three basic managerial processes through which quality can be managed. The others are quality planning and quality improvement,. The Juran trilogy diagram (Figure 2) shows the interrelation of these processes. Figure 2 is used also to describe the relationships between quality planning, quality improvement, and quality

control and the fundamental managerial processes in total quality management. What is important for this section is to concentrate on the two "zones of control." In Figure 2 we can easily see that although the process is in control in the middle of the chart, we are running the process at an unacceptable level of waste. What is necessary here is not more control but improvement—actions to change the level of performance. After the improvements have been made, a new level of performance has been achieved. Now it is important to establish new controls at this level to prevent the performance level from deteriorating to the previous level or even worse. This is indicated by the second zone of control. The term "control of quality" emerged early in the twentieth century (Radford 1917, 1922). The concept was to broaden the approach to achieving quality, from the then-prevailing after-the-fact inspection, to what we now call "defect prevention." For a few decades, the word "control" had a broad meaning which included the concept of quality planning. Then came events which narrowed the meaning of "quality control." The "statistical quality control" movement gave the impression that quality control consisted of using statistical methods. The "reliability" movement claimed that quality control applied only to quality at the time of test but not during service life. In the United States, the term "quality control" now often has the narrow meaning defined previously.

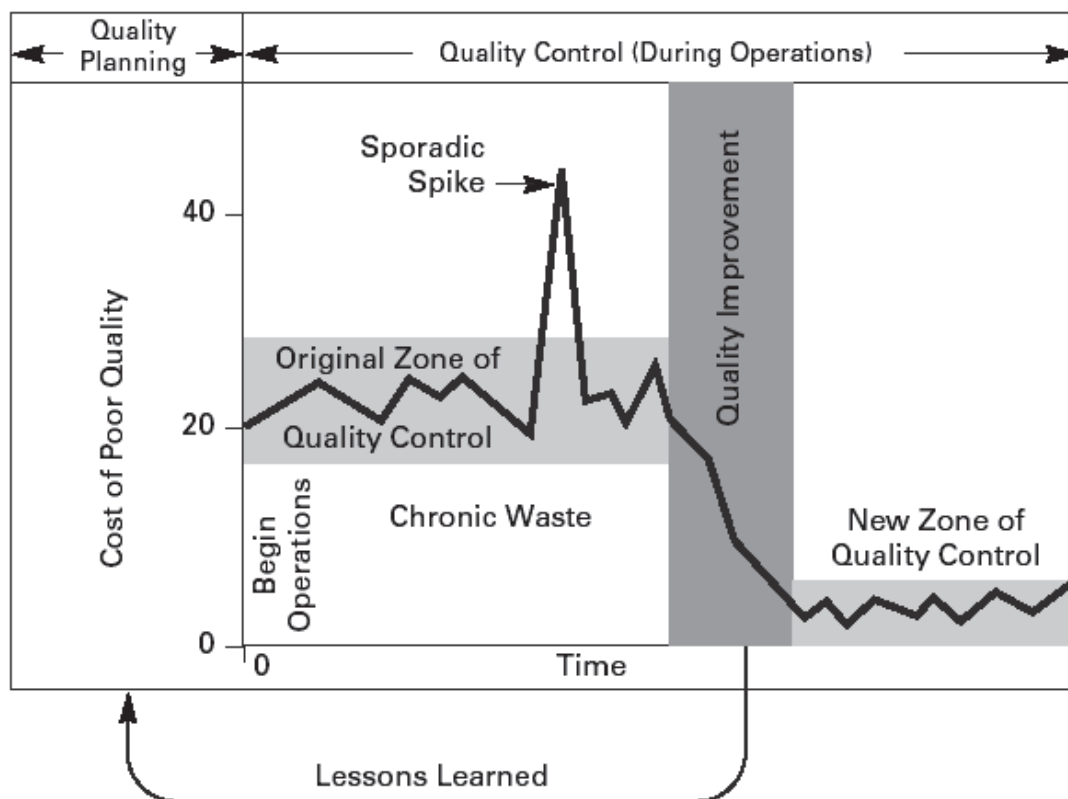The term "total quality management" (TQM) is now used as the all-embracing term.

