Original Paper

Possibilities and limits of quality assurance[1])

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Quality assurance, a few years ago known by insiders only, has in the meantime taken a firm place in the consciousness of the public at large. This paper describes the history of development of quality assurance. Quality assurance as a superterm nowadays is not limited to quality control but also includes ideas and activities in connection with reliability, costs, organisation, liability, process capability, motivation and management. Quality assurance as a matter not only for experts is the challenge of the years to come.

Möglichkeiten und Grenzen der Qualitätssicherung

Qualitätssicherung, vor wenigen Jahren nur ein Begriff für Insider, hat inzwischen einen festen Platz im allgemeinen Bewußtsein eingenommen. Diese Arbeit beschreibt die historische Entwicklung der Qualitätssicherung. Heute ist Qualitätssicherung als Oberbegriff nicht mehr auf Qualitätsprüfung beschränkt, sondern umfaßt vielmehr Vorstellungen und Maßnahmen im Zusammenhang mit Zuverlässigkeit, Kosten, Organisation, Haftung, Einsatzbereitschaft, Motivation und Management. Qualitätssicherung ist nicht nur eine Angelegenheit für Fachleute, sie ist die Herausforderung für die kommenden Jahre schlechthin.

1. Introduction

Quality assurance, a few years ago known by insiders only, has in the meantime taken a firm place in the consciousness of the public at large. Quality assurance has lost the odour of a necessary evil and has become an indispensable specialty in its own right.

In order to assess the possibilities, and also the limits, of quality assurance, the following examples are given to show from where the quality assurance comes and where it will probably go.

2. Development of quality knowledge

2.1. Measuring and testing technology

The development of quality knowledge and quality assurance is inconceivable without measuring technology. Those who, around 1950, had to perform the so-called "quality control" in an industrial undertaking, had to be in control of the measuring technology which was necessary for their functions, of nothing more in fact. For the longitudinal testing technology, this was equivalent to the application of measuring slide, micrometer screw and dial gauge. In conventional production, this type of measuring technology is still the basis of quality assurance.

In the meantime, the extent of the knowledge, especially in measuring technology, has greatly enlarged. The development of intelligent testing systems such as television systems, computer-aided image analysis or measuring robots and even complete measuring centers will open up new possibilities in measuring technology.

2.2. Sampling plans and statistical evaluations

Although in 1931 already, Shewhart had the first appreciable break-through with his publication "Economic control of quality of manufactured product" [1], the methods of applied statistics really gained in importance in the 1950s only.

First steps were done in the development of random sampling methods and systems and, in particular, with the methods for their evaluation. With their aid, the quality controller was in a much better position to make "reproducible" decisions. The acceptance or the rejection of a lot delivered on the basis of an accidental random sampling result could now be substantiated. At the same time, he succeeded in arranging better, and organizing more expressively, the "burial ground of figures" of his series of measurements. For random samples or evaluations, the professionally trained quality expert has now at his disposal readily developed standards.

2.3. Reliability

Then, in the 1960s, the continuing methods of "technical reliability" developed especially in the

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field of electrical engineering, but later on also in mechanical engineering and, in particular, in energy technology. Parameters such as average life, failure frequency and failure probability, gave the engineer for the first time the possibility to figure out the quality during or after a given period of time with given application conditions.

As a "zero" risk does basically not exist, the problem arises within the scope of the reliability planning – as elsewhere in technology – to find for each technical system a compromise acceptable to everybody between the extreme values of a prohibitively expensive safety and an unjustifiable risk.

2.4. Quality costs

Then – starting approximately in 1965 – the cost consciousness in addition to thinking in technical connections gained increasingly in importance for the quality engineer. He had now to try, like any other employee, too, to contribute his share to cost reduction and improvement of income in the company.

Methods were developed for the systematic recording, processing and reporting of costs. In connection with the knowledge of the completion of necessary cost/profit analyses, the quality expert is now optimally prepared for making possible cost-effective thinking also in the field of quality assurance.

2.5. Product liability

The discussion, starting in the late 1960s, of the liability for the consequences resulting from an unsatisfactory quality has gained, during the last years, an ever increasing importance especially also in Europe. Slogans like "consumer protection" and "product liability" are characteristic of this trend.

It must be noted in connection therewith that product liability is not primarily concerned with the supplied product itself, but with the effects resulting from its defectiveness. These consequential damages normally exceed, in most cases, the value of the defective product itself. It is referred, for instance, only to the spectacular recalling actions of the last years due to damage occurred in series.

