

# Survey on Impact of QMS ISO 9001:2000 in an Organization, Increases the Effectiveness of its Operations

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**Abstract**— this research paper will set out to explore the degree to which the practice of ISO 9001:2000 is used in Searle Pakistan limited in developing quality products that meets the customer requirement. The paper focuses on developing the understanding the operation and effectiveness of quality management systems and why companies are also committed to the needs of ISO9001:2000. A survey was conducted on Searle Pakistan limited registered with ISO 9001:2000 to evaluate the head office unit and factory units of the company to know how effective ISO9001:2000 standard to meet customer requirement which enhance to customer satisfaction. Also, to investigate the role of ISO9001:2000 standard that how its implementation help to improve business operation and its impact regarding to quality of the Searle Pakistan limited within the head office unit and factory unit.

**Keywords**-component; Quality; Operation; Effectiveness; ISO; Searle; Customer Satisfaction; Business;

## I. INTRODUCTION

At any time in history, the quest for qualities is probably more widespread and intense globally. Organizations have realized that the key to increased productivity and profitability is improving quality and in order to survive competition from local market and international market, they are forced to return to the basics of better quality management and cost competitiveness measures for their products and services. The factors that relate to business performance can be divided into two categories. First, those that improve the product or service quality differential against competitors and, second, those factors that reduces the cost of quality. An effective quality management system determines the product and service quality conformance as its primary goal. As Jacobson and Aaker found product quality had a positive influence on return on investment, market share and price [1].

Such quality efforts at an international level can be address with the implementation of the ISO 9001:2000 international standard. An effective quality management system based on ISO9001:2000 determine process control as an essential activity. Better process control would be consistently associated with less rework and hence lower costs. These lower costs will lead to better comparative business performance. Therefore, it is methodically line up regarding to importance of quality in line, with Deming who reasons that, as quality

improves, waste is eliminated, costs are reduced, and performance improves [2].

An ISO9001:2000 is a set of processes that describe the organisational attitude and clearly define the areas of responsibility. It creates a common language, a common picture for the entire organisation. An ISO9001:2000 in this definition has two primary purposes.

Firstly, if one needs to perform some work that is not the usual day-to-day work task, the documents serve as support and guideline for carrying out the work.

Secondly, the documents are used if there is a need to review some processes and working procedures due to problems or improvement work.

Nowadays, pharmaceutical companies come across to many new challenges to ensure efficient business operations. There are external challenges from competitors, generic drug manufacturers, health-care organisations, in addition to internal challenges to decrease the costs of sales, R&D, and manufacturing. Government guidelines in the form of regulatory requirements need to be received, interpreted and disseminated in a timely manner to ensure compliance [8].

Therefore, the most fundamental focus of the pharmaceutical companies is an effective quality management system for efficient business operations and to improve the quality to meet the customer requirements which enhance to 'customer satisfaction'. Hence, ISO9001:2000 is an essential part of any organization regarding to its standardization. However, in order to ensure that Pakistani companies do not fall behind whilst competing in world markets all organizations implement quality management system practices for their customer satisfaction.

Searle is one of the leading Pakistani companies in pharmaceutical sector. Searle have a very smart manufacturing plant follow all modern rules. They are consistently investing heavily in new technologies and state-of-the-art equipment; this has been instrumental in improving plant efficiencies and curtailing manufacturing costs. Searle is one of the largest national pharmaceutical companies of Pakistan. As per 4th quarter 2008 of Pakistan Pharmaceutical Index (IMS) which is regarded as a reference publication by Pharmaceutical Industry,

Searle corporate ranking is 11th in the Pakistan Pharmaceuticals market with a market share of 2.4% [3].

The paper is organized as follows: Section II gives the research strategy. Section III describes the research method. Section IV introduces data collecting evidence. Section V describes how the data was collected. Section VI describes the quality of research. Section VII gives the research map. Section VIII describes how the sampling is done. Section IX concludes the result presentation and Section X concludes the paper.

## II. RESEARCH STRATEGY

A central part of research strategy of the survey is to evaluate current practice of ISO9001:2000, awareness of principle of quality management system, flexibility of ISO9001:2000 and give clear concept about the need of ISO9001:2000 standard by research techniques. The research strategy covered the following stages:

- Utilization of existing information, including published and unpublished research and secondary data.
- Qualitative method and Quantitative method for e.g. questionnaire based survey.

## III. RESEARCH METHOD

There are many research methods available which comes from these approaches. No research method is one hundred percent qualitative or quantitative but each method can be considered to be on a continuum.

This survey based on both qualitative and quantitative approaches. Random samples of employees are analysed by both approaches, which allows drawing conclusion based on the results.