Fig. 2. The Juran trilogy diagram. (*Juran Institute, Inc., Wilton, CT.*)

In Europe, the term "quality control" is also acquiring a narrower meaning. Recently, the European umbrella quality organization changed its name from European Organization for Quality Control to European Organization for Quality. In Japan, the term "quality control" retains a broad meaning.

Their "total quality control" is roughly equivalent to our term "total quality management." In 1997 the Union of Japanese Scientists and Engineers (JUSE) adopted the term total quality management (TQM) to replace total quality control (TQC) to more closely align themselves with the more common terminology used in the rest of the world. The quality control process is one of the steps in the overall quality planning sequence,. Figure 3 shows the input-output features of this step. In Figure 3 the input is operating process features developed to produce the product features required to meet customer needs. The output consists of a system of product and process controls which can provide stability to the operating process.
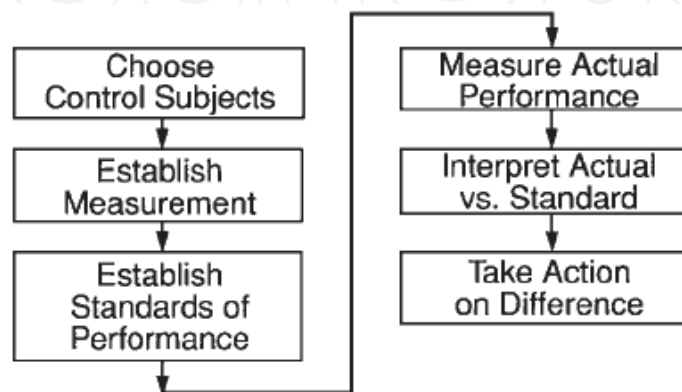
Fig. 3. The input-output diagram for the quality control process.

7. The relation to quality assurance

Quality control and quality assurance have much in common. Each evaluates performance. Each compares performance to goals. Each acts on the difference.

However they also differ from each other. Quality control has as its primary purpose to maintain control. Performance is evaluated during operations, and performance is compared to goals during operations. The resulting information is received and used by the operating forces. Quality assurance's main purpose is to verify that control is being maintained. Performance is evaluated after operations, and the resulting information is provided to both the operating forces and others who have a need to know. Others may include plant, functional, or senior management; corporate staffs; regulatory bodies; customers; and the general public.

The Feedback Loop. Quality control takes place by use of the feedback loop. A generic form of the feedback loop is shown in Figure 4. The progression of steps in Figure 4 is as follows:

1. A sensor is "plugged in" to evaluate the actual quality of the control subject—the product or process feature in question. The performance of a process may be determined directly by evaluation of the process feature, or indirectly by evaluation of the product feature—the product "tells" on the process.
2. The sensor reports the performance to an umpire.
3. The umpire also receives information on what is the quality goal or standard.
4. The umpire compares actual performance to standard. If the difference is too great, the umpire energizes an actuator.
5. The actuator stimulates the process (whether human or technological) to change the performance so as to bring quality into line with the quality goal.
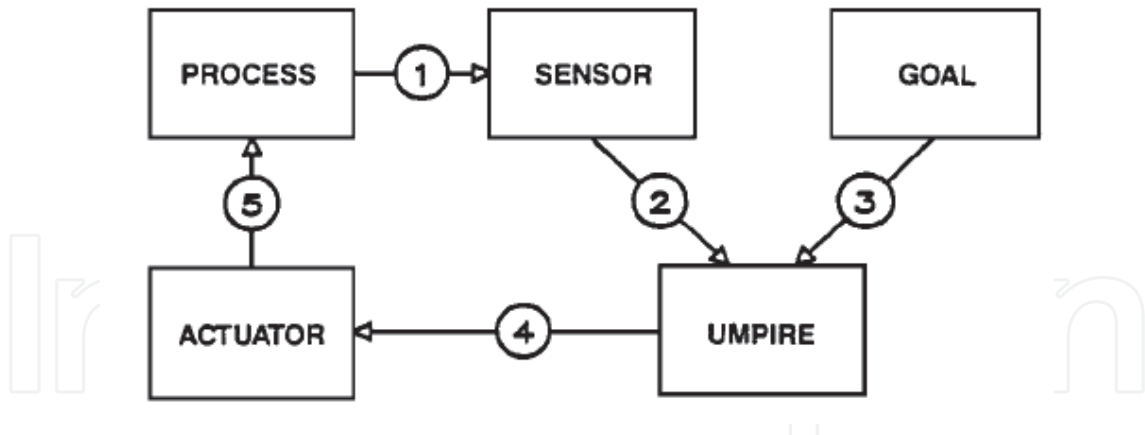
Fig. 4. The generic feedback loop. (*Making Quality Happen, Juran Institute, Inc., senior executive workshop, p. F-3, Wilton, CT.*)

