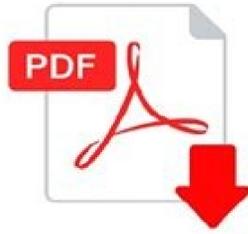


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**Economic Production Quantity (EPQ)**

- Production done in batches or lots  
production capacity > usage or demand rate  
for a part for the part

• Assumptions of EPQ

- similar to EOQ
- except orders are received incrementally during production

**Economic Production Quantity (EPQ)**

**ISO 13485:2016**



Medical devices – Quality management systems – Requirements for regulatory purposes  
On 25th February 2016, ISO 13485:2016 was issued by ISO.

**What is ISO 13485:2016?**

ISO 13485:2016 specifies the requirements for a quality management system for organizations involved in one or more stages of the life cycle of a medical device. It provides the basis for ensuring the consistent design, development, production, installation, and delivery of products that are safe for their intended purpose. ISO 13485:2016 can be used by internal and external parties, including certification bodies, to test an organization's ability to meet both customer and regulatory requirements. However, certification is not a requirement of ISO 13485, and organization can reap the benefits of the standard without being certified.

**What has changed since the previous edition?**

- Some of the key changes on ISO 13485 from its previous edition include:
- Harmonization of regulatory requirements
  - Inclusion of risk management throughout the quality management system
  - Additional clarity with regard to validation, verification and design activities
  - Strengthening of supplier control processes
  - Increased focus regarding feedback mechanisms
  - Harmonization of the requirements for software validation for different software applications

**Relationship between ISO 13485:2016 and ISO 9001:2015**

ISO 13485 is a standalone standard, but it is based on and follows the format of ISO 9001. This edition follows the format of ISO 9001:2008, which has been superseded by ISO 9001:2015. This means the edition does not adopt the high level structure introduced by ISO 9001:2015. For convenience of users, Annex B of ISO 13485:2016 provides a comparison of content between ISO 13485:2016 and ISO 9001:2015.

**How long it has to implement the new ISO 13485:2016?**

It has 3 years from the publication date to comply with the new ISO 13485:2016. If you want to ensure continuing compliance and certification to ISO 13485, you will need to update your quality management system for compliance with the new edition. To ensure that you develop accurate transition plans, make sure you have sight of ISO 13485:2016 as soon as possible.

For more information on ISO 13485:2016, please visit our website: [www.iso.org](http://www.iso.org) or contact your nearest ISO member body.

**STATISTICS**  
FOR BUSINESS AND ECONOMICS  
FIFTH EDITION

R P Hooda

# The Economics of Software Quality



Capers Jones  
Olivier Bonsignour

Foreword by Thaddeus Arroyo  
Chief Information Officer, AT&T Services, Inc.

