The Impact of ISO Quality Assurance Standards Implementation on Adherence to Strategies in Favor of a SCM Philosophy, In Sudanese Pharmaceutical Manufacturing Facilities

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Abstract

The main objective of this study lies right at the integration of these highly topical concepts, quality assurance and SCM. To evaluate the impact of ISO quality assurance standards implementation on adherence to strategies in favor of a SCM philosophy. Sudanese pharmaceutical manufacturing facilities mainly located in Khartoum state (the capital of Sudan) and Aljazera state, at the time this study was conducted there were only 19 working manufacturing facilities other than medical gases, two of them with ISO certification. The two ISO certified facilities were included in the study representing 100% of the targeted sample. The study hypothesis Pharmaceutical manufacturing facilities with International Standards Organization (ISO 9001) license have an effective pharmaceutical quality system that is based on quality concepts; in favor of a SCM philosophy.

Key wards: ISO Quality Assurance Standards, supply chain management, Sudanese Pharmaceutical Manufacturing Facilities


1. Introduction and literature review

“Quality assurance” is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use. Quality assurance therefore incorporates GMP and other factors, such as product design and development. (1)
Within a decade after the first modern pharmaceuticals became available, efforts began to ensure their widespread availability. From the mid. 1950s to the mid. 1970s basic drug management concepts began to evolve in countries as diverse as Cuba, Norway, Papua New Guinea, Peru and Sri Lanka. Over the last 20 years countries have acquired considerable experience in managing drug supply (2). According to (3) cited in (4); (5) 25% of the drugs sold in developing countries are fake. In some countries rates up to 40% and higher have been reported. As a consequence, thousands of people die every year because of the drugs they take do not have the anticipated therapeutic effect. This human tragedy together with the significant economic impact makes it obvious that drug quality assurance throughout the entire supply chain must be a priority for every national drug regulatory authority.

Supply Chain Management are treated as an important and critical function in getting the products to their destination. In fact, in order to sustain and expand the successful interventions experienced to date, the supply chains will need to be made more robust, agile and flexible through better management and increased investment of resources to achieve supply chain optimization. The term supply chain describes the links and the inter-relationships among the many organizations, people, resources, and procedures involved in getting commodities to the customers (in this case, health care consumers). (6) A typical supply chain would include partners from manufacturing, transportation, warehousing and, service delivery. Together, these organizations orchestrate the flow of products to the end-consumer, information for better planning and, finances to cover the transaction costs. A key ingredient of a successful supply chain is that partners are focused on improved coordination, information-sharing and, serving the end-customers. In health care, the supply chain participants usually include; Manufacturers, raw material suppliers, pharmaceutical companies, procurement Agents, ministries of health, health administrative units, united nations agencies, other procurement agents distributors transporters, central, regional and district medical stores Financiers Donors or funding agencies Service Providers NGOs and service delivery points (SDPs) such as hospitals, health centers and pharmacies. (6)

Manufacturers are the source of the prescription drugs in the pharmaceutical supply chain. While most manufacturers focus efforts on improving supply chain efficiency by looking at the supply chain process itself, a few realize that other departments can have an impact on efficiency and speed (7). One of these departments is Quality, which is tasked with inspecting incoming raw materials, in-process work and final product before it is shipped. If there is a way to help the Quality department get its job done faster, then, by definition, the operations process can move along faster, thus reducing time in the supply chain. (7)

To truly benefit from the technology, Quality and Operations need to work together. Once the technology is in place, the Quality department likes the results, and the Operations department appreciates the speed. However, unless and until both departments
sit down and discuss the mutual benefits beforehand, it can be difficult for either
department to want to make the effort to seek funding to purchase the technology. (7)

Independent studies reveal that companies embracing Quality Improvement Programs
perform better than those that don’t. In general, sustainability, particularly in business, is
considered an intangible proposition. Businesses around the world are trying to
understand the concept of what a sustainable business may look like. Some call it
business risk management and others corporate sustainability. Issues such as global
economic recessions, climate change, geo-political landscape, and technological
developments have made sustainability as core proposition for businesses in Middle East.
And, businesses now understand the need for sustainable business practices more than
ever. Sustainability is central to pharmaceutical manufacturer business strategies,
bringing with it competitive advantage, IT security, staff engagement, occupational
safety, services excellence, supply-chain continuity, customer loyalty and brand value
creation.

