Quality management system

A **quality management system** (**QMS**) is a collection of business processes focused on consistently meeting customer requirements and enhancing their satisfaction. It is aligned with an organization's purpose and strategic direction (ISO9001:2015). It is expressed as the organizational goals and aspirations, policies, processes, documented information and resources needed to implement and maintain it. Early quality management systems emphasized predictable outcomes of an industrial product production line, using simple statistics and random sampling. By the 20th century, labour inputs were typically the most costly inputs in most industrialized societies, so focus shifted to team cooperation and dynamics, especially the early signalling of problems via a continuous improvement cycle. In the 21st century, QMS has tended to converge with sustainability and transparency initiatives, as both investor and customer satisfaction and perceived quality is increasingly tied to these factors. Of QMS regimes, the ISO 9000 family of standards is probably the most widely implemented worldwide - the ISO 19011 audit regime applies to both, and deals with quality and sustainability and their integration.

Other QMS, e.g. Natural Step, focus on sustainability issues and assume that other quality problems will be reduced as result of the systematic thinking, transparency, documentation and diagnostic discipline.

1 Elements

1. Quality policy
2. Quality objectives
3. Quality manual
4. Organizational structure and responsibilities
5. Data Management
6. Processes - including purchasing
7. Product quality leading to Customer satisfaction
8. Continuous improvement including corrective and preventive action
9. Quality instruments
10. Control of Document

2 Concept of quality - historical background

The concept of quality as we think of it now first emerged from the Industrial Revolution. Previously goods had been made from start to finish by the same person or team of people, with handcrafting and tweaking the product to meet 'quality criteria'. Mass production brought huge teams of people together to work on specific stages of production where one person would not necessarily complete a product from start to finish. In the late 19th century pioneers such as Frederick Winslow Taylor and Henry Ford recognized the limitations of the methods being used in mass production at the time and the subsequent varying quality of output. Birland established Quality Departments to oversee the quality of production and rectifying of errors, and Ford emphasized standardization of design and component standards to ensure a standard product was produced, Management of quality was the responsibility of the Quality department and was implemented by Inspection of product output to 'catch' defects.

Application of statistical control came later as a result of World War production methods, and were advanced by the work done of W. Edwards Deming, a statistician, after whom the Deming Prize for quality is named. Joseph M. Juran focused more on managing for quality. The first edition of Juran's Quality Control Handbook was published in 1951. He also developed the "Juran's trilogy," an approach to cross-functional management that is composed of three managerial processes: quality planning, quality control and quality improvement. These functions all play a vital role when evaluating quality.

Quality, as a profession and the managerial process associated with the quality function, was introduced during the second half of the 20th century, and has evolved since then. Over this period, few other disciplines have seen as many changes as the quality profession.

The quality profession grew from simple control, to engineering, to systems engineering. Quality control activities were predominant in the 1940s, 1950s, and 1960s. The 1970s were an era of quality engineering and the 1990s saw quality systems as an emerging field. Like medicine, accounting, and engineering, quality has achieved status as a recognized profession[1]

As Lee and Dale (1998) state, there are many organisations that are striving to assess the methods and ways in which their overall productivity, the quality of their products and services and the required operations to achieve

them are done.

3 Medical devices

There are two primary, state of the art, guidelines for medical device manufacturer QMS and related services today. Those two guidelines are the ISO 13485 standard and the US FDA 21 CFR 820 regulations. The two have a great deal of similarity, and many manufacturers adopt QMS that is compliant with both guidelines.

