

ISO 9001 QUALITY MANAGEMENT SYSTEM – A TOOL FOR BUSINESS SUCCESS

BY

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HIGHLIGHTS

- The current business environment and the importance of a management system
- What is a management system?
- ISO 9001 quality management system.
- History of ISO 9001 quality management system
- The latest revised version of ISO 9001:2015 and why it's more of a business management system.
- Benefits and misconceptions of ISO 9001 QMS.

The current business environment and the importance of a management system

- The increase in population in the face of fast paced development in science, technology and telecommunications and increasing demand of the customer in a globalized world has made the business successes more challenging.
- The factors of the competitiveness which were initially predominantly localized moved from low prices achieved on the bases of cheaper workforce in the first half of the 20th century to automated production in the 2nd half but today are now the business' ability to adapt to market demands and quality products and services (Juran, 1995).

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- Companies must permanently seek modalities to improve the quality of products or services they provide. Quality of services, products or management which, in fact, influences the quality of other products or processes of the enterprise, is an important factor in any competitive business on the market.
- This contributes directly or indirectly to increasing turnover, maintaining the market position, conquering new market segments, improving the image of the company (increasing customers and suppliers' confidence in the services and products offered)

What is a quality management system?

- A quality management system is a way of defining how an organization can meet the requirements of its customers and other stakeholders affected by its work.

ISO 9001 QUALITY MANAGEMENT SYSTEM

International Organization for Standardization, headquartered in Geneva and has developed about 10,000 standards of quality, of which the best known is the management system standard ISO 9001 quality.

- - ISO 9001 – is a standard that sets out the requirements for a Quality Management System, it is the world's most popular management system standard, is used by over one million businesses and organizations around the world, helping them run more efficiently and profitably, improve their process performance, organizational capabilities and customer satisfaction. It provides a framework for consistent performance, reliable service and long-term continuous improvement.
- BS 5750 was the original standard that became ISO 9001 helping organizations achieve continuous performance improvement.

- The standard ensures that quality management is completely integrated and aligned with the business strategies of an organization.
- As a business management tool, this will improve performance and drive real value in the organization, embedding healthy performance improvement processes over time
- It gives opportunity to review an organization and current processes ensuring they are aligned with business strategy, to achieve sustainable performance improvements and increase the quality of products and services in a cost-effective way.

- ISO 9001 provides requirements for the management system of an organization that aims to demonstrate its ability to consistently provide a product or service under both customer requirements and legal provisions and to increase customer satisfaction through effective application of the system, including improving processes continue (International Organization for Standardization, 2015a).
- Implementation of ISO 9001 ensures customers of the existence of a constant quality of products and services, entailing numerous benefits for the business, such as: increasing the confidence of customers and suppliers in the products and services, improvement of processes, efficiency, significant cost reduction, increasing competitiveness, maintaining market position and conquering new market niches, increase customer satisfaction, benefits regarding the company image associated with professionalism and high standards (International Organization for Standardization, 2015b).

- ISO 9001 is one of the factors that favor international trade of goods and services. The proof is the number of countries that have adopted this standard and the hundreds of thousands of companies that have obtained ISO 9001 certification. Counting over 1 million certified organizations worldwide.
- It ensures continued development using a continuous improvement process.
- ISO 9001 standard is the most known management system that has proven effective all over the world in over 25 years of existence.

- In 2013 alone, over one million certificates to the standard were issued across 187 countries, and many other companies and organizations have used the standard without seeking certification.
- ISO standards are reviewed every five years to ensure they maintain relevance to changes regarding market demands. In 2015, new edition of ISO 9001, the standard used by organizations worldwide as a framework for quality management system was introduced.

Evolution of ISO 9001 standards from 2000 to 2014 period.

- Since the first edition of standards related to quality, which aimed to implement controls and improve product quality, particularly in the industrial sectors, to the edition from 2000, then to one in 2008 and to the newest edition in 2015, ISO 9001 has seen developments related to market needs, the reality and the context in which businesses operate.
- It is noted that ISO standards has increased steadily each year.