The process of identity change continues throughout each step of the supply chain
making drug verification, and track and trace, difficult to accomplish even with the self-
contained approach for transmitting information. Historically, pharmaceutical
manufacturers and distributors have gathered the information needed for drug
authentication, and track and trace, using detailed forms and secure databases as storage
devices. (8) In even the best situations, this information is difficult to retrieve and seldom
shared with other parties outside of the firm. In the event of a recall, special teams within
firms are charged with the task of accessing data to make important decisions about the
extent of the problem. This is usually a labor-intensive process (8)

When improved geographical access is a goal, distribution presents unique challenges to
factory managers, and success depends on an effective transportation system. The cost of
transporting drugs and raw materials to remote areas can be considerable. Options to
improve the distribution may include strengthening the existing distribution system or
using private or parastatal companies to provide cost-effective alternatives for storage
and distribution. (9)

Additional challenges, such as failure to comply with standard operating procedures and
excessive losses due to theft, may require review and strengthening of supervision and
administrative procedures. At times, it may be necessary to replace personnel and/or
provide incentives to improve performance. Transportation problems, such as lack of fuel
or vehicles in working order, may be solved locally by installing a fuel depot or providing
more spare parts. (9) But a solution to more widespread problems may be to contract out
services to private or parastatal organizations. While it creates more work – including
assessing the costs of existing systems, preparing tender documents specifying service
requirements, assessing the tenderers, and monitoring the contractor performance –
contracting out the services can improve efficiency.
National systems vary with respect to public and private roles in financing, distributing and dispensing drugs and health commodities, ranging from fully public to fully private systems. While traditional systems, such as Central Medical Stores, are important, alternative systems can also help. Program planners, however, need to be aware that policy or legal restrictions may limit the use of other (alternative) strategies. Alternative systems include:

Autonomous or semiautonomous health commodity supply agencies.

Direct delivery systems. The government procurement office tenders to establish the supplier and price for each drug. The supplier then delivers directly to districts and major facilities.

Prime vendor system. The government procurement office establishes a contract with a single prime vendor to manage the distribution of drugs and health commodities. Separate contracts are developed for the suppliers.

Fully private supply, where services are provided by private pharmacies.

Not-for-profit organizations, such as drug supply agencies operated by missions and charities for their own health services.

A secure drug and health commodity storage and distribution system is a requirement for distribution, particularly with drugs that may be more vulnerable to leakage. Possible approaches to maximize security may include separating key functions of staff, increasing transparency and regular auditing. (9)

However, experiences of countless countries and programmes demonstrate that substantive and sustainable improvements in the supply and use of drugs are possible. But an equal or greater number of negative experiences show that success is by no means assured. Clear goals, sound plans, effective implementation and monitoring of performance are essential ingredients in pharmaceutical sector development. And we can be sure that if changes in a drug supply system are not based on a careful analysis of the underlying causes for the weaknesses of the existing system then they are unlikely to produce the desired outcome. Systems chosen, for example, because they function in a “successful” market economy may not prove the solution to the drug supply problems faced in the context of a developing country. (9)

For years, researchers and practitioners have primarily investigated the various processes within manufacturing supply chains individually. Recently, however, there has been increasing attention placed on the performance, design, and analysis of the supply chain as a whole. As cited in the literature (10)–(11)–(12). This attention is largely a result of the rising costs of manufacturing, the shrinking resources of manufacturing bases, shortened product life cycles, the leveling of the playing field within manufacturing, and the globalization of market economies. Supply chain management holds promise as a competitive form, provided that certain hazards are avoided, and that a competitive advantage results.
This study will shed light on supply chain optimization; a major research theme in process operations and management. A great deal of research has been undertaken on facility location and design, inventory and distribution planning, capacity and production planning and detailed scheduling. Only a small proportion of this work directly addresses the issues faced in the pharmaceutical sector. On the other hand, this sector is very much ready for and in need of sophisticated supply chain optimization techniques. (13)

(14) Describes an optimization-based approach to selecting both a product development and introduction strategy and a capacity planning and investment strategy. The overall problem is formulated as a mixed-integer linear programming (MILP) model. This takes account of both the particular features of pharmaceutical active ingredient manufacturing and the global trading structures.