8. The elements of the feedback loop

The feedback loop is a universal. It is fundamental to any problem in quality control. It applies to all types of operations, whether in service industries or manufacturing industries, whether for profit or not. It applies to all levels in the hierarchy, from the chief executive officer to the work force, inclusive. However, there is wide variation in the nature of the elements of the feedback loop. In Figure 5 a simple flowchart is shown describing the quality control process with the simple universal feedback loop imbedded.

The Process. In all of the preceding discussion we have assumed a process. This may also be human or technological or both. It is the means for producing the product features, each of which is a control subject. All work is done by a process which consists of an input, labor, technology, procedures, energy, materials, and output. For a more complete discussion of process.
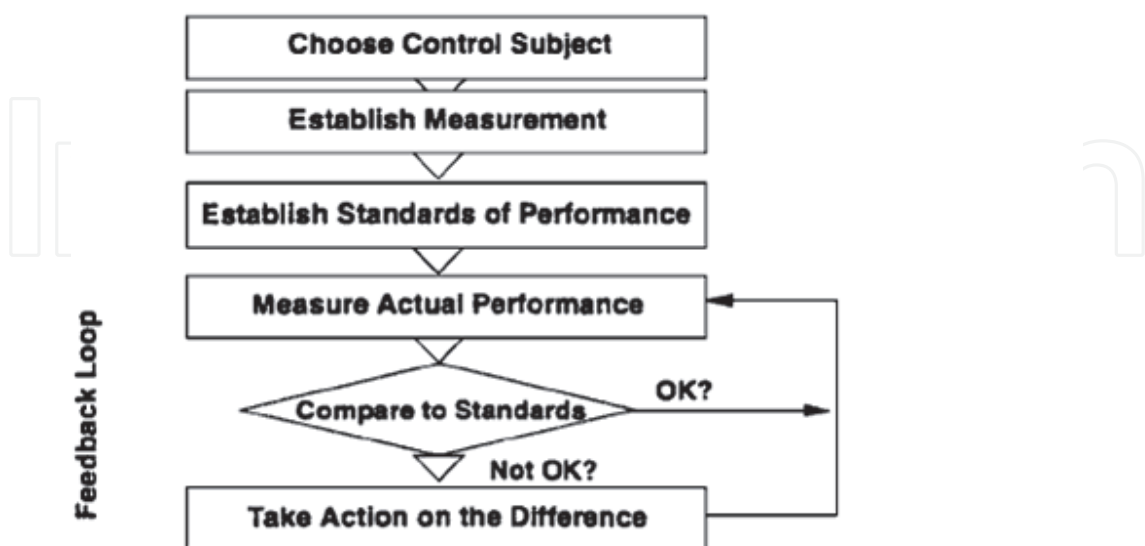

Fig. 5. The qualty control process. ("*Quality Control*", *Leadershitp for the Quality Century, Juran Institute, Inc., senior executive workshop, p. 2, Wilton, CT.*)

