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Assessment of TQM Application Using MBNQA Model
The Case of Palestinian Pharmaceutical Industry

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THESIS APPROVAL

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DECLARATION

I certify that this thesis submitted for the Master's degree in Quality Management is the result of my own research, except where otherwise acknowledged, and that this thesis (or any part of the same) has not been submitted for a higher degree to any other university or institution.

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ABSTRACT

The issue of quality in the pharmaceutical industry is of critical importance since this industry is among the most regulated ones. Hence, pharmaceutical companies are increasingly concerned with applying TQM principles. In this context, many studies confirm that this application affects many corporate variables including, among others, innovation and performance.

Therefore, this study aims to assess the level of TQM application in Palestinian pharmaceutical companies and investigate its effect on their organizational performance, considering the mediating role of organizational innovation. The quantitative hypotheses-testing research approach was adopted. The primary data are collected, through a personally administered questionnaire, from a purposive sample comprising 104 middle and top-level managers working in the five pharmaceutical companies in Palestine.

The questionnaire, which is built on the Malcolm Baldridge National Quality Award (MBNQA) framework, consists of five main parts: (1) respondents' characteristics, (2) companies' characteristics, (3) TQM application, (4) organizational innovation, as well as (5) organizational performance. Data are analyzed using descriptive statistics, including means and standard deviations, and the Partial Least Squares Structural Equation Modeling (PLS-SEM) technique.

The measurement model of the study reveals that the MBNQA framework proves to be a valid and reliable tool to investigate the effect of TQM application on the organizational performance in the Palestinian pharmaceutical companies via organizational innovation. The results also indicate that these companies have high perceived levels of TQM, organizational innovation, and organizational performance. In addition, the path analysis

confirms that TQM has a significant direct positive effect on organizational innovation and organizational performance. Organizational innovation also has a significant direct positive effect on organizational performance. Finally, it is found that the relationship between TQM and organizational performance is partially mediated by organizational innovation.

Last but not least, three main limitations to the study are worth discussing. First of all, this study is confined only to pharmaceutical companies, and hence its conclusions can not be generalized to other manufacturing companies. Second, this study is applied only to the five pharmaceutical companies operating in the West Bank and does not include the companies operating in Gaza Strip. Finally, the time sequence of the relationships between TQM, organizational innovation, and organizational performance is not determined because cross-sectional data are used instead of longitudinal.

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CHAPTER ONE

INTRODUCTION

1.1 Overview

This chapter introduces a general background of the study. The problem of the study is stated, its significance is highlighted, the objectives to be achieved are listed, the hypotheses are formulated, the conceptual model is developed, and finally, the thesis structure is outlined.

1.2 General Background

All organizations struggle to enhance their performance. To do so, particularly in increasingly dynamic and competitive markets, where customers are becoming more aware of quality issues, it is extremely critical for organizations, especially manufacturing ones, to adopt quality philosophies and strategies. A wide range of such philosophies and strategies have been discussed in the literature, including Total Quality Management (hereafter TQM), six-sigma, and lean manufacturing.

Organizational performance is affected by various independent variables, including, among other variables, TQM (e.g., Hussain et al., 2020; Singh et al., 2018; Sirisan et al., 2020). It is also established that the relationship between independent variables and organizational performance is mediated by other variables, such as organizational innovation (e.g., Hussain et al., 2020; Sirisan et al., 2020).

In Palestine, the pharmaceutical industry is among the most critical manufacturing industries since the companies in this industry provide nearly 55 percent of the local demand for pharmaceutical products (MAS, 2019). This is why this study is specifically

applied to the pharmaceutical industry in Palestine, where quality issues are of extreme importance.

Although some empirical studies investigated the impact of TQM on organizational performance, none of these studies, to the researcher's best knowledge, examined this relationship taking organizational innovation as a mediating variable, particularly in the Palestinian pharmaceutical context.

To this end, and to fill the above-mentioned knowledge gap, this study is carried out to assess the level of TQM application in the Palestinian pharmaceutical companies and then investigate its impact on their organizational performance, considering the mediating role of organizational innovation.

The study results are hoped to help the pharmaceutical companies in Palestine improve their application of TQM practices and enhance their organizational innovation to boost their organizational performance. This will help these companies strengthen their competitive advantage and thus succeed and survive over the long run.

1.3 Problem Statement

Pharmaceutical companies in Palestine face several challenges, including the inability to compete in the local, regional, and international markets, difficulties with the acquisition of raw materials, and limited marketing capabilities compared with Israeli and multinational companies (MAS 2019).

These challenges and many others make it critical for these companies to adopt modern management strategies such as TQM, among others, to improve their organizational performance. However, some researchers and practitioners emphasize that implementing TQM is no guarantee that companies will improve their organizational performance

unless some other mediating variables intervene in the TQM-performance relationship. Organizational innovation is one of these variables that may play a mediating role.

Therefore, it is a prerequisite to assess the levels of TQM application, organizational innovation, and organizational performance of pharmaceutical companies in Palestine. Then, the structural relationships between these three variables need to be formally investigated.

1.4 Significance of Study

This study derives its significance from the following main points:

1. This study is specifically applied, as opposed to other previous empirical studies, to the Palestinian pharmaceutical industry, which is getting increasing importance due to many factors, including, among others, the spread of the Coronavirus pandemic.
2. Due to increasing regulations and severe competition, improving both TQM and organizational innovation in pharmaceutical companies becomes crucial for their success and even survival in the long run.
3. Although some empirical studies assessed the levels of TQM application and organizational performance in different sectors in Palestine, only three of these studies used the well-known Malcolm Baldrige National Quality Award (hereafter MBNQA) framework (Baidoun et al., 2018; Sabella et al., 2014 and Sabella et al., 2015). To fill this gap, this study is mainly based on this globally-recognized framework.
4. Worldwide, many empirical studies examined the different relationships between TQM, organizational innovation, and organizational performance in manufacturing

companies (e.g., Sahoo, 2019 and Zeng et al., 2015). However, no studies investigated these relationships in Palestine, particularly in the pharmaceutical context. So, this study is carried out to bridge this gap and provide more empirical evidence, specifically in the Palestinian setting.