A study based upon Zuellig Pharma Inc. in Taiwan has revealed that some TQM methods and tools can be very effective in guiding TQM implementation successfully in a pharmaceutical logistics organization. In addition, the study not only states the importance of the quality of employees but also discusses the integration and transformation of the marketing and sales division during the implementation process. From the training of employees to the formation of the marketing-sales team, the team performed extremely well in reducing costs, increasing profits, and meeting the expected target. More importantly, the commitment from management and the determination from this marketing-sales team have significantly improved their own competitiveness through the heart of continuous improvement. (15)

Quality based design is a new quality assessment system that is focused on critical pharmaceutical quality attributes. It is a concrete and principals implementation of some underlining concepts and principals outlined by the FDA’s pharmaceuticals cGMP. (16)

According to (16) QBD is a systemic approach to pharmaceutical development. It means designing and developing formulations and manufacturing processes to ensure predefined product quality by:

Defining target product quality profile.

Designing product and manufacturing process.

Identifying critical quality attributes process parameters, and source of variability.

Controlling manufacturing process to produce consistent quality over time.

Pharmaceuticals quality is assured using QBD by understanding and controlling formulations and manufacturing variables. Product testing confirms the quality. Implementation of QBD enable transformation of the chemistry, manufacturing and controls review of new drug applications into a science based pharmaceutical quality assessment (16)

A research paper by (17) endorses demand supply chain design based on a thorough market understanding and has to be managed in such a way as to effectively meet
differing customer needs, combining the strengths of marketing and supply chain competencies. Based on a literature review as well as the findings from a co-development workshop and focus group discussions with marketing and supply chain professionals, a conceptual foundation for demand chain management is proposed. Demand chain management involves (1) managing the integration between demand and supply processes; (2) managing the structure between the integrated processes and customer segments and (3) managing the working relationships between marketing and supply chain management. Propositions for the role of marketing within demand chain management and implications for further research in marketing are derived. (17)

Many industries as organizations begin to appreciate the criticality of creating an integrated relationship with their suppliers and customers, as well as all other stakeholders. Managing the supply chain has become a way of improving competitiveness by reducing uncertainty and enhancing customer service. The concept of value chain management (VCM) is becoming quite prevalent in industry. (18)

Within the Manchester Royal Infirmary (MRI) a research project carried out to evaluate and improve the recycling and disposal of pharmaceutical products. Discusses supply chain management practices in the National Health Service and, in particular, focuses on the concept of reverse logistics (the recycling of pharmaceutical stock for later re-use). Concludes by arguing that there are significant financial and operational advantages to the NHS, and other organizations, in developing effective reverse logistics processes. (19)

Information system technology have had a huge impact on the evolution of supply chain management. As a result of technological advances, supply chain partners can now work in tight coordination to optimize the chain-wide performance, and the realized return may be shared among the partners. A basic enabler for tight coordination is information sharing, which has been greatly facilitated by the advances in information technology. Types of information shared inventory, sales, demand forecast, order status, and production schedule. (20)

Internet and new software applications has provided an opportunity for some companies to move towards an extended enterprise business model–one that enhances value across the total supply chain. The prime driver of this trend has been the implementation of Enterprise Resource Planning (ERP) systems (21).

In China the root cause of the market and government failures according to a research by (22) is that higher-than-cost drugs preferred by all suppliers. New drug pricing mechanism is the key to the current pharmaceutical reform and should be implemented in coordination with other health system reforms.

To analyze the pharmaceutical supply chain using the DMAIC process for improvement of the reverse logistics in a recall to avert the possibility of harm to a consumer. A study by (23) found that the majority of the reverse logistics for pharmaceuticals is handled
through third-party providers, and therefore this specific knowledge is well guarded, being a core competency. The improvement concepts were found to have managerial impacts such as improved communication flow, and dedicated group(s) to focus on the reverse logistics to remove miscommunication and perception errors. The ability to make improvements, as well as sustain the improvements, will also require significant and consistent management support.

The implication of quality management in term of ISO 9001 certification; is the route chosen by great majority of companies. In recent years, companies continue to choose this route to improve quality management, certificates continue to increase in number. For example, in Catalonia; a Spanish region, there were about 1000 certificates in 1998. This number increase more than fourfold, to about 4,500 in 2002. (24)

A recent study into the impact of SCM (25), classified the business trends, by analyzing there historical development. It was found that one of the catalyst of these transformation is attributed to focus on work process, as suggested by the quality assurance standards ISO 9001. However, a published study by (26) help to understand how quality could be managed using an SCM prospective, and what is the operative and strategic consequence were for the company and the chain to which it belonged. The study shows how SCM improves the capacity of the companies to recognize the expectations of the end customers.

