THE INTERNATIONAL JOURNAL OF BUSINESS & MANAGEMENT

Reality and Novel Research on ISO 9001 Standards and Comparison of ISO 9001:2008 Vs ISO 9001:2015

P. Arulraj
Associate Professor, Department of Pharmaceutical Biotechnology,
RVS College of Pharmaceutical Sciences, Sulur, Coimbatore, Tamil Nadu, India
C. S. Kandasamy
Professor, Department of Pharmacognosy,
RVS College of Pharmaceutical Sciences, Sulur, Coimbatore, Tamil Nadu, India
Dr. R. Manavalan
Research Director, RVS College of Pharmaceutical Sciences, Sulur, Coimbatore, Tamil Nadu, India
Dr. R. Venkatanarayanan
Principal, RVS College of Pharmaceutical Sciences, Sulur, Coimbatore, Tamil Nadu, India

Abstract:
Aim: The primary objective of this article is to elucidate the importance of ISO standards in Pharmacy educational Institutions, growing organizations. Secondly, to know the updates and basic difference between ISO 9001: 2008 and ISO 9001: 2015. Over the past 60 years the implementation of ISO became more in the competitive society. There are around more than 40 number pharmacy colleges in Tamil Nadu. Still many more colleges are yet to get approval to begin. It makes pleasure that the circle of the pharmacy is getting unlimited. Method: ISO simply says: "say what do you do" and "do what you say". The competitions among the educational institutions are becoming more and more. As per basic local market standard, when there is a demand in the market usually there will be more chances for defilement and dishonesty. Methods of accountability in the education system are failure. Yet to refine and get a newer technology and methodology for assessment. Result: Pharmacy is one of the health care profession also, a practical and product oriented course and hence the adulteration may result severe risk to the society and people. The results are duplication/ manipulation of the task, creating new type of formats, cooking up the results during the time of audit, week internal audit and random inspection process, poor understanding of roles and responsibility, double or triple entry of the same values, vague and blurred concept on ISO standards, etc. Conclusion: The educational institutions must check the quality of the education program provided. Many of the organizations and the institutions are following the ISO standards but, lagging behind Measurement, analysis and improvement. Lack of internal communication, review, follow up, corrective action and tuning and changing the corrective action if not found effective. Quality system will develop by strengthening the internal audit program. This research article may help growing organizations, institutions and other public community shops to lead a quality product by their system.

Keywords: *ISO 9001, quality management system, ISO in pharmacy, ISO 9001:2015*

1. Highlights

- It helps the organization leaders to understand the importance of ISO standards
- How to grow and release quality product in the market with this competitive globe - need of ISO
- Importance of refining the corrective action, route cause analysis, review, follow up, random inspection report, customer satisfaction, feedback, internal communication, interdisciplinary activities, etc..
- Need of standards for the endurance fittest

2. Introduction

In ISO 9001 Certification, highly competent market industries with ISO 9001: 2008 certification hold a distinguished position. These industries hold an advantage over others and have gained trust credibility. The ISO 9001:2008 quality certification is based on the following eight fundamental quality management principles:

- Customer focus
- Leadership

- Involvement of people
- Process approach
- System approach to management
- Continual improvement
- Factual approach to decision making Mutually beneficial supplier relationships

2.1. Overview of the ISO 9001:2008 Standard

ISO 9001:2008 contains five requirements sections, each dealing with one of the fundamental building blocks required by any process. These are:

2.2. Quality Management System

This section details the general and documentation requirements that are the foundation of the management system. The general requirements ask you to look at the processes of the management system, how they interact with each other, what resources you need to run the processes; and how you will measure and monitor the processes. The second part of the section then sets out the requirements for the documentation needed to effectively operate the system and how the documentation should be controlled