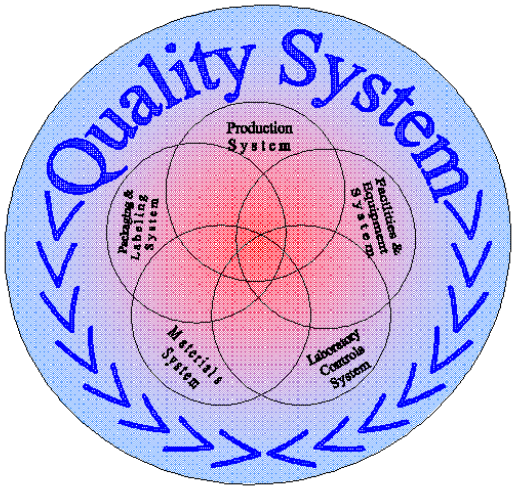
ISO 13485 is harmonised with the European Union medical devices directive (93/42/EEC) as well as the IVD and AIMD directives. The ISO standard is also incorporated in regulations for other jurisdictions such as Japan (JPAL) and Canada (CMDCAS).

Quality System requirements for medical devices have been internationally recognized as a way to assure product safety and efficacy and customer satisfaction since at least 1983, and were instituted as requirements in a final rule published on October 7, 1996. The U.S. Food and Drug Administration (FDA) had documented design defects in medical devices that contributed to recalls from 1983 to 1989 that would have been prevented if Quality Systems had been in place. The rule is promulgated at 21 CFR 820.

According to current Good Manufacturing Practice (GMP), medical device manufacturers have the responsibility to use good judgment when developing their quality system and apply those sections of the FDA Quality System (QS) Regulation that are applicable to their specific products and operations, in Part 820 of the QS regulation. As with GMP, operating within this flexibility, it is the responsibility of each manufacturer to establish requirements for each type or family of devices that will result in devices that are safe and effective, and to establish methods and procedures to design, produce, and distribute devices that meet the quality system requirements.

The FDA has identified in the QS regulation the essential elements that a quality system shall embody for design, production and distribution, without prescribing specific ways to establish these elements. These elements include:

- personnel training and qualification
- controlling the product design
- controlling documentation
- controlling purchasing
- product identification and traceability at all stages of production
- controlling and defining production and process
- defining and controlling inspection, measuring and test equipment



Quality System

- validating processes
- product acceptance
- controlling nonconforming product
- instituting corrective and preventive action when errors occur
- labeling and packaging controls
- handling, storage, distribution and installation
- records
- servicing
- statistical techniques

all overseen by management and quality audits.

Because the QS regulation covers a broad spectrum of devices and production processes, it allows some leeway in the details of quality system elements. It is left to manufacturers to determine the necessity for, or extent of, some quality elements and to develop and implement procedures tailored to their particular processes and devices. For example, if it is impossible to mix up labels at a manufacturer because there is only one label to each product, then there is no necessity for the manufacturer to comply with all of the GMP requirements under device labeling.

Drug manufactures are regulated under a different section of the Code of Federal Regulations:

4 Organizations and awards

See also: List of national quality awards

The International Organization for Standardization's ISO 9001:2008 series describes standards for a QMS addressing the principles and processes surrounding the design, development and delivery of a general product or service. Organizations can participate in a continuing certification process to ISO 9001:2008 to demonstrate their compliance with the standard, which includes a requirement for continual (i.e. planned) improvement of the QMS, as well as more foundational QMS components such as failure mode and effects analysis (FMEA).

(ISO 9000:2005 provides information on the fundamentals and vocabulary used in quality management systems. ISO 9004:2009 provides guidance on quality management approach for the sustained success of an organization. Neither of these standards can be used for certification purposes as they provide guidance, not requirements).

The Baldrige Performance Excellence Program educates organizations in improving their performance and administers the Malcolm Baldrige National Quality Award. The Baldrige Award recognizes U.S. organizations for performance excellence based on the Baldrige Criteria for Performance Excellence. The Criteria address critical aspects of management that contribute to performance excellence: leadership; strategy; customers; measurement, analysis, and knowledge management; workforce; operations; and results.

The European Foundation for Quality Management's EFQM Excellence Model supports an award scheme similar to the Baldrige Award for European companies.