1.5 Objectives of Study

This study aims to assess the level of TQM application in the Palestinian pharmaceutical companies and investigate its effect on their organizational performance, considering the mediating role of organizational innovation.

The specific objectives of the study are listed below:

1. To assess the level of TQM application in the Palestinian pharmaceutical companies.
2. To assess the level of organizational innovation in the Palestinian pharmaceutical companies.
3. To investigate the effect of TQM on organizational innovation in Palestinian pharmaceutical companies.
4. To investigate the effect of organizational innovation on the organizational performance of Palestinian pharmaceutical companies.
5. To investigate the effect of TQM on the organizational performance in the Palestinian pharmaceutical companies.
6. To investigate the mediating effect of organizational innovation in the relationship between TQM and organizational performance in the Palestinian pharmaceutical companies.

1.6 Hypotheses Formulation and Conceptual Model

As mentioned previously, the study's main objective is to assess the level of TQM application in the Palestinian pharmaceutical companies and investigate its effect on their organizational performance, considering the mediating effect of organizational innovation.

Figure 1.1 depicts the study's conceptual model where TQM is hypothesized to have a significant positive effect on organizational innovation. In addition, organizational innovation is hypothesized to have a significant positive effect on organizational performance. Moreover, TQM is hypothesized to impact organizational performance positively. Finally, organizational innovation is hypothesized to mediate the relationship between TQM and organizational performance.

In this context, it is worth saying that six TQM dimensions are adopted from the MBNQA framework to measure TQM: (1) leadership, (2) strategic planning, (3) customer focus, (4) information and analysis, (5) human resource focus, and (6) process management. In addition, the other two dimensions, namely product innovation and process innovation, are used to measure organizational innovation. Finally, the business results dimension of the MBNQA framework is used to measure organizational performance. The measurement of these constructs is discussed in the Research Methodology chapter.

Accordingly, the following hypotheses are formulated to be tested:

H_1: There is a significant positive relationship between TQM and organizational innovation in Palestinian pharmaceutical companies.

H_2: There is a significant positive relationship between organizational innovation and organizational performance in the Palestinian pharmaceutical companies.

H_3: There is a significant positive relationship between TQM and organizational performance in Palestinian pharmaceutical companies.

The fourth hypothesis, which is not shown in the conceptual model of the study, investigates the indirect relationship between TQM and organizational performance in the Palestinian pharmaceutical companies through organizational innovation:

H_4: The relationship between TQM and organizational performance in the Palestinian pharmaceutical companies is mediated by organizational innovation.

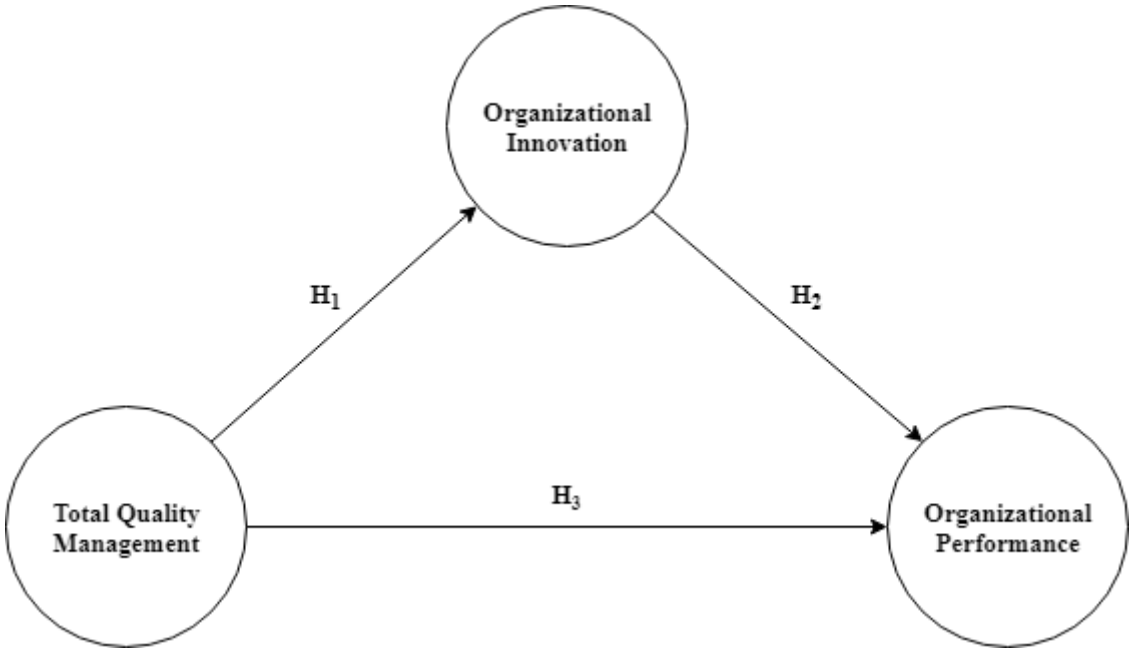

Figure 1.1: Conceptual Model of Study

1.7 Thesis Structure

This thesis is organized into the following five chapters:

Chapter One: Introduction

Sections covered in this chapter include a general background, the problem statement, the significance and objectives of the study, and hypotheses formulation and conceptual model.

Chapter Two: Literature Review

Sections covered in this chapter include total quality management, organizational innovation, organizational performance, an overview of Palestinian pharmaceutical industry, as well as previous empirical studies.

Chapter Three: Research Methodology

Sections covered in this chapter include the research approach, the population and sample of study, the data collection method, the research instrument, the data analysis techniques, and some ethical issues.

Chapter Four: Data Analysis and Discussion

Sections covered in this chapter include descriptive statistical analysis and inferential statistical analysis. The first includes respondents' characteristics, companies' characteristics, and assessment of total quality management, organizational innovation, and organizational performance. On the other hand, the second includes measurement model assessment, hypotheses testing, and structural model assessment.