Table 1. The growth ISO Standards year 2000 / 2014

Year	Africa	North, central & south America	Europe	East, central & south Asia	Middle East	Total
2000	4,769	59,101	219,561	115,628	9,003	408,062
2014	10,308	100,789	483,710	521,392	21,956	1,138,155

Source: International Standard Organization database (<http://www.iso.org/>)

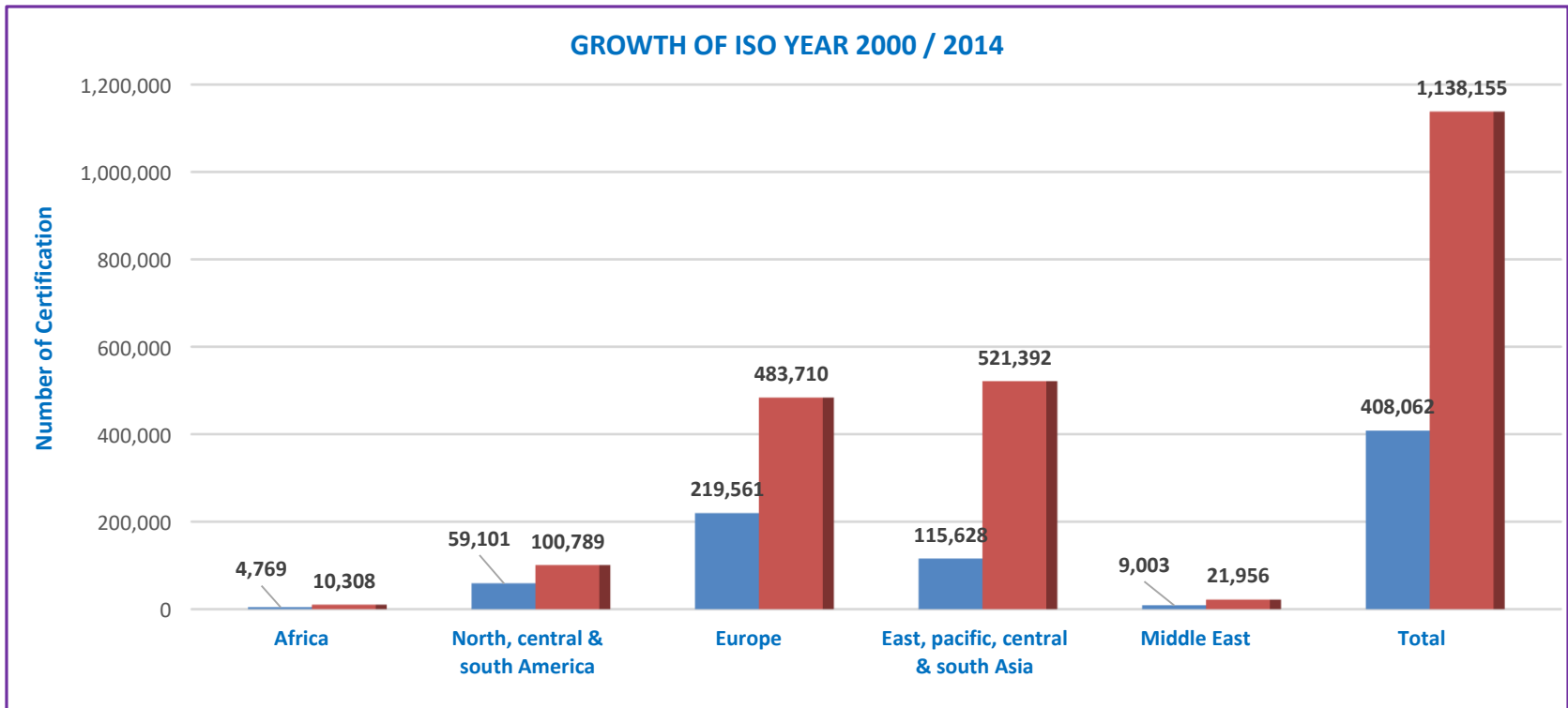


Table 2. First five industrial sectors for ISO 9001 certificates in 2013 and 2014

