FACULTY OF GRADUATE STUDIES

Impact of Quality Management Systems implementation on Cost and Competitiveness in Palestinian Pharmaceutical Companies.

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Birzeit - Palestine
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Dedication

To my loving parents who extended tremendous support and showered me with blessings and sincere prayers for my success in having this humble work accomplished for the benefit of the truly deserving people of my country

To my beloved wife, Isra', who had the patience and endured unbearable pains sharing with me tiresome days and sleepless nights busy with preparations and difficult work from the beginning through the end of this work

To my sweet kids Tareq and Layth who light my life and give me the power to keep going

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LIST OF ABBREVIATIONS

- **ASQ:** American Society for Quality
- **AUPAM:** The Arab Union of the Manufacturers of Pharmaceuticals and Medical Appliances
- **BP:** British Pharmacopoeia
- **CEN:** European Committee for Standardization,
- **CEOH:** The Center for Environmental and Occupational Health / Birzeit University.
- **cGMP:** current Good Manufacturing Practices
- **CI:** Continuous Improvement
- **COQ:** Cost of Quality
- **CPQ:** Cost of Poor Quality
- **DF:** Degree of Freedom
- **EFPIA:** the European Federation of Pharmaceutical Industries Associations
- **EMS:** Environmental Management Systems
- **FDA:** Food and Drug Administration
- **GCP:** Good Clinical Practices
- **GLP:** Good Laboratory Practices
- **ICH:** International Conference on Harmonization of the Technical Requirements for Registration of Pharmaceuticals.
- **IFPMA:** International Federation of Pharmaceutical Manufacturers Association.

- **IP:** International Pharmacopoeia
- **ISO:** International Standards
- **OECD:** Organization for Economic Co-operation and Development
- **(PAF) model:** prevention- appraisal- failure model
- **PMOH:** Palestinian Ministry of Health
- **PMRA:** Health Canada's Pest Management Regulatory Agency.
- **POC:** Price of Conformance
- **PONC:** Price of Non-Conformance
- **QA:** Quality Assurance
- **QC:** Quality Control
- **QMS:** Quality Management Systems
- **R& D:** Research and Development
- **SOP:** Standard Operation Procedure
- **SPSS:** Scientific Package of Social Science
- **TQM:** Total Quality Management
- **UPPM:** Union of Palestinian Pharmaceutical Manufacturers.
- **USP:** United States Pharmacopoeia
- **WHO:** World Health Organization

ABSTRACT

Key Words: Competitive advantage, Competitiveness, Cost of Quality, GMP, ISO, Quality Improvement, Quality Management Systems, Regulations, Standards.

The pharmaceutical industry is one of the most important sectors because pharmaceutical products are used for human health. So, this sector is in general, heavily regulated to ensure that they are fit for their intended use, comply with the requirements and do not place patients at risk due to inadequate safety, quality or efficacy. The attainment of this quality objective is the responsibility of senior management and requires the participation and commitment by staff in many different departments and at all levels within the company, by the company's suppliers and by the distributors. To achieve the quality objective reliably there must be a comprehensively designed and correctly implemented system of Quality Assurance incorporating Good Manufacturing Practice and thus Quality Control.

There is a sever competition in the pharmaceutical industry all over the world, and there is increasing of costs related to production, research and development, etc. Like, other markets all over the world, there is sever pharmaceutical competition in Palestinian market. There are three types of companies competing in the Palestinian market regarding to their origin, Palestinian companies, Israeli companies, and International companies.

Palestinian pharmaceutical companies face many challenges, such as, competition between each others, competition with Israeli companies, and with International

companies, complying with international standards and regulations, and cost reduction.

Palestinian pharmaceutical companies started focusing and working to comply with and to produce according to international regulations such as, FDA-cGMP, EU-GMP, and WHO- GMP since the beginning of 1990s. So, they started to invest in improving quality, in order to face the local competition and to seek for opportunities for exporting their products. They have implemented ISO9000, and ISO 14000, and they are trying to get the certificate of Good Manufacturing Practices (GMP).

The purpose of this study was to investigate the pharmaceutical companies' commitment to improving quality, to investigate the correlation between quality management systems and cost, and to investigate the correlation between quality management systems and competitiveness.

The study used various methods to collect the data and test the hypotheses, such as the literature review, the questionnaire, and interviews. The results proved that there is commitment for improving quality, in order to face competition in the local market and compete globally, after getting GMP certificate.

Moreover, the study showed that a correlation exists between quality improvement and cost reduction, and, it showed that correlation exists between quality and competitiveness.

ملخص

يعتبر قطاع الصناعات الدوائية من القطاعات الهامة, لأنه يعنى بصحة الإنسان. و بالتالي, فان هذا القطاع يعتبر, عموما, من القطاعات الخاضعة للرقابة للتأكد من أن المنتج الدوائي مناسب و مطابق للمعايير و لا يتسبب بأي خطورة على المريض المستخدم نتيجة لخلل في أمانه, جودته, و فعاليته. إن مسؤولية تحقيق أهداف جودة الأدوية تقع على الإدارة العليا للشركة المنتجة كما تتطلب مشاركة و التزام الموظفين من مختلف المستويات و الأقسام. و لتحقيق ثباتية أهداف الجودة لا بد من تصميم شامل و تطبيق دقيق لنظام تأكيد الجودة بالتوازي مع نظام التصنيع الجيد و نظام ضبط الجودة.

المنافسة شديدة في أسواق الدواء على مستوى العام, كما إن هناك زيادة في التكاليف ذات الصلة بالإنتاج و البحث و التطوير و غيره.

كما هو الحال في الأسواق العالمية, فان سوق الدواء الفلسطيني يشهد أيضا منافسة شديدة. حيث هناك ثلاثة أنواع من الشركات المتنافسة في السوق الفلسطيني, اعتمادا على مصدر الشركة, الشركات الفلسطينية, الشركات الإسرائيلية, و الشركات الأجنبية أو العالمية.

إن شركات الأدوية الفلسطينية تواجه العديد من التحديات, مثل المنافسة بين هذه الشركات مع بعضها, منافسة الشركات الإسرائيلية و العالمية, العمل بناء على المواصفات العالمية, و تقليل التكاليف. في مطلع التسعينات من القرن الماضي, بدأت الشركات الفلسطينية تركز و تعمل على الإنتاج بناءا على المواصفات و المتطلبات العالمية في التصنيع الدوائي مثل نظام التصنيع الجيد الصادر عن مؤسسة الغذاء و الدواء الأمريكية, الاتحاد الأوروبي أو منظمة الصحة العالمية. و بالتالي فإنهم بدءوا الاستثمار في تحسين الجودة لمواجهة المنافسة المحلية و للتحسين فرص تصدير منتجاتهم للخارج.

إن الشركات الفلسطينية طبقت نظام ISO 9000 و ISO 14000, كما إنها تحاول الحصول على شهادة التصنيع الجيد (GMP).

الهدف من هذه الدراسة هو التحقق من مدى التزام شركات الأدوية الفلسطينية في تحسين الجودة, هل يوجد علاقة بين تحسين الجودة و التكاليف وهل يوجد علاقة بين تحسين الجودة و التنافسية.

لقد تم استخدام عدة طرق لجمع البيانات و فحص الفرضيات, مثل مراجعة الدراسات السابقة بهذا المجال, استخدام الاستبيان و المقابلات, بالإضافة إلى فحص الفرضيات بواسطة الطرق الإحصائية اللازمة.

لقد أظهرت الدراسة أن هناك التزام من الشركات نحو تحسين الجودة لمواجهة المنافسة المحلية, و للقدرة على التنافس في الأسواق العالمية في حال حصلت هذه الشركات على شهادة المواصفات العالمية. كما أن الدراسة أثبتت وجود علاقة بين تحسين الجودة و تقليل التكاليف, و وجود علاقة بين تحسين الجودة و زيادة الميزة التنافسية.

CHAPTER ONE

Introduction

1.1 Overview

Improving quality has been found to be a wonderful tonic for improving operations for many firms. To build successful strategies of differentiation, least cost, and rapid response, firms need to implement effective quality management systems. Implementing an effective quality management system is an integrated process that can help a firm to produce differentiated products at a high quality to meet the customer quality expectations, rapidly respond to customer orders, and achieving efficient productivity at the lowest possible costs. By achieving differentiation, rapid response, and costs reduction through developing efficient process to produce consistent quality products, sales and profitability will increase. De Feo, (2003) classified quality's evolution into three periods. First was the industrial revolution, which led to higher quality and higher costs. Then mass production era, a period ending well past World War II, when there was moderate quality and lower costs. And now, there is a new era, organizations will create high quality at lowest costs.

In summary, quality means understanding and optimizing the system so that the whole process continues to operate and optimize the whole system of value exchange (Straker, 2001). This means that the definition of quality is related to the product and/ or service and the process and the definition includes requirements and standards, management commitment, customer focus, investment in employees and involving them in the quality process, and operating at minimal cost.

Quality is never an accident. It is always the result of high intentions, sincere efforts, intelligent direction and skillful execution. It is an attribute or characteristic whose dictionary meaning is the degree of goodness or worth of a person, place or

thing, (Kaul, 2004).

In determining the quality of a product, the customer's expectations about the product will be given the top most priority. In the present scenario, customer delight is the need of the hour in order to survive the cutthroat competition. Kaul, (2004), mentioned that in this age of liberalization the quality of products has become a major concern for pharmaceutical industries. To be competitive, an industry needs to provide a product/service, into which quality is designed, built, marketed and maintained at the most economical cost, which brings in customer "delight" instead of customer satisfaction. These competitive edges made the pharmaceutical industries think of approaching quality management efforts in their total form, known as Total Quality Management.

Quality management is the application of a formalized system to achieve maximum customer satisfaction at the lowest overall cost to the organization while continuing to improve. A formal quality management system documents the structure, responsibilities, and procedures required to manage and improve quality effectively (ASQ). As stated by Nichols, (2002); Gilmour and Hunt, (1995) mentioned that quality is described as a concept rather than a technique, so its implementation is very much dependent on the type of organization or process at hand. Deming, (1994); Gilmour and Hunt, (1995) concluded that identifying processes is an important step toward improving them and predicting the consequences of changes; process maps should consider all aspects of the service including suppliers, clients, design, production, and delivery .The job of quality management is not just advising

a sampling plan for the acceptance/ rejection of the incoming materials or products and controlling manufacturing process conditions.

Management commitment for improving quality is one of the most important factors for continuous improvement. The management commitment can be clear through conducting quality policies as main part of quality management systems. Quality policies play an important role in the understanding of a company's operational principles and practices. The most successful policy implementation in the companies studied relied on policies being drafted internally with the cooperation of not only the nominated quality management but also the supporting non-quality management functions. The use of a structured and predetermined implementation plan that is shared across all sectors of the company and the development of supporting systems to monitor progress were also observed to benefit employee involvement and effective policies, (London, 2005)

Quality Management is a company wide activity, involving the combined efforts of various departments such as R & D, engineering, purchase, production, Quality Control, Quality Assurance, Human Resources, Marketing, Distribution, Warehouse, etc in different phases with a view to achieve the desired quality of the end product.

Implementation of a comprehensive quality systems model for human pharmaceutical products will facilitate compliance with Good Manufacturing Practices (GMP). The central goal of a quality system is to ensure consistent production of safe and effective products and that these activities are sustainable. Quality professionals are aware that good intentions alone will not ensure good

products. A robust quality system will promote process consistency by integrating effective knowledge-building mechanisms into daily operational decisions. When fully developed and effectively managed, a quality system will lead to consistent, predictable processes that ensure that pharmaceuticals are safe, effective, and available for the consumer.

1.1.1 Costs and Benefits of Quality

Improving quality requires adding certain amount of effort and cost, so it is essential for every industrial company to know the cost of quality. However, these incremental costs are supposed to be rewarded with increased benefits and reduced costs throughout the life cycle of the solution. Like all things there is a price to pay for quality, so, it costs money and time to build a quality solution; but the benefits of quality improvement can exceed these costs. Consider leaving the quality steps out in order to save money; then you will have to deal with direct and indirect costs of poor quality. These costs may not be apparent when the project is progressing, but should definitely be taken into account as part of the full life cycle cost of the solution being delivered. The costs of quality must be weighed against the benefits of providing a quality solution. Whereas many of the costs of quality show up in the project, many of the benefits of quality show up over the entire life cycle of the solution. In recent years, many companies have recognized the important relationship between cost and quality, unlike the past, when companies generally underestimated the costs of poor quality because they were difficult to quantify.

As stated by Omachonu and Ross, (1994); Garvin (1988) mentioned that there are three views of quality costs:

1- Higher quality means higher cost. This is due to the belief that improving quality adds costs in labor, material, design, and other costly resources and these extra costs are not compensated by additional benefits.
2- The cost of improving quality is less than the resulting savings. This means that the savings result from less rework, scrap, and other direct expenses related to defects are more than the cost of improvement. This view was originally promoted by Deming and is widely held among Japanese manufacturers.
3- Quality costs are those incurred in excess of those that would have been incurred if the product was built or the service was performed exactly right the first time. This view represents the TQM philosophy and this means that costs are not only include direct costs, but they also, include those resulting from lost customers, lost market share, and the many hidden costs and foregone opportunities not identified by cost accounting systems.

The cost of quality is not a new concept and there are a lot of pioneers who tried to focus on this concept. Feingenbaum, (1961) developed the prevention- appraisal-failure (PAF) model. The model classifies the cost of quality into three categories:

1. Cost of Prevention: the cost of any action taken to investigate, prevent or reduce the risk of non- conformity or defects.

2. Cost of Appraisal: The costs of evaluating the achievement of quality requirements.

3. Cost of Failure: The costs of non- conformance, both external and internal failure.

Zairi, (1997), mentioned that both Rank Xerox and Lea Ronal (UK) added two additional elements to the (PAF) model:

1. The cost of exceeding requirements: The costs incurred to provide information or services which are unnecessary or unimportant or of which no agreed requirements have been established.
2. Cost of opportunities lost: The loss of profits resulting from changing the customer purchase attitude to buy competitors' products or cancellation products or services that didn't meet customer requirements.

As mentioned by Chen and Yang, (2002); Grosby, (1984), classified total costs of quality (COQ) into two broad categories:

1. Poor quality or Non Conformance: This area covers the price paid by not having quality systems or a quality product or costs incurred because of defective quality problems occurring on the first run. Examples of this are:

(1) Rework: Doing the job over again because it wasn't right the first time.

(2) Scrap: Throwing away the results of your work because it is not up to the required standard.

(3) Waiting: Time wasted while waiting for other people.

(4) Down Time: Not being able to do your job because a machine is broken.

(5) Client dissatisfaction: defects mean that the client will be more dissatisfied. Lower service quality will also make the client experience less pleasure, which will result in more complaints and may translate into decreasing sales.

(6) Poor Moral: No one likes to work for an organization or a project that has poor processes or produces poor quality solutions. Costs of poor morale include increased absenteeism, higher turnover and less productivity from the staff

1. Cost of Conformance: Conformance is an aim of quality assurance. This aim is achieved at a price, which includes the costs of ensuring that goods are produced defect free. Examples of this are:

(1) Documentation: Writing work instructions, technical instructions and producing paperwork.

(2) Training: On the job training, quality training, etc.

(3) Auditing: Internal, external and extrinsic.

(4) Planning: Prevention, do the right thing on the first time.

(5) Inspection: Vehicles, equipment, buildings and people.

(6) Testing: Testing is a part of the project life cycle, but it is also done to ensure the solution meets requirements and quality standards.

It is clear that no one will deny the importance of quality, but there is confusion in the trade off and pay off between cost and quality. To provide value for money, it is necessary for companies to measure and control all quality costs related to production, by establishing a quality cost system. By using this system, the company can collect costs across the whole lifecycle of the product or service to include consumer and operational failure costs. When the total costs of having poor quality is realized by management, it is easy for the company to make a comparison between cost of improving quality and cost of having poor quality, which leads to better allocation of resources specially in the man power, machine, methods, and materials. According to Omachonu and Ross, (1994), by implementing cost of quality systems, Hewelett- Packard could estimate that the cost of not doing things right the first time was 25 to 30 percent of revenues, and Motorola has reduced the cost of poor quality by about 5 percent of total sales or about $480 million per year.

There is a trend of an increased focus on quality to satisfy customers and to achieve efficacy and effectiveness, which costs money. The raised question is "Are quality-related efforts worth their cost? In other words, what is quality's return on investment?"

To answer this question, a relationship must exist between quality and financial results and the quality costs and results must be measurable in terms of money. According to Leung, Chan, and Lee, (1999) there are many benefits or results of quality management system such as ISO 9000, which can be measurable as benefits for staff, operation and business, and these benefits lead to productivity improvement, competitiveness improvement, and cost reduction, as summarized in

Table (1). So, savings (improved productivity, lower costs, short duration, low defects, and team moral), revenues (client satisfaction and Competitiveness) and reducing cost of poor quality resulted from achieving high quality may be reasonable enough to cover cost of quality and generate more profits.

Table (1); Benefits of quality management systems on staff, operation and business.

Benefits to staff	Benefits to operation	Benefits to business entity
Clearer working procedures	Shorter delivery lead time	Attracted more new local customers
Improved team spirit	Reduced wastage of materials	Increased sales with existing customers
Less staff conflicts	Increased efficiency	Received less complaints
Lower staff turnover rate	Improved quality of product/ service	Increased profits
Received more suggestions from staff	- Acquired a better control of subcontractors - Reduced operational costs - Increased quantity of production	- Attracted more new overseas customers - Customers exercised less control on your process

Adapted from Leung, Chan, and Lee, (1999)

To assess the effect of quality on financial results, Heinloth, (2000), suggested a simple economic equation (Profit = Income – Expenses) to investigate the correlation of good quality and poor quality on income and expenses, which means that if benefits of quality were measured in financial language, the organization can measure or investigate the cost and benefit of quality. However, Corbett, Montes-Sancho, and Kirsch, (2004) concluded that the degree of obtaining benefits of quality management system differs from firm to another, and firms implementing the standard in a more rigorous and comprehensive way than others, are likely to obtain more benefits. Finally, they generalized that careful design and

implementation of consistent and documented quality management systems can contribute significantly to superior financial performance.

More managers than ever before are focusing on quality as a way of increasing productivity, reducing costs, and meeting customer needs. These managers are beginning to understand the importance of continuously improving the quality of their services and products as a way of achieving these goals, (Suarez, 1992).

As mentioned before, pharmaceutical industry is highly regulated to insure safety and efficacy. Regulation of safety, efficacy and quality fundamentally affect the industry's cost structure and the nature of competition, while regulation of price, reimbursement and promotion affect demand and profitability. Adopted regulations have been and remain a critical factor that shape this industry and must be central to any realistic analysis of the industry. Regulatory control may also benefit consumers, by reducing the risk that harmful or useless drugs are admitted to the market. The production of safety and efficacy information is a public good which may be underprovided by the market. For safety, liability may provide an alternative corrective to regulation. For efficacy, the market may acquire information over time, but learning by experience may entail a welfare loss. The optimal regulatory policy would set safety and efficacy standards to achieve the optimal balance between costs and benefits, (Danzon, 1999).

1.1.2 Impact of Quality on competitiveness

Customer satisfaction with a company's products or services is often seen as the key to a company's success and long-term competitiveness. Quality improvement is

important as integral to do a business the smart way leading to customer satisfaction. To drive responsibility for the quality process through the ranks of your organization, you should assess individual contributions to the quality process as part of every employee's periodic review. There is a direct relationship between value and competition. A fundamental rule in crafting a competitive strategy is to view competition from the other player's viewpoints. The firm must become competitor-oriented to be successful and to be able to survive. You must pursue the right competitive strategy - avoid strengths of your competitors and look for weak points in their positions and then launch marketing attacks against those weak points. Berawi, (2004), stated that why and how the company makes progress towards higher level of quality is intangible assets optimization, and companies need superior quality to face global competition.

As mentioned by Talha, (2004), the American Society for Quality Control defines quality as "the total features and characteristics of a product or service made or performed according to specifications to satisfy customers at the time of purchase and during use". Many companies throughout the world have emphasized quality as an important strategic dimension because a quality focus reduces costs and increases customer satisfaction (Talha, 2004).

Customer satisfaction is considered as an important principle of quality. This means that improving quality can satisfy customers leading to good reputations, sales increase, and increase the profitability. So, the key to competitive advantage lies in continuously satisfying customers' needs.

To begin an effective quality management system start-up, management must first decide on exactly what their definition of quality is and where they want to go with

it. Where to begin is also a concern. Implementing TQM provides benefits in both internal and external measures. Waste reduction, lowered costs of quality or improvement in time and operation of the processes are internals. The external relationships of the organization: customer satisfaction, suppliers' satisfaction or increased sales (Escrig-Tena, 2003).

Understanding customer perceptions is essential to remain competitive nowadays. To do this, a company should not only know the customer satisfaction degree to its current product or service, but also know the customer satisfaction degree to the competitors.

Based on the customer satisfaction degree to both the company and competitors' products, a goal is to be decided to show the target for meeting each customer attribute. The goal combines the data describing the customers' perception of the competitive position of the product or service relative to its competitors. The customer satisfaction degree is the customers' rating according to the current product, while the goal is the future-state rating to be reached. The goal is to put customer satisfaction benchmarking to work for the company to achieve world-class competitive capability.

In the pharmaceutical industry today, as with many other industries, demands for quality have never been higher. The pharmaceutical industry is in an increasingly complex and dynamic environment. There have been a lot of changes in recent years in the pharmaceutical industry and this trend is likely to continue. In global market, pharmaceutical companies must meet many new challenges to ensure efficient

business operations. There are external challenges from competitors, generic drug manufacturers, health-care organizations, in addition to internal challenges to decrease the costs of sales, R&D, and manufacturing. Competition and technological advances have increased levels of uncertainty (McAdam, and Barron, 2002). Bashe, (2000), stated that the increase in consumer power will fundamentally force pharmaceutical companies to change the way they do business. For these reasons, Quality is now the major differentiator in this increasingly competitive business environment.