Chapter Five: Conclusions and Recommendations

Sections covered in this chapter include conclusions and recommendations of the study, limitations of the study, and some directions for future researchers.

CHAPTER TWO

LITERATURE REVIEW

2.1 Overview

This chapter is devoted to reviewing the related literature. More specifically, TQM, organizational innovation, and organizational performance are all discussed. Then, an overview of the Palestinian pharmaceutical industry is given. Finally, the most relevant previous empirical studies are reviewed.

2.2 Total Quality Management

This section is devoted to discussing TQM, including its definition, importance, and measurement.

2.2.1 Concept of Total Quality Management

The concept of total quality management (TQM) is a complex one to define in a precise way since it represents a philosophy of overall organizational engagement in improving all aspects of quality (Allen, 2004). Though, TQM can be broadly defined as a quality improvement philosophy that is based on a holistic approach and requires active participation of all employees. There are several other definitions which are briefly reviewed below.

TQM is an integrated system that aims to manage the whole organization to surpass its competitors concerning the products or services significant to its customers (Bouranta et al., 2019; Mehta et al., 2019).

In addition, TQM is defined as an administration tool that leads to the constant improvement of products and services in an organization with ethics, systems, and procedures (Qasrawi et al., 2017).

Many researchers (e.g., Aladwan and Forrester, 2016; Giaccio, 2013; Weckenmann et al., 2015) view TQM as a management approach involving all activities and processes to achieve business excellence.

According to Dimyati et al. (2016), TQM is a method of managing an organization that aims to enhance its competitive advantage by continuously improving its goods or services, staff, procedures, and institutional environment.

In addition, Wibowo (2016) defines this concept as an organizational policy committed to continuously enhancing customer satisfaction by improving organizational processes.

Likewise, TQM is viewed as a management approach adopted to regularly improve an organization’s products, services, or processes by focusing on customer anticipations to increase customer satisfaction and thus enhance organizational performance (Sadikoglu and Olcay, 2014).

It also refers to the strategy and procedures that set the bases of a constantly improving organization (Krajewski et al., 2013). Also, TQM can be defined as a management philosophy that strives to strengthen organizational functions and procedures to meet customers' continuous wants better than its rivals do (Demirbag et al., 2006).

Finally, Kaynak (2003) summarized the definition of TQM by saying that it is a comprehensive management notion that aims to achieve continuous improvement in all organizational functions based on the philosophy of total quality from the purchase of resources to after-sale services.

In this study, TQM is operationally defined as all management strategies and practices that the Palestinian pharmaceutical companies apply to improve their products, employees, processes, and organizational environment to meet their customer needs better than their competitors do.

2.2.2 Importance of Total Quality Management

Many organizations strive to implement TQM as an essential approach to improve quality on an ongoing basis (Lazaros et al., 2017). In this section, the importance of implementing TQM is briefly reviewed.

According to Aydin and Kahraman (2019), TQM is the most extensively implemented strategy in organizations to achieve efficiency, improve quality, and increase customer satisfaction to have ideal international competition.

TQM is a management methodology for effectively carrying out organizational operations. Therefore, it leads to business excellence and improves organizational performance (Sweis et al., 2019).

Qasrawi et al. (2017) suggest that the long-run objective of properly implementing TQM practices involves guaranteeing enhanced customer satisfaction by continuously improving the quality of products or services via using resources efficiently.

Many academics and practitioners view TQM as a strategic management tool to enhance corporate performance through continuous improvement in corporate processes (e.g., Baig et al., 2018; Kim et al., 2012; Laosirihongthong et al., 2013; Zeng et al., 2015).

In addition to the above, it is argued that TQM, as a customer-focused philosophy, is a key driver of both organizational innovation and financial performance (Sousa and Madeira, 2016).

Soreshjany and Dehkordi (2014) stress that it is vital for an organization to apply TQM to create an environment of innovation and knowledge management that can produce quality products and services that satisfy customer needs and thus ensure corporate success.

Kim et al. (2012) and Zeng et al. (2015) summarize the importance of properly implementing TQM by emphasizing that it is related to improving organizational performance (operationally and financially) and creating a long-lasting competitive advantage over competitors.

In addition, Habtay (2012) says that TQM improves core capabilities which sequentially help organizations create innovative structures that eventually deliver solutions to their exceptional problems.

According to Loke et al. (2012), TQM results in better knowledge management capabilities and enhanced organizational learning, which yields improved organizational performance operationally and financially (Ghadiri et al., 2013).

Sako (2012) confirms that TQM has five main benefits: (1) restructuring work innovatively, (2) changing management behavior, (3) introducing innovation in business policies, (4) creating a flexible organizational structure, and eventually (5) improving corporate performance.

Finally, Demirbag et al. (2006) emphasize that TQM is a crucial variable that outlines organizational success by ensuring continuity in increasingly competitive markets.

2.2.3 Business Quality Models

A comprehensive review of previous literature indicates that TQM is a multidimensional variable with no consensus on its dimensions. However, several business quality models

provide an essential framework for organizations to apply TQM successfully. The three most widely well-known and used of these models are (1) Deming Prize, (2) Malcolm Baldrige National Quality Award (MBNQA) Model, and (3) European Foundation for Quality Management (EFQM) Model (Carvalho et al., 2019). Each of these models is briefly discussed in the following sections.

2.2.3.1 The Deming Prize

Being the first universally recognized business quality model, the Deming Prize was developed in 1951 by the Union of Japanese Scientists and Engineers (Agrawal, 2019). The prize is granted to organizations that achieve steady improvements in TQM and profits. Firstly, the award was open to Japanese organizations only, and from 1985 and afterward, it was available to organizations from all over the world (Rajashekharaiah, 2014).