As product liability concerns all those who, in the widest sense, make the product and put it into circulation, as well as those who are in some way involved in this, for instance, testing institutes, subcontractors, distributors or importers, adequate quality assurance steps are to be taken for the respective scope of responsibility. The quality expert now is completed to grapple with legal thinking.

2.6. Organization

The expansion described of the quality knowledge started about the early 1970s and led consistently to the development of quality assurance systems, the defined organization of setup and sequence for the implementation of the quality assurance. Quality assurance is no longer now the affair of particular divisions, but comprises – seen as a system – the whole company. Accordingly, it is neither any longer an individual person or office being responsible for putting into action the quality assurance system.

Typical of methods of modern quality assurance is, on the contrary, the fact that the responsibility of the individual extends into the work sequence of another organization unit. To ensure a smooth sequence, and to avoid disturbances, it is absolutely necessary to describe the activities of certain personnel positions and to coordinate this with, and to inform thereof, other offices.

The systematic compilation of certain rules which must be adhered to for safeguarding the quality, resulted, first of all in the military field, in aviation and space navigation as well as in nuclear engineering, in voluminous guidelines for specific lines of business and products, which are the starting point for the present quality assurance system standards as, for instance, ISO 9000 to 9004 [2 to 6]. It is only the existence and the logical application of a quality assurance system standard which put the quality assurance expert in a position to think comprehensively and encompassing all branches, i.e., within the system.

3. Quality assurance – the challenge of the years to come

Since the early 1980s, there can be no more recorded a precipitous development of individual crucial subjects, but the evolution of the quality knowledge takes place simultaneously at all fronts. Yet, part of them are not exclusively innovations in the field of quality assurance, but also already existing areas of knowledge are taken up again and consistently improved.

Only a few essential ones of the abundance of the pending problems and functions with which the quality assurance expert is currently confronted are cited in the following.

3.1. Consumer behaviour and legal claims

3.1.1. Consumer behaviour and quality

During the last years, users and consumers have been thoroughly informed and instructed. The consumer is nowadays ready to pay a reasonable price for products of a provable high quality. He will, however, critically scrutinize the fulfilment of his quality requirements. The average citizen believes that the industry does not care enough about the

quality of its products as long as they sell well. In addition, he is crammed with real or exaggerated horror stories about inadequate products, i.e., unsatisfactory quality and environmental pollution, so that he gradually loses faith in the statements made by the industry.

The consumer who becomes ever more critical, expects satisfactory quality, great benefit and sufficient safety for everything he wears, uses, employs or consumes. Testing institutes and laboratories safeguard the interests of the consumer and check all sorts of products as to whether they meet all the requirements of the market. Moreover, the consumer is ever less tolerant towards products which do not meet his quality requirements, and expresses increasingly his displeasure also towards public authorities or even in court.

All this happens simultaneously with increasing competition and rising manufacturing costs. Manufacturers are, therefore, well advised if they earnestly try to learn more about the comprehension of the consumer for quality and benefit of a product, in order to being able to derive therefrom more effectively the quality requirements for their own products. Only if they succeed in this will they recover the confidence of the consumer.

3.1.2. Quality and legal claims

It is possibly due to the now more critical basic attitude of the consumer that manufacturers are deluged by a continuously rising flood of instructions, ordinances, regulations and rules of all kinds of authorities. Many of these imposed requirements seem to restrict the free market economy. Manufacturers might now rightly complain about the increasing influence of the authorities granting permits as well as the supervisory authorities. Nevertheless, they have to put up with the fact of an increasing number of regulations. Manufacturers must be aware of this influence being exerted in the future in nearly all fields of industry, from development to final product manufacture. In putting through consumer protection and other interests meriting preservation, authorities and institutes will no longer confine themselves to state which (quality) requirements are to be met, but they will more and more proceed to dictate to manufacturers how these requirements are to be met. However, the controlling measures and regulations of the most recent past have, at least, one positive effect: the executives of the industry are emphatically forced to procure more and more comprehensive information on quality and knowledge of quality assurance.

If the industry accepts the fact that quality assurance is gaining ever more significance for a lasting success in business, it can only gain by the broadening knowledge of its executives.

