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ISO 9001 Certificate and impact on food quality

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ABSTRACT

ISO 9001:2015 specifies requirements for a quality management system when an organization: a) needs to establish its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and b) aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

Methods: There are two main categories of audits; an internal and an external. Audits are a key component for becoming ISO certified and you must have internal auditors, and pass the 2-stage registrar audit by an external party in order to become ISO 9001 certified. Below we will break down the different ways audits can be conducted and discuss internal, external and certification audits.

The three ways audits can be conducted are: On-site audits are performed in full days. The number of days needed for an audit depends on several factors including size, complexity, risk, and nature of an organization. The International Accreditation Forum (IAF) has provided guidelines for registrars to calculate audit time. Remote audits may be performed via web meetings, teleconferencing or electronic verification of processes. Remote audits are less common and typically not as effective as on-site audits. Self-audits do not always mean an internal audit. A self-audit can be requested of your customer to eliminate the need for them to use their resources and still offer some assurance that you are meeting requirements

1. INTRODUCTION

The important role of quality management system implementation has been recognized by food manufacturing companies. This is due to the high awareness of customers on the importance of food product quality and safety. The food companies that produce safe and good quality product will survive and even win the competition. Food manufacturing companies have been familiar with the various standards relating to quality assurance.

ISO 9001 is an international standard of quality management system. The standard describes the requirements of a quality management system that needs to be implemented consistently so that the companies can produce the products according to customers' requirements, achieve customer satisfaction, and achieve continual improvement on the effectiveness of their quality management system. Furthermore, ISO 9001 requirements represent quality management system best practices. Thus, food manufacturing companies that implement ISO 9001 are expected to obtain significant outcomes. Given this, it is interesting to study

2. SCEENTIFIC BACKGROUND

ISO 9000 family – Quality management

The ISO 9000 family addresses various aspects of quality management and contains some of ISO's best-known standards. The standards provide guidance and tools for companies and organizations who want to ensure that their products and services consistently meet customer's requirements, and that quality is consistently improved (Beulens et al., 2005).

The Definition of ISO 9001 Certification

"ISO 9001 Certified" means an organization has met the requirements in ISO 9001, which defines an ISO 9001 Quality Management System (QMS). ISO 9001 evaluates whether your Quality Management System is appropriate and effective, while forcing you to identify and implement improvements.
(Zaramdini, 2007)

There are five main requirements of ISO 9001

The first requirement, quality management system, relates to the obligation of organization to manage quality management system processes and documentations. The second requirement, management responsibility, refers to the responsibilities of top management on quality management system. The third requirement, resource management, requires organization to manage resource needed by quality management system. The fourth requirement, product realization, relates to the obligation of the organization's core process. The fifth requirement, measurement, analysis, and improvement, refers to the obligation of organization

to measure, analyze, and improve quality management system (Martinez-Croucher et al., 1994).

ISO 9001 Quality Management certification helps you to continually improve, streamline operations and reduce costs, win more business and compete in tenders, satisfy more customers, be more resilient and build a sustainable business show you have strong corporate governance, and work effectively with stakeholders and your supply chain

Seven quality principles include; 1) Customer Focus, 2) Leadership, 3) Engagement of people, 4) Process approach, 5) Improvement, 6) Evidence based decision making, and 7) Relationship management (Escanciano et al., 2014).

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ISO 9001 Clauses

ISO 9001 Clauses - PLAN: 1) Scope**,** 2) Normative references**,** 3) Terms and Definitions**,** 4) Context of the organization, and 5) Leadership

ISO 9001 Clauses - DO: 7 Support. 7.1 Resources and 8 Operation

ISO 9001 Clauses - CHECK: 9 Performance evaluation.

9.1. Monitoring, measurement, analysis and evaluation
9.1.2. Customer Satisfaction
9.2. Internal Audit
9.3. Management Review

ISO 9001 Clauses – ACT include 10 Improvement

10.1 General
10.2 Nonconformity in ISO 9001
10.2 What is Non-conformance
10.2 Corrective Action (Trienekens., 2008)

ISO 9001 in Food Sector

ISO 9001 is a generic standard. Therefore, the standard can be implemented in every sector, including food sector.