## IV. DATA COLLECTING EVIDENCE

The methods use in this survey is:

- Documents; in the form of reports to shareholders, books, journal and newspapers.
- Articles in form of brochures and product descriptions.
- Direct observation in the form of informal observations and notes taken during the period of the study.
- Participant observation; in the form of field-notes taken after facilitating questionnaire survey.

## V. COLLECTING THE DATA

Questionnaire was designed to evaluate the current practices of ISO9001:2000 within the two areas of Searle Pakistan limited. Two types of questionnaire are formulated for the two different areas of the organisation which are head office and factory. A total of Fifty-Seven employees including directors, general manager ,manager assistant manager, technical staff and sale persons in both areas of **Searle Pakistan limited** approaches to provide the primary input into the study. Although there are commonalities in the nature of questions used in them, each one was adapted to ensure

relevance and suitability for each type of areas of the **Searle Pakistan limited**.

Each questionnaire divides into three main areas:

- **Part A:** General
- **Part B:** Quality management system's strategies
- **Part C:** Practice and experience of ISO9001:2000

The questionnaire contains mainly 'open' questions where respondents are invited to express their opinions. In addition there are a number of questions involving rating or scale as well as Yes/No choice. The layout of the questionnaire design so that it seems easy to complete and this involve using some widely accepted principles of good practice:

- Provide a short covering letter explaining the purpose of research.
- A brief description of the subject areas under consideration.
- A brief instruction about how to complete.
- Started with simpler factual questions (e.g. biographical details such as age and length of service), moving on to items of opinion or values.
- Types of question varied occasionally.

Enclosed envelopes is distribute to appropriate employees in head office and factory areas. Each envelope contains a covering letter, questionnaire and reply envelope which delivered and collected from the reception of head office and factory.

It requested to reply within a week such that the study may proceed to next stage.

It was assured to the respondents that completed forms will be treated as strictly confidential. A summary of the final results will be made available upon requested.

## VI. QUALITY OF THE RESEARCH

The quality of research depends on:

### A. Validity

For a successful research attitude the quality of it must be high, to judge this the *validity* and *reliability* is assessed.

Validity concerns the issue whether or not the findings can be shown to be valid for the problem that is being investigated. Data collected must be relevant to the problem and the purpose of the research otherwise there will be low validity. Irrelevant data and unnecessary information leads to low validity [4]. There are six strategies that can be used to check validity

- Triangulation,
- Checks,
- Long-term observation,
- Peer examination,

- Participatory/ collaborative models of research,
- Researcher’s biases [5].

In this survey all the irrelevant questions have been ignored and all the relevant questions are included and secondary data collected from the reliable and trusted sources. This data base is updated at regular intervals of time, just after conducting them so that all information stores correctly and these factors will make to feel that the contents is relevant to the purpose of the research.

### B. Reliability

Reliability concerns the issue of consistent results of the study if it was replicated. A good guideline is to make sure that if someone did the project again, the same results would be found [6]. Reliability is an important aspect of doing a survey and the goal of reliability is to minimise biases and errors in the research study. A prerequisite for reliability is that all the documentation is in proper order and can be easily found [4].

Trying to maintain a transparency in how sense is made from the raw data the designed questions is follow a specific or set agenda in order to generate relevant and reliable results; however answers from employees is highly subjective as they give response on perception. Questionnaire is designed in a clear understandable manner so that question doesn’t mislead employees and helps them in giving reliable and consistent answers.

A written statement is given about the extent to which will disclose the information about the organisation in this report, and also the secrecy of the questionnaire, so that they give vital and the exact information which helped in doing this research. Each case recorded and referred with a code but not with any personal detail.

The findings of the survey can be applied to other organisations in Pakistan. The results identify important factors in the development process and it believes that the research will be both valid and reliable.

## VII. RESEARCH MAP

To fulfill the research aim and objectives, it is essential the collection of data in pre-planned manner and to use the available data in an effective format. Table I shows how the collected information fulfils the required objectives.

**TABLE I. HOW TO FIND THE ESSENTIAL INFORMATION TO FULFIL RESEARCH OBJECTIVES**

Research Objective	Research Map
<i>What to find Out</i>	<i>How the essential information find</i>
To understand the operation and effectiveness of quality management systems is and why companies are also committed to the needs of ISO9001:2000.	Literature Review, Comprehensive search on internet such as company’s web site, Journals, articles and annual report. Literature Review, study of market segments, questionnaire with the managers of the firm follow up with lots of informal chats.

	Articles about the performance of the firm in the recent years, annual reports.
To determine the actual experiences and opinions of the operating managers and employees in relation to ISO (9001:2000) in their organisation.	Questionnaire to target managers and employees in order to gauge view and some informal interviews if necessary
The main focus would be identifying how companies can exploit their use of ISO(9001:2000) to gain competitive advantage and also to improve the flexibility and efficiency of the organisation	Comprehensive data analysis from which required results can be collected and manipulated to establish conclusion and recommendations.