3.1.3. Quality and liability

The liability for damages arising from a faulty product or a poor performance, hence the product liability, is, as shown already by the Codex Hammurabi, basically age-old. What is new in this, is the modified legislation which now requires of industrial manufacturers, as opposed to former times, the evidence of the discharge from liability (reversal of the burden of proof), i.e., that he is not to blame and that he has done everything possible which can reasonably be expected of him, in order to avoid this deficiency.

A fault arises, in particular, from the infringement of duties of care. This is a wide field for the quality assurance expert.

In the field of organization the areas of responsibility are to be defined. Dependable and qualified personnel has to be selected and employed. The staff members in all kinds of divisions are to be instructed and supervised in regular intervals.

In the division of development and design, every possible risk must be reconsidered from the point of view of the "state of the art", and, among other things, standards – e.g. for the Federal Republic of Germany: DIN (Deutsches Institut für Normung) and VDE (Verband Deutscher Elektrotechniker) – and other protective instructions are to be followed. Drawings, specifications and evaluations are to be checked before release for series production.

In the production division, among other things, steps for maintenance and control of machinery and equipment, mainly measuring instruments are to be taken. Qualified suppliers shall be selected.

In the instruction division, attention shall be paid to the requirement that adequate accompanying notes, operating instructions, maintenance specifications, provisions against risks and the like shall be prepared.

In the product observation division, manufacturers shall do everything which can be reasonably expected of them to do, for instance, also a recalling action in order to avert dangers, as soon as they realize the same. Conclusions shall accordingly be drawn from notifications of damage, and shall be evidenced.

To sum up, it can be said that manufacturers shall do everything within their power to ensure that their products are still safe and reliable, also after long periods of use. They must, of course, be able to furnish clear evidence of the way they have solved this problem.

3.2. Quality of the draft and control of methods

A new and large group of functions includes the subjects of quality of draft, quality planning, process control, automation of tests and computer aid for development, production and testing.

3.2.1. Quality in the development stage

The quality assurance methods which were common practice so far, were mainly confined to the detection of defective products before their delivery. For effective removal of causes of errors, it is no longer sufficient to perform subsequent corrective action after the product test and the evaluation of results. It will rather be necessary to take preventive quality assurance steps during the development and – what must not be forgotten – also in the experimental stage.

Quality assurance in the development stage includes considerations on reliability, maintainability, operability and safety of the product. This task can be accomplished only by cooperation of all the parties concerned, where everybody contributes his share, in the course of the product cycle, to the determination and definition of the quality requirements and of the quality plan.

Quality assurance must be an integral part of all planning activities to ensure that the aspects of quality are adequately considered already in the development stage, before the product reaches the actual production or even the critical purchaser.

3.2.2. Assurance of quality capacity

The growing demands on efficiency, flexibility, profitability and life of products lead to ever increasing demands on quality capacity of machinery and processes. This complex has recently become known by the slogan "Statistical Process Control" (SPC), meaning analytical investigations and ratings of materials and products during the entire production sequence with the aid of applied statistics.

Inasfar as technically and economically feasible, possibilities of control are provided already in the production line. Thereby a direct return notification of the process results is obtained. It is now possible to intervene more rapidly in the process control.

The assurance of the quality capacity also includes testing and release of the processes before commencement of production. Together with the subsequent control of the process parameters during the production, they confirm the validity of the processes found to be correct. The target, to obtain a quality improvement at a cost as low as possible, can be realized most effectively by practical application of the process control.

3.2.3. Automation of tests

Up-to-date microprocessors lead to an increase of accuracy and of the degree of automation not only in production, but also in testing. The application of intelligent measuring and testing systems in the direct process sequence, with computer-aided evaluation and return notification for process control, leads to the nearly complete relief of the examiner of his previous function. The ability of the examiner to take decisions, can no longer keep pace with the automated manufacturing processes. Computer-aided automated tests, with a measuring robot, for instance, and high-speed non-destructive testing methods will, therefore, be applied increasingly. The microprocessor, with its possibility of application for permanent control of processes, will replace the testing of lots and production units, which is dependent on individuals and still common practice in many branches of industry.

The activities of the examiner will be confined to the testing and rating of a few test specimens only. Instead of his traditional function, the "inspector" will have to accomplish new and more exacting tasks.

3.2.4. Computer-aided development, production and testing

The necessity of increase in productivity, the improvement of quality and the rise of flexibility, with lot sizes becoming ever smaller, are a compelling reason for continued automation. An enormous growth of product-related data is the consequence thereof. Automation and a comprehensive exchange of information can henceforth be mastered only with the selective application of computers.