Although ISO 9001 is a topic widely discussed in quality management literatures, there are lack of researchers have tried to study ISO 9001 implementation in food sector. Foutopolos et al. (2009) studied the implementation of ISO 9001 in the Greek food sector. They found that the major reason for ISO 9001 certification relates to the internal business environment. It is also found that the benefits of ISO 9001 certification is positively influenced by the companies' reason in implementing ISO 9001 and negatively influenced by the difficulties to meet the standard's requirements.

Management System (QMS), based on its components, meaning the ISO 9001 objectives; and validated the instrument in the food manufacturing sector. They found that the effectiveness of ISO 9001 implementation in food manufacturing sector can be measured using three dimensions, namely continuous improvement, prevention of nonconformities and customer satisfaction focus.

Psomas and Fotopoulos (2010) studied 92 Greek food companies that were ISO 9001 certified. They identified three latent factors/constructs regarding the results of their quality management practices implementation. The results include market benefits, customer satisfaction, and quality improvement.

6, 4, 3. Impact of ISO 9001:2015 on ISO 22000 and food safety management systems (FSMS)

The edition of ISO 9001:2015 prompted ISO to review ISO 22000: 2005 International Standard with the aim of adopting the same format as other management systems standards (MSSs) following an identical structure with common texts, terms and definitions, which will facilitate users understanding and the integrated use with ISO 9001, as many organizations use ISO 22000 in conjunction with ISO 9001. Additionally, based on user feedback collected by ISO, the future ISO 22000 should clarify certain key concepts (such as critical control points required to be managed, operational programs needed, approach to risks, product withdraws and recalls) update terms and definitions and making the standard more user friendly. As an outcome of the analysis of both ISO 22000:2005 and ISO 9001:2015 International (Yarmen and Sumaedi, 2015).

There are nine core elements of a quality management system

1. Quality Objectives

The creation of quality objectives is a common requirement of QMS standards, including ISO 9001. These objectives are designed to encourage organizations to define strategic goals and a purpose for the QMS. Objectives translate an organization's vision into practice by creating a link between customer requirements and specific, measurable, and attainable goals. Well-written objectives lend purpose to a QMS initiative and establish a customer-centric culture in an organization.

A pharmaceutical start-up in the research phase may have identified a customer need for affordable therapeutics to treat a common skin condition. Since the product is being developed, the organization may create a quality policy with a stated goal "To develop a safe, effective treatment for eczema patients which is available at a lower cost than alternatives."

Quality objectives for this organization could include.

- To obtain total compliance with staff training requirements and raise average assessment scores from 90% to 95%.
- To successfully implement a QMS software within three months and eliminate paper and spreadsheet-based record keeping methods within six months.
- To achieve a successful initial synthesis of the drug and complete all necessary processes for FDA initial review within 12 months.

2. Quality Manual

A quality manual is defined as the first documentation of a QMS. It states the motivation for adopting a QMS framework and the role of quality within the

organization. ISO 9000 requirements for a quality manual prescribe that this document should:

- Describe the scope of the QMS
- Detail the requirements of the QMS standard or framework
- List any elements of the QMS which are excluded from the implementation
- Reference specific quality procedures used within the organization
- Provide visual documentation of critical processes via flowchart
- Explain the organization's quality policies and objectives

3. Organizational Structure and Responsibilities

A QMS should include a clear and updated model of the organization's structure and responsibilities of all individuals within the organization. Documentation of structure and responsibilities should include visual guides such as flowcharts and clear documentation.

Within the context of a QMS, the organization is broadly defined in World Health Organization guidance as both people and structure. For a life sciences company in the early phases of the product development lifecycle, initial efforts to identify organizational components may reveal a list similar to the following:

- Personnel
- Equipment
- Information Systems
- Tools for Assessment
- Facilities
- Purchasing & Inventory
- Process Controls
- Documents & Records

4. Data Management

Data is at the core of modern approaches to total quality management. Data quality and availability are critical to the success of a QMS framework to drive continuous improvement and preventative quality control activities.