Palestinian pharmaceutical companies have similar challenges, and they also have their unique situation and challenges such as, competition of Israeli companies and international companies, they are all producing generics (they don't develop or innovate new products), they are selling locally only (some exceptions) which increase the severity of competition, and finally, customers' perception, which means that customers believe that the Palestinian pharmaceutical products, like all other locally produced items have less quality than Israeli or foreign products, which affects their competitiveness. The customers' perception toward Palestinian pharmaceutical products was investigated through some studies like Massar, 1997, and Massar, 2000.

1.2 Purpose of the Study:

The purpose of this study is to investigate the management commitment for improving quality in Palestinian Pharmaceutical Companies and to investigate the correlation between improving quality through implementing effective quality management systems, such as ISO 9000 and ISO 14000, and complying

with the international regulations, such as cGMP and cost and/ or competitiveness.

1.3 Problem Statement:

1.3.1 The Problem Statement of the study is:

To what extent managements are committed to improve quality of Palestinian Pharmaceuticals? What is the correlation between effective quality management systems implementation, Cost, and competitiveness in Palestinian pharmaceutical companies?

1.3.2 Justifications of selecting the problem statement:

Demand for quality is now higher than before and it is now the major differentiator in the current increasingly competitive business. Pharmaceutical companies are working in sever competitive business and they must meet many challenges, such as competition and reducing costs, to ensure efficient business operations (McAdam and Barron, 2002).

Today, pharmaceutical companies are working hardly to minimize costs, increase productivity and maintain a high level of quality and regulatory compliance. Pharmaceutical products are directed to satisfy consumer needs in there health care which is vital for society.

Minimizing costs, increasing productivity, achieving customer satisfaction, and maintaining high level of quality are challenges for pharmaceutical companies.

According to Kaul, (2004), the top most priority of determining the quality of a product is the customer's expectation about the product, and the customer delight is the need to survive and to effectively compete. To delight customers and to face

competition, the quality of products has become a major concern for pharmaceutical industries. Pharmaceutical industries need to provide products, into which quality is designed, built, marketed and maintained at the most economical cost, which brings in customer "delight" instead of customer satisfaction and they started to think of approaching quality management efforts in their total form. So, the study tries to answer the following questions:

- Is there a commitment to improve quality?
- is the investment in quality (through quality management systems implementation) worthwhile?

1.4 Importance of the Study:

Pharmaceutical Industry in Palestine could be considered as a unique industry if compared with other sectors in terms of its innovation and development. Considering the importance of the Pharmaceutical sector and the crucial performance of such industry within the Palestinian economy and the high demand for quality of pharmaceutical products, there is essential need for further in-depth research directed at studying the quality management systems implementation and the benefits of these systems on opportunities and needs imbedded within the sector's environment. The ultimate objective is to asses the impact of quality management systems on cost and competition in pharmaceutical firms and to find the best way of getting benefits in promoting their products in the specialized target markets.

Quality is critical in the pharmaceutical industry for achieving both safety and efficacy. Safety and efficacy of pharmaceutical products are critical and the

pharmaceutical industry is heavily regulated to assure the safety and efficacy, which push Pharmaceutical companies to implement effective quality management system and produce according to international manufacturing standards. Implementing effective quality management systems and producing according to international regulations (GMP) requires a lot of investment. On the other hand, by assuring safety and efficacy of the products, pharmaceutical companies can achieve benefits, like, customer satisfaction and getting more sales and better market share. The importance of this study is:

-Lack of studies about impact of quality in Palestinian pharmaceutical industry on both customers and producers.

- The study is a descriptive and it can be reference for further studies to search in depth in this sector.

- The outcome of the study can be used by the pharmaceutical industry to get better benefits of implementing quality management systems and complying with regulations and standards.

- The Ministry of Health can also, use the outcome of the study to improve this sector and to help Palestinian pharmaceutical industry competing locally and globally.

1.5 Palestinian Pharmaceutical Industry as a focus of the research:

1.5.1 History

Before the 1967 war, all pharmaceutical products were imported from foreign companies via importers in Amman, Jordan. After the 1967 war and isolating West Bank from the rest of Arab World, the only products available were either Israeli medicine products or products imported through Israeli agents, and importing from Jordan was prevented. So, Pharmaceutical Industry in Palestine was developed to meet these challenges and offer the market some of the needs.

In 1969, nine pharmacists in West Bank established small laboratories to manufacture simple syrups and anti-diarrhea products. In 1970 these nine small laboratories merged to become three larger companies: Jordan Chemicals in Beit Jala; Palestine Medical Company in Ramallah; and, Jerusalem Pharmaceuticals in El-Bireh. From 1972 – 1984, another seven companies were established: Balsam Co. in El-Bireh in 1972 and Birzeit Co. in Birzeit in 1973; Eastern Medical Co. and Gama in 1978, both in Ramallah; and Pharmacare in 1985 in Beitunia, and MASCO in Gaza in 1984. During the 1990's, mergers occurred between some companies, like Birzeit and Palestine Medical Company in 1993, Jerusalem Pharmaceuticals and Balsam in 1995, and Birzeit and Eastern Medical Co in 1997. Currently, there are six major Palestinian companies predominantly located in the Ramallah area, where

70% of local producers are located, all of which are members of the Union of Palestinian Pharmaceutical Manufacturers (UPPM). Local production is relatively unfocused, with manufacturers tending to produce homogeneous product lines. This has created strong inter-industry competition and has weakened the sector in its attempt to develop and improve into a distinctive sector that invests in real research and development and benefits from economies of scale. Palestinian pharmaceutical companies are mainly, selling in the local market which is relatively small and this forces companies to work below there full capacities. According to Makhoul, (1999), Palestinian pharmaceutical companies' working capacities are in general below 83% of the full capacity, and the limited market of these companies also, created sever competition, and, in general, companies produce identical products. Moreover, companies severely compete in introducing high potential new products.
The Industry employed more than 857 persons, with total sales of about 32.2 Million USD during the year 2003. Recent statistics indicated that more than 50% of pharmaceuticals consumed in Palestine are Palestinian made. Although Palestinian manufacturers focus on generic products, they cover more than 80% of the needed product categories essential to combat diseases and relief sickness.

1.5.2 The Development of Palestinian Pharmaceutical Industry

The industry is growing rapidly targeting local as well as international markets. According to UPPM, the introduction of automated production lines, improved management and production processes, continuous training of management and line workers and the institution of quality control practices have led to significant

increases in production capacities. All six companies are currently participating in a program of training and technical assistance aimed at complying with all GMP requirements. These programs have been reflected in the continually improving range and quality of products and increased the market share of the local manufacturers to nearly 40 percent of the estimated total market of $65 million with the balance being provided by Israeli and other international suppliers. Piece wise their market share exceeds 50%. Although Palestinian manufacturers focus on generic products, they cover more than 80% of the needed product categories essential to combat diseases and relief sickness. There are 12 major product categories (groups) that are produced by the Palestinian manufacturers, these categories are the best selling groups of products, constituting approximately 85-90% of the total sales in the local market. Each category contains different generic products, ranging from 1 to 14 products per manufacturer and an average of three new products introduced annually by each producer. Under each product, there are different brands, forms, dosage and sizes. The total number of Palestinian pharmaceutical products is 991 items as registered by Palestinian Ministry of Health.

Among the 12 categories, antibiotics capture the largest percentage of total sales, approximately one-third of the sales of all products. Central nervous system products and non-steroidal anti inflammatory come second with small differences between the two categories. The rest of the categories capture between 1 to 7 percent of the total sales, these categories are urinary antiseptic, anti diabetic, anti protozal, allergic reaction, hormones, anti fungal, vitamins, peptic ulcer, and cardio vascular.

Table (2): Sales, Investment, Exports, and Employees of Palestinian Pharmaceutical Companies.

	1999	2000	2001	2002	2003
Sales ($)	20762532	22134037	20207730	23761755	32200000
Investment ($)	6670407	7304448	6388000	6411245	10666700
Exports ($)	855000	876470	764000	981781	1432000
Employees (No.)	600	631	656	732	857

Source: UPPM, 2004

Foreign products easily access the Palestinian market, while Palestinian products do not enjoy access to Israeli and foreign markets. The prices of Palestinian pharmaceuticals are relatively controlled, in contrast to the Israeli and foreign products. This may on one hand be an advantage, where local products can compete on prices against foreign products. However, it may be considered a constraint as far as profitability and development are concerned. Local manufacturers do not enjoy the same economies of scale as their competitors; in addition they do not obtain lower prices of their raw materials purchases because they do not buy in bulks. On the other hand, the cost of labor is less than that of Israel and foreign countries. This gives local manufacturers a labor cost advantage, although foreign companies use capital-intensive operations. This advantage, however, might be offset by the inefficiencies and the capacity under-utilization of Palestinian factories. Moreover, Palestinian pharmaceutical industry is affected by Israeli pharmaceutical competition and Israeli products can easily enter Palestinian market, whereas, Palestinian products are not allowed to be soled in Israeli market.

1.5.3 Palestinian pharmaceuticals toward complying with regulations and standards.

Several Palestinian companies are already investing millions of dollars in upgrading their facilities and equipment which required modernization of procedures to comply with the "Good Manufacturing Practices" (GMP) to face the following situations:

1- The limited market in Palestine forces manufacturers to seek out export market.
2- The increasing competition because of increased imports of new products coming from neighboring Arab countries.
3- Finally, increasing awareness and sophistication among Palestinian consumers, which require improved quality and higher standards.

In 1986, implementation of GMP in the Palestinian pharmaceutical industry started, according to the guidance of the Institute for the Standardization and Control of Pharmaceuticals in Jerusalem. The Israeli requirements were the main ones. In 1992, a guide to GMP requirements was prepared in Arabic, based mainly on the European Community guidelines, the Israeli Orange Guide, European GMP and the Israeli guide. Local manufacturers and concerned people, however, recommended the use of the guidelines issued by the Arab Union of the Manufacturers of Pharmaceuticals and Medical Appliances (AUPAM), which had been adopted by the Arab Ministers of Health Council. This recommendation was made because the West Bank and Gaza Strip are part of the Arab world and future markets for the Palestinian pharmaceutical industry might consist of Arab countries. To date, no

local company has been certified as GMP-compliant. However, some are believed to be very close. It is expected that full compliance with GMP by the local pharmaceutical industry will increase the quality of drugs in the West Bank and Gaza Strip, for both the public and the private sectors.

One major factor affecting the position of the Palestinian industries as a whole is the perception of the customers of the Palestinian products. For several reasons, this perception was very negative, for the pharmaceutical industry one of the main reasons for this perception is the quality of information received by customers. Thus, during the last decade the Palestinian pharmaceutical companies struggled and still struggling to change this perception. A study conducted by the Ministry of Planning and International Cooperation in 1997 concluded that most of the pharmaceutical customer segments and intermediaries perceived the Palestinian pharmaceutical as of low quality and less effectiveness comparing to the Israeli and foreign products. In 2001 the Union of Palestinian Pharmaceutical Manufacturers UPPM had commissioned a consulting firm to assess the status of the industry's image and consumer attitudes towards industry products, targeting a number of key respondents: physicians, pharmacists, health services providers and product end users. The main findings of this study clearly show a significant change of the customer perception toward the Palestinian drugs and the image was generally positive with some variation of quality between the products of the same company or products from different companies.

In this study, four Palestinian Pharmaceutical Companies were selected, Birzeit Pharmaceutical Company, Jerusalem Pharmaceutical Company, Jordan Chemical Laboratory, and Pharmacare. The four companies lead the local market and have

the majority of the market share of local pharmaceutical companies (about 95% of local pharmaceuticals). These companies are working hardly to achieve high quality and to produce according to good manufacturing practices. The four companies have both ISO 9000- 2000 and ISO 14000 certifications and they are in advanced position in complying with cGMP, as international pharmaceutical manufacturing standards.

1.5.4 Ministry of Health Roles in Pharmaceutical Regulations

The pharmaceutical industry is highly regulated in most countries of the world if not in all countries. Specific international standards set by defined bodies should be followed by the manufacturers during the production process as well as for the final product itself. Batches' testing is one of the main tools to insure high quality of products sold in the markets. The Palestinian Ministry of Health (MOH) is the local official body who is responsible for insuring quality of drugs in the market. The Center for Environmental and Occupational Health (CEOH) at Birzeit University recognized by MOH as the official Palestinian center for quality control for pharmaceuticals. The MOH and the CEOH classify the failure of pharmaceutical products into tow main categories, either minor or critical. If the test indicates a minor failure, the MOH send a warning to the company to solve the problem concerned within a specific period of time. If the failure is critical on the other hand, the product should be recalled and the product line is totally stopped. It has been never happened that there is any critical failure recorded during quality control tests that done by the

CEOH. The pharmaceutical products sometimes experienced failure during testing procedures, but this failure is common in the pharmaceutical testing process throughout the world. According to MOH statistics, in 1990's 3% of the tested batches on average failed for minor reasons as classified by the international standards and for non-critical reasons. During the last few years the average of failed tested batches has not been exceed 2%. The minor failure usually resulted if one or more of the following elements failed in the testing process: Assay, Color, Consistency, Labeling, Dissolution, PH-limit, Size and Registration.

The issue of quality is a crucial; all products manufactured by Palestinian companies have received authorization from the MOH to be marketed. For quality issues and testing procedures, it is possible for the new product to be in the market within one year of its inception; however it takes sometime three years for the Palestinian products to be approved by the MOH. This process is not applied on Israeli and foreign products, which gives them an advantage over the Palestinian drugs, and increase the cost for the local manufacturers.

The following procedures are followed by the MOH to register and market any pharmaceutical products:

1. The applying company should be registered as a pharmaceutical manufacturer.
2. The applicant's product line must meet the relevant standards and specifications.

3. The presented application should contain detailed information on the product, bio-equivalency test, the mix, the use, side effects, etc.
4. Registration fees should be paid with the application.
5. The MOH issue the approval within six months from the application completion date.
6. The first three batches must be tested and analyzed before selling the product in the market.

1.6 Limitations of the study

- The study is conducted on four Palestinian pharmaceutical companies. Therefore the results of the study can't be universally generalized due to the differences in perception, attitude and culture.

- There are not enough studies conducted about Palestinian pharmaceutical industry.

- The difficulties of getting some statistics and accurate data.

- The study is a descriptive which could investigate the impact of quality from the perspective of top level managers and middle managers and supervisors of the companies. And all the data were collected from the companies. So, the results are in general, qualitative and to get more quantitative impacts, especially for costs, it is recommended for further in depth researches.

1.7 Organization of the thesis

This research has been divided into six chapters. Chapter one is the introduction which includes a background about quality, cost and benefit of quality, and impact of quality on competitiveness, followed by purpose of the study, the problem statement, a brief description of Palestinian pharmaceutical industry, importance of the study, and finally limitations. Chapter two provides a review of the literature in several areas and characteristics of quality and its impact on cost and competitiveness in general and in pharmaceutical industry in specific, and finally a review of literature about Palestinian pharmaceutical industry. Chapter three describes the quality control and assurance in pharmaceutical industries and description of standards and regulations that pharmaceutical manufacturers should implement to survive and globally compete. Chapter four explains the methodology used in collecting data including the design of the research, limitations of the design and scale, how the sample has been selected, and reliability and validity check. Chapter five provides description of the data collected from the questionnaires and the interviews of the opinion leaders and the corresponding analysis. Chapter six presents the discussion, conclusions, and recommendations to Palestinian pharmaceutical industry as the focus of the research, the contribution to the theoretical and practical knowledge, and finally recommendations to other studies.

1.8 Definition of terms

Appraisal Cost: any cost incurred in an effort to detect a failure in meeting requirements, (Oakland (1993).

Cost of Quality (COQ): the total of the costs incurred through (a) investing in the prevention of non-conformance to requirements; (b) appraising a product or service for conformance to requirements; and (c) failure to meet requirements (the American Society for Quality Control (ASQC))

External Failure Cost: any cost incurred for products that do not meet requirements and have been transferred to the customer, (Oakland, 1993).

Good Clinical Practice (GCP): A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected, (ICH, 1996).

Good Laboratory Practices: a quality system concerned with the organizational process and the conditions, under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported, (www.oecd.org/department, 2004).

Good Manufacturing Practices (GMP): are considered part of the Quality Control System for companies producing food or pharmaceutical products. GMP principle aims to ensure the regular production for products that confirm with the health standards required from regulatory Bodies. GMP provides the general basics to determine the minimum acceptable requirements for the production at Good products, covering all the activities related to the production process, (http://www.fda.gov/cder/gmp/gmp2004/GMP_finalreport, 2004).

Internal Failure Cost: any cost incurred for products that do not meet requirements and have not been transferred to the customer, (Oakland, 1993).

ISO 14000: series of voluntary environmental standards developed by the International Organization for Standardization (ISO), a worldwide group that promotes uniform standards. ISO 14000 is a voluntary standard designed to provide a consistent means of managing environmental impacts of business operations, (www.iso.org).

ISO 9000 series: A set of international standards on quality management and quality assurance developed to help companies effectively document the quality system elements to be implemented to maintain an efficient quality system, which were first published in 1987, (www.iso.org).

Prevention Cost: is any cost incurred in an effort to prevent a failure in meeting requirements, (Oakland, 1993).

Quality Assurance (QA): All the planned and systematic activities implemented within the quality system and demonstrated as needed, to provide adequate

confidence that an entity (service, product, process, activity, organization) will fulfill the requirements for quality, (http://www.fda.gov/cder/gmp/gmp2004/GMP_finalreport, 2004).

Quality Control (QC): The operational techniques and activities that are used to fulfill the requirements for quality, (http://www.fda.gov/cder/gmp/gmp2004/GMP_finalreport, 2004).

Quality Management System: a structured and documented system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring the quality in its work processes, products, items, and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC, *(ANSI/ASQ, 1995)*.

Requirement: A formal statement of a need and the expected manner in which it is to be met, (EPA, 2002).

Standards: A document, established by consensus and approved by a recognized body that provides, for common and repeated use, rules, guidelines, or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context." (International Organization for Standardization (ISO). http://www.iso.ch/infoe/ (2/18/99))

Standard Operating Procedures (SOPs): A written document that details the method for an operation, analysis, or action with thoroughly prescribed techniques

and steps and that is officially approved as the method for performing routine or repetitive tasks (EPA, 2002).

Total Quality Management (TQM): The integration of all functions and processes within an organization in order to achieve continuous improvement of the quality of goods and services.

Validation: Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality attributes. Process validation is a requirement of the Current Good Manufacturing Practices Regulations for Finished Pharmaceuticals and of the Good Manufacturing Practice Regulations for Medical Devices, and therefore, is applicable to the manufacture of pharmaceuticals and medical devices (EPA, 2002).

CHAPTER TWO

Literature Review

Literature Review

This chapter is divided into four parts as follows:

- Part one reviews the concept and definition of quality and the role of quality management systems on pharmaceutical industry.
- Part two reviews the cost of quality
- Part three reviews the quality and the competitive strategy.
- Part four reviews the studies that have been conducted about Palestinian pharmaceutical sector.

2.1 The role of quality management in pharmaceutical industry

Every pharmaceutical product has established identity, strength, purity, and other quality characteristics designed to ensure the required levels of safety and effectiveness. So, achieving quality means achieving these characteristics for the product. The following characteristics of a drug determine its quality:

· Identity: The correct active ingredient is present.

· Purity: The drug is not contaminated with potentially harmful substances.

· Potency: The correct amount of active ingredient is present, usually between 95 and 110 percent of the labeled amount.

· Uniformity: Consistency, color, shape, and size of the dosage form do not vary.

· Bioavailability: Bioavailability refers to the speed and completeness with which an administered drug enters the blood stream. This must be consistent to provide a predictable therapeutic result. Drug bioavailability differences exist between manufactures of the same product. Therefore, careful evaluation of generic drugs may be necessary before purchase and use.

· Stability: The activity of the drug is ensured for the period of time stated on the product label, that is, until the expiration date.

· Pharmacopoeia standard: A drug is of good quality if its characteristics meet the standards described in a widely accepted pharmacopoeia such as the British Pharmacopoeia (BP), European Pharmacopoeia, International Pharmacopoeia (IP), or United States Pharmacopoeia (USP).

Quality management in the drug industry is discussed in the WHO GMP for Pharmaceutical Products. In this document the following are presented:

• The basic elements of quality management are:

- An appropriate infrastructure or “quality system”, encompassing the organizational structure, procedures, processes, and resources; and

- Systematic actions necessary to ensure adequate confidence that a product (or service) will satisfy given requirements for quality. The totality of these actions is termed “quality assurance”.

• The concepts of quality assurance, GMP, and quality control are interrelated aspects of quality management. They are of “fundamental importance to the

production and control of pharmaceutical products". QA encompasses all of the arrangements made to ensure that pharmaceutical products meet the quality required for their intended use. Although QA is not specified in all

GMP documents, the WHO GMP guidelines (ref 27) present the principles of QA are to ensure that GMP and other regulatory codes (GLP - Good Laboratory Practice, and GCP - Good Clinical Practice) are respected; that responsibilities are clearly specified; all testing, controls, calibrations, validations, etc are performed as specified; that products are not sold before the correct authorizations have been obtained; that products are appropriately handled throughout their shelf-life; and that there is a procedure for self inspections (quality audit).