The Deming Prize involves three separate steps. First, an organization is required to have customer-oriented goals and strategies, considering social responsibility. Second, TQM is required to be applied appropriately to attain the goals. Finally, and as a consequence of applying the first and second steps, the organization is required to have the potential for future growth. Therefore, the first step is about "formation of policies," the second is about "implementation of TQM," and the third is about "results." Each of these three steps has a score of 100 points, with a total of 300 points. The organization must get a minimum of 70 points in each of the three steps to be eligible to get the prize.

The Deming Prize consists of ten areas: (1) policy, (2) organization and operations, (3) collecting and using data, (4) analysis, (5) planning for the future, (6) education and training, (7) quality assurance, (8) quality effects, (9) standardization, and (10) control.

Finally, it is worth saying that the Deming Prize model is a TQM model, contrary to the MBNQA model and the EFQM model, which are regarded as business excellence models rather than TQM models.

2.2.3.2 The MBNQA Model

Suggested by the Congress of the United States in 1987 to increase awareness of quality, the Malcolm Baldrige National Quality Award (MBNQA) is granted every year to organizations that strive to improve quality and achieve business excellence. This award covers hard and soft elements of TQM (American Society of Quality, 2018).

This MBNQA framework (Figure 2.1) consists of seven main dimensions: (1) leadership, (2) strategic planning, (3) customer focus, (4) information and analysis, (5) human resource focus, (6) process management, and (7) business results (Prybutok et al., 2011). Each of these dimensions is briefly discussed below.

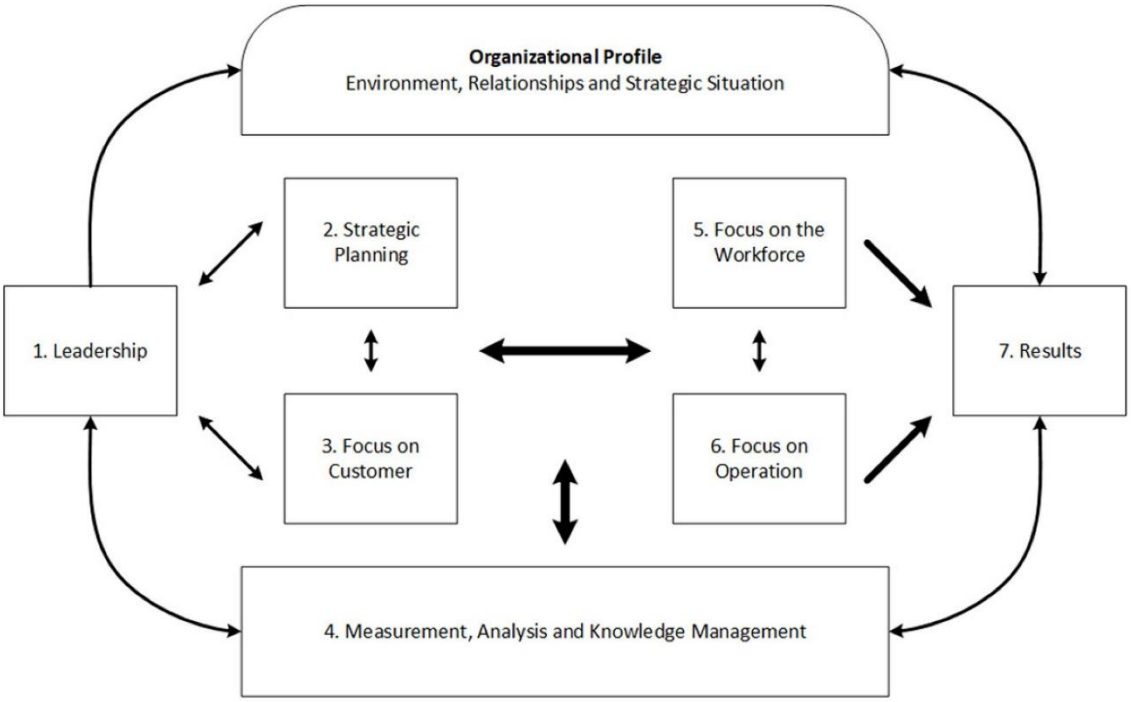

Figure 2.1: Malcolm Baldrige National Quality Award Framework

But before discussing each of the seven dimensions, it is worth saying that this model is based on eleven core values: (1) visionary leadership, (2) systems perspective, (3) customer-centered excellence, (4) valuing people, (5) organizational learning and agility, (6) focus on success, (7) managing for innovation, (8) management by fact, (9) societal contributions, (10) ethics and transparency, and (11) delivering value and results.

Dimension 1: Leadership

Leadership, one of the main constituents of TQM practices, refers to how senior management directs the organization, exercises its responsibilities to the general public, and demonstrates good citizenship. This dimension has broadly been recognized by academics, researchers, and practitioners because of its importance in successfully implementing TQM (Abbas et al., 2014; Donate and Sanchez de Pablo, 2015).

It has a significant positive effect on employees and organizational performance and positively impacts other stakeholders, including, among others, customers and suppliers (Gorski, 2017).

In addition, it is argued that knowledge-focused leadership is more likely to enhance their organization's innovation, that eventually leads to improved organizational performance (Donate and Sanchez de Pablo, 2015).

Dimension 2: Strategic Planning

As one of the core dimensions of TQM, strategic planning refers to how the organization determines its strategic guidelines and sets action plans. This dimension plays a significant role in quality management. Thus, energetic organizations constantly review and adjust their strategies based on changing market requirements (Yusr et al., 2017).

In dynamic and competitive markets, an efficient, market-oriented strategy enables an organization to compete and be the market leader (Abbas and Sagsan, 2019). Hence, particularly in this age of knowledge-based economies, organizations need to draft inclusive strategies and use these strategies as driving engines (Tang, 2015).

Additionally, strategic planning guides organizations in the resource management process. It also aids organizations in developing relationships with stakeholders to ensure operational sustainability, active decision-making, and profitability (Sztangret, 2016).

