Quality assurance

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Quality assurance (**QA**) is a way of preventing mistakes or defects in manufactured products and avoiding problems when delivering solutions or services to customers; which ISO 9000 defines as "part of quality management focused on providing confidence that quality requirements will be fulfilled".[1] This defect prevention in quality assurance differs subtly from defect detection and rejection in quality control, and has been referred to as a *shift left* as it focuses on quality earlier in the process.[2]

The terms "quality assurance" and "quality control" are often used interchangeably to refer to ways of ensuring the quality of a service or product.[3] For instance, the term "assurance" is often used as follows: *Implementation of inspection and structured testing as a measure of quality assurance in a television set software project at Philips Semiconductors is described.*[4] The term "control", however, is used to describe the fifth phase of the DMAIC model. DMAIC is a data-driven quality strategy used to *improve* processes.[5]

Quality assurance comprises administrative and procedural activities implemented in a quality system so that requirements and goals for a product, service or activity will be fulfilled.[3] It is the systematic measurement, comparison with a standard, monitoring of processes and an associated feedback loop that confers error prevention.[6] This can be contrasted with quality control, which is focused on process output.

Quality assurance includes two principles: "Fit for purpose" (the product should be suitable for the intended purpose); and "right first time" (mistakes should be eliminated). QA includes management of the quality of raw materials, assemblies, products and components, services related to production, and management, production and inspection processes. The two principles also manifest before the background of developing (engineering) a novel technical product: The task of engineering is to make it work once, while the task of quality assurance is to make it work all the time.[7]

Suitable quality is determined by product users, clients or customers, not by society in general. It is not related to cost, and adjectives or descriptors such as "high" and "poor" are not applicable. For example, a low priced product may be viewed as having high quality because it is disposable, whereas another may be viewed as having poor quality because it is not disposable.

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History

Initial efforts to control the quality of production

During the Middle Ages, guilds adopted responsibility for the quality of goods and services offered by their members, setting and maintaining certain standards for guild membership.[8]

Royal governments purchasing material were interested in quality control as customers. For this reason, King John of England appointed William Wrotham to report about the construction and repair of ships. Centuries later, Samuel Pepys, Secretary to the British Admiralty, appointed multiple such overseers.

Prior to the extensive division of labor and mechanization resulting from the Industrial Revolution, it was possible for workers to control the quality of their own products. The Industrial Revolution led to a system in which large groups of people performing a specialized type of work were grouped together under the supervision of a foreman who was appointed to control the quality of work manufactured.

Wartime production

During the time of the First World War, manufacturing processes typically became more complex with larger numbers of workers being supervised. This period saw the widespread introduction of mass production and piece work, which created problems as workmen could now earn more money by the production of extra products, which in turn occasionally led to poor quality workmanship being passed on to the assembly lines. To counter bad workmanship, full-time inspectors were introduced to identify, quarantine and ideally correct product quality failures. Quality control by inspection in the 1920s and 1930s led to the growth of quality inspection functions, separately organized from production and large enough to be headed by superintendents.

The systematic approach to quality started in industrial manufacturing during the 1930s, mostly in the U.S., when some attention was given to the cost of scrap and rework. The impact of mass production required during the Second World War made it necessary to introduce an improved form of quality control known as Statistical Quality Control, or SQC. Some of the initial work for SQC is credited to Walter A. Shewhart of Bell Labs, starting with his famous one-page memorandum of 1924..

SQC includes the concept that every production piece cannot be fully inspected into acceptable and non-acceptable batches. By extending the inspection phase and making inspection organizations more efficient, it provides inspectors with control tools such as sampling and control charts, even where 100 percent inspection is not practicable. Standard statistical techniques allow the producer to sample and test a certain proportion of the products for quality to achieve the desired level of confidence in the quality of the entire batch or production run.

Postwar

In the period following World War II, many countries' manufacturing capabilities that had been destroyed during the war were rebuilt. General Douglas MacArthur oversaw the re-building of Japan. During this time, General MacArthur involved two key individuals in the development of modern quality concepts: W. Edwards Deming and Joseph Juran. Both individuals promoted the collaborative concepts of quality to Japanese business and technical groups, and these groups utilized these concepts in the redevelopment of the Japanese economy.

Although there were many individuals trying to lead United States industries towards a more comprehensive approach to quality, the U.S. continued to apply the Quality Control (QC) concepts of inspection and sampling to remove defective product from production lines, essentially ignoring advances in QA for decades.

Approaches

Failure testing

A valuable process to perform on a whole consumer product is failure testing or stress testing. In mechanical terms this is the operation of a product until it fails, often under stresses such as increasing vibration, temperature, and humidity. This exposes many unanticipated weaknesses in a product, and the data is used to drive engineering and manufacturing process improvements. Often quite simple changes can dramatically improve product service, such as changing to mold-resistant paint or adding lock-washer placement to the training for new assembly personnel.