Quality is not a new or recent development, but now, quality has become an increasingly predominant feature of our lives and people are constantly involved in the search for quality products, quality services and even quality time with which to share with their partners and families (Walsh, Hughes and Maddox, 2002).

The quality means a lot in pharmaceutical industry and this sector has its own characteristics. Alongside other industries where safety is critical, the pharmaceutical industry is heavily regulated and for obvious reasons: mistakes in product design or production can have severe, even fatal, consequences for patients (Gough, 1999; McAdam and Barron, 2002).

The pharmaceutical industry in the world represents a considerable economic weight: the market is estimated at US$300,000 million, with a demand continuing to grow year after year (due in particular to the aging of population, evolution of life styles, appearance of new pathologies, prevention policies, etc).(Hermel and Bartoli, 2001).

EC directives 91/356/EEC and 91/412/EEC state: The manufacturer shall establish and implement an effective pharmaceutical QA (Quality Assurance) system, involving the active participation of the management and personnel of the services involved. To ensure quality and safe products, pharmaceutical companies build their quality approach around good manufacturing practice (GMP). Validation and auditing are widely used to assess the effectiveness of pharmaceutical companies' quality control (QC) and quality assurance (QA) systems. Good Manufacturing Practice (GMP) is part of QA aimed at ensuring that products are consistently manufactured to the required quality. "QC is part of GMP and comprises: the testes, inspections and measurements carried out on samples taken before, during and after manufacturing and packaging to provide events that a finished product will or will not meet its written specifications" (Rowley and Sneyd, 1996).

Bashe (2000), stated that the increase in consumer power will fundamentally force pharmaceutical companies to change the way they do business, which makes quality now a major differentiator in this increasingly competitive business environment.

According to Grobler, (1995), the increasing competitiveness, indicates that managers have to maintain effective control of their companies through effective management skills and systems. These management skills help managers to be able to measure the day to day performance. Without measurement, effective control is impossible.

2.2 Cost and benefit of Quality

Developing and maintaining quality systems can be viewed as efforts that cost money or efforts that save money. Products and/or services that meet customers' needs, produce customer satisfaction, and are free of defects generate revenue (Kastango, 2002). As cited by Motwani, (2001), Deming mentioned that, higher quality leads to less rework, lower costs, higher productivity, lower prices, and increased market share, as quality measures that affect business performance.

As mentioned by Suarez, (1991), Crosby (1984) stated that, quality is either present or not present. There is no such thing as differing levels of quality. Management must measure quality by continually tracking the cost of doing things wrong. Crosby, (1984) referred to this as the price of nonconformance. To aid managers in tracking the cost of doing things wrong, he developed the following formula: Cost of Quality (COQ) = Price of Conformance (POC) + Price of Nonconformance (PONC). The POC refers to the cost of getting things done right the first time. PONC provides management with information regarding the wasted cost and a visible indication of progress as the organization improves.

According to Chen and Yang, (2002), Cost of quality (COQ) concepts affect operating costs, profitability, and customer needs. COQ is a significant cost driver that firms need to control effectively to sustain their competitive advantage.

These absolutes help management focus on quality improvement and, more importantly, help them make the shift from what Crosby calls conventional wisdom (the idea that if quality goes up, so does the cost) to the idea that quality and costs are not in competition with each other. According to Crosby, (1979), as quality

increases, cost decreases--thus, quality doesn't cost. This reasoning led to Crosby s famous phrase, Quality is free, but it is not a gift.

However, tracking cost of quality stills limited and is not widely used. Sower and Quarles, mentioned that there is a need to track cost of quality to translate the language of things that quality professionals use (e.g. defects, units) to the language of dollars that managers use (e.g. costs, financial performance). As Cited by Sower and Quarles, Evans and Lindsay, (2002) mentioned that the use of dollars instead of defect rates also makes it easier to aggregate performance measures across departments or divisions and to compare to other dollar measures.

For many years, the concept of economics of quality was known as a cost reduction tool and has applied to the three levels of quality costs Prevention, Appraisal, and Failure costs (PAF Model) which has been developed by Feingenbaum, (1961), and Process Cost Model. But effects of the both two models are very limited, because they look only at the production costs and the larger portions of total costs are hidden under the title of overheads. According to Carr, (1995), by implementing a program called Cost of Quality (COQ) in 1989; Xerox saved the company $53 million, $77 million in 1990 and $20 million in 1991. However, Xerox was no longer able to use COQ effectively. Therefore, any company can follow in Xerox's success of the implementation of COQ but must be aware of how eventually the COQ system broke down at Xerox.

Omachonu; Suthummanon, and Einspruch, (2003), concluded that there is an inverse relationship between appraisal cost plus prevention cost and failure cost,

there is a direct relationship between appraisal cost plus prevention cost and quality, and there is an inverse relationship between failure cost and quality.

The quality cost data can be used in an effort to be proactive, and to identify causes of problems. It provides a methodology for pinpointing improvement priorities. Once the causes are resolved, the defects do not occur and failure costs decrease, (Omachonu; Suthummanon, and Einspruch, 2003).

In pharmaceutical industry, quality assurance has economic impacts on both medicine producers and consumers. For the producer, Applying quality assurance from the very start of production has important economic benefits, which means that detecting and correcting or rejecting any defect or process faulty at the very start of the procedure is more economical than detecting it after finishing the production or at late stages of production which leads to discard the whole batch of fully processed finished product. Quality costs money, but the cost of not applying quality assurance in the pharmaceutical manufacturing is much higher (IFPMA, 1997).

McDonald, (2003), determined seven elements for life science firms to reduce the risks and high costs associated with not complying with current Good Manufacturing Practices (cGMP) into an effective training strategy. An effective training strategy includes Teaching the theory behind the practice, Allowing for experience sharing during training, Motivating learners to learn, Allocating the appropriate amount of training time, Creating a comfortable learning environment, Choosing an effective trainer, and Evaluating the learning experience.

According to Kastango, (2002), developing and maintaining quality systems can be viewed as efforts that cost money or efforts that save money. But because products or services will generate revenue, if they meet customers' needs, produce customer

satisfaction, and they are free of defects, so, quality systems can be considered as efforts that save money for organizations that adopt it.

Walsh, Hughes, and Maddox, (2002), mentioned that a TQM philosophy offers many

- The elimination of defects;
- Reduced scrap and rework;
- Reduced levels of cost;
- Increased levels of efficiency and productivity;
- Increased employee morale and motivation.

Implementing TQM in ICI pharmaceuticals in Australia helped the company to save $2million in its working capital in one year (1991- 1992), (www.oliverwight.com/client/successes/ici.). The savings were resulted from:

- Stock Reduction, about 38% as a percent of sales.
- Slash cycle time reduction by 50%.
- Sales increase by 15%
- More and frequent communications between sales and marketing group and operation group which helped the company to manage the production and sales in shorter lead time.

There are many benefits of TQM implementation in pharmaceutical companies and some of the most important of these are less reworks, cost reduction, and improving productivity and efficiency (Rowley and Sneyd, 1996; McAdam and Barron, 2002). Rowley and Sneyd, (1996), found that the cost of implementing TQM in a

pharmaceutical ranged from £ 1- £ 500k, the estimated savings are ranged from £ 1k - £ 1m.

According to Asubonteng, McCleary and Munchus, (1996), TQM is implemented in health care to improve quality and reduce costs, through many strategies including, identifying and meeting customer needs, reducing the cost of non-compliance with standards, striving for zero defects, reducing outcome variability, eliminating the cost of poor quality, using statistical methods to identify and monitor processes, and continually working for improved quality.

Cost of quality must be kept at an acceptable level. If the cost is too high it may have significant implication with regard to competitive pricing (Mehra and Agrawal, 2003).

Rust, Moorman, and Dickson, (2002), mentioned that financial results from quality improvements can come from increased revenues, decreased costs, or both at once. Companies can increase revenues by making their goods and services more appealing, which increases customer satisfaction. Likewise, they can decrease costs by making their operations more efficient. After testing the strategies across a sample of 71 business units, Rust, Moorman, Dickson, (2002), found that emphasis on increasing revenues may be better than an emphasis on decreasing costs or a simultaneous emphasis on both revenues and costs and companies in the sample that emphasized quality improvements focused on revenue expansion had better financial performance—both self-reported by managers and measured objectively by return on assets and stock returns. These results suggest that revenue-building efforts such as efforts to improve customer satisfaction and customer loyalty may be more

profitable than cost-reducing efforts. The results also suggest that it should be difficult for firms to build customer satisfaction and customer-perceived quality profitably in an environment that is steeped in cost-reduction methods. The results suggest that having a market orientation within the firm is not enough; there should also be a stronger emphasis on the customer than on internal efficiency because of the inevitable trade-offs between the two.

As mentioned by Destefani, (2004)**,** The FDA estimates that total annual incremental costs of the new CGMP regulations to U.S. device manufacturers at about $81.9 million. But these costs are more than offset, the agency says, by benefits to public health and by economic benefits to the medical device industry.

FDA' s best estimates indicate benefits to public health will include 36 to 44 fewer deaths, and 484 to 677 fewer serious injuries per year that are attributable to design-related device failures.

What's a human life worth? According to the FDA, studies on the value of a statistical-life have reported estimates ranging from $1.6 million to $8.5 million. Assuming an economic value of $5 million per fatality avoided, the monetary value of saving 36 to 44 lives each year will be $180 to $220 million. Therefore, the value of the public health benefits of preventing deaths alone easily exceeds the cost of compliance even without estimating benefits from a reduced number of serious injuries, the agency says.

Economic benefits to medical device manufacturers will result from cost savings due to fewer design-related product recalls, better product quality, and greater

productivity. The agency received reports on an average of 359 medical device recall events per year between the years1988 to 1991. Based on data from a recent survey of recall costs, FDA estimates that the industry would avoid roughly $29 million worth of recall expenses per year by complying with the final CGMP regulation.

Finally, because the EU is adopting ISO 9000 as a basis for its medical device manufacturing quality system, harmonization of the two quality requirements will eliminate the need for device manufacturers to maintain different quality systems for each market. Reciprocity for quality assurance inspections could save the medical device industry millions of dollars.

Maani, Putterill and Sluti, (1994), concluded that their study has been able to show empirically that in manufacturing companies, improving quality positively enhances operational performance and productivity, and certain indicators of business performance. The association is most pronounced between quality and process utilization, with the second largest impact of quality being on manufacturing costs. However, the majority of firms are improving quality for competition and image improvement more than focusing on impact of quality on productivity and cost. These findings were supported by a subsequent survey of manufacturing trends in New Zealand which conducted by, Corbett, (1990) in which managers rated quality as the element most needed to compete successfully in the marketplace.

Quality costs are powerful indicators to motivate management to go to TQM programs. By reporting grand total costs of quality, management can be convinced

of the need to improve quality. Reporting quality costs as a percentage of profit, quality costs as a percentage cost of goods sold, quality costs as a percentage of product prices, and so on; management can be presented with the size of a quality problem. This will also stimulate management to look for opportunities to reduce costs. The opportunity costs of lost sales will force management to think about reducing customer dissatisfaction and defection to competitors. The COQ concept will also help a company introduce a financial control system for the quality control function (Madu 1998).

Firms should strategically plan for quality improvement and they must allocate required resources for successful quality management systems implementations. This will enable the firms to get benefits from the link between quality management and business performance. As mentioned by Chapman, Murray and Mellor (1996); Garvin, (1988) found a strong correlation between productivity (both labor and capital) and quality as well as between profitability (ROI) and quality. Garvin found that the relationships between quality and profitability were less well established because of the many other variables affecting ROI measures. Moreover, Maani, Putterill, and Sluti, (1994), found strong relationships between productivity improvement and organizational success in customer satisfaction programs, product quality improvement, reduction in waste and strategic quality improvement.

2.3 Quality and Competitive strategy

For organizations, the focus of quality lies in how to continually achieve customer satisfaction. Juran and Gryna (1980) defined quality as ``fitness for use''. Similarly, Crosby (1979) identified quality as meaning ``conformance to requirements''. Both

of these definitions focus on the satisfaction of customer needs. The key to competitive advantage lies in continuously satisfying your customers' needs in a fashion that is superior and more consistent than your competitors. Organizations should be aware about customer needs and wants, and anticipate the future needs and wants of the customer (Linus Osuagwu, 2002). The emphasis on customer or client requirements should be determined from the customer requirements for a product/service including specification, performance, reliability, value for money and on-time delivery at the lowest cost (Bank, 1992). Deming (1986) has seen competition as a function of customer/client satisfaction.

As mentioned by Kastango, (2002), Juran, 1994 classified the effect of quality in Compounded Preparations into two approaches: effects of high-quality products that meet customers' needs and effects of high-quality products that are free from defects. Meeting customers' needs leads to increase customer satisfaction, sell for premium prices, meet or exceed the quality of competitive products, increase the market share of the product sold, provide sales income. Producing high quality products that are free of defects has benefits in reducing error rates, reducing the need to rework the preparation, reducing the number of field failures, warranty claims, and waste, reducing customer dissatisfaction, reducing the number of inspections required and the need for product testing, increasing product yield or output, enabling greater operating capacity and efficiency, and improve delivery performance.

There are different scenarios of quality movement of tomorrow. There is continuous changing of market dynamics, new challenges that change new global markets constantly causing stressful competitive environments. Businesses operating

beyond their national boundaries cannot depend upon previously proven domestic quality practices. Therefore, a global business may have to revise its quality-based elements of competitive strategy, (Mehra and Agrawal, 2003).

The emergence of quality as a top priority in many corporate entities is primarily due to the globalization and competitive pressure brought about by the escalating demands of consumers, who want better products and services. Globalization of markets and the fast improvements in information flow capabilities have increased competition worldwide. In order to compete in today's turbulent competitive business environment, organizations are focusing on the satisfaction of customers' needs as a means of securing competitive advantage and even survival (Magd and Curry 2003). According to Kranton, (2001), the increased of global competition and improved communications have lead to greater customer expectation. Because price competition can eliminate the profits necessary to induce firms to produce high-quality goods, industry associations may play a role in guaranteeing product quality. So, competition motivates firms to provide the highest quality at the lowest price to meet customers' expectations and satisfy there needs (Henderson Committee, 1992; Watson, 2002,). Latham Report, (1994), concluded that "Total quality management is a way of managing an organization to ensure the satisfaction at every stage of the needs and expectation of both internal and external customers, that is shareholders, consumers of its goods and services, employees and the community in which it operates, by means of every job, every process being carried out right, first time and every time'". Continuous improvement is a basic tenet in TQM that can enable manufacturers to meet the competitive pressures of the global economy head-on, and to develop strategies for making products that are both high in quality and

commercially successful. For device manufacturers faced with a competitive marketplace made up of increasingly demanding customers, continuous improvement can be more than merely a formal system of business management. Companies that do not continuously improve everything they do for their customers may soon find themselves out of business (Sahni and Gaertner1996).

Many corporate enterprises have found that the key to competitive success lies in emphasizing product and service quality as a strategic issue when doing business (Kano, 1993; Belohav, 1993; Pulat, 1994). According to Tan, Kannan, Handfield and Ghosh, (2000) if companies strive to compete in increasingly competitive global markets, it is natural to view quality as one way by which they can do so. It is apparent however that a lack of clarity exists regarding the strategic use of quality and responses to global competition. Survey results indicate that innovation and effective product development are crucial to providing a response to global competition. However, while companies strive to improve the quality of their products, they cannot overlook the threat from companies that have been able to reduce costs while maintaining high quality standards. But, even in the absence of competition, improvements in quality can facilitate an organization's competitiveness, though as witnessed over the last decade, competition has for many organizations been the driver of quality improvement efforts.

Over the last few years the global pharmaceutical market has undergone significant change, forcing pharmaceutical companies, more than ever before, to focus on customer needs and upon their own internal efficiency in order to continue to compete effectively.

Unmet medical needs, an aging population, rising health-care costs, and sparse pharmaceutical pipelines are forcing healthcare companies to reevaluate their competitive strategies. Also, consumers are playing a larger role in healthcare. Patients are more knowledgeable and assertive regarding their individual healthcare decisions and are putting additional pressure on the industry to lower cost through innovation (Mendricks, Vanroeyen, And Wang, 2003).

To improve competitiveness, organizations are looking for a higher level of effectiveness across all functions and processes and are choosing (TQM) as the application of quality principles and common factors for the integration of all functions and processes within the organization in order to stay in business (Oakland, 2000).

Buttle, (1996) concluded that companies pursue ISO 9000 certification in order to enjoy both operational and marketing benefits which impact on costs, revenues, and, by inference, profit.

The most important benefit sought from certification is profit improvement, second are process improvements and third most important are marketing benefits. Marketing benefits include gaining new customers, keeping existing customers, using the standard as a promotional tool, increasing market share, increasing growth in sales and improving customer satisfaction.

2.4 Studies about Palestinian Pharmaceutical Industry:

The global pharmaceutical competition is based on the quality, products effectiveness, and innovation more than price competition. But in Palestinian

market, because of the similarities of the local products, it is mainly price competition (Makhool, 1999).

By conducting a study to identify ways to improve product sales performance and to increase market share of Palestinian pharmaceutical companies in a competitive and rapidly changing environment through increased consumer awareness and enhanced positive perception, Massar,2000, found that to define technical quality it is necessary to list certain features that are considered as quality of the product and each segment of the customers can define the product quality according to certain features that satisfy there own needs. For consumers (end users), product is ambiguous, and patient satisfaction is one measure used to assess the performance of pharmaceuticals. Doctors and pharmacists define quality as product effectiveness and safety, whereas Ministry of Health determined two dimensions to define quality: first, quality is to comply with good manufacturing practices (GMP) and second, is the safety.

According to Makhool, (1999); Massar, (2000); Obeidallah, *et al*, (2000), Palestinian pharmaceutical products quality is good. All the Palestinian companies have recognized the importance of commitment to Good Manufacturing Practices, and four of them are seriously seeking the GMP certificate, but tell now no one could achieve it, which affects the competitiveness of these companies in the external market.

There are differences of quality of pharmaceutical products between the Palestinian companies and between different products of the same company

(Makhool, 1999; Massar, 2000). However, there is a major problem still facing Palestinian pharmaceutical industries which is the customer perception. According to Massar, (1997), 8% of customers (Doctors and pharmacists) believe that Palestinian pharmaceutical products are not up to standard. According t o Massar, 2000, the general evaluation of Palestinian pharmaceuticals is positive. 67% of doctors and 65% of pharmacists believe that Palestinian Pharmaceuticals are having good quality and some of these products can equally compete with foreign and Israeli products, but there is significant percentages of doctors (32%), pharmacists (34%) and households (41%) believe that Palestinian pharmaceutical products are moderate. There are significant proportions of doctors and pharmacists still perceive Palestinian pharmaceutical products as non- competitive to foreign products (Massar, 2000).

CHAPTER THREE

Pharmaceutical regulations and standards

3.1 Introduction

In pharmaceutical market, there are two types of regulations and standards, the regulation of the organization and the government interference (health authorities), because it differs from other markets in several important characteristics which do not apply to other consumer goods. Broun, (1994), summarized these characteristics as follows:

(a) The user (patient) generally does not select the drug-- it is prescribed by a physician or other health worker;

(b) In the case of over-the-counter medicine, the patient may select the drug, but he or she lacks the specialized knowledge to make a critical comparison of various products in terms of suitability, quality, and value for money.

(c) The health workers build their knowledge about the drug, mainly, from the seller, and they are insufficiently trained to make a full assessment of drugs. Furthermore, positive results of pre- marketing studies of safety and efficacy are sometimes contradicted by results when the drugs are used widely.

(d) The user is often insulated from the price consequences of consumption decisions, as the public sector or private insurers often pay for the drugs;

(e) Even after the drug has been taken, neither the user nor the health care provider is fully able to assess its effects, since these are highly variable and the course of the ailment may be influenced by other factors.

(f) In cases where the user might in theory be capable of objective assessment, this can be impaired by hope and expectations: some 35 percent of the physically ill and 40 percent or more of the mentally ill respond to an ineffective product (placebo).

(g) Fear of illness can create illogical and costly demands: health professionals and patients have often generated a vast demand for worthless drugs.

So, the need for high standards built by governments and health authorities, to ensure that drugs are effective, pure and of consistent quality, has grown further with the increasing sophistication of drugs in the 20th century, as many contemporary products can only be adequately produced under highly specialized industrial conditions. Detailed standards of "Good Manufacturing Practice" for pharmaceuticals have been laid down in recent years and have been widely recognized and implemented. WHO defined global standards in 1987 but some national authorities require substantially higher standards, such as US-FDA. Quality control systems and regulations are built to assure that pharmaceuticals of low quality, either imported or locally produced, should not reach the population. However, upgrading of manufacturing standards often has to be staged over time.

Regulations regarding quality must be enforced by a well-organized and trained inspection administration and independent from commercial pressure.

Internally, the manufacturer should establish, document, and implement an effective system for managing quality that involves the active participation of management and appropriate manufacturing personnel.

The system for managing quality should encompass the organizational structure, procedures, processes and resources. All quality related activities should be defined and documented.

There should be a quality unit(s) that is independent of production and that fulfills both quality assurance (QA) and quality control (QC) responsibilities.

Quality assurance is a system of activities designed to ensure production that meets pre-established requirements. It gives the customer a guarantee of quality by measuring product conformance with processes and performance specifications. Quality improvement refers to all efforts directed to increase effectiveness and efficiency in meeting accepted customer expectations. It is a continuous process to achieve a better understanding of the market; to innovate products and processes; to manage and distribute material and products; and to provide service to customers. The success of quality improvement is based on an understanding by every member of the organization concerning the needs of their customers (internal and external) (Schlenker, 1998).