Dimension 3: Customer Focus

As a critical dimension of TQM, customer focus refers to how the organization deals with customers' and markets' anticipations. In this context, it is essential to say that dynamic markets and substitute availability have recently increased competition among organizations since customers have extra options. In addition, business environments have boosted customers' requirements and anticipations from organizations.

Thus, customer-focused organizations gather customer data and use it in strategy drafting, improving their processes, and taking necessary actions to meet and exceed their customers' needs (Guilbault, 2018). In this regard, customer dissatisfaction is different if the projected and perceived quality levels of products and services are different (Shabbir, 2020).

Accordingly, the key objective of customer focus is to add value for customers and thus enhance their satisfaction by meeting their current and future needs. To do so, the data obtained from customers must be communicated to other employees to make unique products so that performance is improved and a competitive advantage is created (Shabbir et al., 2015).

Dimension 4: Information and Analysis

In TQM implementation, the dimension of information and analysis refers to how organizations obtain and analyze information to support the decision-making process. Organizations need to make numerous decisions every day, and making correct decisions mainly depends on the availability and analysis of information (Ooi, 2014).

Organizations that get the correct information at the right time are expected to be more successful than others. The reason is that organizations that invest in IT are more likely to have more innovation, efficient operations, enhanced employees' performance, satisfied customers, and increased profits (Abbas et al., 2014; Yusret al., 2017).

Successful organizations are more dynamic in gathering information and making appropriate analyses. Numerous organizations take advantage of customer relationship management systems to get information about their customers (Barao et al., 2017) and communicate the information with various departments to develop new products and services by considering customers' requirements.

Dimension 5: Human Resource Focus

As a dimension of TQM, human resource focus refers to how organizations empower human resources to reach full potential and how these resources are consistent with organizational objectives.

Energetic organizations consider human resources as their most valuable assets. Thus, they develop their competencies by training them, engaging them in decision-making, and inspiring them to be more innovative and creative (Al-Busaidi and Olfman, 2017).

Dimension 6: Process Management

As a construct of TQM, process management refers to how organizational processes are designed, managed, and improved. It emphasizes operational activities through which the final product or service is provided. It aims, among other things, to add value to processes, increase productivity, decrease operating cost and cycle-time, and improve the quality of organizational operations (Yusr et al., 2017).

Dimension 7: Business Results

The dimension of business results refers to how the organization performs in its key business areas: (1) customer satisfaction, (2) financial and market performance, (3) human resources, suppliers, and partners performance, and (4) operational performance. It also deals with how the organization performs compared with its rivals.

2.2.3.3 The EFQM Model

The European Business Excellence Award, established by the European Foundation for Quality Management (EFQM) in 1992, is the business quality award granted across Europe. The EFQM model is acknowledged as an international structure that assists organizations in managing change and improving their organizational performance.

The EFQM 2013 model, shown in Figure 2.2, consists of nine dimensions classified into the two categories of enablers and results. The first category includes five dimensions: (1) leadership, (2) strategy and planning, (3) people, (4) partnership and resources, and (5) processes, products, and services. On the other hand, the second category includes four dimensions: (1) customer results, (2) people results, (3) society results, and (4) key results.

In 2019, The European Foundation for Quality Management introduced EFQM 2020 model, which is shown in Figure 2.3. This model consists of three major dimensions: (1) direction (i.e., why), (2) execution (i.e., how), and (3) results (i.e., what).

The first dimension consists of two subdimensions: (1) purpose, vision, and strategy, and (2) organizational culture and leadership. The second dimension consists of three subdimensions: (1) driving performance and transformation, (2) creating sustainable value, and (3) engaging stakeholders. Finally, the third dimension consists of two subdimensions: (1) stakeholders' perceptions and (2) strategic and operational performance.

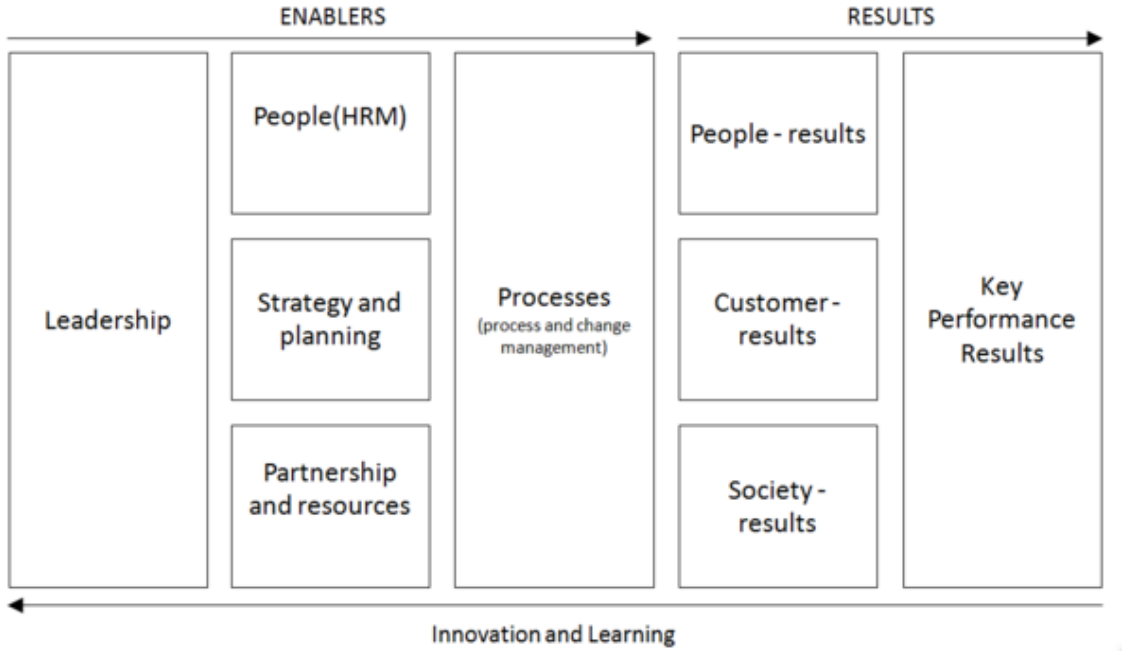

Figure 2.2: European Foundation for Quality Management Model 2013

In this study, six dimensions are adopted from the Malcolm Baldrige National Quality Award (MBNQA) framework to measure the level of TQM application in Palestinian pharmaceutical companies. These dimensions are (1) leadership, (2) strategic planning, (3) customer focus, (4) information and analysis, (5) human resource focus, and (6)

process management. The operationalization of these dimensions is discussed in Chapter Three.