The types of data required to demonstrate effective QMS performance can vary significantly between organizations. However, at a minimum it should include the following sources:

- Customer Satisfaction
- Supplier Performance
- Product and Process Monitoring
- Non-Conformances
- Trends
- Preventative or Corrective Action

5. Processes

QMS are inherently process-driven approaches to quality control and assurance. Standards for quality management. require organizations to identify and define all organizational processes which use any resource to transform inputs into outputs. Virtually every responsibility in the organization can be tied to a process, including purchasing.

Initial efforts to define processes should create a high-level picture of how processes serve the organization and intersect with resources such as employees, machines, or technology. After identifying processes, organizations can begin to define standards and success metrics:

- Identify organizational processes
- Define process standards
- Establish methods for measuring success
- Document a standardized approach to ensuring quality output
- Drive continual improvement

6. Customer Satisfaction with Product Quality

A core component of QMS is the requirement for organizations to monitor customer satisfaction to determine if quality objectives are achieved. Some standards do not prescribe specific methods for measuring customer satisfaction since the definition of product quality and available data can vary significantly between organizations.

A first step to establishing monitoring systems for customer satisfaction should be the definition of appropriate methods for measuring customer attitudes and complaints. This could include:

- Satisfaction Surveys
- Complaints Procedures
- Analytical Applications to measure satisfaction trends
- Management Review of customer satisfaction

7. Continuous Improvement

Continuous improvement and adaptation are necessary for organizations to drive benefits with the QMS and maintain customer satisfaction. QMS dictate that continual improvement is an organization-wide responsibility. However, ISO 9001 is clear that leadership should play a core role in implementing a quality-driven culture. Clause 5.1.1 states "top management shall demonstrate leadership and commitment with respect to the quality management system by taking accountability for effectiveness."

Designing organizational processes to meet QMS standards for continuous improvement requires clear documentation of controls across the organization. Improvement documentation should encompass, at a minimum:

- Quality Planning Procedures
- Compliance Requirements
- Safety Design
- Risk-based Thinking
- Corrective Action (CAPA)
- Innovation
- Assessment of the QMS

8. Quality Instruments

The control and calibration of tools used to measure quality are integral to the success of a QMS. If machines or equipment are used to validate products or processes, this equipment must be carefully controlled and calibrated according to industry standards. Depending on the instrument, this could involve periodic calibrations or calibration before every measurement. The QMS system design within an organization should dictate a clear policy for the maintenance of quality instruments based on nationally or internationally recognized standards for each piece of quality equipment.

This documentation should address:

- Intervals for instrument calibration
- Recognized Standards for instrument calibration
- Manufacturer Instructions for adjustment

- Procedures for identifying and documenting calibration
- Controls against tampering or adjustment post-calibration

9. Document Control

The definition of a document in a quality-driven organization is broad, according to ISO. It includes all records of:

- Communications
- Evidence
- QMS Conformity
- Knowledge Sharing (Robert et al ., 2001).

Mandatory Requirements - Documents and Records

Mandatory requirements need to be complied with, while non-mandatory requirements may be submitted for documentation purposes. To be certified compliant with ISO 9001:2015, the following documents must be submitted.

ISO 9001 Mandatory Requirements — Documents and Records

- Monitoring and measuring equipment calibration records
- Records of training, skills, experience and qualifications
- Product/service requirements review records
- Record about design and development outputs review
- Record about design and development inputs
- Records of design and development controls
- Records of design and development outputs
- Design and development changes records
- Characteristics of product to be produced and service to be provided
- Records about customer property
- Production/service provision change control records
- Record of conformity of product/service with acceptance criteria
- Record of nonconforming outputs
- Monitoring measurement results
- Internal audit program

Results of internal audits (Naveh et al., 2005).