All quality related activities should be recorded at the time they are performed and any deviation from established procedures should be documented and explained. Critical deviations should be investigated, and the investigation and its conclusions should be documented.

No materials should be released or used before the satisfactory completion of evaluation by the quality unit(s) unless there are appropriate systems in place to allow for such use.

Procedures should exist for notifying responsible management in a timely manner of regulatory inspections, serious GMP deficiencies, product defects and related actions (e.g. quality related complaints, recalls, regulatory actions, etc.).

The knowledge of WHO, EU, and US- FDA GMPs is becoming a necessary aspect of doing business in today's market. Medicinal products have to fit for their intended use, comply with the requirements of the national and international standards and regulations and do not place patients at risk due to inadequate safety, quality or efficacy. The attainment of this quality objective is the responsibility of senior management and requires the participation and commitment by staff in many different departments and at all levels within the company, by the company's suppliers and by the distributors. To achieve the quality objective reliably there must be a comprehensively designed and correctly implemented system of Quality Assurance incorporating with Good_Manufacturing Practice and thus Quality Control. All parts of the Quality Assurance system should be adequately resourced with competent personnel, and suitable and sufficient premises, equipment and facilities.

In general, the pharmaceutical industry is accustomed to working with regulatory standards (Rowley, and Sneyd 1996), which include:

• Goods manufacturing practices (GMP).

• Good laboratory practices (GLP).

• Good clinical practices (GCP).

• ISO 9000, the national and international standards, respectively,.

• ISO 14000, environmental management system (EMS)

3.2 The concepts of regulatory Standards

3.2.1 Good laboratory practices (GLP)

In 1979 and 1980, an international group of experts established under the Special program on the Control of Chemicals developed the "OECD Principles of Good Laboratory Practice" (GLP), utilizing common managerial and scientific practices and experience from various national and international sources. These Principles of GLP were adopted by the OECD Council in 1981. Good Laboratory Practice (GLP) is a quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported. The purpose of these Principles of Good Laboratory Practice is to promote the development of quality test data. Comparable quality of test data forms the basis for the mutual acceptance of data among countries. If individual countries can confidently rely on test data developed in other countries, duplicative testing can be avoided, thereby saving time and resources. The application of these Principles should help to avoid the creation of technical barriers to trade, and further improve the protection of human health and the environment (PMRA, 1998).

3.2.2 Good clinical practices (GCP)

Good clinical practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the

participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and well-being of trial subjects are protected; consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible. They are listed to give an idea of the basic concepts of GCPs. Before becoming involved in clinical trials, one should have a good, working knowledge of GCP and understand that failure to comply with GCP can lead to disciplinary action including prosecution (ICH, 1996)

3.2.3 ISO 9000 & ISO 14000

In this part, the study will summarize the history and concept of the standards that are mainly adopted by the Palestinian Pharmaceutical Companies. These Standards are ISO 9000 and ISO 14000.

The ISO 9000 and ISO 14000 families are among ISO's most widely known standards ever. ISO 9000 has become an international reference for quality management requirements in business-to-business dealings, and ISO 14000 is well on the way to achieving as much, if not more, in enabling organizations to meet their environmental challenges (iso.org).

The **ISO 9000** family is primarily concerned with "quality management". This means what the organization does to fulfill the customer's quality requirements, and applicable regulatory requirements, while aiming to enhance customer satisfaction, and achieve continual improvement of its performance in pursuit of these objectives.

ISO certification is expected to help organizations to enhance quality and efficiency, improve communications, achieve competitive advantage and an increase in market share, reduce costs and achieve a higher stock price (Magd and Curry2003)

There is a very good reason why the EN-ISO 9000 series is the world's best selling quality standard. If applied correctly, and sensibly, ISO series has the potential to generate significant and sustainable business benefits through improved performance, reduced failure costs, and increased competitiveness (APIC, 1997).

The ISO 14000 family is primarily concerned with "environmental management". This means what the organization does to:

- Minimize harmful effects on the environment caused by its activities, and to
- Achieve continual improvement of its environmental performance.

1- ISO 9000

ISO 9000 comes from a non-governmentally run organization established in 1947 - the International Organization for Standardization (ISO). The term "ISO" is derived from the Greek word "isos", meaning equal. ISO standards are developed and administered by the International Standards Organization, an international organization to which approximately one hundred countries belong.

ISO first published its quality standards in 1987, revised them in 1994, and then republished an updated version in 2000. These new standards are referred to as

the "ISO 9000 2000 Standards". ISO: 9000 series of standards deal with Quality Management Systems (QMS) for assuring quality of products and services and have become international reference for quality requirements in business to business dealings. These standards apply to all types of organizations - engineering, service, software, process industries (including pharmaceuticals). ISO 9000 applies to all types of organizations. It doesn't matter what size they are or what they do. It can help both product and service oriented organizations achieve standards of quality that are recognized and respected throughout the world. The term ISO 9000 refers to a set of quality management standards.

.ISO 9000:2000 family contains 3 main standards:

- ISO 9000:2000 - QMS - fundamentals and vocabulary.
- ISO 9001:2000 - QMS - requirements.
- ISO 9004:2000 - QMS - guidelines for performance improvement.

The general purpose of ISO is to provide standards for the development, implementation and management of a quality management system. ISO 9000 registration is best viewed as a management tool that reaches far beyond the province of "quality control" in a manufacturing environment, the application that first comes to mind to many business people. For ISO 9000 purposes, the term "quality" should be viewed as being synonymous with "excellence" and as applying to all segments of a company's operations, even those administrative functions that are sometimes not viewed as being part of the overall goals of the company in meeting its customers' needs. When used properly, ISO 9000 is a great management

tool to promote excellence throughout all functions or all enterprises in all sectors of the economy, from manufacturing companies to service businesses to health care providers. The ISO 9000 quality management systems (QMS) standards are not specific to products or services, but apply to the processes that create them.

The essence of ISO 9000 is for a company to "document what it does and do what it documents." The documentation is developed through the facilitation process and consists essentially of work instructions and quality and operational procedures designed to assure that goods and services are developed, created and delivered in a consistent manner that reflects the quality goals of the organization.

Procedures and quality systems are necessary to maintain the consistency of the company's products or services and that these procedures and systems are properly and timely documented." ISO 9000 is sweeping the world. It is rapidly becoming the most important quality standard, because it controls quality, it saves money, customers expect it, and competitors use it.

The principles of ISO 9001:2000 are universally applicable, but the application is specific to product, process size of organization and competence levels of employees. As such, the application of ISO 9001: 2000 for the pharmaceutical industry is totally different from engineering software or service organization.

ISO 9001:2000 QMS is based on the following generic principles:

- Customer focus to meet and expectations of the society

- Leadership to provide direction.
- Involvement of people to produce high quality medicines
- Process approach to improve efficiency and effectiveness of processes
- Systems approach to decision making to have a base for right decisions.
- Mutually beneficial supplier relationship to get the best from suppliers.

A few additional requirements for a pharmaceutical organization to be considered while developing a QMS are as follows:

Quality policy shall include a statement on hygiene, environmental control and product security apart from meeting customer expectations and organization's objectives.

The QMS of pharmaceutical organizations should include good manufacturing practices apart from requirements of ISO 9001:2000. The requirements of GMP became a part of drug rules in the year 1984. These must be included as a part of the QMS. Similarly, the practice of purchasing shall cover that the organization shall not employ subcontractors without prior approval of purchaser.

Where raw materials and packing materials are supplied to customer, it is important that containers and packaging are adequately labeled. Special precautions, if any supplied by the customer, shall be followed.

The product traceability is a specified requirement for the pharmaceutical sector. The method adapted is use of batch manufacturing records. Raw material batch number shall be identified in the batch control record where specified by purchasers.

2- ISO 14000

ISO 14000, released in 1996, is a global series of environmental management systems (EMS) standards, providing a framework for organizations to demonstrate their commitment to environmental responsibility.

An EMS enables an organization to control the environmental aspects and impacts of its activities, products and services by establishing targets and objectives related to identified environmental management goals. Once implemented, an EMS will improve compliance with legislative and regulatory requirements, reduce exposure to liability, prevent pollution, reduce waste and create a more positive public image. ISO 14001 is the specific standard that provides guidance for the development of a comprehensive environmental management system (EMS). The EMS is based on the Total Quality Management (TQM) business concept of continuous improvement, or the Plan-Do-Check-Act cycle in which a procedure is developed, implemented, and then reviewed and improved upon if necessary. This cyclic nature ensures that the EMS is both proactive and continuously improving.

Organizations that register to ISO 14001, the most important of the ISO 14000 standards, demonstrate sound environmental management practices, are able to prevent environmental disasters and government sanctions, and experience fewer regulatory audits by correcting environmental problems. ISO 14000 supporting

documents include environmental labeling, life-cycle assessment, environmental aspects in product standards, and environmental performance evaluation.

The expectation is that eventually 14001 will follow suit, and companies without certification will not be able to engage in international trade. This has contributed to the large numbers of European and Asian companies certifying their EMSs under the standard. However, in the US, companies have been both slow to adopt the standard and highly critical of its potential value.

According to Poksinska, Dahlgaard and Eklund, (2002), ISO 14000 is based on the concept that better environmental performance can be achieved when environmental aspects are systematically identified and managed. ISO, (1998), states that potential benefits for ISO 14001 users can be achieved such as, reduced costs of waste management, savings in the consumption of energy and materials, an enhanced corporate image, regulatory cost savings, more effective supply chain management, improved customer relationships, and increased market competitiveness.

3.3 The Concepts of Quality Assurance, GMP, and Quality Control

The language of quality management is chock full of acronyms and abbreviations: ISO and QS, TQM and CI, SPC and SQM. When it comes to medical device manufacturing, however, the initials to keep in mind are GMP.

According to EC Directive, FDA, and WHO GMP regulations and guidelines, the basic concepts of Quality Assurance, Good Manufacturing Practice and Quality

Control are interrelated aspects of quality management. EC directives 91/356/EEC and 91/412/EEC stated that: To ensure quality, all pharmaceutical manufacturers are required to establish and implement an effective pharmaceutical QA system, involving the active participation of the management and personnel of different services involved. To assess the effectiveness of this QA system and ensure that it follows good manufacturing practice (GMP), regular audits must be performed. Audits may be performed by the manufacturer on itself (internal), or on its vendors (external). Alternatively, audits may be conducted on a manufacturer by its customers or by a regulatory body (governmental authority).

GMP, QA, and QC, are described here in order to emphasize their relationship and their fundamental importance to the production and control of pharmaceutical products.

3.3.1 Quality Assurance

"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, including those outside the scope of this guide such as product design and development.

The system of quality assurance appropriate to the manufacture of pharmaceutical products should ensure that.

(a) Pharmaceutical products are designed and developed in a way that takes account of the requirements of GMP and other associated codes such as those of good laboratory practice (GLP) and good clinical practice (GCP).

(b) Production and control operations are clearly specified in a written form and GMP requirements are adopted.

(c) Managerial responsibilities are clearly specified in job descriptions.

(d) Arrangements are made for the manufacture, supply, and use of the correct starting and packaging materials.

(e) All necessary controls on starting materials, intermediate products, and bulk products and other in-process controls, calibrations, and validations are carried out.

(f) The finished product is correctly processed and checked, according to the defined procedures.

(g) Pharmaceutical products are not sold or supplied before the authorized persons have certified that each production batch has been produced and controlled in accordance with the requirements of the marketing authorization and any other regulations relevant to the production, control and release of pharmaceutical product.

(h) Satisfactory arrangements exist to ensure, as far as possible, that the pharmaceutical products are stored by the manufacturer, distributed, and subsequently handled so that quality is maintained throughout their shelf-life.

(i) There is a procedure for self-inspection and/or quality audit that regularly appraises the effectiveness and applicability of the quality assurance system.

3.3.2 Good Manufacturing Practice for Medicinal Products (GMP)

Good Manufacturing Practices were officially introduced in 1976 in the Code of Federal Regulations, Title 21 (CFR 21) Parts 210 and 211. CFR 21 stipulates that written procedures must be followed in pharmaceutical manufacturing.

Failure to comply with this regulation is a criminal act. Standard Operating Procedures (SOPs) are the written procedures that firms create to ensure that they are adhering to cGMPs. SOPs not only provide direction to operators and technicians in how to perform their jobs correctly, they also serve as guidance documents to help a firm prove it is committed to cGMP compliance.

Good manufacturing practice is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization. GMP rules are directed primarily to diminishing the risks, inherent in any pharmaceutical production that cannot be prevented completely through the testing of final products. Such risks are essentially of two types: cross-contamination (in particular by unexpected contaminants) and mix-ups (confusion) caused by false labels being put on containers.

Under GMP guidance:

(a) All manufacturing processes are clearly defined, systematically reviewed in the light of experience, and shown to be capable of consistently manufacturing pharmaceutical products of the required quality that comply with their specifications.

(b) Critical steps of manufacturing processes and any significant changes made to the processes are validated.

(c) All necessary facilities are provided, including:

(1) Appropriately qualified and trained personnel.

(2) Adequate premises and space.

(3) Suitable equipment and services.

(4) Correct materials, containers, and labels.

(5) Approved procedures and instructions.

(6) Suitable storage and transport.

(7) Adequate personnel, laboratories, and equipment for in-process controls under the responsibility of the production management.

(d) Instructions and procedures are written in clear and unambiguous language, specifically applicable to the facilities provided.

(e) Operators are trained to carry out procedures correctly.

(f) Records are made (manually and/or by recording instruments) during manufacture to show that all the steps required by the defined procedures and instructions have in fact been taken and that the quantity and quality of the product are as expected; any significant deviations are fully recorded and investigated.

(g) Records covering manufacture and distribution, which enable the complete history of a batch to be traced, are retained in a comprehensible and accessible form.

(h) The proper storage and distribution of the products minimizes any risk to their quality.

(i) A system is available to recall any batch of product from sale or supply.

(j) Complaints about marketed products are examined; the causes of quality defects investigated, and appropriate measures taken in respect of the defective products and to prevent recurrence.

GMP provides the general basics to determine the minimum acceptable requirements for the production at Good products, covering all the activities related to the production process. These basics are divided into several categories: **O**rganization and Personnel**, B**uildings and Facilities, **E**quipment, **C**ontrol of Components and Drug Product Containers and Closures, **P**roduction and Process Controls, **P**ackaging and Labeling Controls, **H**olding and Distribution, **L**aboratory Control, **R**ecords and Reports, and **R**eturned Drug Products.

3.3.3 Quality Control

Quality control is the part of GMP concerned with sampling, specifications, and testing and with the organization, documentation, and release procedures which ensure that the necessary and relevant tests are actually carried out and that materials are not released for use or products released for sale or supply, until their quality has been judged to be satisfactory. Quality control is not confined to laboratory operations but must be involved in all decisions concerning the quality of the product.

The independence of quality control from production is considered fundamental. The quality control department should be independent of other departments and under the authority of a person with appropriate qualifications and experience, who has one or several control laboratories at his or her disposal. Adequate resources must be available to ensure that all the quality control arrangements are effectively and reliably carried out. The basic requirements for quality control are summarized as follows:

(a) Adequate facilities, trained personnel and approved procedures must be available for sampling, inspecting, and testing starting materials, packaging materials, and intermediate, bulk, and finished products, and where appropriate for monitoring environmental conditions for GMP purposes.

(b) Samples of starting materials, packaging materials, intermediate products, bulk products and finished products must be taken by methods and personnel approved of by the quality control department.

(c) Test methods must be validated.

(d) Records must be made (manually and/or by recording instruments) demonstrating that all the required sampling, inspecting, and testing procedures have actually been carried out and that any deviations have been fully recorded and investigated.

(e) The finished products must contain ingredients complying with the qualitative and quantitative composition of the product described in the marketing authorization; the ingredients must be of the required purity, in their proper container, and correctly labeled.

(f) Records must be made of the results of inspecting and testing materials and intermediate, bulk, and finished products against specifications; product assessment must include a review and evaluation of the relevant production documentation and an assessment of deviations from specified procedures.

(g) No batch of product is to be released for sale or supply prior to certification by the authorized person(s) that it is in accordance with the requirements of the marketing authorization. In certain countries, by law, the batch release is a task of the authorized person from the production department together with the authorized person from the quality control department.

(h) Sufficient samples of starting materials and products must be retained to permit future examination of the product if necessary; the retained product must be kept in its final pack unless the pack is exceptionally large.

The quality control department as a whole will also have other duties, such as to establish, validate, and implement all quality control procedures, to evaluate, maintain, and store the reference standards for substances, to ensure the correct labeling of containers of materials and products, to ensure that the stability of the active pharmaceutical ingredients and products is monitored, to participate in the investigation of complaints related to the quality of the product, and to participate in environmental monitoring. All these operations should be carried out in accordance with written procedures and, where necessary, recorded.

Assessment of finished products should embrace all relevant factors, including the production conditions, the results of in-process testing, the manufacturing (including packaging) documentation, compliance with the specification for the finished product, and an examination of the finished pack. Quality control personnel must have access to production areas for sampling and investigation as appropriate.

According to Broun, (1994), pharmaceuticals of low quality, either imported or locally produced, should not reach the population. This calls for a system of quality control (including a national or regional control laboratory) and strict criteria for enforcement of the quality of distribution (storage, transport, and packaging). The approach recommended by WHO is to restrict drug purchasing to drug suppliers who follow Good Manufacturing Practices (GMP) in production facilities, both for imported and locally produced goods. Local producers should proceed as fast as possible towards GMP standards and not be awarded a "right" to produce sub-standard drugs because of their nationality. However, upgrading of manufacturing standards often has to be staged over time. Regulations regarding quality must be

enforced by a well-organized and trained inspection administration, independent from commercial pressure.

Finally, the concepts of QA, GMP and QC, are identified by WHO, EC directive, FDA, and all other national and/ or international organization of pharmaceutical manufacturing regulations. All the international and national regulations have the same identification of these concepts with minor differences. Finally, to ensure quality, all pharmaceutical manufacturers are required to establish and implement an effective pharmaceutical QA system, involving the active participation of the management and personnel of different services involved.

3.4 Relationship between ISO certification and GMP compliance.

All the six Palestinian pharmaceutical companies have ISO 9000 and five of them have ISO 14000 certificates, but no one has GMP. There are many international companies having both ISO Certificates and GMP compliance, or one of them. There are rising questions about the two systems, such as, the relationship between GMP and ISO.

Both GMP and ISO are quality systems in their own right. As the revised GMP became final in June 1997, the two systems became closer in how they are written and how a company should be achieving quality. There is, however, a real difference between GMP compliance and ISO certification. Schwartz, (1998), summarized the similarities and differences between ISO series and GMP certificates, as follows:

The GMPs are a regulatory requirement mandated by law, and if you are manufacturing medical products or devices, you must be in compliance with these regulations. ISO, on the other hand, is a voluntary certification obtained by a company when they determine that the certification is beneficial to their operations and/or marketing strategies. The ISO 9000 standard is not specific for any industry or service, while GMP is specific for medical device, drug, blood bank, and low acid canned food industries.

The revised GMP includes design review, management review, vendor qualification, and corrective and preventive action. ISO is precision, while GMP is compliance. Precision is the ability to repeat a task time after time and obtain the same results. An ISO certification audit certifies that your system is in place, assuring capability of providing precision. If precision cannot be achieved, policies and procedures will address these issues.

The fundamental difference between GMP and ISO is that both have different agendas. Once this is understood, the road to achieving ISO certification for a medical device company (who is in GMP compliance) will be much easier, faster, and less expensive.

Finally, implementation of a comprehensive quality systems model for human pharmaceutical products will facilitate compliance with international regulations and standards. The central goal of a quality system is to ensure consistent production of safe and effective products and that these activities are sustainable. Quality professionals are aware that good intentions alone will not ensure good

products. A robust quality system will promote process consistency by integrating effective knowledge-building mechanisms into daily operational decisions. When fully developed and effectively managed, a quality system will lead to consistent, predictable processes that ensure that pharmaceuticals are safe, effective, and available for the consumer.

CHAPTER FOUR

Research Methodology

4.1 Introduction

The purpose of any research study is to investigate a solution for a given problem through the application of scientific approaches. These approaches are developed in order to gather relevant, reliable and unbiased information to the asked question about that particular problem. This implies that the research is started by identifying a clear and specific problem that needs to be resolved. The problem is represented by a question to be answered through the application of scientific approaches or methods. The approach will include many steps to be taken for gathering and analyzing the data, determining the associated factors, providing answers to the questions, and taking the necessary corrective measures.

The main question of this research is related to the impact of quality management systems on cost and competitiveness in Palestinian pharmaceutical companies *(is the investment in quality worthwhile?)*. Therefore, this chapter will start with discussing related research design and methodological issues and then decide the appropriate research techniques to find the answers for the questions raised by this study.

4.2 Research Methodology Selection

The basic concern of this study is to investigate the impact of quality on cost and competitiveness in Palestinian pharmaceutical companies, by investigating the understanding of the quality concept and understanding and knowledge about the cost and benefits of quality between middle level and top level managers. So, there is a need for appropriate approach to be carefully designed, either quantitative and/or qualitative, taking into consideration collecting, processing and analyzing the

data very carefully. Selecting the appropriate methodology depends on the purpose of the research, the process, and the desired outcomes. Downey and Ireland, (1979) stated that: "Methodologies are neither appropriate nor inappropriate until they are applied to a specific research problem. This perspective treats methodologies as tools for inquiry; each inquiry requires careful selection of the proper tools".

4.2.1 Research Tools

The collected data were both primary and secondary. Secondary data were collected through literature review and other published and unpublished reports. Whereas, primary data were collected by using two tools, interviews with general managers of the Palestinian pharmaceutical companies, executive manager of Union for Palestinian Pharmaceutical Manufacturers (UPPM), and Quality Control Director in Palestinian Ministry of Health. The second tool was a questionnaire for managers and supervisors of each of four Palestinian pharmaceutical companies.