Statistical control

Statistical control is based on analyses of objective and subjective data.[9] Many organizations use statistical process control as a tool in any quality improvement effort[10] to track quality data. Any product can be statistically charted as long as they have a common cause variance or special cause variance to track.[11]

Walter Shewart of Bell Telephone Laboratories recognized that when a product is made, data can be taken from scrutinized areas of a sample lot of the part and statistical variances are then analyzed and charted. Control can then be implemented on the part in the form of rework or scrap, or control can be implemented on the process that made the part, ideally eliminating the defect before more parts can be made like it.[9]

Total quality management

The quality of products is dependent upon that of the participating constituents,[12] some of which are sustainable and effectively controlled while others are not. The process(es) which are managed with QA pertain to Total Quality Management.

If the specification does not reflect the true quality requirements, the product's quality cannot be guaranteed. For instance, the parameters for a pressure vessel should cover not only the material and dimensions but operating, environmental, safety, reliability and maintainability requirements.

Models and standards

ISO 17025 is an international standard that specifies the general requirements for the competence to carry out tests and or calibrations. There are 15 management requirements and 10 technical requirements. These requirements outline what a laboratory must do to become accredited. Management system refers to the organization's structure for managing its processes or activities that transform inputs of resources into a product or service which meets the organization's objectives, such as satisfying the customer's quality requirements, complying with regulations, or meeting environmental objectives. WHO has developed several tools and offers training courses for quality assurance in public health laboratories.[13]

The Capability Maturity Model Integration (CMMI) model is widely used to implement Process and Product Quality Assurance (PPQA) in an organization. The CMMI maturity levels can be divided into 5 steps, which a company can achieve by performing specific activities within the organization.

Company quality

During the 1980s, the concept of "company quality" with the focus on management and people came to the fore. It was realized that, if all departments approached quality with an open mind, success was possible if the management led the quality improvement process.

The company-wide quality approach places an emphasis on four aspects :-

1. Elements such as controls, job management, adequate processes, performance and integrity criteria and identification of records
2. Competence such as knowledge, skills, experiences, qualifications
3. Soft elements, such as personnel integrity, confidence, organizational culture, motivation, team spirit and quality relationships.
4. Infrastructure (as it enhances or limits functionality)

The quality of the outputs is at risk if any of these aspects is deficient.

QA is not limited to manufacturing, and can be applied to any business or non-business activity, including: design, consulting, banking, insurance, computer software development, retailing, investment, transportation, education, and translation.

It comprises a quality improvement process, which is generic in the sense that it can be applied to any of these activities and it establishes a behavior pattern, which supports the achievement of quality.

This in turn is supported by quality management practices which can include a number of business systems and which are usually specific to the activities of the business unit concerned.

In manufacturing and construction activities, these business practices can be equated to the models for quality assurance defined by the International Standards contained in the ISO 9000 series and the specified Specifications for quality systems.

In the system of Company Quality, the work being carried out was shop floor inspection which did not reveal the major quality problems. This led to quality assurance or total quality control, which has come into being recently.

In practice

Medical industry

QA is very important in the medical field because it helps to identify the standards of medical equipments and services. Hospitals and laboratories make use of external agencies in order to ensure standards for equipment such as X-ray machines, Diagnostic Radiology and AERB.

Aerospace industry

The term product assurance (PA) is often used instead of quality assurance and is, alongside project management and engineering, one of the three primary project functions. Quality assurance is seen as one part of product assurance. Due to the sometimes catastrophic consequences a single failure can have for human lives, the environment, a device, or a mission, product assurance plays a particularly important role here. It has organizational, budgetary and product developmental independence meaning that it reports to highest management only, has its own budget, and does not expend labor to help build a product. Product assurance stands on an equal footing with project management but embraces the customer's point of view.[7]

Software development

Software Quality Assurance consists of a means of monitoring the software engineering processes and methods used to ensure quality. The methods by which this is accomplished are many and varied, and may include ensuring conformance to one or more standards, such as ISO 9000 or a model such as CMMI. In addition, enterprise quality management software is used to correct issues such as: supply chain disaggregation and regulatory compliance which are vital among medical device manufacturers.[14]

Using contractors and/or consultants

Consultants and contractors are sometimes employed when introducing new quality practices and methods, particularly where the relevant skills and expertise are not available within the organization or when allocating the available internal resources are not available. Consultants and contractors will often employ Quality Management Systems (QMS), auditing and procedural documentation writing CMMI, Six Sigma, Measurement Systems Analysis (MSA), Quality Function Deployment (QFD), Failure Mode and Effects Analysis (FMEA), and Advance Product Quality Planning (APQP).