2.3. Management Responsibility

The management of the systems is the responsibility of the "top management" at a strategic level in the organization. The "top management" must know customers' requirements at a strategic level and make a commitment to meeting these as well as statutory and regulatory requirements. "Top management" must also set policies; and to achieve these policies set objectives through planning how the objectives will be met. "Top management" should also ensure that there are clear internal communications and that the management system is regularly reviewed

2.4. Resource Management

This covers the people and physical resources needed to carry out the processes. People should be competent to carry out their tasks and the physical resources and work environment need to be capable of ensuring that the customers' requirements are met

2.5. Product/Service Realization

These are the processes necessary to produce the product or to provide the service. This is the act of converting the input of the process to the output. For a manufacturing organization, this may be the process of converting iron ore to steel via a blast furnace for example. For a service organization, this may be the process of moving a product or person from one place to another, for example, a taxi journey.

2.6. Measurement Analysis and Improvement

These are the measurements to enable the systems to be monitored to provide information on how the systems are performing with respect to the customer, the management systems themselves through internal audits, the processes and the product. Analyzing these, including any defect or shortfall in performance, will provide valuable information for use in improving the systems and products where this is required.

Each of these five fundamental building blocks is required for any process because, if one is missing, a controlled process does not occur.[1,2]

2.7. The Advantages of being ISO 9001:2008 Compliance

1. Improved outcome of process
2. Professional image
3. Increased customer confidence
4. Better marketability
5. Clarity of responsibility and authority
6. Better and defined system

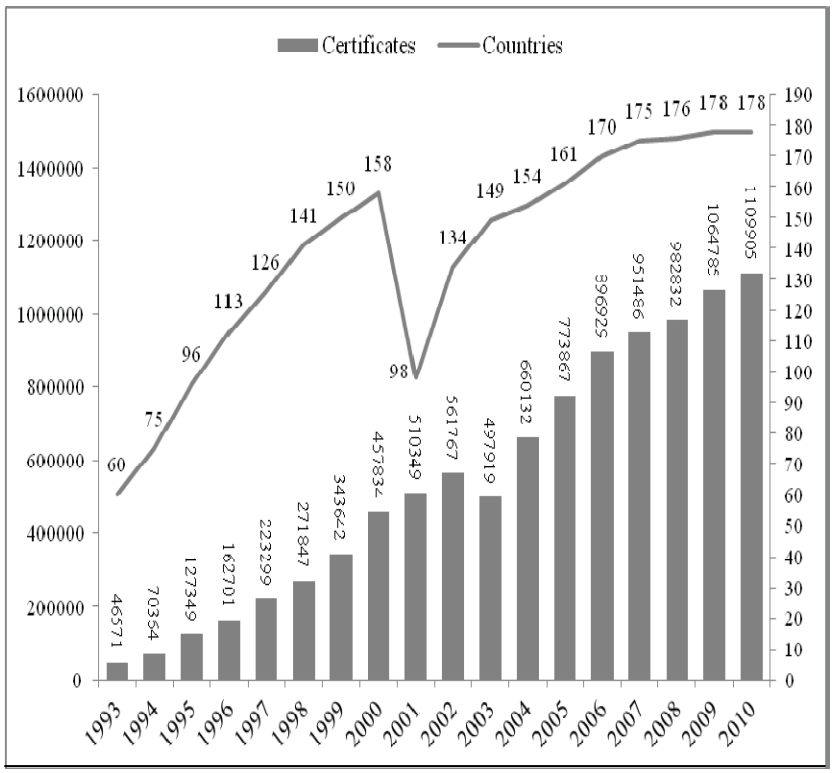

Figure 1: Total amount of issued ISO 9001 certificates and countries in the world, years 1993-2010[5,6]