4.2.2 Questionnaire Design

The questionnaire was designed:

- To investigate the management commitment to quality and concept of the quality awareness.
- To investigate if there is a resistance to change toward quality management systems implementation which may affect employees performance and productivity
- To investigate the benefits of quality.
- To investigate the impact of quality on competitiveness.

- To investigate the reasons of complying with international standards and producing according to requirements.

The questionnaire was designed according to three types of scales, nominal scales (Part one), likert scales (Part two), and ordinal scale (Part three).

- Part one consists of two questions about the position and department.
- Part two contains of 58 questions divided into four categories, quality concept and organization commitment for quality, cost of quality related to employees resistance, tracking cost of conformance and nonconformance, benefits of quality, and impact of quality on competitiveness.
- Part Three contains one question to investigate the most important and least important reason of implementing quality management systems (ISO9000 & 14000) and complying with GMP requirements.

4.2.3 Face to Face Interviews

The main purpose of interviewing top level mangers of the pharmaceutical companies was to collect more information about the impact of quality management systems on these companies and how companies can benefit of implementing effective quality management systems and complying with international standards and regulations.

The purpose of interviewing some experts in Palestinian pharmaceutical industry was to investigate the effect of quality management systems on the pharmaceutical industry and if the companies could benefit from these implementations.

4.3 Study Population and Sample

The population represents managers and supervisors of four out of six pharmaceutical companies in Palestine located in the West Bank (5 companies), and Gaza Strip (one company). Because the population is not large, the sample of the study represents the population. The sample is limited to managers and supervisors of these four West Bank -located companies (Birzeit Pharmaceutical Company, Jerusalem Pharmaceutical Company, Pharmacare Company, and Beit Jala Pharmaceutical Company). The total number of managers and supervisors is about 70 (40 managers and 30 supervisors). But the respondents to the questionnaire were 47 (31 managers and 16 supervisors), as classified in Table (3).

Table (3); Respondents' classifications (position and departments).

Position Department	Managers	Supervisor
1. Production	4	6*
2. Finance	3	-
3. Sales and Marketing	6	3
4. Quality control/ Assurance	6	5
5. R&D	4	1
6. Others	9	-
Total	31	16

* *The collected questionnaires are (6), but one of them was dropped out.*

The respondents of the first five departments, Production, Finance, Sales and marketing, Quality control and or assurance, and R&D, represent the majority of respondents (81%). All managers of production, marketing, quality control, and R&D answered the questionnaire.

4.4 Goodness of data

4.4.1 Validity:

All instruments of the research were used in previous studies; moreover, before distributing the questionnaire to respondents, a pilot study was conducted by sending the questionnaire to five experts in the pharmaceutical industry, to Professor Nidal Sabri and to the supervisor (Dr. Munther Nijim), who advised introducing changes and edits to achieve high validity. So, the questionnaire is expected be valid for measuring the variables.

4.4.2 Reliability:

To check the reliability of the questionnaire, chronbach's alpha was calculated (0.890) which is implying that the results are acceptable, and there is internal consistent reliability.

4.5 Hypothesis

Two hypotheses will be tested in the research to find the relation between effective quality management systems, cost and competitiveness.

To accomplish the purpose of this study, the following null hypothesis (H_0) and alternative hypothesis (H_a) have been stated.

1. $H_0$1: There is no correlation between quality management systems implementation in pharmaceutical companies and cost.
2. H_a1: There is a correlation between quality management systems implementation in pharmaceutical companies and cost.

3. $H_0$2: There is no correlation between quality management systems implementation in pharmaceutical companies and competitiveness.
4. H_a2: There is a correlation between quality management systems implementation in pharmaceutical companies and competitiveness.

4.6 Data Analysis

The purpose of data analysis was to answer the research question (problem statement) which was stated in section 1.4 of chapter one. The question was "To what extent managements are committed to improving quality of Palestinian Pharmaceuticals and what is the correlation between effective quality management systems implementation, Cost, and competitiveness in Palestinian pharmaceutical companies?"

4.6.1 Data Management

4.6.1. a) Editing: All received questionnaires were checked to make sure that every question was properly answered and there are no missing data. From 47 received questionnaires, one questionnaire was dropped out because more than 25% of the statements was either improperly answered or left without answers.

4.6.1.b) Data Entry: Excel sheets were used for data entry, because it is easy to transfer the collected data to a data analysis program such as SPSS. After completing data entry, the data was transferred to Scientific Package of Social Science (SPSS) version 12.0 programs for data analysis and testing.

4.6.2 Statistical Analysis

After transferring the data from excel sheets to SPSS sheets, proper coding and scoring were done for each question to make the proper analysis. The main part of the data (q3 – q60) was collected as likert scale (from (1) strongly agree to (5) strongly disagree) so, each answer was converted into score (1= 100, 2= 25, 3= 75, 5= 0), except questions 14, 15, 16, and 21, which were oppositely scored. Then a cut point was selected to be (60), which means that the accepted score to each statement must be more than sixty to be significant for measuring the phenomena. The next step was gathering the 58 statements in 5 variables according to the relationships and correlations between each group of questions. The five new variables were Quality concept and management commitment, Quality cost related to employees' resistance, Cost of Conformance and Nonconformance tracking, Benefits of Quality, and Impact of Quality on Competitiveness. The required statistic analyses were done for the 58 statements and the generated five new variables, like frequencies, means, and other related tests.

The third part of the questionnaire was designed as ordinal scale, by asking respondents to rank the reasons of complying with international standards and regulations according the importance of each item, 1 is the most important and 6 is the least important. Then the frequencies and means of answers were calculated.

Finally, to check if there are significant differences in the answers between managers and supervisors or between respondents from different departments, the second and third part of the questionnaire were correlated to the first part which consists of two questions, position of the respondent and the department he works

in. To find if there are significant differences in answers between respondents from the different companies, answers were al correlated to the company that every respondent work for.

The analysis and the findings were presented in different tables and figures in chapter five

4.8 Hypothesis Testing

The two hypotheses were tested in the research, by using One Sample T- test. They are stated by the null hypothesis (H_0) and alternative hypothesis (H_a). The concept of quality and management commitment was also tested to measure the degree of awareness about quality concept and management commitment to quality improvement.

The mean, standard deviation and standard error of each variable were calculated in comparison with the cut point. By using SPSS program the population is expected to be infinity so the program neglects the effect or power of the population and the proportion of the sample. But, in this case, the population is finite (70 managers and supervisors). To improve the power of the measurements, the population effect was taken into consideration by calculating (t) value using the mathematical equations:

H0: P = P0 = 60

Ha: P >P0 > 60

(P) is the proportion of the population. $\hat{P}$ is the mean of the result.

$$\sigma_{\hat{p}} = \sqrt{\frac{N-n}{N-1}} * \sqrt{\frac{\hat{P}(1-\hat{P})}{n}}$$; Where n = sample size = 46, N = the population size = 70, and σ is the standard deviation.

Then (t) test statistic was used to decide if the hypothesis is rejected or accepted:

$$t = \frac{\hat{P} - P}{\sigma_{\hat{P}}}$$

The level of significance for the test was selected at α = 0.05. From the normal distribution table the value corresponding to ($t_{0.05}$) was found to be (1.645). The hypothesis will be rejected if the computed (t) < 1.645. However, the calculated (t) values were significant enough which made no need to recalculate (t) by using the equation.

CHAPTER FIVE

Findings and Results of the Study

5.1 Introduction

The questionnaire and the structured interviews were designed to get the proper investigation by answering the stated study question in Chapter one (section 1.4). So, the findings and results were collected to answer of the following central questions:

- To what extent managements are committed to improving quality of Palestinian Pharmaceuticals?
- What is the correlation between quality management systems implementation and Cost?
- What is the correlation between quality management systems implementation and competitiveness in Palestinian pharmaceutical companies?

The findings of the questionnaire were collected from managers and supervisors responding as follows:

- Position and departments that respondents fill and work in.
- The concept of quality and management commitment toward improving quality.
- The costs of Quality incurred as a result of employees resistance
- Cost conformance and nonconformance tracking Concept
- The benefits of quality
- The impact of quality on competitiveness
- The reasons of implementing quality management systems and complying with international standards and regulations.

5.2 Companies, Positions and Departments

The analysis of data, gathered through the questionnaire, revealed the following results in terms of position (manager or supervisor), and department (production, finance, sales and marketing, R&D, Quality control / assurance, others).

Table (5.1), the respondents' distribution between the four companies

Company*	Number of respondents	%	Valid %	Cumulative %
Company 1	14	30.4	30.4	30.4
Company 2	10	21.7	21.7	52.2
Company 3	12	26.1	26.1	78.3
Company 4	10	21.7	21.7	100
Total	46	100%	100%	

* *The numbers were used instead of names to avoid any inconvenience with companies' names.*

Table (5.2): Positions of respondents

Position	Number of respondents	%	Valid %	Cumulative %
Manager	31	67.4	67.4	67.4
Supervisor	15	32.6	32.6	100
Total	46	100	100	

Table (5.3) Respondents' distribution in companies' departments.

Department	Number of respondents	%	Valid %	Cumulative %
Production	9	19.6	19.6	19.6
Finance	3	6.5	6.5	26.1
Sales and Marketing	9	19.6	19.6	45.7
Quality control/ assurance	11	23.9	23.9	69.6
R&D	5	10.9	10.9	80.4
Others	9	19.6	19.6	100
Total	46	100	100	

Table (5.4) Distribution of managers and supervisors according to their departments.

Position	Production	Finance	Sales& Marketing	Q C & QA	R&D	Others	Total
Manager	4	3	6	5	4	9	31
Supervisor	5	0	3	6	1	0	15
Total	9	3	9	11	5	9	46

The previous four tables show the following characteristics of respondents:

1. The total number of respondents was 46 from four companies. The numbers of respondents of the four companies are varied as follows: Respondents of company 1 are 14 (30.4%) and company 3 are 12 (26.1%) where as respondents of companies 2 and 4 are 10 for every one (21.7) for each company. These variations may be due to the organizational structure for each company.
2. The majority of respondents were managers (67.4%), whereas the supervisors' percentage was (32.6%)
3. The majority of respondents are working in the key operating departments such as (Production, R&D, Quality control/ assurances, Sales and marketing, and finance) (80.4%).

5.3 Quality concept and management commitment for improving quality

To investigate the awareness about the quality concept and management commitment for improving quality, 14 related statements were included in the questionnaire. After collecting the data, means of the 14 statements were calculated. Then the 14 statements were recoded as one variable called (Quality concept), then the mean of means of the 14 statements' answers was calculated as the mean of the quality concept.

Table (5.5.a): The quality concept and management commitment for improving quality

	Statement	N	Mean	Std. Deviation	Std. Error Mean
1	Employees in my department are adequately informed about the quality standards that apply to their jobs	46	84.24	19.263	2.840
2	Employees in my department are adequately informed about the quality objectives of our department.	46	85.87	18.747	2.764
3	We have the technical and managerial skills necessary to measure the quality of work.	46	84.24	17.763	2.619
4	The quality improvement process is considered an important priority by Senior Management	46	87.5	18.066	2.663
5	The quality improvement process is considered an important priority b y Myself	46	92.39	11.630	1.7148
6	The quality improvement process is considered an important priority b y My department employees	46	80.43	20.353	3.001
7	Too much emphasis is placed upon quality of work produced rather than its quantity	46	73.37	24.382	3.595
8	Quality improvement is viewed as a long term commitment, not to be compromised by short- term financial goals	46	80.98	21.848	3.221
9	My department's emphasis on quality has resulted in measurable improvement in our products and services	46	83.15	16.712	2.464
10	Management commitment to quality is apparent in what we do on day-to- day basis	46	71.20	20.390	3.006
11	The top management and the middle level management are implementing programs and processes for quality improvement	46	76.63	20.001	2.949
12	The top and middle level management are providing tools and resources required for quality improvement.	46	73.37	18.561	2.737
13	The company feels more confidence that the company's products meet relevant regulatory requirements	46	84.78	17.856	2.633
14	The company often sacrifices the quality of products in order to cut costs	46	43.48	36.68	5.408
	QUALITY CONCEPT AND MANAGEMENT COMMITMENT FOR IMPROVING QUALITY	46	79.62	12.329	1.818

The previous table shows that the majority of respondents responded positively to the statements. The response to statement (14) " The company often sacrifices the quality of products in order to cut costs" had different direction from the other 13 statements, which means that the direction of respondents was toward company commitment to quality, but the direction of response to statement was that

companies some times scarifies quality to cut costs. This might be due to misunderstanding the statement or it might be intentional response.

By comparing the achieved results ($\hat{P}$) with the cut point (ρ_0 = 60), the results reveal that only about (13%) of results ($\hat{P}$) are less than (ρ_0), and the mean of the 14 statements' means is (79.62). To test the significance of the results (one sample T- Test) was calculated, as summarized in the following table:

Table (5.5.b) One-Sample Test

	Test Value = 60					
	t	df	Sig. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
					Lower	Upper
Quality Concept	10.793	45	.000	19.61957	15.9582	23.2809

In the table (5.5.b), (t) calculated = 10.793; at 95% confidence is grater than (t) tabulated (1.645), which means that there is a correlation between the statements and that the results are significant, consequently it indicates:

1. The quality concept is well understood
2. There is managements' commitment for improving quality.

5.4 Cost of Quality incurred as a result of employees' resistance.

The study tried to investigate the concept of quality cost by answering indirect questions. The cost of quality wasn't measured as calculations of investments in quality improvement, but the effect of quality management systems on the culture and employees performance so as to investigate if there was resistance for change (ie. Implementing quality management systems and operating according to

standards). So, the results revealed that there was some resistance or misunderstanding to some quality regulations and aspects. The investigation of the cost of quality incurred as a result of employees' resistance was represented by three statements in the questionnaire. The three statements were converted into one variable called (Quality Cost incurred as a result of employees' resistance), then mean of the 3 means was calculated and tested to check its significance.

The mean of the three statements means is 55.4349 % of the total score (100) which mean that the direction of responses of the statements was not identical and this also means that the correlation between the quality and costs resulting from resisting the change and complying with regulations and international standards is not clear. This may be due to the respondents understanding of statements or the resistance to change might not be tracked or assessed as a result of quality management systems. See, Table (5.6.a)

Table (5.6.a): Quality cost related to employees resistance

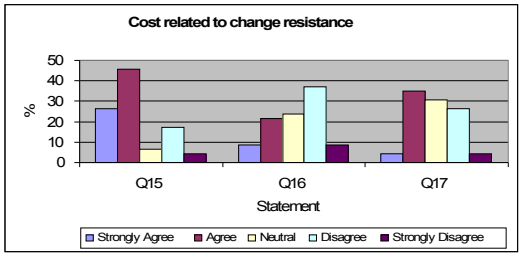
	ISO 9000, and 14000 certificates and complying with GMP requirements increase costs as follows.	N	Mean	St. Deviation	St. Error
15	Operating according to ISO and GMP requirements force employees to spend a lot of time on documentation and inspection which can be used for production.	46	67.93	29.185	4.303
16	The continuous concentration on the rules and requirements of ISO and GMP, causes employees to feel inconvenience, which affects there productivity and performance.	46	46.196	28.366	4.182
17	Some employees feel that a lot of steps used according to standards are not necessary, and they some times resist doing them.	46	52.17	24.623	3.630
	QUALITY COSTS RELATED TO EMPLOYEES RESISTANCE	46	55.43	20.429	3.012

The frequencies and percentages of respondent answers were also, calculated to build more information about this factor.

Table (5.6.b): Percentages of answers of statements (15,16,and 17)

ISO 9000, and 14000 certificates and complying with GMP requirements increase costs as follows.	St. Agree	Agree	Neutral	Disagree	St. Disagree
Operating according to ISO and GMP requirements force employees to spend a lot of time on documentation and inspection which can be used for production.	26.09	45.65	6.52	17.39	4.35
The continuous concentration on the rules and requirements of ISO and GMP, causes employees to feel inconvenience, which affects there productivity and performance.	8.70	21.74	23.91	36.95	8.70
Some employees feel that a lot of steps used according to standards are not necessary, and they some times resist doing them.	4.35	34.78	30.43	26.09	4.35

Figure (1): Percentages of answering to questions (15,16, & 17)



5.5 Cost of Conformance and non-conformance Awareness

Eight statements were used to investigate the cost of quality concept. Every one of the eight statements was asked to investigate if the managers and supervisors understand the concept of quality cost as cost of conformance and nonconformance, if they can analyze the cost and benefit of quality, and finally, if they can measure

the impact of poor and high quality on costs, competitiveness, sales, profits and customer loyalty.

Table (5.7.a): Cost conformance and nonconformance concept.

	Statement	N	Mean	St. Deviation	St. Error
18	The cost of poor quality in short- term are due to scrap rate, rework, defects, etc.	46	63.04	26.739	3.942
19	The cost of poor quality results in long- term loss of sales, customers, and competitive advantages.	46	78.80	20.390	3.006
20	The cost of not having good quality is much more than cost of having high quality (cost of quality)	46	84.78	23.850	3.517
21	The cost of failure correction is higher than failure prevention	46	83.70	24.277	3.579
22	The management tracks cost of having good quality and bad quality	46	45.65	28.04	4.134
23	The management continuously measures the cost of quality and return on quality	46	60.33	23.319	3.438
24	The company concentrate on failure prevention more than failure treatment	46	77.17	21.619	3.188
25	The benefits of having high quality are more than costs of having high quality.	46	76.63	21.345	3.147
	Cost of conformance and nonconformance	46	71.26	10.283	1.516

Table 5.7.b. One-Sample Test

Test Value = 60

	t	df	Sig. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
					Lower	Upper
COC and CONC	7.429	45	.00	11.264	8.2099	14.317

The mean of quality cost tracking is 71.26, which is an acceptable result. By determining the score (60) as test value, the one sample T- Test revealed that results are significant (calculated (t) = 7.429> tabulated (t) = 1.645). So, these significant results indicate that there is an understanding to cost of poor quality, cost of good quality, and return on quality.

5.6 Benefits of quality on cost, culture, productivity, performance, sales, and profits

This part of the questionnaire was designed to investigate if Palestinian pharmaceutical companies' middle level managements are aware of benefits of implementing effective quality management systems and complying with international regulations and standards. The statements of this part were designed to investigate if companies could reduce operational costs, staff conflicts, time, and defects. These statements were also, designed to investigate if companies could increase productivity and efficiency, encourage suggestions, increase sales due to customer satisfaction, and generate more profits.

Table (5.8.a): Benefits of Quality

	The effective implementation ISO 9000 &14000 certificates and complying with GMP requirements leads to:	N	Mean	St. Deviation	St. Error
26	*Reducing staff conflicts*	46	67.93	22.150	3.266
27	*Enhancing more suggestions*	46	79.89	16.347	2.410
28	*Reducing wastage of materials*	46	80.44	16.594	2.447
29	*Shortening delivery lead time*	46	77.72	18.430	2.717
30	*Increasing employees efficiency*	46	75.54	20.062	2.958
31	*Increasing quantity of production (Productivity)*	46	77.72	17.661	2.604
32	*Reducing operational costs*	46	72.28	26.472	3.903
33	*Increasing profits*	46	68.48	24.964	3.681
34	*Achieving customer satisfaction and more competitive advantages which creates customer loyalty.*	46	79.35	21.281	3.138
35	By focusing on investment on designing programs to prevent or reduce errors or failure, the company can reduce the costs of correction, leading to decrease cost of quality.	46	76.09	23.545	3.471
36	High Returns on investment due to quality improvement and international standards and regulations achievements justify the company to focus on achieving higher quality.	46	78.80	16.639	2.453
	QUALITY BENEFITS	46	75.84	12.238	1.804

The above table shows that the mean of the eleven statements means (Quality benefits) is (75.84) which are acceptable comparing with the tested value (60). This means that the majority of respondents agrees or strongly agrees that there is a

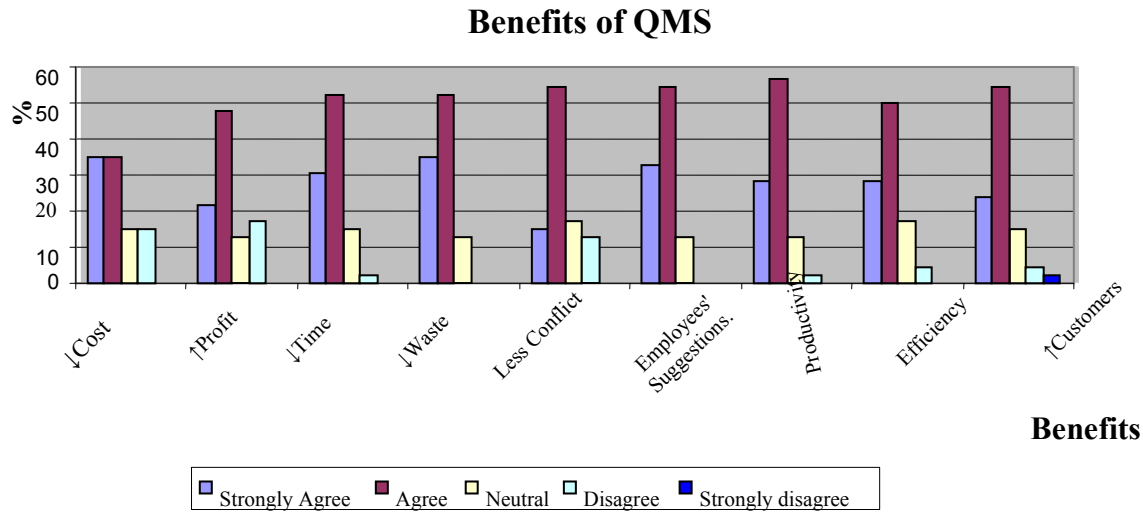
positive impact of quality in reducing cost, waste material, and staff conflict. There is also impact of quality in enhancing more suggestions, increasing sales, generating more profits, improving productivity and efficiency. By calculating the frequencies of the answers, the following results were obtained:

Table (5.8.b): Percentages of respondents' answers to statements (26 – 34)

Score	↑Profit	↑Employees' suggestions	↑Productivity	↑Efficiency	↑Customers
Strongly Agree	21.74	32.61	28.26	28.26	23.91
Agree	47.83	54.35	56.52	50	54.35
Neutral	13.04	13.04	13.04	17.39	15.22
Disagree	17.39		2.18	4.35	4.35
Strongly disagree					2.17

Score	↓Cost	↓Time	↓Wastages	↓Conflict
Strongly Agree	34.78	30.44	34.78	15.22
Agree	34.78	52.17	52.18	54.35
Neutral	15.22	15.22	13.04	17.39
Disagree	15.22	2.17		13.04
Strongly disagree				

Figure 2: Percentages of Respondents' answers to statements (26- 34)



5.7 Impact of quality on competitiveness

The impact of quality on competitiveness was addressed by the bulk of statements (22 statements). This part was designed to investigate if companies agree that implementing quality management systems could improve their competitive advantages. The statements focused on customer satisfaction, and the effect of customer satisfaction on sales and market share.