The MBNQA framework is specifically selected to measure TQM since it has been extensively recognized as one of the most important quality models worldwide (Carvalho et al., 2019; Bandyopadhyay and Leonard, 2016; Zgodavova et al., 2017). This is why several researchers used this framework in their studies (e.g. Abbas, 2020; Ooi, 2014; Yusr et al., 2017).

Figure 2.3: European Foundation for Quality Management Model 2020

2.3 Organizational Innovation

This section is devoted to discussing organizational innovation, including its definition, importance, and measurement.

2.3.1 Concept of Organizational Innovation

Generally speaking, organizations introducing and implementing new ideas and procedures can be described as having organizational innovation. However, there is no specific definition of organizational innovation upon which researchers and practitioners agree. Some of the definitions of this concept are provided below.

First, Ferreira et al. (2020) define organizational innovation as complicated actions that lead to producing and adopting novel ideas that create products, services, or business processes.

Similarly, organizational innovation is the capability of an organization to combine and manage available resources to generate a set of new products and services (Ganguly et al., 2020).

Lumpkin and Dess (2015) provide the same definition. They say that organizational innovation refers to assembling resources and skills and moving them towards creating developed business processes or offering novel products and services.

In addition, Mansoori et al. (2013) define organizational innovation by saying that it is the capability to convert knowledge and ideas into novel products or services, procedures, and systems for the organization's advantage and its stakeholders.

According to Kim et al. (2012), organizational innovation refers to applying novel knowledge, policies, or procedures that produce new competencies and increase the competitive sustainability of organizations.

Moreover, Hogan et al. (2011) explain the nature of organizational innovation by saying that it is a continuous process that aims to improve the capacities and resources of an organization by discovering and making use of product and process development opportunities to satisfy customer wants.

Chen (2009) views organizational innovation as the different abilities embedded in an organization's activities, procedures, and structures that can be used in product and process improvement.

Xu et al. (2008) define organizational innovation as an organization's capability to develop and apply state-of-the-art technologies to produce new products and services that compete in the marketplace. Finally, business innovativeness refers to novel approaches and strategies implemented by organizations to achieve long-term sustainable competitive advantage (Kenedy 2007).

In this study, organizational innovation is operationally defined as the set of policies, activities, and procedures, typically in research and development units, that aim to utilize available resources in the Palestinian pharmaceutical companies to generate new products or processes or develop existing ones.

2.3.2 Importance of Organizational Innovation

Organizations strive to be more innovative, particularly in increasingly dynamic environments and severely competitive markets. Some of the benefits generated from organizational innovation are briefly reviewed below.

But before discussing the importance of organizational innovation, it is necessary to stress that pharmaceutical companies' research and development (R&D) departments are directly involved in organizational innovation. These departments play a significant role in enhancing innovation through two primary mechanisms: (1) they strengthen absorptive capacity to build on externally generated sciences, and (2) they directly enhance innovation using internally generated sciences (Leten et al., 2021).

According to Kijkasiwat and Phuensane (2020), organizational innovation, mainly product and process innovation, is recognized as one of the important drivers of corporate performance.

Antunes et al. (2017) explain that organizational innovation has a positive effect on the performance of organizations, provided that all units in these companies sufficiently support it. Similarly, Kim et al. (2012) say that innovation is a key tool that provides new products and processes which add additional value for customers and thus generate more profits for organizations.

In addition, many academics and researchers emphasize that organizational innovation is one of the key sources of creating competitive advantage (e.g., Aas and Breuning, 2017; Anwar, 2018; Augusto et al., 2014; Conto et al., 2016).

Organizational innovation is also critical for organizations to achieve business excellence, enhancing their competitive positions against their rivals (Juneja et al., 2011; Karani and Bichanga, 2012).

Finally, it is argued that organizational innovation paves the way for developing a range of important capabilities that improve the efficiency of companies and offer solutions to their critical problems (Damanpour et al., 2009).

2.3.3 Measurement of Organizational Innovation

Like many other management concepts, organizational innovation is a multidimensional variable with no consensus on its measurement. Below is a brief review of the most important dimensions making up this variable.

Two main dimensions are suggested to measure organizational innovation: (1) product innovation, and (2) process innovation (Lei et al., 2019; Najafi-Tavani et al., 2018). In this regard, the former is how companies can provide new products and services or improve existing ones to meet customer wants (Aljanabi, 2020; Najafi-Tavani et al., 2018). On the other hand, the latter is how companies can improve the processes and techniques used to provide these products and services (Aljanabi, 2020).

Some academics and researchers classify organizational innovation into four categories: (1) product innovation, (2) process innovation, (3) managerial innovation, and (4) marketing innovation (e.g., Lee and Hsieh, 2010; Mansoori et al., 2013).

Moreover, Kim et al. (2012) identify five crucial dimensions of innovation: (1) incremental product, (2) incremental process, (3) radical product, (4) radical process, and (5) administrative innovation. In this regard, incremental innovation refers to additional improvements made to current products or processes to satisfy the wants of existing customers. On the other hand, radical innovation is related to applying new technologies to generate new demand. Finally, administrative innovation is linked to internal structures and operations.

Marques and Ferreira (2009) propose four main components of innovation: (1) product innovation, (2) process innovation, (3) market innovation, and (4) organizational innovation.

Finally, Liao et al. (2007) view organizational innovation as a multidimensional variable consisting of three major constituents: (1) product innovation, (2) process innovation, and (3) managerial innovation.