Non-mandatory requirements-but often included non-mandatory requirements, but often included

- Procedure for determining context of the organization and interested parties
- Procedure for addressing risks and opportunities
- Procedure for competence, training and awareness
- Procedure of equipment maintenance and measuring equipment
- Procedure for document and record control
- Sales procedure
- Procedure for design and development
- Procedure for production and service provision
- Warehousing procedure.
- Procedure for management of nonconformities and corrective actions
- Procedure for monitoring customer satisfaction
- Procedure for internal audit
- Procedure for management review

After reading through the lists above, you might be thinking that his must include a lot of paperwork!

However, do note that because each company is unique and is run differently, having this certification lets other companies and people know that what your company does and produces passed an international standard of quality.

Not only does the ISO certificate benefit your consumers, it also benefits your company itself (Naveh et al., 2005).

Benefits of ISO 9001 Certification

Organizations find that using the standard helps them:

- Organize a quality management system (QMS)
- Create satisfied customers, management, and employees
- Continually improve their processes
- Save costs

Customer satisfaction

Deliver products that consistently meet customer requirements and a service that is dependable and can be relied on:

Reduced operating costs: Continual improvement of processes and resulting operational efficiencies mean money saved.

*Improved stakeholder relationships***:** Improve the perception of your organization with staff, customers and suppliers.

*Legal compliance***:** Understand how statutory and regulatory requirements impact your organization and its customers.

*Improved risk management***:** Greater consistency and traceability of products and services means problems are easier to avoid and rectify.

*Proven business credentials***:** Independent verification against a globally recognized industry standard speaks volumes.

*Ability to win more business***:** Procurement specifications often require certification as a condition to supply, so certification opens doors (Gill, 2009.)

***Some of the benefits to your organization*:**

- Provides senior management with an efficient management process
- Sets out areas of responsibility across the organization
- Mandatory if you want to tender for some public sector work
- Communicates a positive message to staff and customers
- Identifies and encourages more efficient and time saving processes
- Highlights deficiencies
- Reduces your costs
- Provides continuous assessment and improvement
- Marketing opportunities (Hoyle et al., 2009)

Some of the benefits to your customers

- Improved quality and service
- Delivery on time
- Right first-time attitude
- Fewer returned products and complaints
- Independent audit demonstrates commitment to quality (Sampaio et al., 2009)

3.Findings

After presenting of previous data about Iso9001

The author can find the following ISO 9001 Nonconformances Mean for Your Company. Any nonconformance is an opportunity for improvement. Issues of any size should lead to corrective action. However, major and minor nonconformances mean different things for your organization. The primary difference between these two classifications is based on how the issue impacts the rest of the system or product:

A minor nonconformance is generally a system weakness which could potentially lead to significant QMS failures in the future. An example of this could be a single unauthorized change to a document or an instrument which is not correctly calibrated.

A major nonconformance is evidence of a significant failure in the management system which could threaten an organization's ability to achieve goals or protect customers. These could include a pattern of unauthorized document changes or poor calibration procedures which result in incorrectly tested products.

A minor nonconformance finding is not a barrier to certification or successful surveillance audits, but your organization must respond with an effective plan of corrective action to avoid failing initial certification or suspension of an existing certification. The average number of minor nonconformities discovered in an audit is 4-6.

Major nonconformance findings can prevent your organization from achieving an initial certification or act as a barrier to re-certification based on annual surveillance audits. There are also generally downstream risks which can include regulatory risks of noncompliance, quality concerns, waste, reputational damage, and more.

If you don't take corrective action?

ISO 9001:2015 includes clear and in-depth guidance on how to respond to any nonconformity discovered through customer complaints or audits. Section 10.2 states organizations must:

- Correct nonconformities
- Eliminate the root cause
- Implement corrective action
- Verify results
- Update the risk register
- Implement permanent system change
- Document corrective action results

But, theoretically speaking, what if you don't take corrective action?