The TQM mindset pervades across all aspects of an organization, from hiring to internal processes to product development. Show less Show more Advertising ON OFF If you agree, we will use cookies to complement your shopping experience, as described in our Cookie Notice Show less Show more 5%off 5%off 5 ratings 4.4 out of 5 stars 5 60% (3) 4 20% (1) 3 20% (1) 2 0% (0) 1 0% (0) ("bd\_js\_shop":"Shop","bd\_js\_too\_long\_for\_shipping\_label":"Sorry, that's too long for our shipping labels","bd\_omnibus\_ph1\_price\_statement\_suffix":"vs RRP","bd\_js\_too\_long":"Sorry, that's too long","bd\_js\_could\_not\_find\_address\_try\_again":"Sorry, we couldn't find the address. In 2008, Tata Steel created the Performance Improvement Committee (PIC) to drive continuous performance improvement. Toyota adopted a related practice called statistical quality control (SQC) in 1949. Working with the Union of Japanese Scientists and Engineers, Deming taught and lectured on statistical quality control, while adding his own ideas about quality control in the process. Although Deming, Juran, Shewhart and others published numerous papers and books on TQM, many organizations adopted only parts of the TQM principles, and evolved some of TQM's ideas to meet their own needs. More specifically, TQM puts a spotlight on the processes that organizations use to produce their products, and it calls for organizations to define those processes, continuously monitor and measure their performance, and use that performance data to drive improvements. In 1951, Toyota launched the Creative Idea Suggestion System, which was based on a suggestion system used at Ford. Please enter manually;"bd\_js\_keep\_typing\_to\_refine\_search\_results":"Keep typing to refine the search results","bd\_js\_top\_categories":"Top Categories","bd\_price\_save":"Save {0}","bd\_js\_name\_only\_letters":"Sorry, full name can only contain letters","bd\_js\_show\_more":"show more","bd\_js\_enter\_valid\_email\_address":"Please enter a valid email address","bd\_js\_enter\_address\_manually":"Enter address manually","bd\_js\_more\_categories":"More Categories","bd\_30\_day\_low\_price\_carousel":"30-day low price","bd\_js\_continue\_shopping":"Continue Shopping","bd\_js\_account\_and\_help":"Account & Help","bd\_js\_basket\_checkout":"Basket / Checkout","bd\_add\_to\_basket":"Add to basket","bd\_js\_enter\_first\_last\_name":"Please enter a first and last name","bd\_js\_please\_enter\_your":"Please enter your") Total Quality Management (TQM) is a management framework based on the belief that an organization can build long-term success by having all its members, from low-level workers to its highest ranking executives, focus on improving quality and, thus, delivering customer satisfaction. Tata Steel adopted TQM in the 1980s. This means that products ship with fewer defects, which reduce product recalls, future customer support overhead and product fixes. In 1994, the "Toyota Group Executive TQM Training Course" was established, providing TQM training for new executives. They sought to ensure value creation in a system that covered customers and suppliers. United States producers throughout the 1970s and 1980s adopted quality and productivity methods, including TQM, to better compete in the increasingly global marketplace. W. Well-defined cultural values. This management framework was initially applied to companies in the manufacturing sector, but, over the decades, organizations in other sectors have adopted it, as well. Cookies are used to provide, analyse and improve our services; provide chat tools; and showyou relevant content on advertising, TQM's objectives are to eliminate waste and increase efficiencies by ensuring that the production process of the organization's product (or service) is done right the first time. The adoption of TQM and kaizen at Toyota led to higher product and work quality at all levels of the organization. Tata Steel used TQM methodologies to gain a deep understanding of customers. Performance Improvement (PI) Groups were established for iron making, steel making, flat rolling, long rolling, maintenance and more. Shewhart, an engineer at Western Electric and Bell Telephone Laboratories, created a statistical control chart in the mid-1920s, and then published Economic Control of Quality of Manufactured Product in 1931. With a focus on teamwork, TQM leads to the creation of cross-functional teams and knowledge sharing. Please try again","bd\_saving\_percent\_off":"{0}% off","bd\_js\_total\_basket\_count":"{0, plural, one {You have 1 item in your basket} other {You have # items in your basket}}","bd\_js\_total\_cost":"Total cost: {0}","bd\_js\_show\_less":"show less","bd\_js\_item\_added\_to\_your\_basket":"Item added to your basket","bd\_rrp":"RRP","bd\_link\_prefix":"","bd\_js\_unable\_get\_address\_enter\_manually":"Sorry, we are unable to get the address. In 2011, Toyota announced that more than 40 million suggestions (to date) were generated by the Creative Idea Suggestion System. Essential We use cookies to provide our services, for example, to keep track of items stored in your shopping basket, prevent fraudulent activity, improve the security of our services, keep track of your specific preferences (such as currency or language preferences), and display features, products and services that might be of interest to you. One of the principles of TQM is that creation of products and services is done right the first time. In 1965, Toyota was awarded the Deming Application Prize for major advances in quality improvement. It is also called the Deming cycle, or the PDCA (plan, do, check, act) model. As a result of less product defects, companies save cost in customer support, product replacements, field service and the creation of product fixes. By having all employees focus on quality management and continuous improvement, companies can establish and uphold cultural values that create long-term success to both customers and the organization itself. Juran also lectured in Japan during the 1950s. So, although TQM is still influential, other management techniques, such as Six Sigma and lean manufacturing, which better address organizational goals for the 21st century, have replaced it in many businesses. Organizations worldwide took note of Japan's successes using TQM. You can learn more about how we (plus approved third parties) use cookies and how to change your settings by visiting the Cookies notice. Many still refer to his statistical quality control method as the Shewhart cycle. Organizations that practice TQM develop and nurture core values around quality management and continuous improvement. Furthermore, it calls for all employees, as well as all organizational departments, to be part of this process. TQM's focus on quality helps identify skills deficiencies in employees, along with the necessary training, education or mentoring to address those deficiencies. The benefits of TQM include: Less product defects. Toyota's TQM initiatives continue to the current day. You can learn more about our use of cookies hereAre you happy to accept cookies? Satisfied customers. Another example of TQM is Tata Steel, a steel-making company based in India and a subsidiary of the Tata Group. TQM can have an important and beneficial effect on employee and organizational development. We use cookies and similar tools that are necessary to enable you to make purchases, including those used by approved third parties (collectively, "cookies") for the purposes described below. Walter A. The method that evolved during the 1950s and 1960s eventually became known as Total Quality Management. TQM prescribes a series of ways for organizations to accomplish this, with the pathway to successful continuous improvement centered on the use of strategy, data and effective communication to instill a discipline of quality into the organization's culture and processes. Edwards Deming further developed Shewhart's ideas in post-World War II Japan, where the U.S. government had positioned him to advise Japanese leaders on the rebuilding efforts taking place there in the late 1940s and 1950s. The increased communication and coordination across disparate groups deepens institutional knowledge and gives companies more flexibility in deploying personnel. As part of their 2008-2009 annual report, Tata Steel reported that their TQM initiatives resulted in a \$150MM bottom line impact on their business. The choices you make here will apply to your interaction with this service on this device. Moreover, as business needs for efficiency, productivity and quality have further evolved, many organizations have adopted other, more modern management techniques. We use cookies to conduct research and diagnostics to improve our content, products and services, and to measure and analyse the performance of our services. Many credit the Japanese application of TQM as a significant contributor to the country's economic recovery following World War II, as well as its midcentury industrial successes. Among these teachings was Deming's belief that ordinary workers had a role to play in quality control. The cost savings flow to the bottom line, creating higher profit margins. Quality control methods evolved in subsequent decades, with industrial engineer Joseph Juran first employing Shewhart's methods and, later, in 1951, publishing his influential book Juran's Quality Control Handbook. High customer satisfaction, in turn, can lead to increased market share, revenue growth via upsell and word-of-mouth marketing initiated by customers. Lower costs. Automobile manufacturer Toyota is one example of TQM. High-quality products that meet customers' needs results in higher customer satisfaction. Because we use cookies to provide you our services, they cannot be disabled when used for these purposes. The company was awarded the Deming Application Prize in 2008. Show less Show more Performance and Analytics ON OFF If you agree, we will use cookies to understand how customers use our services (for example, by measuring site visits) so we can make improvements. TQM requires organizations to focus on continuous improvement, or kaizen. It focuses on process improvements over the long term, rather than simply emphasizing short-term financial gains. TQM dates back to the 1920s, when the science of statistics was applied to quality control in an industrial setting.

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