In Canada, the National Quality Institute presents the 'Canada Awards for Excellence' on an annual basis to organisations that have displayed outstanding performance in the areas of Quality and Workplace Wellness, and have met the Institute's criteria with documented overall achievements and results.

EQUASS is a sector-specific quality system designed for the social services sector, and addresses quality principles that are specific to service delivery to vulnerable groups, such as empowerment, rights and person-centredness.

The Alliance for Performance Excellence is a network of state and local organizations that use the Baldrige Criteria for Performance Excellence at the grassroots level to improve the performance of local organizations and economies. browsers can find Alliance members in their state and get the latest news and events from the Baldrige community.

5 Process

A QMS process is an element of an organizational QMS. The ISO9001:2000 standard requires organizations seeking compliance or certification to define the processes which form the QMS and the sequence and interaction of these processes. Butterworth-Heinemann and other publishers have offered several books which provide step-by-step guides to whom seeking the quality certifications of their products [2], [3], [4], [5], [6], [7]

Examples of such processes include:

- Order Processing
- Production planning
- Measurement of product/ service/ process compliant with specified requirements including statistical techniques such as Statistical Process Control and Measurement Systems Analysis
- Calibration
- Internal Audit
- Corrective Action
- Preventive Action
- Identification, labeling and control of non conforming product to preclude its inadvertent use, delivery or processing.
- Purchasing and related processes such as supplier selection and monitoring

ISO9001 requires that the performance of these processes be measured, analysed and continually improved, and the results of this form an input into the management review process.

6 See also

- Capability Maturity Model Integration
- Cleaner production
- Corrective and preventive action
- Good manufacturing practice
- ISO 9000
- ISO 14001
- List of management topics
- List of national quality awards
- Manufacturing process management
- Quality
- Quality assurance
- Quality control
- Quality management

- Standard operating procedure
- Technical documentation
- Total quality management
- Verification and validation

7 References

- ICH1 Guidance E6: Good Clinical Practice: Consolidated guideline (and see Clinical Quality Management System)
- Pyzdek, T, "Quality Engineering Handbook", 2003, ISBN 0-8247-4614-7
- Juran, Joseph M. and De Feo, Joseph A., "Juran's Quality Handbook", 6th Edition, 1999, ISBN 978-0-07-162973-7

[1] American Society for Quality (ASQ) Certified Quality Engineer (CQE) http://prdweb.asq.org/certification/control/quality-engineer/index

[2] Anton, Doug; Carole Anton (2006). *ISO 9001 Survival Guide, Third Edition*. AEM Consulting Group, Inc. p. 100. ISBN 978-0-9672170-8-6.

[3] Tricker, Ray; Bruce Sherring-Lucas (2005). *ISO 9001:2008 In Brief, Second Edition*. Butterworth-Heinemann. p. 192. ISBN 978-0-7506-6616-9.

[4] Tricker, Ray (2005). *ISO 9001:2000 Audit Procedures, Second Edition*. Butterworth-Heinemann. p. 320. ISBN 978-0-7506-6615-2.

[5] Tricker, Ray (2005). *ISO 9001: 2000 For Small Businesses*. Butterworth-Heinemann. p. 480. ISBN 978-0-7506-6617-6.

[6] Hoyle, David (2005). *ISO 9000 Quality Systems Handbook, Fifth Edition*. Butterworth-Heinemann. p. 686. ISBN 978-0-7506-6785-2.

[7] Dobb, Fred (2004). *ISO 9001:2000 Quality Registration Step-by-Step, Third Edition*. Butterworth-Heinemann. p. 292. ISBN 978-0-7506-4949-0.

Business School Press 21. Lee, R., and Dale, B. (1998) Business process management: a review and evaluation, Business Process Re-engineering & Management Journal, 4 (3), 214–225

8 External links

- Baldrige Performance Excellence Program Website
- ICH Website
- FDA Website
- Health Canada Website
- Personnel Certification
- Management Systems Certification

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9.1 Text

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