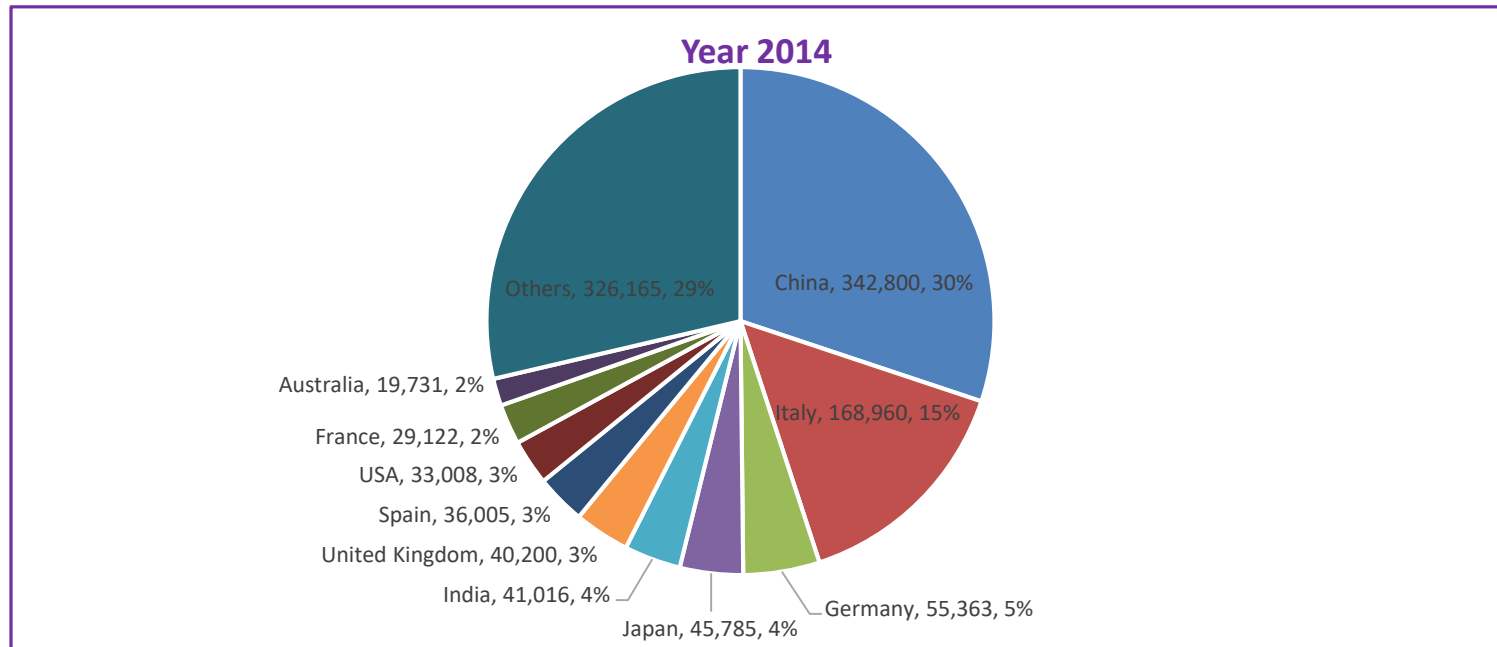
First five industrial sectors for ISO 9001 certificates		In 2014	In 2013
1	Basic metal & fabricated metal products	118,272	116,602
2	Electrical and optical equipment	86,523	87,797
3	Construction	76,862	80,920
4	Wholesale & retail trade, repairs of motor vehicles	73,676	73,167
5	Machinery and equipment	64,699	63,497

Source: Data collected from International Standard Organization database (<http://www.iso.org/>)

Table 3. First 10 countries for ISO 9001 certificates 2014.