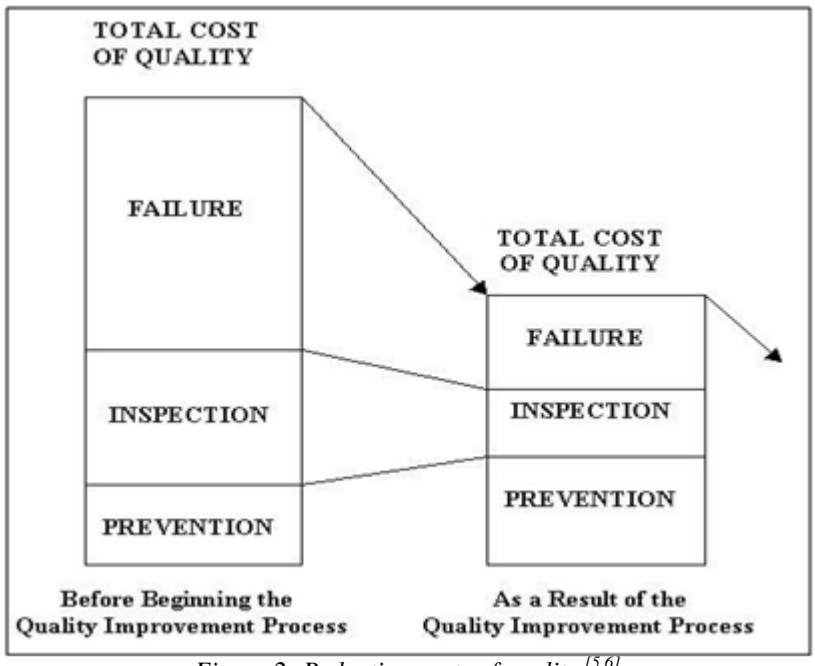

Figure 2: Reduction costs of quality [5,6]

3. ISO 9001:2008 Vs ISO 9001:2015

3.1. ISO 9001:2015 – No Quality Manual

3.1.1. What is Required in ISO 9001:2008?

Clause 4.1 (Quality management system – General requirements) of ISO 9001:2008 requires:

"The organization shall establish, document, implement and maintain a quality management system"

In addition clause 4.2.1 (Documentation requirements – General) of ISO 9001:2008 requires organizations to have a Quality Manual as a part of documentation.

Clause 4.2.2 (Quality manual) provides the details on what should be included in the Quality Manual.

3.1.2. What is Proposed in Recently Released ISO 9001:2015 Committee Draft?

Clause 4.4.1 (Quality management system – General) of ISO 9001:2015 Committee Draft (CD) requires:

"The organization shall establish, implement and maintain a quality management system"

- Difference

Newly release committee draft does not include the requirement to "document" the Quality Management System.

Also there is no mention of the word "Quality Manual" anywhere in the draft standard.

A Manual is not required to be produced for Environmental Management System (ISO 14001) and some other management standards.

In an effort to ensure harmony between different management systems the requirement to produce a Quality Manual might no longer exist after the release of new version of ISO 9001.

3.2. ISO 9001:2015 - No "Continual Improvement" Only "Improvement"

ISO recently issued the committee draft of ISO 9001:2015 for commenting and voting by member nations. One of the changes in this new revision is to replace the term "continual improvement" with "improvement". The word "continual" has been proposed to be deleted.

ISO 9001 is being developed to make more explicit use of the Quality Management Principles (QMP). These quality management principles were recently revised and in the latest Quality Management principles the term "continual improvement" has been replaced with "improvement"

3.3. ISO 9001:2015 - No "Preventive Action" - Potential non Conformities

ISO recently issued the committee draft of ISO 9001:2015 for commenting and voting by member nations. One of the proposed changes in this new revision is to remove the specific "Preventive Action" clause from the standard.

In the existing standard ISO 9001:2008 organizations are required to determine action to eliminate the causes of "potential nonconformities" in order to prevent their occurrence.