One of the first studies (27) demonstrate the relationship between the performance in SCM and the adoption of TQM practices. By means of a rigorous study in the electronic component industry, it spells out four aspects strongly related to quality management policy:

Maintain and improve quality control department.
Provide the supplier (and suppliers of suppliers) by incentives to encourage quality.
Collect data on defects and get these information to all employee.
Give employee training, recognition and incentive for their full corporation on quality management.

2. Methodology

2.1. Study design

This is a descriptive comparative study design based on a survey form and interview to evaluate the effect of international standard implementation of QA guidelines in the SCM system of the pharmaceutical manufacturer.
2.2. Originality value

The present study is one of the first at the pharmaceutical sector; to analyze the compliance with quality assurance guideline through the SCM of pharmaceutical manufacturer, and to evaluate the impact of ISO quality assurance standards implementation on adherence to strategies in favor of a SCM philosophy.

2.3. Study population:

ISO certified Sudanese pharmaceutical manufacturing facilities.

2.4. Study time and location:

Sudanese pharmaceutical manufacturing facilities mainly located in Khartoum state (the capital of Sudan) and Aljazera state, at the time this study was conducted there were only 19 working manufacturing facilities other than medical gases, two of them with ISO certification.

The study was conducted during March - June 2014.

2.5. Ethical consideration

All the study population; managers of the manufacturing facilities and the person in charge of the quality assurance, have been clearly informed about the academic purpose of the study. And assured that, the data provided will not be used in any way to support a decision; or harm against them.

2.6. Sample Size

Fourteen of the facilities are not ISO certified and only two were ISO certified. The two ISO certified facilities were included in the study representing 100% of the targeted sample.

Data collection

The data were collected by the researcher using a designed pretested interview questionnaires’ for each one of the three specified study population as follow:

The researcher evaluate the impact of ISO quality assurance standards implementation on adherence to strategies in favor of a SCM. Using a pretested interview questionnaire of 15 questions.

A pilot test was done in one manufacturing facility where the questionnaire was distributed by hand. The answered questionnaire copies were collected and analyzed. After the preliminary analyses, the questionnaire was judged by professional experts in the area of pharmaceutics. According to their comments and guidance some questions were omitted, modified or rearranged.

The questionnaire in its final form was distributed by the researcher to:
The Sudanese pharmaceutical manufacturing facilities.

An interview was conducted with the managers of each of the manufacturing facilities or the quality assurance manager on their deputies. The questionnaire was filled by the quality assurance manager in presence of the researcher. In some of the facilities the documents, records and SOPs were actually checked by the researcher. A reliability test was conducted in each case.

Data analyses

The data were collected using three pretested questionnaires. The collected data was organized, tabulated, classified, and analyzed using statistical software program. Data entry and analyses took place once each data collection forms (questionnaires) was reviewed for clarity and completeness using Statistical Package for Social Science (SPSS) version 12.0. The results were further tabulated, interpreted and discussed, figures were plotted using Microsoft excel program (2007). Descriptive statistics including frequency, mean, and standard deviation were used. To determine if there is a relationship between two nominal variables or whether they are independent of each other, non-parametric chi-square test was used. The non-parametric Krushal-Wallis test was used when more than two independent variables on ordinal data existed.

Variables under the study:

Based on the recommended guidelines of the WHO, united Arab emirate, food and drug administration, international conference of harmonization for pharmaceutical product preparation (ICH) and European union orange guide, other health commodities, and ISO 9001-2008 quality standard. With the aim of adapting a questionnaire to the issue in question, the researcher used the theoretical framework adapted by the WHO (28) proposed the following strategies for implementation of effective SCM:

Managing inventory investment in the chain.

Establishing supplier relationships.

Increase customer responsiveness.

Build competitive advantage for the channel.

Introduce SCM solution and enable information technology.

Using these strategies and the previous mentioned international guideline as starting point, the researcher developed the variables under the study. On one hand, the researcher chose the indicators from WHO and IPEC which are representative of each strategy and guidelines, to evaluate the study population compliance with the guideline, in other words, if the study population consider that they had been in compliance with the guideline substantially, had not exactly comply or it had not comply.

The following variables were used to carry out the study; for the specified study population as follow:
Five variables were examined to assess the effect of ISO standard implementation in ISO certified factories

To examine the effect of ISO certification on the compliance with the quality assurance standards, and the improvement in SCM system if any. The researcher was sure that the ISO certificate for quality brings benefit but what kind of benefit? And do these benefits directly favor SCM? The purpose of this part of the study is not to evaluate the benefits of implementing ISO standards but to evaluate the impact of these implementation on SCM in term of improvement, the researcher asked group B (the ISO certified manufacturers), to evaluate how much each indicator had been affected by the ISO standard implementation. On other words, if the manufacturer considered that the indicator had improved substantially, had not improved or had even been affected.