See also

- Best practice
- Data quality
- Data integrity
- Farm assurance
- GxP, a general term for Good Practice quality guidelines and regulations
- ISO 9000
- Mission assurance
- Production assurance
- Program assurance
- QA/QC
- Quality engineering
- Quality infrastructure
- Quality management
- Quality management system
- Ringtest, part of a quality assurance program in which identical samples are analyzed by different laboratories
- Software testing
- Software quality assurance
- Total quality management
- Verification and validation

References

1. ISO 9000:2005, Clause 3.2.11
2. Larry, Smith (2001). "Shift-Left Testing" (http://www.drdobbs.com/shift-left-testing/184404768).
3. "Quality Assurance vs Quality Control - Learning Resources - ASQ" (http://asq.org/learn-about-quality/quality-assurance-quality-control/overview/overview.html).
4. "ASQ - Practical Quality Assurance for Embedded Software" (http://asq.org/data/subscriptions/sqp_open/1999/june/sqpv1i3vanveenendaal.html).
5. "Define, Measure, Analyze, Improve, Control (DMAIC Approach) - ASQ" (http://asq.org/learn-about-quality/six-sigma/overview/dmaic.html).
6. The Marketing Accountability Standards Board (MASB) endorses this definition as part of its ongoing Common Language in Marketing Project (http://www.commonlanguage.wikispaces.net/).
7. Prause, Christian; Bibus, Markus; Dietrich, Carsten; Jobi, Wolfgang (2016). "Software Product Assurance at the German Space Agency". *Journal of Software: Evolution and Process*. **28** (9): 744–761.
8. ASQ – History of Quality (http://asq.org/learn-about-quality/history-of-quality/overview/overview.html). Retrieved 17 November 2014
9. Evans, James R. (1994) Introduction to Statistical Process Control (http://www.flexstudy.com/catalog/schpdf.cfm?coursenum=9561a) Archived (https://web.archive.org/web/20131029203204/http://www.flexstudy.com/catalog/schpdf.cfm?coursenum=9561a) October 29, 2013, at the Wayback Machine., *Fundamentals of Statistical Process Control*, pp 1–13
10. http://www.nctr.usf.edu/jpt/pdf/JPT%208-2%20Smith_Chaudhry.pdf
11. "Statistical Process Control & Process Control Tools - ASQ" (http://asq.org/learn-about-quality/statistical-process-control/overview/overview.html).
12. Thareja, Mannu; Thareja, Priyavrat (February 2007). "The Quality Brilliance Through Brilliant People". *Quality World*. **4** (2). SSRN 1498550 (https://ssrn.com/abstract=1498550).

13. The World Health Organization, Public Health Laboratory Quality Assurance: tools and training (http://www.euro.who.int/en/health-topics/Health-systems/laboratory-services/quality-tools-and-training)
14. "Managing Quality Across the Enterprise: Enterprise Quality Management Solution for Medical Device Companies" (http://www.slideshare.net/spartasystems/managing-quality-across-the-enterprise). Sparta Systems. 2015-02-02.

Further reading

Journals

- *The Quality Assurance Journal*, ISSN 1087-8378, John Wiley & Sons
- *Quality Progress*, ISSN 0033-524X American Society for Quality
- *Quality Assurance in Education*, ISSN 0968-4883, Emerald Publishing Group
- *Accreditation and Quality Assurance*, ISSN 0949-1775
- *Food Quality and Preference*, ISSN 0950-3293
- *Asigurarea Calitatii*, ISSN 1224-5410

Issues

- Alvaro, Alexandre; De Almeida, Eduardo Santana; De Lemos Meira, Silvio Romero (2007). "A component quality assurance process". *Fourth international workshop on Software quality assurance in conjunction with the 6th ESEC/FSE joint meeting - SOQUA '07*. p. 94. ISBN 9781595937247. doi:10.1145/1295074.1295093.
- Feldman, Stuart (2005). "Quality assurance". *Queue*. **3**: 26. doi:10.1145/1046931.1046943.
- Wagner, Stefan; Meisinger, Michael (2006). "Integrating a model of analytical quality assurance into the V-Modell XT". *Proceedings of the 3rd international workshop on Software quality assurance - SOQUA '06*. p. 38. ISBN 1595935843. doi:10.1145/1188895.1188906.

Books

- Majcen N., Taylor P. (Editors): Practical examples on traceability, measurement uncertainty and validation in chemistry, Vol 1; ISBN 978-92-79-12021-3, 2010.
- Pyzdek, T, "Quality Engineering Handbook", 2003, ISBN 0-8247-4614-7
- Godfrey, A. B., "Juran's Quality Handbook", 1999, ISBN 0-07-034003-X
- Marselis, R. & Roodenrijs, E. "the PointZERO vision", 2012, ISBN 978-90-75414-55-4
- da Silva, R.B., Bulska, E., Godlewska-Zylkiewicz, B., Hedrich, M., Majcen, N., Magnusson, B., Marincic, S., Papadakis, I., Patriarca, M., Vassileva, E., Taylor, P., Analytical measurement: measurement uncertainty and statistics;ISBN 978-92-79-23070-7, 2012.