First 10 countries for ISO 9001 certificates - 2014		
1	China	342,800
2	Italy	168,960
3	Germany	55,363
4	Japan	45,785
5	India	41,016
6	United Kingdom	40,200
7	Spain	36,005
8	USA	33,008
9	France	29,122
10	Australia	19,731
11	Others	326,165

Source: Data collected from International Standard Organization database (<http://www.iso.org/>)



The evolution of the number of ISO certifications emitted worldwide highlights the increased interest of present organizations for quality and how product quality has become a strong determinant factor of business successes.

THE SEVEN PRINCIPLES OF ISO QMS

ISO 9001 builds on seven quality management principles which ensure that organizations or businesses are set up to consistently create value for her customers.

The seven quality management principles are:

1. **Customer focus.** Organizations depend on customers, who are the primary focus of QMS. Understanding, meeting and exceeding their current and future needs is necessary to attract and retain customer confidence. Customer should be fully understood, transmitted and properly recorded.
2. **Leadership.** Having a unified direction and purpose that comes from strong leadership is essential to ensure that everyone in the organization understand, follow and assume the objectives of the organization.
3. **Engagement of people.** People represent the core of an organization; they are at the best to achieving set objectives when they are competent, empowered and engaged at all levels of the business or organization.

THE SEVEN PRINCIPLES OF ISO QMS

-CONTND.

4. Process approach. Understanding activities as processes that link together and function as a system helps achieve more consistent and predictable results when related resources and activities are managed as a whole.
5. Improvement. Successful organizations make continual improvement as a permanent objective. Monitoring and reacting to changes in the internal and external environment is necessary and of paramount importance in today's fast and ever evolving society. Apple and Middle East stability example.
6. System-based approach to management - identification, understanding and management of interdependent processes like a system contribute to increase efficiency and effectiveness of the organization in achieving its objectives
7. Evidence-based decision making. Decisions should be based on data and information analysis.

WHY IS THE NEW REVISED ISO 9001:2015 MORE OF A BUSINESS MANAGEMENT SYSTEM?

1. The latest version, ISO 9001:2015 integrates features of stronger focus on stakeholders and the wider context of an organization to match the dynamic and progressive demands needs of modern business.
2. The standard is designed to be flexible enough for use by different types of organizations, including service and knowledge-based organizations.
3. It does not specify what the objectives relating to “quality” or “meeting customer needs” should be, but requires organizations to define these objectives themselves and continually improve their processes in order to reach them
4. Puts greater emphasis on leadership engagement

WHY IS THE NEW REVISED ISO 9001:2015 MORE OF A BUSINESS MANAGEMENT SYSTEM?

- CONTND

5. Helps address organizational risks and opportunities in a structured manner. This has always been part of the standard, but the new version gives it increased prominence.
6. Uses simplified language and a common structure and terms, the high-level structure, particularly helpful to organizations using multiple management systems.
7. Addresses supply chain management more effectively
8. Flexibility for documented information.

Who is ISO 9001 for?

ISO 9001 is suitable for organizations of all types, sizes and sectors, including companies that do not have staff dedicated to quality.

In fact, one of the key improvements of the newly revised ISO 9001:2015 was to make it more applicable and accessible to all types of enterprises

Benefits and misconceptions of ISO 9001 QMS

Benefits

Implementing a quality management system will help:

1. Assess the overall context of your organization to define who is affected by your work and what they expect from you. This will enable you to clearly state your objectives and identify new business opportunities.
2. Put your customers first, making sure you consistently meet their needs and enhance their satisfaction. This can lead to more repeat custom, new clients and increased business for your organization.
3. Work in a more efficient way as all your processes will be aligned and understood by everyone in the business or organization. This increases productivity and efficiency, leading to better use of resources and bringing internal costs down.
4. Meet applicable statutory and regulatory requirements.
5. Expand into new markets, as some sectors and clients require ISO 9001 before doing business.
6. Identify and address the risks associated with your organization.
Improved risk control

Benefits and misconceptions of ISO 9001 QMS - CONTND

Misconceptions:

1. Isn't it an old document designed for the way businesses worked in the 1990s?

First published in 1987, ISO 9001 has been around for many years, but it is regularly updated to ensure that it remains relevant to today's business environment.