## VIII. SAMPLING

The sampling frame that was adopted for this research findings is probability sampling because; smaller number of cases for possible a higher overall data means that more time can be spend designing and piloting the means of collecting these data. Using sampling makes possible a higher overall accuracy. And the sampling technique will be ‘Simple Random Sampling’ technique because it depends on research questions and objectives, selecting the sample of employees at random from the sampling edge [7].

## IX. RESULT PRESENTATION

This section provides a result of the response of the survey. This analysis based on the survey respondents of gender, age group, number of years with present employer, and the source of quality management knowledge. This is followed by an overview of the results from the questionnaires sent to head office and factory of Searle pharmaceutical company.

### A. Rate of response to the survey

Table II shows that the overall response rate to the questionnaire survey is 66.6%.A breakdown of the response rate by head office and the factory are shown below:

**TABLE II. OVERALL RESPONSE RATE**

Unit	Total Sent Out	Total Recieved	% Received
Factory	32	20	62.5
Head Office	25	18	72
Total	57	38	66.6

Whilst, the overall response rate of 66.6 % is not significant surprise, the 72% returned from the head office and .62.5% returned from the factory. Keeping in mind that there are some major concerns over Factory’s sensitivity and security therefore, given the current response from the factory is understandable.

The response rate could have been higher with improved questionnaire design. On reflection, the length of the questionnaire probably over reflected the amount of time required for completion. Whilst all sections did not necessarily require completing this may not have been readily apparent.

However, even with the responses received a great deal of consistent and quantitative results have been established.

### B. Profile of respondents

The proportion of women responding to the questionnaire is 29% and this consisted six individuals from head office and five individuals from factory. The proportion of men responding to the questionnaire is 71% and this consisted twelve individuals from head office and fifteen individuals from factory. All respondents are aged in over eighteen years consisted 5.55% under twenty, 44.44% twenty plus, 33.33% thirty plus and 16.66% of forty years old. Just 16.66% of the respondents have spent ten plus years with their present employer, 16.66% up to two years service, 44.44% of two plus year's service and 22.22% of five years service with their present employer in the head office.

In the factory 10% up to two years, 40% two plus years, 30% five plus years and 20% ten plus years of service with their present employer in the factory.

By far most common source of ISO knowledge is by way of training consisted 85% in factory and 86% in the head office. From the work experience 15% in factory and 12% in head office. 4% respondent from head office claimed that their source of knowledge regarding to ISO knowledge is seminars.

### C. By source of ISO knowledge

An evaluation of the responses by sex and age group failed to generate any significant differences in the analysis of questionnaires.

This is because tapered distribution across these ranges. However, respondent which indicated work experience as the source of their knowledge of ISO provided a detail qualitative data and this tends to be positive impact by comparison. But, the wide range of knowledge sources claimed by the head office and factory unit is training. It is because of number of years with present employer consisted of 40% from factory and 44.44% head office is 2-4 years. These employees have only source of knowledge of ISO is training, which reflected in a more holistic view in terms of the depth and detail of the responses provided.

## X. CONCLUSION

Results indicated that a vast majority of respondents were satisfied with most aspects of the ISO9001:2000. The ISO9001:2000 indicate that achieving conformance to specification with low levels of rework has a direct effect on competitive advantage and as well as in terms of 'Customer Satisfaction'. In general, satisfied customers are likely to engaged in repeat purchase and reflect strong loyalty toward the Searle. Seeing as ISO9001:2000 is an important component of the total package of value required by customers, and the Searle use accreditation of ISO9001:2000 to attract new customers from local market as well as international markets. Employees are a significant part of the service delivery process and play a significant role in company-customer interaction.

The results of the study show that the majority of Searle employees are well trained regarding to ISO9001:2000 standard. Outstanding figures of respondents were aware of quality management principles and its generic requirements due to training conducted periodically in both units of Searle. Majority of employees are young. They are currently working in Searle which impact on the company is optimistic as aspects of improving their skills due to training conducted periodically. As it seen that young people can adopt changes more quickly and effectively which is very beneficial for both of units of Searle which directly lead to quality improvement.

Also, employee's awareness and usage rates are fairly high for key quality management principles and general requirements of ISO9001:2000. As high-quality control and processes are related to competitive advantage. ISO9001:2000 is an effective quality management system which has process control as an essential activity. Better process control, be consistently associated with less rework and hence lower costs. These lower costs will lead to better comparative business performance. This is lined up with Deming [2] who reasons that, as quality improves, waste is eliminated, costs are reduced, and financial performance improves. The results also indicate that ISO9001:2000 company's management system provides a framework for controlling and improving business activities. Which Adds value to products, services and competitiveness and provides a marketing edge.

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