The researcher characterized the ISO certified manufacturer (Group B) and chose the indicators according to (24) use by (29) (30) which are considered representative for each strategy to study those factors concerned with SCM in which, once the ISO has been implemented, the company recognized there is still room for improvement:

Managing inventory investment in the chain.
Has implementation caused an increase in stock rotation?
Has implementation caused a decrease in lead time?
Establishing supplier relationships.
Has ISO implied an improvement in your relation with your supplier?
Increase customer responsiveness.
Has implementation been favorable in term of customer loyalty?
Has implementation improved customer satisfaction?
Has implementation decreased customer complaint?
Build competitive advantage for the channel.
Reducing logistic cost.
Decreasing non conformity cost.
Meeting delivery deadline.
Increase sales.
Increase market share.
Introduce SCM solution and enable information technology.
The use of software program.
The integration of automatic management system with customer.

The integration of automatic management system with supplier.

2.10. Limitation of the study

The study was not intended to give a detailed evaluation of the supply chain management, and quality assurance implementation.

3. Results

Five variables were examined to assess the effect of ISO certification in ISO certified factories:

ISO certified factories Chart (1)
When evaluating the impact of ISO standard implementation on SCM in term of improvement (results shown in (chart (1))). Analyses of the results shows that, ISO implementation has been favorable (substantially improved) on SCM in 32 percent of the indicators used. On the other hand, ISO standard implementation was unfavorable in 47 percent of the indicators used. It must be pointed out that ISO implementation has been unfavorable in customer responsiveness. Compared to 21 percent of the indicators had even been affected. Chart (2).

Table (1): ISO certified facilities.

<table>
<thead>
<tr>
<th>Variables</th>
<th>improved substantially</th>
<th>Not improved</th>
<th>Even been affected</th>
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<tbody>
<tr>
<td>Managing inventory investment in the chain.</td>
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<tr>
<td>increase in stock rotation</td>
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<td>1</td>
<td>0</td>
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<tr>
<td>decrease in lead time</td>
<td>0</td>
<td>1</td>
<td>1</td>
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<tr>
<td>Establishing supplier relationships.</td>
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<tr>
<td>improvement in supplier relationship</td>
<td>1</td>
<td>0</td>
<td>1</td>
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<tr>
<td>Increase customer responsiveness.</td>
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<tr>
<td>customer loyalty</td>
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<td>customer satisfaction</td>
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<tr>
<td>decreased customer complain</td>
<td>0</td>
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<tr>
<td>Build competitive advantage for the channel.</td>
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<tr>
<td>reduce logistic cost</td>
<td>1</td>
<td>1</td>
<td>0</td>
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<tr>
<td>decreasing non conformity cost</td>
<td>1</td>
<td>0</td>
<td>1</td>
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<tr>
<td>increase in meeting delivery deadline</td>
<td>1</td>
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<td>increase in sales</td>
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<td>Market share</td>
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<td>Introduce SCM solution and enable information technology.</td>
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<td>software program</td>
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<td>2</td>
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<tr>
<td>integration of automatic management system with customer</td>
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<td>1</td>
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<tr>
<td>integration of automatic management system with supplier</td>
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Table (2) Indicators used for measuring ISO certification effect

<table>
<thead>
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<th>Variables</th>
<th>improved substantially</th>
<th>Not improved</th>
<th>Even been affected</th>
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<tbody>
<tr>
<td>Managing inventory investment in the chain.</td>
<td>1</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Establishing supplier relationships.</td>
<td>1</td>
<td>0</td>
<td>1</td>
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<tr>
<td>Increase customer responsiveness.</td>
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<td>0</td>
<td>6</td>
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<tr>
<td>Build competitive advantage for the channel.</td>
<td>5</td>
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<td>3</td>
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<tr>
<td>Introduce SCM solution and enable information technology.</td>
<td>2</td>
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4. Discussion

This study is proposed to evaluate the implementation of QA guidelines in the SCM system of the pharmaceutical manufacturer. To fulfill the objectives of the study, the researcher composed four questions raised by its problem, accordingly the researcher hypothesized answers to these questions as stated in chapter three. Here by, the discussion of results for each section then the four hypotheses of the study will be reviewed individually against the results obtained by the data analysis.