The majority of respondents agreed or strongly agreed that quality could improve the competitiveness of companies through customer satisfaction and loyalty, which consequently reduces customer complaints and increases sales. The majority of respondents believed that their companies are trying to find the best way of serving customers, through producing high quality products that comply with customers needs. Companies are also, soliciting customer feedback, which fosters stronger relationships between customers and companies.

The mean of the results is about 75.4 which is acceptable, and testing the results using one sample T- Test revealed that there is a significant correlation between

quality and improving competitiveness, (calculated (t) = 10.484 > tabulated (t) = 1.645) at 95% confidence.

Table (5.9.a) Impact of quality on competitiveness

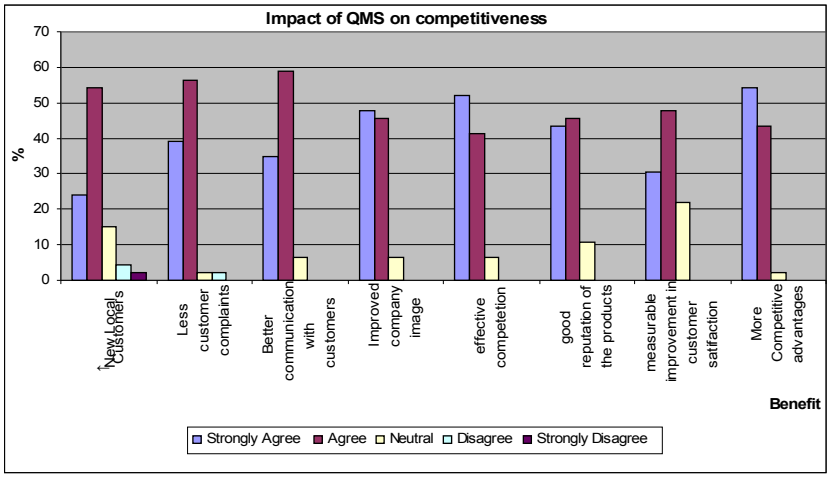
#	Statement	N	Mean	St. Deviation	St. Error
37	The company understands how the product and service attributes fulfill basic customer needs.	46	76.09	18.971	2.797
38	The company furnishes clear and complete information to customers to ensure that customers formulate accurate expectations of products.	46	75	19.00	2.802
39	The company provides easy access to customers who seek assistance, wish to comment, or wish to complain.	46	77.72	21.232	3.130
40	The company proactively follows up with customers to seek feedback for improvement on products.	46	76.09	16.630	2.452
41	Improvements in the quality of the company's products over the past years have been translated into stronger customer loyalty.	46	71.20	22.34042	3.294
42	The company regularly compares its customer satisfaction levels with those of competitors.	46	67.93	17.210	2.538
43	The company uses the comparative assessment of customer satisfaction levels in its continuous improvement process.	46	65.76	19.263	2.840
44	The company documents trends and current levels of customer satisfaction relative to competitors.	46	64.67	20.122	2.967
45	The company documents trends in gaining or losing customers from or to competitors.	46	63.04	17.272	2.546
46	The company documents trends in the market share of competitors.	46	60.87	20.851	3.074
47	The company evaluates and improves its processes for determining customers' future requirements and expectations for current and future products.	46	69.02	15.078	2.223
48	Increasing sales with existing customers, as a result of customer loyalty	46	71.74	19.443	2.867
49	Improving quality helps gaining more new local customers	46	73.37	21.986	3.242
50	Improving quality leads to reducing customer complaints	46	83.15	15.85906	2.338
51	Improving quality enhances communication with customers	46	82.06	14.590	2.151

52	Improving quality making customers to feel more confident that they will receive products conforming to their requirements, which in turn results in higher customer satisfaction	46	79.89	17.175	2.532
53	By producing high quality products, the company image will be improved.	46	85.33	15.434	2.276
54	Improving quality adds more competitive advantages.	46	88.04	13.682	2.017
55	By improving the quality, the company can effectively compete and can gain new customers	46	86.41	15.551	2.293
56	The company has established a good reputation of the quality of its products.	46	83.15	16.712	2.464
57	My department's emphasis on quality has resulted in measurable improvement in customer satisfaction	46	77.17	18.125	2.672
58	My department constantly looks for better ways to serve its customers.	46	80.98	18.397	2.713
	Impact of quality on competitiveness	46	75.4	9.959	1.468

Table (5.9.b): Percentages of degree of agreement for each statement (48- 51 & 53- 55)

Impact	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
↑ New Local Customers	23.91	54.35	15.22	4.35	2.17
Less customer complaints	39.14	56.52	2.17	2.17	
Better communication with customers	34.78	58.70	6.52		
Improved company image	47.83	45.65	6.52		
effective competition	52.17	41.31	6.52		
Good reputation of the products	43.48	45.65	10.87		
measurable improvement in customer satisfaction	30.43	47.83	21.74		
More Competitive advantages	54.35	43.48	2.17		

Figure 3: Percentages of degree of agreement for each statement (48- 51 & 53- 55)



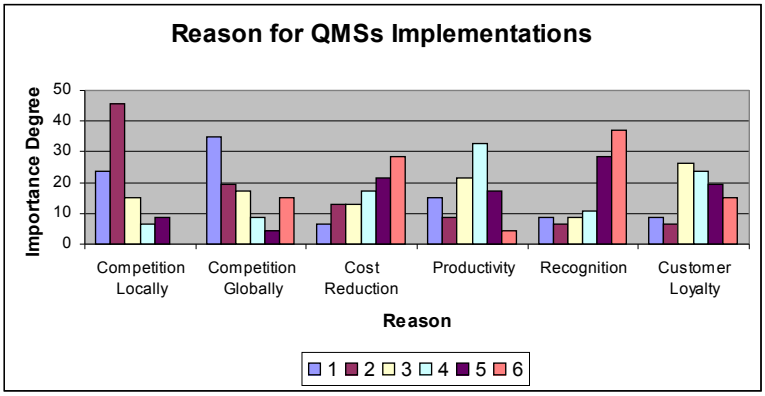
5.8 Reasons for complying with international standards and regulations

In this part, the respondents were asked to rank the reasons that push companies to comply with international standards, requirements and regulations according to their importance in the respondents' point of view.

Table (5.10.a) Percentages of reasons for complying with international standards, regulations and requirements:

Importance	Competition in Local Market	Competition in Global Markets	Cost Reduction	Productivity and Efficiency	Recognition	Customer Loyalty
Most Imp	23.9 %	34.8 %	6.5 %	15.2 %	8.7 %	8.7 %
Second	45.7%	19.6 %	13 %	8.7 %	6.5 %	6.5 %
Third	15.2%	17.4 %	13 %	21.7 %	8.7 %	26.1 %
Fourth	6.5%	8.7 %	17.4 %	32.6 %	10.9 %	23.9 %
Fifth	8.7 %	4.3 %	21.7 %	17.4 %	28.3 %	19.6 %
Least Imp		15.2 %	28.3 %	4.3 %	37 %	15.2 %

Figure 4: Percentages of the importance of reasons for QMSs Implementation.



The results in the table explained that 34.8% of respondents believe that competition in global markets is the most important reason for companies to comply with international standards and regulations, whereas, 15.2 % believe that competition in global markets has the least importance. The competition in local market was ranked mainly as the second important reason (45.7 %). Gaining customer loyalty had the highest percentage as the third important reason (26.1 %), Improving productivity and efficiency got the highest percentage as the fourth important reason (32.6 %), (28.3 %) of respondents ranked the recognition as the fourth important reason, and 37% of respondents ranked it as the least important reason for complying with international standards and regulations. Cost reduction didn't get a high score in the ranking, and if the percentages are gathered in two categories (most important + Second important+ Third important) and (Fourth

important + Fifth important + Least Important), the results will indicate that 67.4% of respondents believe that cost reduction is not the most, the second or the third important reason to push companies into complying with international standards and regulations. 28% of respondents ranked cost reduction as the least important reason.

By calculating the mean of each factor or reason, competition in local market was ranked to be the most important reason, competition in global markets was placed as second important reason, the third important factor was considered to be improving productivity and efficiency, while, customer loyalty was ranked as fourth important, compared to cost reduction which was ranked as the fifth reason, and recognition was ranked as the least important reason.

Table (5.10.b).: Means of the six reasons for implementing QMSs.

	Listed Reasons	Mean	Rank
1	Competition in local Market	2.30	1
2	Competition in global markets	2.74	2
3	Cost Reduction	4.2	5
4	Productivity and efficiency	3.41	3
5	Recognition	4.54	6
6	Customer loyalty	3.85	4

5.9 Hypothesis Testing

5.9. 1. The main hypothesis testing

1 H01 : There is no correlation between quality management systems implementation in pharmaceutical companies and cost.

2 Ha1: There is a correlation between quality management systems implementation in pharmaceutical companies and cost.

3 H02: There is no correlation between quality management systems implementation in pharmaceutical companies and competitiveness.

4 Ha2: There is a correlation between quality management systems implementation in pharmaceutical companies and competitiveness.

The two hypotheses were tested by applying the independent sample t-test, the output data were tested to determine whether the results are significant at the test level of 0.05 significance.

- The first stated null hypothesis "There *is a correlation between quality management systems implementation and cost in Palestinian pharmaceutical companies*" is rejected because the calculated (t) value is greater than the tabulated value at (.05 level of confidence). Calculated (t) value = 8.779 > Tabulated (t) value = 1.645, and the results were significant (sig. (2-tailed) = 0.000). This means that the first alternative hypothesis is accepted which is *"There is a correlation between quality management systems implementation and cost in Palestinian pharmaceutical companies"*, and this correlation states that the effective implementation of quality management systems leads to cost reduction.

Table (5.11): One-Sample Test

	Test Value = 60					
	t	df	Sig. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
					Lower	Upper
Quality Benefit	8.779	45	.000	15.83992	12.2058	19.4741

- The second null hypothesis was also, tested and the results revealed that the second null hypothesis was rejected, because the calculated (t) value is greater than the tabulated value at (.05 level and df 45). Calculated (t) value = 10.484 > Tabulated

(t) value = 1.645, and the results were significant (sig. (2-tailed) = .000). This means that the second null hypothesis is rejected which is *"There is no correlation between quality management systems implementation and competitiveness in Palestinian pharmaceutical companies"*, so, the second alternative hypothesis is accepted which is *"There is a correlation between quality management systems implementation and competitiveness in Palestinian pharmaceutical companies"*. This correlation states that the effective implementation of quality management systems could improve the competitiveness of Palestinian pharmaceutical companies.

Table (5.12): One-Sample Test

	Test Value = 60					
	t	df	Sig. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
					Lower	Upper
Quality Comp	10.484	45	.000	15.39526	12.4377	18.3528

5.9.2 The sub-hypothesis testing

There were three sub-hypothesis for the respondents, Position, Department, and Company.

H01: *There are no differences between respondents' answers from the four companies*

$\mu_{C1} = \mu_{C2} = \mu_{C3} = \mu_{C4}$

Ha1: *There are significant differences between respondents' answers from the four companies*

$\mu_{C1} \# \mu_{C2} \# \mu_{C3} \# \mu_{C4}$

H02: *There are no differences between managers and supervisors' answers.*

$\mu_{Manager} = \mu_{Supervisor}$

Ha2: *There are significant differences between managers' and supervisors' answers.*

$\mu_{Manager} \# \mu_{Supervisor}$

H_{03}: *There are no differences between answers of respondents from different departments.*

$\mu_{Production} = \mu_{finance} = \mu_{sales\ and\ marketing} = \mu_{Quality\ control} = \mu_{R\&D} = \mu_{Others}$

H_{a3}: *There are significant differences between answers of respondents from different departments.*

$\mu_{Production} \# \mu_{finance} \# \mu_{sales\ and\ marketing} \# \mu_{Quality\ control} \# \mu_{R\&D} \# \mu_{Others}$

The first null sub hypothesis was tested by using one way ANOVA test to measure if there are differences between the four companies in answering the likert part of the questionnaire. The Table (5.13), shows that there are significant differences in the quality cost (sig. 0.03 < 0.05), and slight significance in both quality concept and management commitment (Sig. 0.08) and cost of conformance and nonconformance tracking (0.08) between the four companies. On the other hand, there is no significant difference in the quality benefits (0.134) and quality and competitiveness (0.97). This means that the null hypothesis is accepted in quality cost, in quality concept and cost of conformance and non conformance tracking.

Where as the null hypothesis is rejected in both quality benefits and impact of quality on competitiveness.

Table (5.13): ANOVA (Company)

	df	F	Sig.
Quality Concept	45	2.453107	0.08 *
Quality Cost	45	5.377974	0.003**
COC & CONC	45	4.52225	0.08*
Quality Benefit	45	1.964628	0.134
Quality Comp	45	0.081437	0.97

The second null sub hypothesis was also tested by applying one way ANOVA. The table (5.14) shows that there are no significant differences between the respondents from the different departments, which mean that the null sub hypothesis is accepted.

Table (5.14): ANOVA (Department)

Variable	df	F	Sig.
Quality Concept	45	2.056	0.091
Quality Cost	45	0.329	0.89
COC and CONC	45	1.980	0.10
Quality Benefit	45	1.471	0.22
Quality Comp	45	0.489	0.78

The third null sub hypothesis was tested by applying the independent sample test. Table, (5.15) shows that there are significant differences between managers and supervisors in answering the statements on quality concept and management commitment (0.05). On the other hand there are no significant differences in the other four factors, quality cost, quality benefits, cost of conformance and non conformance tracking, and impact of quality on competitiveness. This means that the third null sub hypothesis is rejected for the quality concept and management commitment for improving quality, yet, it is accepted in the remaining variables.

Table (5.15): Independent Samples Test (Position)

	df	F	Sig.	t	Sig. (2-tailed)
Quality Concept	44	8.553	0.005	2.015	0.050
Quality Cost	44	4.199	0.046	-0.154	0.878

COC and CONC	44	0.023	0.880	-0.563	0.576
Quality Benefit	44	0.285	0.596	-0.258	0.798
Quality Comp	44	2.098	0.155	1.348	0.185

For the third part of the questionnaire (ordinal scale), one way ANOVA was applied to test the first and third null sub hypothesis.

For the first sub hypothesis the table (5.16), indicates that there are no significant differences between the four companies in ranking the reasons for complying with international standards and regulations. This means that the null sub hypothesis was accepted at a significant level 0.05.

$$\mu_{C1} = \mu_{C2} = \mu_{C3} = \mu_{C4}$$

Table (5.16); Differences in ranking the reasons of complying with international standards (Companies).

Reason	Mean	df	F	Sig.	Rank
Competition in local Market	2.30	45	0.942	0.429	1
Competition in global markets	2.74	45	0.794	0.504	2
Cost Reduction	4.20	45	1.127	0.349	5
Productivity and efficiency	3.41	45	0.904	0.447	3
Recognition	4.54	45	0.037	0.99	6
customer loyalty	3.85	45	0.24	0.868	4

As illustrated in Table (5.17), the third null sub hypothesis was retained, at 0.05 level of confidence, for all the six reasons which mean that there are no significant differences between respondents from different departments in Palestinian pharmaceutical companies in ranking the reasons for complying with international standards and regulations.

$$\mu_{Production} = \mu_{finance} = \mu_{sales\ and\ marketing} = \mu_{Quality\ control} = \mu_{R\&D} = \mu_{Others}$$

Table (5.17) the differences between pharmaceutical departments in ranking reasons of complying with international standards.

Reason	Mean	df	F	Sig.	Rank
Competition in local Market	2.30	45	0.786	0.566	1
Competition in global markets	2.74	45	0.114	0.989	2
Cost Reduction	4.20	45	1.042	0.406	5
Productivity and efficiency	3.41	45	0.365	0.870	3
Recognition	4.54	45	1.647	0.170	6
customer loyalty	3.85	45	1.096	0.38	4

U- test was applied to test the second sub null hypothesis. The U- test is nonparametric test and Mann- Whitney U was used at (0.05) significance to examine whether there is a significant difference between managers and supervisors' answers. The Mann- Whitney U- test is a popular test that can be used for testing the differences between rankings of two independent groups. Based on the U value and the significant level of 0.05, the existing differences for each of the stated reasons for complying with international standards and regulations were determined and reported.

As illustrated in Table (5.18), the U test indicates that the second stated null sub hypothesis "There *is no difference between managers and supervisors"* is accepted at a significant level of 0.05 or less for all the six factors.

$\mu_{Manager} = \mu_{Supervisor}$

Table (5.18); The differences between positions in ranking the reasons of complying with international standards.

	Listed Reasons	Mann- Whitney U	Significant at 0.05
1	Competition in local Market	174	0.145566
2	Competition in global markets	225.5	0.86575
3	Cost Reduction	203.5	0.487427
4	Productivity and efficiency	179	0.197423
5	Recognition	231	0.97084
6	customer loyalty	176.5	0.179819

5.10 Correlation between results

The aim of measuring this correlation was to investigate if there is a correlation between the five factors and in specific, the correlation between the quality concept and the other four factors. The results showed that there are significant correlations between four of the variables, Quality concept, cost of conformance and non conformance tracking, benefits of quality, and finally quality competitiveness. Also, the results didn't show a strong correlation between quality cost related to employees' resistance and any other factor. The table (5.19), shows that there is a significant correlation between quality concept and quality benefits (p value= 0.557 at sig.(2-tailed) = 0.000), quality concept and quality competitiveness (p value = . 656 at sig. (2- tailed) = 0.00). On the other hand there is a weak correlation between quality concept and cost of quality (p value = 0.022 at sig. (2- tailed) = 0.887), and a weak correlation between quality concept and cost of conformance and non conformance tracking (p value = 0.205 at sig. (2- tailed)= 0.172). These results show that the concept of quality and management commitment are well understood and clear for employees, but tracking and measuring the costs are not well adapted or understood. These findings may be logical if they will be matched with the third

part of the questionnaire, in which the cost reduction was among the least reasons that force companies to implement effective quality management systems and comply with international standards and regulations such as ISO or cGMP.

Benefits of quality and impact of quality on competitiveness have significant correlation between each others (p value = 0.430 at 0.01 level (2- tailed) = 0.003). Also, both of them have significant correlation with cost of conformance and non conformance tracking and quality concept at 0.01 levels (2- tailed).

Table (5.19): Correlation between the five variables:

	Quality Benefits	Quality and Competitiveness	Cost of Quality	COC & CONC	Quality Concept
Quality Benefits					
Pearson Correlation	1	.430**	.999	.436**	.557**
Sig. (2-tailed)	.	.003	.000	.002	.000
N	46	46	46	46	46
Quality and Competitiveness Pearson Correlation	.430**	1	.173	.314*	.656**
Sig. (2-tailed)	.003	.	.249	.033	.000
N	46	46	46	46	46
Cost of Quality					
Pearson Correlation	.000	.173	1	.016	.022
Sig. (2-tailed)	.999	.249	.	.915	.887
N	46	46	46	46	46
COC & CONC					
Pearson Correlation	.436**	.314*	.016	1	.205
Sig. (2-tailed)	.002	.033	.915	.	.172
N	46	46	46	46	46
Quality Concept					
Pearson Correlation	.557	.665	.022	.205	1
Sig. (2-tailed)	.000	.000	.887	.172	.
N	46	46	46	46	46

**. Correlation is significant at the 0.01 level (2-tailed).
*. Correlation is significant at the 0.05 level (2-tailed).

5.11 Findings of the Interviews

5.11.1 Findings of top management interviews.

The interviews with top managements of pharmaceuticals were focusing on the impact of quality on cost and competitiveness. All general managers believe that quality leads to cost reduction. Companies have statistics and figures proving the benefits of quality improvement. This includes, but not limited to, improving productivity, reducing defects, recall batches, rejected batches, and generating more sales and profits. Yet, they don't usually use these statistics as a strong point to continue improving quality or they don't deal with quality improvement as a power for cost reduction. However, the impact of quality improvement might not be clearly felt due to the small size of the Palestinian market. So, it was clear that top management don't take into consideration the impact of quality management systems on cost reduction. The data obtained from companies clearly show that there is a positive impact of quality improvement on cost reduction and improving competitiveness and these findings comply with the findings of the questionnaire. The following tables summarize some components of costs and how companies could reduce them through quality management systems implementations.