Inasfar as it can be realized, the result of Computer-Aided Development (CAD), for instance, is partly used, at the same time, for the control of production and assembly equipment (CAM) and for the automatic performance of tests (CAI). With the application of appropriate computer programs, potential errors can be detected and eliminated already from the outset. At the same time the risk of transmission and recording errors is reduced. A prerequisite for the smooth application of computers in the total process sequence is, of course, also in this case the consideration of quality assurance in the planning stage.

Adding to the aforementioned application possibilities CAD, CAM and CAI to tasks of the integrated quality assurance (CAQ), work scheduling (CAP), production planning and control (PPS), then with the comprehensive term "Computer-Integrated Manufacturing" (CIM) the threshold of the factory of the future is reached. It should not be forgotten, however, that the application of the new computer-aided processes requires a large number of highly qualified personnel also in quality assurance.

3.3. Management, motivation and training

The quality of the performance and thus the success of a company are decisively shaped by the individual performances of the people working in said company.

Two factors determine the performance and thus the quality capability of the employees: on the one hand the knowledge in the specialized field of quality assurance and on the other hand the motivation.

3.3.1. Motivation

For the future of a company, the degree of the motivation, hence the identification of the employees with the company and with their own work, is a matter of life and death.

For the executives of quality assurance and the management, the motivation of the employees is one of the greatest challenges. More satisfaction at the work place and an increase in the quality of the work can be achieved only by direct participation of the persons affected. All company divisions should be pervaded by the awareness that a satisfactory quality can only be the result of a positive basic attitude. Quality is no longer only a matter of technical experts, but it is a concern of each individual. A matter which concerns everyone, is all the more a matter for executives.

The example of the executives in matters of quality assurance plays an important role for the motivation of the employees.

As the term "quality" has been given a new and higher status, the quality expert has also to take over a new and more important part. His task is to assist the executives in their efforts to develop an effective strategy in the direction of quality consciousness. Nothing will change if the conduct of the executives changes neither.

3.3.2. Training

Employee-related quality promotion requires, in addition to the motivation of the employees, imparting the knowledge and the methods of quality assurance. It is a regrettable fact that no vocational training is currently offered in the Federal Republic of Germany for the subject "quality assurance". Even in universities and colleges, the "science of quality" is taught not at all or not integrally. The modern-type production process with its increasing automation, rationalization and product optimization expects, however, sufficiently qualified personnel for performing the multiple functions in the field of quality assurance.

For more than 35 years, the Deutsche Gesellschaft für Qualität e. V. (DGQ), Frankfurt am Main, (German Society for Quality, Inc.) has, therefore, offered a comprehensive inter-company training program. The DGQ itself is recognized as a non-profit institution and its training program as deserving aid by public authorities. Such inter-company training can by no means replace any intra-plant training

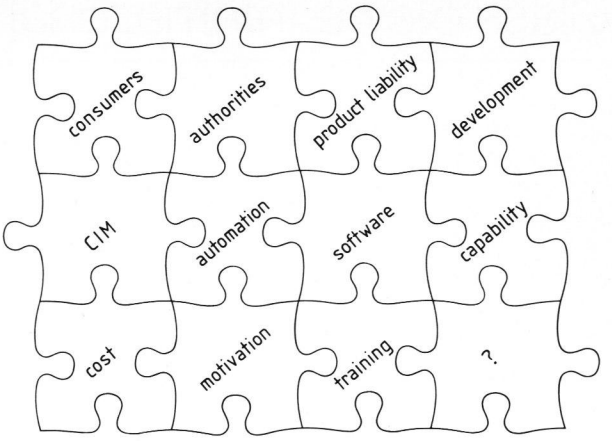

Figure 1. The "quality puzzle" of the 1980s.

in this field. It will remain the task of the companies to provide for methodical and adequate training of their employees. It is also evident that such training must not be restricted to the employees of the quality department. Also in the 1980s the "quality puzzle" as shown in figure 1 has had to be solved.

Summary

From the faint beginnings of quality control the exacting and large scope of activities of quality assurance has meanwhile developed. The term "quality assurance" can today no longer automatically be attributed to one specific case of application only. Quality assurance has become a subject which is by far too comprehensive to be put simply into one single drawer which can be opened and closed at will. Quality assurance is no longer a coercive measure or provisional solution, but is has become an effective tool in every executive's hand. Consequently, quality assurance is and for the years to come will remain a challenge for the manufacturer.

5. References

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