2. It is the preserve of big business and manufacturers?

The standard can be used by any organization, regardless of size or type and can be used by any organization, including service providers such as hospitals, banks or universities.

3. Is it very expensive?

The standard itself is reasonably priced and can be purchased from the ISO member in most countries or through the ISO Store. Preventing a problem is less expensive than dealing with the consequences after a problem occurs.

4. Will it help increase profits?

ISO 9001 can help bring financial benefits in a number of ways:

- Using ISO 9001 can increase productivity and efficiency, thus lowering the costs of an organization.
- Using ISO 9001 can improve customer experience, resulting in repeat business, increased sales and additional income for your business.
- Getting certified to ISO 9001 can enhance your reputation, attracting new customers to your organization.

Misconceptions. - CONTND

5. Does it mean lots of extra paperwork?

Not necessarily! The standard requires you to document a number of things and allows you to find a way of using it that fits your organization without requiring unnecessary paperwork

6. Management system certification is not required; therefore, my organization doesn't need it

Management system standards contain a collection of best practices that have evolved over the last 200 years and it provides a pragmatic, systematic methodology for organizations, helping them achieve results for themselves and their customers

7. It does not guarantee product quality

Nothing can absolutely guarantee product quality. However, it can go a long way toward preventing problems from occurring in the first place, thus providing dramatic improvements in results while reducing costs.

8. I don't need it because I have other certifications (FDA, UL, GLP, GMP)

None of these certifications represent full management systems that are verified by accredited certification bodies. In fact, many of these deal only with product attributes and inspections. They are often narrowly related to production and do not touch on the full range of preventive practices embedded in true management systems.

How is the standard structured?

ISO 9001:2015 (the most recent version of the standard) is made up of a number of different sections, each concentrating on the requirements involved in different aspects of a quality management system.

- Clause 0-3 – Introduction and scope of the standard
- Clause 4 – Context of the organization
- Clause 5 – Leadership
- Clause 6 – Planning
- Clause 7 – Support
- Clause 8 – Operation
- Clause 9 – Performance evaluation
- Clause 10 – Improvement

..... -What you don't measure, you cannot improve.

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Performance Evaluation. The organization shall determine:

- a) What needs to be monitored and measured?
- b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
- c) when the monitoring and measuring shall be performed;
- d) when the results from monitoring and measurement shall be analyzed and evaluated.

Customer Satisfaction is essential (Internal and external customers) determine the customer's perception of the degree to which their needs and expectations have been met. This can be through the means of customer survey, feedback, warranty claims, market share analysis etc.

Analysis and evaluation.

- Appropriate data and information arising from the monitoring and measurement are used to determine the
- Inputs- the performance of external providers
- Internal processes - if planning has been implemented effectively, the effectiveness of actions taken to address risks and opportunities, the performance and effectiveness of the QMS; and the need for improvements to the QMS.
- Products and services - conformity of products and services
- Customers - the degree of customer satisfaction.

Internal and External Audits. The International standard mandates the organization to conduct internal audits at planned intervals to provide information on whether the run QMS:

a) Conform to:

1) the organization's own requirements for its quality management system;

2) the requirements of this International Standard;

b) is effectively implemented and maintained.

Management Review - top management shall review the organization's QMS, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.

The management review shall be planned and carried out taking into consideration:

- a) the status of actions from previous management reviews;
- b) changes in external and internal issues that are relevant to the QMS;
- c) information on the performance and effectiveness of the QMS, including trends in:
 - 1) customer satisfaction and feedback from relevant interested parties;
 - 2) the extent to which quality objectives have been met;
 - 3) process performance and conformity of products and services;
 - 4) nonconformities and corrective actions;
 - 5) monitoring and measurement results;
 - 6) audit results;
 - 7) the performance of external providers;
- d) the adequacy of resources;
- e) the effectiveness of actions taken to address risks and opportunities;
- f) opportunities for improvement.

The outputs of the management review include decisions and actions related to:

- a) opportunities for improvement;
- b) any need for changes to the QMS;
- c) resource needs.

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