9. Deming chain reaction

The so-called Deming Chain Reaction was actually borrowed from a model that Walter Shewhart developed. He probably borrowed the idea from another thinker. Basically the idea was for management to move away from thinking about quality as a desirable outcome, to thinking about quality as a competitive strategy. Competitive strategy as a concept has been around for centuries. A person selling an item similar to that sold by another can compete on price, by selling it for less money. Perhaps the seller may try to compete by adding extras, gift-wrapping, for example. Technical companies compete by being technology leaders and being on the cutting edge of new developments. There are no end to methods to compete. But some methods are more effective in the long run than others. It is not a mistake that Deming's first published book on the subject was entitled "On Quality, Productivity and Competitive Position". In the book, he sets forth the reasons why emphasis on quality leads to productivity improvement and how that is a very effective competitive strategy in the long run. Phil Crosby in the early 80s in his book, "Quality is Free" pointed out that improving quality lowered cost. But Deming had shown this to the Japanese 30 years earlier. And, Deming pointed out the benefits of developing a competitive strategy based on quality. One of the problems in talking about quality is that many people have pre-conceived notions of quality is. For some it is meeting specifications. Joseph Juran defines it as 'meeting customer requirements'.

Fig. 6.

Zero Defects was Crosby's nostrum, but is really just another way of saying quality is meeting specfications. Deming's ideas are much broader than that and are, perhaps, best captured with the phrase 'continual improvement'. This term connotes the ongoing nature of the strategy. According to Deming, quality is not a state to be achieved in manufacturing, but is, rather, an ongoing company-wide effort at continual improvement. What Bill Conway called "the process – the way everyone thinks, talks, works and acts every day." After all the nonsense is stripped away, the fact is that Japanese automakers (Toyota, Honda and Nissan) make better cars than American automakers (GM, Ford and Chrysler) and have done now for years. Buyers are not idiots. They understand value, and realize that better quality at the same or lower cost is excellent value. End of story. But the implications of the story are not just confined to the auto industry. Cameras, computers, appliances, power tools, earthmoving equipment, and more have fallen from America's basic manufacturing industries to a legacy of plant closings, job losses and dwindling revenues and profits.

10. Quality control: what is new?

Recent decades have witnessed a growing trend to improve the effectiveness of quality control by formal adoption of modern concepts, methodologies, and tools. These have included: Systematic planning for quality control, with extensive participation by the operating personnel Formal application of the feedback loop, and establishment of clear responsibility for the associated
decisions and actions Delegation of decisions to the work force through self-control and self-inspection Wide application of statistical process control and the associated training of the operating personnel A structured information network to provide a factual basis for decision making A systematic process for corrective action in the event of sporadic adverse change Formal company manuals for quality control, with periodic audits to ensure up-to-dateness and conformance.

11. Quality control in pharmaceutical industries

11.1 Responsibilities of quality control unit
a. There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company.
b. Adequate laboratory facilities for the testing and approval (or rejection) of components, drug product containers, closures, packaging materials, in-process materials, and drug products shall be available to the quality control unit.
c. The quality control unit shall have the responsibility for approving or rejecting all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product.
d. The responsibilities and procedures applicable to the quality control unit shall be in writing; such written procedures shall be followed.

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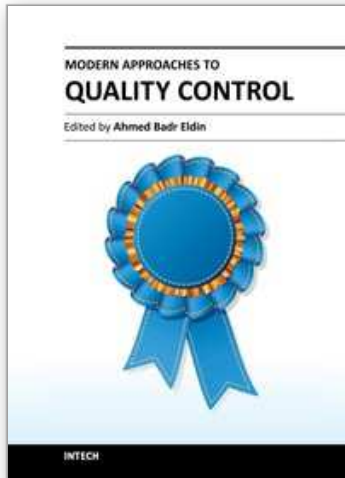
Modern Approaches To Quality Control

Edited by Dr. Ahmed Badr Eldin

Rapid advance have been made in the last decade in the quality control procedures and techniques, most of the existing books try to cover specific techniques with all of their details. The aim of this book is to demonstrate quality control processes in a variety of areas, ranging from pharmaceutical and medical fields to construction engineering and data quality. A wide range of techniques and procedures have been covered.

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