Table 5.20; Impact of quality in Company 1

Item	2000	2001	2002	2003	2004

Productivity (%)	+ 3%	+ 4%	+ 22%	+ 24%	+ 16
Rework Rate	-	12%	11%	7%	5%
Recall Batches		4	5	3	2
Rejected Batches		12	8	6	5
Actual Yield		93%	93%	92%	91%
Sales (%)	+ 7.14	- 6.67	+ 2.9	+ 33.33	

Table 5.21; Impact of quality in Company 2

Item	2000	2001	2002	2003	2004
Productivity (%)	88-90	90-92.5	90-94	>94	95-98
Defect Rate	10-12%	7-10	6-10	~6	2-5
Rework Rate	8	8	6	5	2
Recall Batches	4	0	0	0	1
Rejected Batches	2	0	0	0	0
Actual Yield	88-90	90-92.5	90-94	>94	95-98
Accountability	95	95	97	98.5	99.5
Sales (%)	+ 9.6	- 9.2	+ 33.1	+ 19.3	

Table 5.22; Impact of quality in Company 3

Item	2000	2001	2002	2003	2004
Productivity (%)			12+	19+	-6*
Defect Rate	1%	.55	1.3**	.11	1%
Rework Rate	NA				
Recall Batches	0	0	0	2	0
Rejected Batches	0	0	0	0	0
Actual Yield					
Accountability		96.1	96.6	94.4*	96.7
Sales (%)	- 0.06	+3.4	- 2.4	+ 28.04	NA

** because of removing production equipments to the new building buildings*
** Due to continuous curfew*

Table 5.23; Impact of quality in Company 4

Item	2000	2001	2002	2003	2004
Productivity (%)	+	- 3%	+ 13%	+ 1%	+ 2%
Defect Rate	3.99%	3.8 %	3.72 %	3.26%	2.96%
Rework Rate					
Recall Batches	-	-	-	-	-
Rejected Batches	5	10	2	2	5
Actual Yield	96.01%	96.20%	96.28%	96.73 %	97.04%
Accountability	98.01 %	98.2 %	98.6 %	99%	99.2%
Sales (%)	+ 6.7	- 11.9	+ 27.13	33.76	NA

Table (5.21): The % of non-conformance (Recalled) Batches (1982 – 2004)

	1982- 1985	1995	1996	1997	1998	2002	2003	2004
% of Recall Batches	40%	6.3%	14.8%	3.3%	2.2%	2.5%	2%	0.9%

Source: MOH, 2004

The previous tables show that there is general improvement in cost reduction and productivity improvement, but there are some differences in the results or percentages and types of improvements between the four companies. This depends on each company culture, policies, and costs calculation procedures. There are also, differences in sales improvement, which may related to type of products, sales and marketing policies, the differences in images of the companies.

When general managers were asked about reasons for investment in quality, there answers were generally similar. They are committed for improving quality in order to face the sever competition in local market and to meet requirements of expanding globally. One of the respondents said that "quality is a must", and what he meant by this is in order to compete specially in the global markets; companies have to get international standards and (GMP) certificates.

As mentioned in the introduction, none of the Palestinian pharmaceutical companies could achieve the GMP certificate. The GMP certificate is required by the majority of the world countries as a condition to allow for the flow for companies' pharmaceutical products. Getting GMP certificate will help companies to export and compete globally, or at least this certificate will help them export to neighboring Arab countries. About the reasons of not having GMP certificates tell now, the top managements mentioned many reasons such as:

- Non ending rules and requirements

- Lack of cooperation from external auditors

- Problems related to buildings

- Financial problems.

- Validation requirements are the most constraints. Validation is one of the most important requirements and requires huge investments in man, machines, buildings, and process. Validation simply is the establishment of documented evidence that a system does what it is supposed to do. Other definitions also exist, e.g. that given in the guidelines on GMP for pharmaceutical products. Unlike many other requirements of GMP, validation in itself does not improve processes, it can only confirm that the process has been properly developed and is under control. Ideally, any development activity in the later stages should be finalized by a validation phase.

- Lack of support and help from the Palestinian National Authority, specially, Ministry of Health and Ministry of National Economy. These responsible ministries didn't promote Palestinian pharmaceutical industry in the Arab countries, adding more to the difficulties of Palestinian pharmaceutical companies that do not have a Palestinian GMP to start with.

- All companies' buildings were established before trying to comply with GMP requirements. When managements of these companies decided to comply with the international standards and regulations, they had to redesign the buildings or build new buildings which required much more investment that consumed a lot of time and efforts.

When they were asked about the estimated time to get GMP certificate, the answers varied from two years to five years. Referring to the remaining

requirements for GMP certificate, all of them believe that they are implementing most of GMP requirements and there is no long gap to achieve the certificate. They believe that the major gap is the validation, and no one of these companies could achieve that.

5.11.2 Interviews with pharmaceutical industry Experts

The interviews with the experts focused on their assessments or evaluation of the Palestinian pharmaceutical industry situation related to quality. The feedback was generally positive. All interviewed experts believed that Palestinian pharmaceutical companies worked well on quality improvement and they have strong commitment for improving quality and getting the GMP certificate.

When the director of quality control and registration department in Ministry of Health was asked about the quality improvement levels of Palestinian pharmaceuticals, he answered that Palestinian pharmaceutical companies could positively improve the quality, and they passed a lot of important steps toward achieving the certificate of GMP, which will enable them to export to many countries all over the world. However, he believes that Palestinian pharmaceutical companies need more effort to achieve this goal. The major problem for pharmaceutical companies is the validation which is one of the main requirements for GMP certificate. When the director was asked about the reason of not offering Palestinian GMP, he answered that having a Palestinian GMP will not add advantage for Palestinian pharmaceutical companies, as, that majority of countries don't ask for national requirements certificate, and they focus on GMP as international standards and regulations.

Referring to the failed items or batches, the experts agree that the recall batches or items were sharply decreased (from the year 1982 to the year 2004) *,see table (5.20)*, as a result of quality improvement, and they believe that these failures cost companies a lot of money, and reducing the number of failed items has a positive impact on cost reduction. Moreover, experts believe that the percentage of products with conformance to international requirements is, in general, similar to that of multinational companies, with some exceptions. But, they believe that Palestinian pharmaceutical companies still have a long way to go before achieving the GMP certificate. According to the director of registration and quality control department in the Ministry of Health, the Palestinian pharmaceutical products are of good quality and equivalent to the best quality products of neighboring Arab countries, but the problem of not achieving GMP certificate is due to the fact that Palestinian pharmaceutical companies built their factories and started production (1969 – 1986) neglecting complying with standards, which means that buildings were not designed according to the requirements, so, when they started their journey toward getting GMP certificates, they had to make many changes on the buildings and they had to build new buildings to comply with the requirements which cost a lot of money and time. Moreover, the most critical stage of getting GMP is the Validation which is expensive and too complex to be achieved.

One of the interviewed persons believed that Palestinian pharmaceuticals have to invest in Human Resources through training programs and they have to be convinced that training is not a cost but rather a worthwhile.

The evaluation of the external ISO Auditor for the four companies was positive. He believes that the pharmaceutical companies could effectively improve their quality

which positively affects their competitiveness and productivity. The external auditor believes that the pharmaceutical sector could win many advantages of implementing ISO 9000:2000 and ISO 14000, especially that many of ISO requirements are also, required by GMP, so, pharmaceutical companies could save time, money and efforts to comply with GMP requirements and they could by pass these steps. Moreover, he believes that they could win more competitive advantages, especially, that having ISO certificate was a condition for companies to compete for tenders offered by NGOs like Care International. But, he believes that tracking costs of each item is a difficult process in pharmaceuticals, because the production process of each item takes many steps which makes tracking the cost of each step very complicated, so, pharmaceutical companies calculate the overall costs and productivity monthly, quarterly, or annually.

5.12 Conclusion

This chapter summarizes the general findings of the survey distributed, to supervisors and managers, and findings of interviews with top level managements of Palestinian pharmaceuticals and few experts. Since the questionnaire was divided into five parts, questions related to benefits of quality and impact of quality parts were planned to measure the validity of the hypotheses and the questions of the other parts were used to support the validity of the hypothesis. Finally, statistical analysis was conducting and hypotheses were tested.

CHAPTER SIX

Conclusions and Recommendations

6.1 Introduction

One of the basic assumptions about a quality system is that it is primarily a management function and secondarily a technical function. It would then follow that the senior management of an organization should play a leading role in the development of a quality system. If senior management recognizes that the quality system will provide real benefit to the organization and to management itself, and communicates this message to the staff, there is a greater likelihood that the quality system will be successful.

The role of senior management is one of the most significant factors in creating successful cultural change and policies. Employees can also become involved in the process and establish an emotional link with their responsibilities (London, 2005). As Hagen (1999) discussed, when employees become emotionally involved with their work, they will invest more to pursue excellence and the required targets and deal with quality improvement as a norm. Without this leadership, the process lacks direction and momentum and the resulting policies are largely ignored by those who do not have an investment in their success.

The implementation of quality management systems should be part of comprehensive strategic plans, and the cost benefit analysis of improving quality should be done to achieve optimal benefits of this implementation. Thus, tracking cost of conformance and cost of non-conformance is required to justify the journey of quality. Customer focus which leads to customer involvement in the quality improvement process will definitely lead to customer satisfaction and competitive advantage improvement.

To assess the perception of the above mentioned factors needed for successful quality management systems implementation, this study aimed to investigate the understanding of quality concept and management commitment for improving quality, cost of quality related to employees resistance, and then to investigate the impact of quality on both cost and competitiveness. The study was directed to managers and supervisors of four Palestinian pharmaceutical companies, Jordan chemical Laboratory- Beit Jala, Jerusalem pharmaceutical company- AlBereh, Birzeit pharmaceutical company- Birzeit / Ramallah, and Pharmacare- Ramallah. The study tried to do these investigations using a questionnaire composed of three parts. The main part for the investigation was part two, which was the likert scale. It included 58 statements to be later collected and classified into five variables, quality concept and management commitment for improving quality, Cost of quality related to employees resistance, quality cost tracking procedures, Benefits of quality, and finally impact of quality on competitiveness.

Part three of the questionnaire was designed to investigate the main reasons for pharmaceutical companies to seek implementing effective quality management systems and complying with international standards and regulations. This part was designed as ordinal scale, in which respondents were asked to rank the reasons of implementing effective quality management system according to their importance.

To gain more information about the pharmaceutical industry situation, interviews were conducted with many experts in the pharmaceutical industry. Interviews were also, conducted with top managements of the four targeted pharmaceutical companies to gain further information about the core subject of the study.

Finally, the study aimed to investigate the concept of quality management and how companies could benefit of implementing quality management systems regarding to cost and competitiveness. But the study didn't try to track every item of operation costs and how companies could improve the quality to reach minimum cost. This was because of lack of accurate data provided by companies and due to the fact that companies don't use cost of quality systems to track the cost in every step.

6.2 Conclusion

The study is a descriptive and the impact of quality on cost was investigated from the perspective of companies' manages and supervisors, and by using data from companies about some items that could companies improved through quality improvement. These items are scrap rate, rework, productivity, recall batches, rejected batches, defect rate, accountability, sales, and market share. These measurements were used before as indicators of impact of quality on cost or business performance by many researchers, like, (Deming, (1994); Imberman and DeForest (1995); Rowley and Sneyd, 1996; Leung, and Chan,(1999); etc..)

.

The conclusion would go over the main points illustrated in the previous chapters, by summarizing the foremost issues illustrating the concept of quality, management commitment for improving quality, and impact of quality on both cost and competitiveness. The following issues were investigated:

- The quality concept and management commitment for improving quality

- Cost of quality related to employees resistance
- Benefits of quality
- Cost of conformance and Cost of nonconformance concept
- Impact of quality on competitiveness.
- The reasons of seeking to implement effective quality management systems and complying with international standards and regulations.

The principle findings of the study include the following:

1. Quality offers organizations significant opportunities for improvement, including reduced costs, increased sales, better performance to schedule, and more satisfied customers. A successful quality system does more than ensuring the quality of products and services; it drives vigorous operations and leads to a healthy bottom line.
2. The concept of quality is well understood by the four pharmaceutical companies.
3. In general, the managements of the pharmaceutical companies are committed to improving quality, and the quality is taken seriously. More than 91% of respondents strongly agree or agree that quality improvement process is considered as important priority. The middle level managements are actively involved in the quality improvement. This was clear from respondents' answers to questionnaire, through the interviews, and through reviewing some publications about quality.

4. The cost of quality: Palestinian pharmaceutical companies can spend money on quality by investing in good quality or by paying for poor quality. Successful ones invest in good quality because they know it costs much less over the long run. Respondents agree that preventing failures can save more money than having poor quality. Generally, as the costs dedicated to achieving good quality increase, the costs of poor quality decrease.
5. The cost of quality related to employees' resistance: Manufacturing personnel believed that they would be overburdened with work and thus did their best to defeat the improvement scheme. While some managers were supportive in explaining the importance of the initiative, it was ineffective in assisting in implementation. This resistance was due in part to the lack of top management commitment, and also due to the lack of training and understanding of how the quality system would benefit the organization. People will accept or reject change depending on how the change will affect them. A strategy that convinces employees is needed to overcome this hurdle through emphasis on teamwork, brainstorming sessions, and consistent meetings. Employees' participation and cooperation in the improvement programs must be recognized and encouraged for effective implementation of the improvement program (Bhuiyan and Alam, 2005). This concept was not easy to be investigated. There was no clear direction for the related questions. This was clear from answering the three related statements in the questionnaire, in which

the number of respondents who answered (Neutral or nor agree neither disagree) were high. But in general, there are employees still believing that implementing effective quality management systems may increase time and reduce productivity, especially in documentation, auditing, and testing processes.

6. Benefits of quality: It was clear that implementing quality management systems and complying with international standards and regulations has many advantages and benefits for the company, such as, staff conflict reduction, waste time reduction, defects reduction, scrap rate reduction, reworks reduction, recall items reduction, improving productivity and efficiency, customer satisfaction and loyalty, increasing sales, and gaining more profits. Though research into the relationship between quality and profitability is inconclusive, proves that long-term investments in quality lead to greater profitability through increases in market share, greater productivity, and lower costs. Theses results are complying with many previous studies results in pharmaceutical industry and other industries, such as results obtained by (Rowley and Sneyd, 1996). An additional benefit to learning and applying quality practices is that, in doing so, employees gain valuable knowledge and skills desired by other quality-minded organizations in the job market, which leads to improving employees efficiency. The results of the study showed that majority of respondents agrees that their efficiency was improved by improving quality (Mean= 75.45).

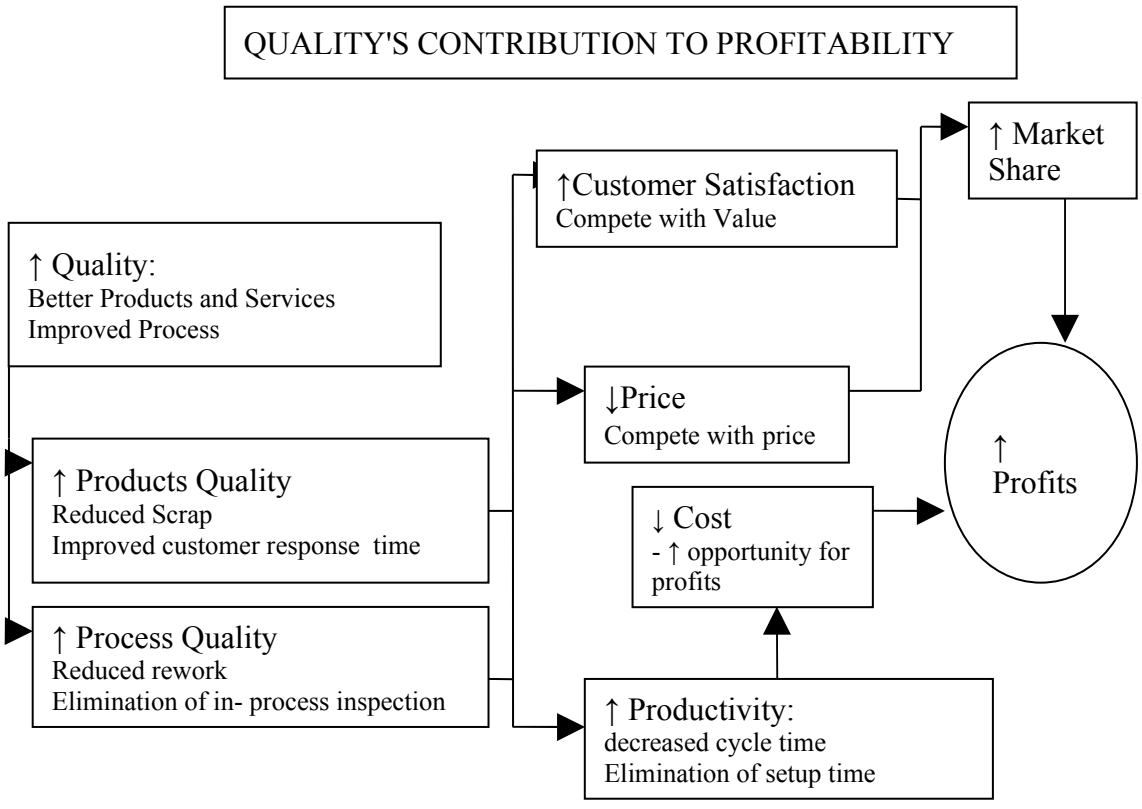
The historical data obtained from the four companies, show that, the positive impact of quality may not clear or significant especially in items related to costs, this may be due to two facts. First, companies are focusing on production and complying with international standards more than calculating the cost of conformance and non conformance. Second, companies are, in general, improving quality, through complying with international standards and producing according to international regulations, in order to improve their competitive advantages locally and globally, and to be able to export their products. According to competitive advantage improvement, the previous literature show that there is positive improvement of the companies' images, but tell now, the image about Palestinian pharmaceutical industry need a lot of efforts to be improved.

7. Quality improvement and Productivity Relationships: Perhaps the most important quality cost relationship is the one between quality and productivity. Productivity is the ratio of output to input, so any decrease in the amount of input needed to get the same amount of output increases productivity. Improving quality by reducing defects, scrap, and rework will increase good output and reduce inputs. In this study, it was clear that majority of respondents believes that improving quality has positive impact on productivity improvements (mean = 77.75). The overall benefits of quality management systems implementations were also approved by many studies. Lee, Leung, and Chan,(1999), conducted a survey about the impact of ISO 9000 certifications and they concluded that certified companies are able to derive a certain degree of benefits from the standard in construction, service and manufacturing firms as summarized in Table (6.1)

Table (6.1) Benefits of ISO certification

	Manufacturing	Service	Construction	All companies
Clearer Work Procedure	99%	95%	96 %	96%
Improved quality of product	88%	92 %	85 %	88%
Improved team spirit	89%	86%	63%	77%
Better control of subcontractors	73%	79%	68%	73%
Increased efficiency	68%	71%	58%	65 %
Less customer complaint	61%	73%	54%	62%

Source: Lee, Leung, *and* Chan,(1999)



Adapted from: *American Society for quality (quality 101)*

8. Quality cost tracking process (Cost of conformance and cost of non conformance) Concept: the price of conformance is the cost of training, testing, auditing, and documentation. But the price of non conformance or price of failure (external or internal), which includes the price of defects, scrap, rework, recall batches, less productivity and efficiency, and customer complaints and dissatisfaction which leads to customer loss. The price of non conformance includes cost increase and sales decrease, which leads to profit decrease.

Cost of Quality (COQ) = Price of Conformance (POC) + Price of Nonconformance (PONC).

The results showed that companies understand the concept of quality costing, but they didn't use effective quality costing systems, however, recently, three of the four companies started implementing a computerized system to measure availability, performance, and quality. This may help companies to track cost of conformance and non conformance. Companies started seriously focusing on training, documentation and inspection, which indicates that they concentrate on the cost of conformance. This means that managements know that preventing errors costs less than correcting them, and will have better returns than correction, but they don't use this fact to convince employees to operate efficiently. However, they don't try to build the relation between investment in quality and the return on this investment, or at least the study couldn’t establish the opposite of this finding. These results are similar to many results of literature who found that majority of companies don't track cost of quality. Sower, and Quarles, (2003), found that only about one third of

organizations in a sample of (2507 firms) systematically track quality costs. The principle reasons for not tracking COQ were identified as lack of management support or absence of management interest in tracking such costs, company economic conditions or status contributed to the lack of cost of quality tracking, Lack of knowledge of how to track the cost of quality and the benefits of a COQ program, lack of adequate accounting and computer systems necessary to track cost of quality, and finally, organizations did not see the benefit of COQ or that they needed to focus on areas which they perceive to be more important.