This study measures organizational innovation in the Palestinian pharmaceutical companies using seven items adapted from Calantone et al. (2002) and Prajogo and Sohal (2006). The operationalization of this variable is discussed in Chapter Three.

2.4 Organizational Performance

This section discusses organizational performance, including its definition and measurement.

2.4.1 Concept of Organizational Performance

Generally, organizations assess their performance by comparing premeditated objectives with actual outcomes. Therefore, organizational performance arises as a management concept that academics and practitioners have agreed on its importance in determining organizational results (Rehman et al., 2019; Wang et al., 2020). Yet, there is no consensus on its definition or its measurement. Some of the definitions of this concept are provided below.

First, organizational performance can be defined as the sum of the accomplishments achieved by all units in an organization during a specific period (Kamau and Wanyoike, 2019).

Moreover, Zhou et al. (2019) describe the organizational performance as a comprehensive system that measures and analyzes organizational results so that related parties can easily identify any deficiencies.

Ali et al. (2019) perceive organizational performance as the output resulting from transforming different resources to realize organizational goals. Thus, it is the output of its members in terms of revenues, profits, development, and growth.

According to Muthuveloo et al. (2017), organizational performance is how an organization can realize its predetermined goals by using its scarce resources effectively and efficiently. Similarly, Uluskan et al. (2017) define organizational performance as the result of organizational operations or the attainment of organizational objectives.

Organizational performance is also defined as a measurement tool used to evaluate the organizational success in adding and delivering value to various stakeholders of the organization (Antony and Bhattacharyya, 2010).

In addition to the previous definitions, Richard et al. (2009) view organizational performance as a measure that identifies how well an organization attains its planned goals. In short, it is actual output compared to projected output.

In this study, organizational performance is operationally defined as the extent to which Palestinian pharmaceutical companies can achieve their predetermined goals by adding and delivering value to their stakeholders.

2.4.2 Measurement of Organizational Performance

All organizations –small or large, public or private, NGOs or profit-making, service or manufacturing– need to measure their performance level. This is because unless it is measured, it can not be improved. However, there is no consensus on the conceptualization of organizational performance (Scott and Davis, 2015). Therefore, different perspectives, including the accounting, the balanced scorecard, and the strategic

ones, are used to measure it. Below is a brief discussion of measuring organizational performance.

First, Sirisan and Pianthong (2017) used three dimensions to measure organizational performance while investigating the relationship between TQM and organizational performance: (1) business results, (2) product quality, and (3) innovational performance.

On the other hand, Kunze et al. (2013) measured organizational performance using four main dimensions: (1) financial indicators, (2) organization growth, (3) staff productivity, and (4) staff retention.

Some academics and researchers, particularly in the health care context, used the business results dimension of the Malcolm Baldridge National Quality Award (MBNQA) framework to measure organizational performance (e.g., Souza and Sequeira, 2019; Wiguna, 2018).

In addition, Zakuan et al. (2010) used three dimensions to assess the level of organizational performance: (1) staff satisfaction, (2) customer satisfaction, and (3) business results (e.g., productivity, new products, cost, and profits).

According to Richard et al. (2009), organizational performance is a multidimensional construct. It consists of financial performance, customer-linked performance, innovational performance, and internal processes performance.

Rizov and Croucher (2009) measured organizational performance using an index made of five subjective dimensions: (1) quality, (2) productivity, (3) profitability, (4) product-to-market time, and (5) innovation.

In 1992, Kaplan and Norton proposed a multidimensional performance measurement system called the balanced scorecard (BSC). Four perspectives are used to measure

performance according to this system: (1) the financial perspective (i.e., how do our shareholders perceive us?), (2) the customers' perspective (i.e., how do our customers perceive us?), (3) the internal processes' perspective (i.e., what should we excel at?), and finally (4) the learning and growth perspective (i.e., are we continuing to improve and create value?) (Kaplan, 2010).

In this study, the business results dimension of the Malcolm Baldrige National Quality Award (MBNQA) framework is used to measure organizational performance in Palestinian pharmaceutical companies. This dimension is specifically used since it is the most important strategic perspective used to measure organizational performance, particularly manufacturing companies. The operationalization of this variable is discussed in Chapter Three.

2.5 Overview of Pharmaceutical Industry in Palestine

The Palestinian pharmaceutical industry dates back to 1969, when the first pharmaceutical company was established. Since then, the industry has witnessed considerable growth and development compared to other Arab countries. Yet, the Palestinian pharmaceutical industry is still at an emerging stage.

Currently, five pharmaceutical companies are operating in Palestine. Half of these companies are in Ramallah (namely Birzeit Pharmaceutical Company, Jerusalem Pharmaceutical Company, and Pharmacare Pharmaceutical Company). One company is located in Beit Jala (Beit Jala Pharmaceutical Company), another was recently established in Nablus (Sama Pharmaceuticals Manufacturing Company), and one is situated in Gaza Strip.

Despite the relatively low contribution of these pharmaceutical companies to the Palestinian economy in terms of many economic indicators such as production, exports, and employment, supporting these companies is critical to achieving drug security. This is particularly important if we know that these companies provide nearly 64 percent of the total quantity of drugs available in the Palestinian territory (MAS, 2019).

Despite the restrictions imposed by the Israeli occupation, pharmaceutical companies have achieved good results. For example, drug production increased by 3.45 percent between 2013 and 2016. In addition, these companies reported a total of $14 million of profits in 2016 (MAS, 2019).

In this context, it is worth saying that several challenges are encountering pharmaceutical companies operating in Palestine. First, these companies only manufacture certain types of traditional (general) and not complicated drugs, which weakens their ability to compete in the local, regional, and international markets. Second, Palestinian pharmaceutical companies face severe competition, mainly from Israeli and foreign companies. Third, local pharmaceutical companies have difficulties acquiring raw materials, including chemicals, due to restrictions imposed by Israel. Last but not least, pharmaceutical companies in Palestine have limited marketing capabilities compared with Israeli and multinational companies.