In the ISO 9001:2015 Committee Draft (CD) this requirement has not been included

- Explanation for Removing this Clause
- A Formal quality management system acts as a preventive tool.
- Requires organizations to adopt risk driven approach to preventive actions.
- The new version of ISO 9001 requires organizations to :
    - assess the issues which affect organization's ability to achieve its goals (intended outcomes).
    - determine risks and opportunities

3.4. ISO 9001:2015 - "Product" Replaced with "Goods and Services"

Recently the committee draft (CD) of ISO 9001:2015 was released for comments and ballots. One significant change proposed in this version of the standard is to replaced the term "product" with "goods and services".

The reason provided for this change is to make the standard more generic and more applicable to service industries. The use of the single term "product" to cover the physical products and services had been a hindrance to service organizations understanding and applying the standard.

This change will be subjected to commenting and ballot by member countries.

3.5. ISO 9001:2015 - No "Management Representative"

ISO 9001:2000 required the organization to appoint a Management Representative.

ISO 9001:2008 added the requirement that Management Representative should be a member of the organization management

ISO 9001:2015 Committee Draft assigned the role of management Representative to the top management of the organization and does not require a person to be specifically assigned as a Management Representative

4. Conclusion

By understanding the importance of Quality management system not only the manufacturing companies, Schools, educational institutions, public community shops, anything can reach the pinnacle of the standards. The result of poor awareness regarding the ISO leads to failure in the system. Once Quality system is build up then all other process will flow offhandedly. It is still very important and strategic component of competitiveness. The developing organizations and all institution must get aware about ISO and hence the outgoing products will be in quality and standards in the society. Recently maagi and other noodles got in to trouble because of not following the standards of permissibility. Still we can find quality as important component in universal Competitiveness report which determines organizational / institutional escalation towards novelty country. One of the most accepted quality management systems in the globe is ISO 9001 standards. It has much strength that makes it so popular within entrepreneurs, institutions, organizations. The developed organizations/ institutions are most engaged in quality management from perspectives of ISO 9001 recognizing quality management as strategic tool for improving processes, accessing international markets and increasing competitiveness. Transparency

makes the system better. By finding out the route cause analysis, the entire problem gets in to a solution. Refining the corrective action initiated will lead to better resolution to attain the target.

5. Acknowledgement

Authors would like to acknowledge the Chairman, Management, Principal for providing an opportunity to understand and to work under certified quality group of institutions. We Thank TUV Rheinland Pvt Ltd. German based company, Mr. V. Viswanathan, Team leader & Lead Auditor, TUV Rheinland Pvt Ltd, Who did spend maximum of his time and patience with our associated institutions for the development of departments. Mr. Pradeep, Mr. Chandru, Expert auditors, TUV Rheinland Pvt Ltd. We thank our team of faculty members for their cooperation for making this institution to international standards of quality management system. The importance of the International organization for standardization also is conveyed to all of our fruitful students and all our customers. We satisfy the customers.

6. References

i. "ISO members". International Organization for Standardization. Archived from the original on 9 February 2015.
ii. "How to use the ISO Catalogue". ISO.org. Archived from the original on 4 October 2007.
iii. "About ISO". ISO. Archived from the original on 4 October 2007.
iv. The number of member working countries an be found on the first page of the report. "Annual Report 2013" (PDF).*ISO*. Retrieved 18 June 2014.
v. The ISO Survey 2011. Geneva, ISO Central Secretariat, 30 p.
vi. The ISO Survey 2005. Geneva, ISO Central Secretariat, 22 p.
vii. Zaramdini W (2007)"an emperical study of the motives and benefits of ISO 9000 certification : the UAE experience" International Journal of Quality & Reliability Management, Vol. 24 No. 5, pp. 472-491
viii. Quality procedure RVSCOPS ISO 9001:2008
ix. Quality Manual RVSCOPS ISO 9001:2008
x. Hand book of ISO 9001 store by E.L.Ceon
xi. http://www.qualitygurus.net
xii. http://www.kvaliteta.net/
xiii. Tuv Rhineland Pvt. Ltd
xiv. http://www.tuv.com/