Pharmaceutical manufacturing facilities with International Standards Organization (ISO 9001) license.

The hypothesis (Pharmaceutical manufacturing facilities with International Standards Organization (ISO 9001) license have an effective pharmaceutical quality system that is based on quality concepts; in favor of a SCM philosophy.)
To test this hypothesis the researcher conducted a field visit observing the work and a questionnaire of five headings with fourteen questions were filed, according to the results obtained:

Managing inventory investment in the chain.
Has implementation caused an increase in stock rotation?
Has implementation caused a decrease in lead time?

The aim of the two questions is to evaluate improvement in stock management in two areas: maintaining low cost levels by means of high product rotation or by means of shortened lead times. Analysis of results shows that, implementation has been favorable on stock management. The researcher also found that any improvement in management of the inventory was more a result of shortened lead times that of an increase in stock rotation. Nevertheless, it must be pointed out that for most of the study sample there was no difference in terms of improvement of the inventory through ISO 9001 implementation.

Establishing supplier relationships.
Has ISO implied an improvement in your relation with your supplier?

With regard to the suppliers, it’s interesting to note that 50% of the certified facilities establish long-term relationships with their suppliers. It is also noticeable that the manufacturers prioritize product quality and service rather than price, which reinforce the idea of SCM philosophy in which product commercialization is a key process. The other 50% of the certified facilities; reported that their relationship with their suppliers has be insignificantly affected by ISO 9001 implementation.

Increase customer responsiveness.
Has implementation been favorable in term of customer loyalty?
Has implementation improved customer satisfaction?
Has implementation decreased customer complaint?

In term of customer satisfaction, we can definitely say that it have even been affected by ISO 9001 implementation in the facilities surveyed. On the other hand, with respect to decreasing customer complaints as an indicator of improvement in business relations with the customer, the impact of ISO 9001 implementation has not been quite so strong.

Build competitive advantage for the channel.
Reducing logistic cost.
Decreasing non conformity cost.
Meeting delivery deadline.
Increase sales.

Increase market share.

ISO 9001 implementation according to the results obtained led to reduction in logistic cost and nonconformity costs, such a reduction contributes enormously to improving the flow of materials promulgated by SCM philosophy.

The last two items relating to the fourth strategy are connected to improvement in economic aspects of the company for the success of the chain: for both indicators (increase in sales and market share, implementation had a favorable impact according to 50% of the sample surveyed, so we cannot say that implementation brings a competitive advantage to the chain in term of improving economic aspects.

Introduce SCM solution and enable information technology.

The use of software program.

The integration of automatic management system with customer.

The integration of automatic management system with supplier.

There are several studies that have related the application of (information technology programs) to improvement of the processes (schniederjans and kim, 2003). There exists a certain amount of discussion as to whether IT systems are integrated in the company or it’s the company that adapts to the IT system that is chosen.

More interesting is the fact that the facilities surveyed admit that they do not use such management tools even if they might need them. These cases show that in spite of ISO 9001 implementation, the companies have not provided themselves with an integrated IT system. They believe there is no need to integrate the different agents of the supply chain. This gives an idea of how far the certified manufacturer have to go to get genuine integration in their production systems.

Conclusion:

In conclusion it was rare to find cases where ISO 9001 implementation had been a disadvantage. The worst of the possibilities here an increase of the logistic costs. This lead to believe that ISO 9001 implementation does not have a negative effect on strategies designed to improve the implementation of SCM philosophies.

The study shows it is not possible to affirm that ISO 9001 implementation totally favors SCM strategies; however, there is precise area that have been shown to be reinforced: Build competitive advantage for the channel. Nevertheless there are two aspects that stand out as disadvantages of ISO implementation; the market share and the logistic cost. To some up the results discussed above shows that most of the manufacturing facilities investigated does not comply with the previous guideline. This strengthens the above and to a very high degree proved that the first hypothesis (Pharmaceutical manufacturing facilities with International Standards Organization (ISO 9001) license have an effective...
pharmaceutical quality system that is based on quality concepts; in favor of a SCM philosophy.) incorrect.

Abbreviations:

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Stands for</th>
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<tr>
<td>GMP</td>
<td>Good manufacturing practice.</td>
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<tr>
<td>ISO</td>
<td>international standard organization</td>
</tr>
<tr>
<td>QBD</td>
<td>quality based design.</td>
</tr>
<tr>
<td>SCM</td>
<td>supply chain management</td>
</tr>
<tr>
<td>WHO</td>
<td>World health organization</td>
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