The potential impact on your organization depends on the size of the nonconformance. You are near-certain to face barriers to certification or re-certification. You could potentially slide through until your surveillance audit if the nonconformance is minor, but uncorrected issues will eventually act as a barrier to ISO certification.

Certification challenges aren't the only risk, though. Major nonconformances can result in a host of issues, including:

- Regulatory noncompliance
- Product delivery delays
- Rework
- Rejected product
- Creeping operational costs

CONCLUSION

The ISO 9001:2015 quality standard is a set of requirements that affect virtually all aspects of the operations of corporate enterprises, non-profit organizations and government entities.

- *Clauses 0-3*: Introductory chapters
- *Clauses 0-3 of ISO 9001*:2015 are introductory chapters that don't contain any requirements.
- *Clause 4*: Context of the organization
- This section sets the requirements for the foundation of the ISO 9001 Quality Management System. The "context of the organization" is the business environment in which the company operates.
- *Clause 5*: Leadership
  This section of ISO 9001:2015 is all about the involvement of top management in the ISO 9001 Quality Management System.
- *Clause 6*: Planning
  This section focuses on planning and the concept of risk-based thinking.
- *Clause 7*: Support
  This section of ISO 9001:2015 is all about support functions: various resources, competence and training, communication and documentation.
- *Clause 8*: Operation
  In this section, the ISO 9001:2015 standard sets the requirements for the processes needed to achieve the product or service. This is how your product or service is designed, produced, tested, handled, shipped.
- *Clause 9*: Performance evaluation.
  This section is all about measuring and evaluating.
- Clause 10: Improvement
  The last section of ISO 9001:2015 requires companies to determine and identify opportunities for improvement

REFERENCES

1. Beulens, A.J.M., Broens, D.F., Folstar, P., & Hofstede, G.J. (2005), Food safety and transparency in food chains and networks, Food Control, 16 (6), 481-486.
2. Escanciano, C. and Santos-Vijande, M.L. (2014), Reasons and constraints to implementing an ISO 22000 food safety management system: Evidence from Spain, Food Control 40, 50-57.
3. Fotopoulos, C.V., Kafetzopoulos, D.P., & Psomas, E.L. (2009), Assessing the critical factors and their impact on the effective implementation of a food safety management system, Int. J. Qual. Reliab. Manag. 26(9), 894-910.
4. Gill, J. 2009. Quality follows quality: Add quality to the business and quality will multiply the profits. TQM Journal, 21(5), 530-539.
5. Hoyle, D. ISO 9000 Quality System Handbook, Using the Standards as A Framework for Business Improvement. 6th Ed. Butterworth-Heinemann. 2009.
6. Martinez-Costa, M., Choi, T. Y., Martinez, J. A., and Martinez-Lorente, A. R. (2009): ISO

9000/1994, ISO 9001/2000 and TQM: The performance debate revisited. Journal of Operations Management, 27, 495-511.
7. Psomas, E.L. and Fotopoulos, C.V. (2010): Total quality management practices and results in food companies. Int. J. Prod. Perform. Manag., 59 (7), 668 - 687.
8. Sampaio, P., Saraiva, P., and Rodrigues, A. G. (2009): ISO 9001 certification research: questions, answers and approaches. Int. J. Qual. Reliab. Manag., 26(1): 38-58.
9. Companies: A Proposed Measurement Instrument. International Symposium on Food and Agro-biodiversity (ISFA2014). Elsevier Ltd. Procedia Food Science 3 (2015), 436 – 444.
10. Zaramdini, W. 2007. "An empirical study of the motives and benefits of ISO 9000certification: the UAE experience. International Journal of Quality & Reliability Management, 24(5), 472-491.
11. Trienekens, J., & Zuurbier, P. (2008), Quality and safety standards in the food industry, developments and challenges, International Journal of Production Economics, 113(1), 107-122.
12. Yarmen M. and Sumaedi, S. (2015): The Effectiveness of ISO 9001 Implementation in Food Manufacturing. Procedia Food Science 3: 436-444