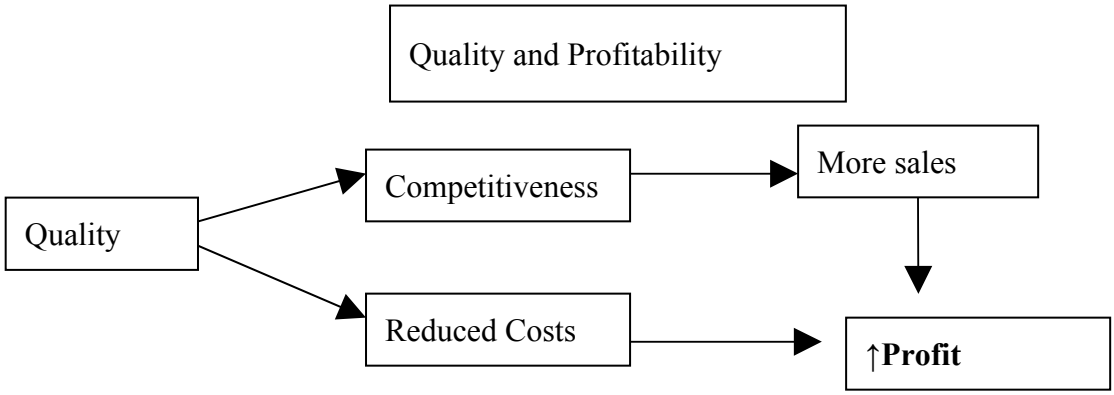
The results are similar to the data reported by Imberman and DeForest (1995) about tracking Cost of Poor Quality (CPQ) such as rework, scrap), and comparing these costs to industry profits. Nearly all firms have such costs, but they seldom collect them for an overall view. Eliminating cost is not easy. For any cost reduction to occur, the company must first gain control of processes. It was also; clear from the collected data that there are differences in getting benefits of quality between the four companies.

9. Impact of quality on competitiveness: the study results show that implementing quality management systems can effectively improve the competitive advantages of the companies, and also can push companies to look for better ways of satisfying customers, this comply with one of the most important principles of quality which is the customer focus. Marketing benefits of quality management include gaining new customers, keeping existing customers, using the standard as a promotional tool, increasing market share, increasing growth in sales and improving customer satisfaction were classified as top priorities for the companies.

10. Improving competitiveness and reducing costs will automatically increase sales and profits and this can be viewed in the following profit equation:

Profits = Sales – Expenses

By improving quality, sales will increase as a result of meeting customers' requirements which leads to customer satisfaction and gaining new customers. The cost reduction occurring as a result of quality improvement will reduce the total expenses. As sales increase and expenses decrease, profits will increase.



When respondents were asked to rank reasons of quality improvement, it was clear that facing sever competition locally or globally is the main stimulator for companies. But implementing quality management systems in order to manage and reduce operational or other costs was ranked as fifth of the six reasons, which means that companies don't track cost and benefit to check if investment in quality can have positive impact on cost reduction. So, companies emphasis on competitiveness as a key reason, which means that they are focusing on the first part of profit equation which is sales increase. This may be because (1) firms do not usually know what costs can be attributed to a lack of quality control process, and (2) firms usually focus on improving performance through increasing sales instead of reducing costs. But, if companies emphasis on the both parts, sales increase and expenses reduction, they can make better assessment of the impact of quality.

11. The results of the questionnaire and the interviews support that there is a positive impact of quality on cost reduction. The sharp decrease

of recall items or non conformed items clearly means that improvement of quality lead to decrease of failure which reduces costs. Improvement of productivity and efficiency and eliminating time, wastage, scrap, reworks, and defects also, reduce the costs.

12. The results, also, show that sales and market share of Palestinian pharmaceuticals are positively improved and there is an annual increase in sales and market share.
13. Customers' perception also, positively improved from 1998 to 2000 (Massar), which will help in improving Palestinian pharmaceuticals competitiveness.
14. Quality improvement and investments in implementing effective quality management systems are worthwhile. This is clear in the impact of quality and these results are obtained by many previous studies like, Leung, Chan, and Lee, (1999), who conducted a survey of some 500 ISO 9000 certified companies, has been carried out. Among them, more than 65 per cent believe that ISO 9001 certification is worthwhile, and more than 76 per cent believe that the cost of certification is inexpensive. They also found that concern for high costs is much less after initial certification.

6.3 Recommendations

Based on the findings of this study, the following practical and policy implications may be formulated for Palestinian Pharmaceuticals and Ministry of Health:

6.3.1 Practical Implications for Palestinian Pharmaceutical Companies:

- Quality improvement has a good impact on cost reduction and competitive improvements, these correlations may push companies to continue improving quality. Pharmaceutical companies can use the fact of benefits of quality as tools to convince their employees to improve quality of processes and products as self commitment for every employee and not because of the control process and to deal with documentations, auditing, and testing as improvement tools not as tools for control and punishments.
- Without superior quality, operational efficiency, or innovation, the only basis for international competition is price. This may allow companies to win some contracts or some sales in the private market, but in the long run their products will always be cheaper.
- It is strongly recommended that Palestinian pharmaceutical companies focus more and more on reaching international quality standards like GMP certificates. Having GMP certificates will enable companies to export to

Arab countries and other countries all over the world, which may help companies to expand and to use full capacity.

- To get GMP certificates, Palestinian pharmaceutical companies have to pass few important steps and one of the most important and critical steps is getting validations. To obtain validation, companies need to invest heavily in buildings, manpower, and equipments, which cost a lot of money. So, companies may act in two parallel plans, the first is increasing there market shares in local market which can generate better returns. Second, companies can plan for expanding globally and try to find potential markets for their products.
- Cost and Benefit of quality: By analyzing the cost and benefit of quality, companies can assess the effect of quality improvement on the cost, productivity, and performance. Cost of quality tracking system advantages were summarized by Bottorff, (1997) as follows:

    1. Quality data are more readily accepted because they are gathered and analyzed with the accounting department in a team environment. The quality cost data can be used in an effort to be proactive, and to identify causes of problems. It provides a methodology for pinpointing improvement priorities. Once the causes are resolved, the defects do not occur and failure costs decrease.
    2. The COQ system aids in the evaluation of capital investment alternatives.

3. The COQ system helps justify and steer investments in prevention activities, which lowers quality costs. It also helps justify and steer other quality improvement efforts and investments.
4. The COQ system leads to the development of a more advanced performance measure in the areas of customer satisfaction, production and design to better target indirect quality costs.
5. Return on investment and sales are improved while reducing costs.

Quality costing can be considered as a measurement of a company's performance with respect to the process by which a product is produced or a service delivered. The quality cost system concept can also, be applied to improve productivity. There is a need for an analytical framework that explains the relationship between quality cost components and quality. Once these relationships are defined and clearly understood, the ability of an organization to make decisions related to improving quality, reducing quality costs and increasing productivity will be substantially enhanced.

- Specialization: To reduce competition between Palestinian pharmaceuticals, each company can specialize in a small number of product lines which also, help companies to focus on certain products and innovate in producing and promoting these items.
- Palestinian companies have about 50% of the market share. Because they mainly, operate and produce for the local market they have opportunity to dominate the local market and increase their market share and percentage of coverage.

- International and / or local Partnership: This may help companies to compete and survive in the extreme global competition and this may help in investment in R&D.
- Investment in human resources: Companies need to invest more and more in employees by recruiting skillful staffs and training the existing staffs. The well qualified people can perform better and their productivity and efficiency can be improved; this also, will eliminate failure or non compliance. According to, McDonald, (2003), the costs associated with current Good Manufacturing Practices (cGMP) noncompliance is skyrocketing. Many of these noncompliance issues directly correlate to inadequate training. Firms need to focus on developing a training strategy to tackle cGMP non-compliance head on. An effective training strategy includes teaching the theory behind the practice, allowing for experience sharing during training, motivating learners to learn, allocating the appropriate amount of training time, creating a comfortable learning environment, choosing an effective trainer, and evaluating the learning experience. By implementing these elements into an effective training strategy, pharmaceutical firms can greatly reduce the risks and high costs associated with non compliance to GMPs.
- Employees' involvement in the quality improvement is critical and is a must in order to overcome any resistance for change and to enhance their commitment for improving quality and to understand that "Quality must be improved and cannot be controlled".
- Pharmaceutical companies have to convince customers that their products are high quality products and to promote themselves as producers of high

quality products or as producers according to international regulations and standards and they have to try changing local customer perception about quality level of Palestinian pharmaceuticals. This may be through coordination with MOH and/ or any other institutions, or through the UPPM. Changing local customers' perception is critical for companies to compete.

Changing customers' perceptions can be done in three levels of customers:

1. Doctors: They are the main target customers because doctors are the decision makers of selecting the medicine. Positive feedback of doctors about local pharmaceuticals can help in reputation and loyalty, leading to better prescription and more sales.
2. Pharmacists: they are important especially in selecting over the counter drugs (OTC) and many patients prefer consulting pharmacists and asking them for treatment without visiting doctors' clinics. In general, pharmacists believe that Palestinian pharmaceuticals can compete mainly in price and bonus, not in quality. So, it is recommended to change the sales policies and change the perception from bonus and price oriented to quality oriented.
3. End users: End users of medicine have minor roles in selecting medicine but some times they influence doctors to select items according to their origins, and according to Massar, (1997: 2000),(41%) patients prefer using foreign or Israeli medicine more than Palestinian drugs, for quality reason. If companies believe that they are producing according to international standards and their products' safety and efficacy are guaranteed, so, it is a challenge for Palestinian pharmaceutical companies to prove this and try to

change the perception which believes that Palestinian pharmaceuticals have lower quality than foreign and Israeli products.

6.3.2 Policy Implications for Palestinian Ministry of Health:

To help both customers getting effective, safe, and high quality medicine and to help pharmaceutical sector to continue improving quality which enables it to compete and survive, there are some policy implications for Ministry of health that could possibly be adopted.

- Promoting Palestinian pharmaceuticals, regionally and internationally, as good quality products may help companies to compete and gain revenues. The additional revenues may help companies to continue investing in quality improvement.
- The quality control department in MOH has to be reconstructed. This will help in having better controlled products.
- Establish a technology incubator for pharmaceutical R&D: Innovation creativity, competition and quality are challenges for pharmaceutical industry locally and globally to survive. So, technology incubator for pharmaceutical R&D will help to face these challenges.
- Establish a clear set of standards and regulations: This will help companies to implement these standards and regulations and to evaluate their situations and will also, help the sector to use the standards as corner stone for quality improvement.

- Create a regulatory agency which can be used as a competitive advantage: The regulatory agency may help in creating positive image of the Palestinian pharmaceutical sector, because customers will feel more confidence that the products are controlled by authorized regulatory agency, and the quality is ensured. This will help in competition and customer loyalty.
- Continue efforts to open new markets through fair trade agreements: this will help companies to realize growth plans which will consequently lead to decrease the total cost.
- Continue work to improve import/export abilities.

6.4. Recommendations to other studies

It is not easy to decide to implement Cost of Quality systems in organizations, especially pharmaceutical organizations, because they are concentrating on complying with international standards and regulations and aiming to increase sales and profits, which minimizes there interest in tracking cost of achieving good quality products and/ or tracking the cost of having poor quality products. Therefore, the first recommendation is to show the importance of implementing this process. Secondly, in this study it was apparent that impact of implementing effective quality management systems and complying with international regulations and standards was not easy to be investigated, because it requires many details either from the customer perspective, competitors' situation, or performance of employees, equipments, and the system as a whole. Thirdly, implementing effective quality management system is heavily dependent on the contribution of key people

concerned, senior management of the organization and their willingness to make it success, since this technique has strategic implications on the organization implementing such a system. Fourth, bringing this study to an end at this stage is a waste of time and effort, i.e. pursue the recommendations and strictly implement them; continuously improve the level of quality in Palestinian pharmaceuticals; and make quality improvement as a culture change agent and has to be gradually integrated as part of bigger umbrella of change, a total quality management program, which drives efficiency, effectiveness and continuous measurement for superior competitiveness. Fifth, this study investigated the correlation between quality and cost by using a questionnaire distributed to companies' managers and supervisors and interviews with the top level managements, so, it is recommended to search deeply in the items of costs that are affected by quality improvement. This may be done by tracking the cost per unit and assessing the changes of these costs to get more precise calculations and results.

Furthermore, it can be concluded that implementing quality management systems is a powerful tool in TQM and has been used in pharmaceutical manufacturing in many other countries.

6.5. Contribution to the theoretical knowledge

This survey is a pioneer study in the field of pharmaceutical industry in Palestine or may be in the Middle East. This study stressed the management commitment for improving quality, continuous improvement of employees' participation, impact of quality improvement on cost and competitiveness. The data are provided by middle

management research and analysis and the top management and other experts interviews. This study is considered a pioneer especially in the process of translating impact of quality from qualitative perceptions and understanding of employees in to quantitative measurements, where it would be precise to determine what exactly should be done to achieve the target of study, namely cost reduction and improving competitiveness in pharmaceutical industry.

6.6. Contribution to the practical knowledge

The study addressed a number of recommendations to both Palestinian Pharmaceutical Companies and the Palestinian Ministry of Health (the authorized institute to control pharmaceutical products' registration and quality in Palestine). For companies, the recommendations focused on how to improve the performance of their strategic and action plans to eventually achieve a level of customers' satisfaction, and to positively change customer perception about products' quality, which will definitely affect their competitiveness and share in the local market place. In addition to meeting their obligation towards the society when providing high quality products and to cover the local market needs. Moreover, the study recommended companies to continue their efforts toward achieving GMP certificates which enable them to export their products all over the world, and this will help them to compete in the global market and if they could export this will increase their production (mass production) and generate more profits. Finally, the study recommended companies to measure costs and benefits of quality which will justify companies to continue improving quality.

The recommendations for Ministry of Health were focused on how to help Palestinian pharmaceutical companies achieving international standards and regulation such as GMP, to promote Palestinian pharmaceuticals in Arabic countries and other global markets as high quality products and signing agreements with these countries to import Palestinian pharmaceuticals.

If both companies and Ministry of Health implement some or all these recommendations, it will be beneficial for companies' achievements, customer loyalty, and national economy.

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Appendices

Appendix - 1-

Questionnaire Covering letter

Dear Manager / Supervisor:

I am a student in the MBA program – Bir Zeit University and I am conducting a master thesis about the impact of quality management systems on cost and competitiveness in Palestinian pharmaceutical companies. The purpose of the study is to investigate the relationship between effective implementation of quality management systems (ISO 9000, ISO 14000, and GMP), cost and competitiveness, and to investigate whether the companies can benefit from having high quality products.

It would be highly appreciate, if you would please spend a little of your precious time and answer the following questionnaire, assuring you that all information provided will be treated with utmost confidence and will never be used for any other purpose than this research. I am sure that any provided information will be valuable and will enrich my research.

Thanking you in advance for your kind cooperation and assistance in completing this research.

Sincerely:

Ziyad Abu Rob

Bir Zeit University

Appendix – 2-

Questionnaire

PART ONE

1. Position
1) Manager 2) Supervisor
2. Department / Division
1) Production 2) Finance 3) Sales and Marketing 4) Quality Control/ Assurance 5) R& D 6) Others

PART TWO

Please choose the suitable score of each of the following statements:

1) Strongly Agree 2) Agree 3) Neither agree nor disagree 4) Disagree 5) Strongly Disagree

Statement	1	2	3	4	5
QUALITY CONCEPT AND ORGANIZATION COMMITMENT FOR QUALITY					
1- Employees in my department are adequately informed about the quality standards that apply to their jobs.	1	2	3	4	5
2- Employees in my department are adequately informed about the quality objectives of our department.	1	2	3	4	5
3- We have the technical and managerial skills necessary to measure the quality of work.	1	2	3	4	5
4- The quality improvement process is considered an important priority by Senior Management	1	2	3	4	5
5- The quality improvement process is considered an important priority b y Myself	1	2	3	4	5
6- The quality improvement process is considered an important priority b y My department employees	1	2	3	4	5
7- Too much emphasis is placed upon quality of work produced rather than its quantity.	1	2	3	4	5
8- Quality improvement is viewed as a long term commitment, not to be compromised by short- term financial goals.	1	2	3	4	5
9- My department's emphasis on quality has resulted in measurable improvement in our products and services	1	2	3	4	5
10- Management commitment to quality is apparent in what we do on day-to- day basis.	1	2	3	4	5
11- The top management and the middle level management are implementing programs and processes for quality improvement	1	2	3	4	5
12- The top management and the middle level management are providing tools and	1	2	3	4	5

resources required for quality improvement.					
13- The company feels more confidence that the company's products meet relevant regulatory requirements.	1	2	3	4	5
14- The company often sacrifices the quality of products in order to cut costs.	1	2	3	4	5
COST OF QUALITY					
ISO 9000, and 14000 certificates and complying with GMP requirements increase costs as follows.					
15- Operating according to ISO and GMP requirements force employees to spend a lot of time on documentation and inspection which can be used for production.	1	2	3	4	5
16- The continuous concentration on the rules and requirements of ISO and GMP, causes employees to feel inconvenience, which affects there productivity and performance.	1	2	3	4	5
17- Some employees feel that a lot of steps used according to standards are not necessary, and they some times resist doing them.	1	2	3	4	5
COST OF QUALITY TRACKING	1	2	3	4	5
18- The cost of poor quality in short- term are due to scrap rate, rework, defects, etc.	1	2	3	4	5
19- The cost of poor quality results in long- term loss of sales, customers, and competitive advantages.	1	2	3	4	5
20- The cost of not having good quality is much more than cost of having high quality (cost of quality)	1	2	3	4	5
21- The cost of failure correction is higher than failure prevention					
22- The management tracks cost of having good quality and bad quality					
23- The management continuously measures the cost of quality and return on quality					
24- The company concentrate on failure prevention more than failure treatment	1	2	3	4	5
25- The benefits of having high quality are more than costs of having high quality.	1	2	3	4	5

BENEFITS OF QUALITY					
The effective implementation ISO 9000 &14000 certificates and complying with GMP requirements leads to:					
26- Reducing staff conflicts	1	2	3	4	5
27- Enhancing more suggestions	1	2	3	4	5
28- Reducing wastage of materials	1	2	3	4	5
29- Shortening delivery lead time	1	2	3	4	5
30- Increasing employees efficiency	1	2	3	4	5
31- Increasing quantity of production (Productivity)	1	2	3	4	5
32- Reducing operational costs	1	2	3	4	5
33- Increasing profits	1	2	3	4	5
34- Achieving customer satisfaction and more competitive advantages which creates customer loyalty.	1	2	3	4	5
35- By focusing on investment on designing programs to prevent or reduce errors or failure, the company can reduce the costs of correction, leading to decrease cost of quality.	1	2	3	4	5
36- High Returns on investment due to quality improvement and international standards and regulations achievements justify the company to focus on achieving higher quality.	1	2	3	4	5

Statement					
IMPACT OF QUALITY ON COMPETITIVENESS					
37- The company understands how the product and service attributes fulfill basic customer needs.	1	2	3	4	5
38- The company furnishes clear and complete information to customers to ensure that customers formulate accurate expectations of products.	1	2	3	4	5
39- The company provides easy access to customers who seek assistance, wish to comment, or wish to complain.	1	2	3	4	5
40- The company proactively follows up with customers to seek feedback for improvement on products.	1	2	3	4	5
41- Improvements in the quality of the company's products over the past years have been translated into stronger customer loyalty.	1	2	3	4	5
42- The company regularly compares its customer satisfaction levels with those of competitors.	1	2	3	4	5
43- The company uses the comparative assessment of customer satisfaction levels in its continuous improvement process.	1	2	3	4	5
44- The company documents trends and current levels of customer satisfaction relative to competitors.	1	2	3	4	5
45- The company documents trends in gaining or losing customers from or to competitors.	1	2	3	4	5
46- The company documents trends in the market share of competitors.	1	2	3	4	5
	1	2	3	4	5
47- The company evaluates and improves its processes for determining customers' future requirements and expectations for current and future products.	1	2	3	4	5
48- Increasing sales with existing customers, as a result of customer loyalty	1	2	3	4	5
49- Improving quality helps gaining more new local customers	1	2	3	4	5
50- Improving quality leads to reducing customer complaints	1	2	3	4	5
51- . Improving quality enhances communication with customers	1	2	3	4	5
52- Improving quality making customers to feel more confident that they will receive products conforming to their requirements, which in turn results in higher customer satisfaction	1	2	3	4	5
53- By producing high quality products, the company image will be improved.	1	2	3	4	5
54- . Improving quality adds more competitive advantages.	1	2	3	4	5
55- By improving the quality, the company can effectively compete and can gain new customers	1	2	3	4	5
56- The company has established a good reputation of the quality of its products.	1	2	3	4	5
57- My department's emphasis on quality has resulted in measurable improvement in customer satisfaction	1	2	3	4	5

58- My department constantly looks for better ways to serve its customers.	1	2	3	4	5

PART THREE

Reasons for getting ISO 9000 and 14000 certificates and GMP requirements:
Please rank the reasons that forced the company to get ISO certificates and complying with GMP requirements according to the importance (number 1 is the most important and 6 is the least important)

Reason	Importance
Competition in the local market	
Competition in the global markets	
Cost Reduction	
Productivity and efficiency	
Recognition	
Customer Loyalty	

Appendix – 3-

Interview questions to the top management of Palestinian pharmaceutical companies.

- What is the most important reason for implementing quality management systems and producing according to international regulations (GMP):

Reason	Importance
Competition in the local market	
Competition in the global markets	
Cost Reduction	
Customer Loyalty	
Productivity and efficiency	
Recognition	
Exporting Requirements	

- Benefits of quality on operational costs:

Item	% decrease or increase
Defects reduction	
Productivity	
Time management improvement	
Rework	
Electrical consumption	
Water Consumption	
Employees performance (productivity and efficiency)	
Recall Batches before introducing to the market (internal failure)	
Recall Batches after introducing to the market (external failure)	

- Impact of quality improvement on sales and competitiveness:
- How can the company use the benefits of quality management as a competitive advantage?
- How does the top management involve employees in the quality management system?

- How does the company overcome employees' resistance for change?
- No Palestinian pharmaceutical company has achieved Good Manufacturing Practices certificate (GMP), why? And where is the gap?
- What is the estimated time to have GMP certificate?
- What are the most important reasons for not having Palestinian GMP?

Reason	Importance
Lack of experience and expertise	
Lack of knowledge	
Lack of needed budget	
Lack of control	
Benefits of complying with international requirements are better than complying with national requirements (in global market).	