Regardless of the above challenges, this industry has many prospects. First, the steady increase in the population growth rate in Palestine indicates that the local demand for drugs will also increase. Second, the steady increase in the population growth rate in most Arab countries opens the opportunity to export drugs to these countries. Third, many Pharmaceutical companies in Palestine have been granted international quality

certificates, which means that drug exports to the USA and some European countries are expected to increase in the coming years. Finally, pharmaceutical companies in Palestine are increasingly becoming aware of the need to make alliances with Arab, regional, and international companies to diversify pharmaceutical products, increase exports, and open new markets for Palestinian pharmaceutical products.

Finally, it is worth mentioning that the Palestinian Ministry of Health, namely the General Administration of Pharmacy Drug Control and Registration Department, has adopted the Good Manufacturing Practices (GMP) Inspection Checklist. This checklist is provided in Appendix B.

2.6 Previous Empirical Studies

Many previous empirical studies investigated the potential impact of TQM on organizational performance. Some of these studies included organizational innovation as a mediating variable. Below is a review of the most relevant of these studies, arranged from the most to the least recent.

In Pakistan, Najmi et al. (2021) assessed the level of total quality management (TQM) in the pharmaceutical companies and examined its impact on their performance. The quantitative research approach was used whereby primary data were gathered via a self-managed questionnaire. Among the 350 questionnaires distributed, 301 were returned and used in data analysis. The collected data were analyzed using partial least squares structural equation modelling (PLS-SEM).

The main result of path analysis confirms that the application of TQM dimensions has a significant positive impact on the overall performance of pharmaceutical companies in the country.

In Taiwan, Sirisan et al. (2020) examined the effect of TQM on the organizational performance of electric and electronic companies, considering organizational innovation as a mediating variable. The quantitative hypothesis-testing approach was employed. Primary data were collected through a fully-structured questionnaire using proportional stratified sampling from 899 managers. Data were mainly analyzed using the structural equation modeling (SEM) technique.

The results of path analysis confirmed that TQM has a significant positive effect on organizational performance. In addition, the results proved the existence of a significant positive relationship between TQM and organizational innovation. Also, organizational innovation is found to have a significant positive effect on organizational performance. Finally, the results showed that the relationship between TQM and organizational performance is mediated by organizational innovation.

In Pakistan, Hussain et al. (2020) examined the impact of TQM on SMEs' performance, considering the mediating effect of both organizational innovation and knowledge management. To achieve this objective, the quantitative hypothesis-testing research approach was employed. The primary data were collected, via a questionnaire, from 280 SMEs using the simple random sampling technique. The structural equation modeling (SEM) technique was used as a main data analysis tool.

The results of path analysis confirmed that TQM has a significant positive effect on SMEs' performance. Also, the results proved that TQM has a significant positive effect on organizational innovation. Moreover, it was found that organizational innovation has a significant positive effect on SME's performance. Finally, the results established that

organizational innovation mediates the relationship between TQM and SMEs' performance.

In Indonesia, Suhendah and Brigita (2020) investigated the impact of TQM and entrepreneurial orientation on companies producing crude palm oil performance, considering the mediating role of innovation. The quantitative hypothesis-testing research approach was employed. Using the non-probability quota sampling procedure, the primary data were collected from eight companies, and the data were analyzed using the structural equation modeling (SEM) technique.

The study results indicated that TQM has no significant impact on organizational performance, contrary to what is expected. However, it was found that TQM has a significant positive effect on organizational innovation. Moreover, organizational innovation is proved to have a significant positive effect on organizational performance. Finally, TQM has an indirect positive impact on organizational performance through the mediating effect of organizational innovation.

In India, Sharma and Modgil (2020) examined the effect of total quality management and supply chain management on operational performance in the pharmaceutical sector. The quantitative research design was used. Primary data were collected, using a self-managed survey, from 262 pharmaceutical companies. Data analysis was carried out using structural equation modeling (SEM) via AMOS software.

The findings of the study confirmed that TQM has a significant positive effect on operational performance. In addition, TQM directly affects supply chain management, which, in sequence, affects operational performance.

In Ethiopia, Mohammed et al. (2019) investigated the influence of TQM on the operational performance of pharmaceutical companies. The quantitative hypotheses-testing approach was employed. Primary data were gathered, using a self-managed questionnaire from 57 respondents selected from 13 companies. Through reviewing the related literature, seven dimensions of TQM that are applicable to the pharmaceutical sector are identified. Data were analyzed using correlation and regression analysis techniques.

The results of the study indicate that there is a significant association between TQM and operational performance in the pharmaceutical companies. More specifically, the four TQM dimensions of customer focus, process management, product design, and people management are proved to have a significant positive influence on at least one of the operational performance measures. In contrast, the other three TQM dimensions of top management support, suppliers' quality management, and continuous improvement have no significant influence on operational performance.

In India, Singh et al. (2018) assessed the level of TQM application and investigated its effect on organizational performance. The quantitative hypothesis-testing research design was adopted where data were collected from 236 samples belonging to eight services and manufacturing SMEs. Data were mainly analyzed using the structural equation modeling (SEM) technique, utilizing AMOS software.

The study results confirmed that TQM has a significant positive effect on organizational performance. In addition, the results indicated that there are no significant differences in the level of TQM knowledge between employees and managers.

In Pakistan, Chaudhry et al. (2018) examined the impact of TQM on organizational performance (financial as well as operational) using learning capability and innovation as mediating variables. The quantitative cross-sectional approach was adopted. Primary data were gathered using a structured questionnaire via simple random sampling from 540 respondents working at 244 companies in three different country areas.

Contrary to what is expected, the study's main results revealed no significant direct impact of TQM on organizational performance. However, the results confirmed that TQM has a significant positive impact on innovation. In addition, the results confirmed that innovation has a significant direct impact on organizational performance in terms of both financial and operational performance. Finally, innovation was proved to fully mediate the relationship between TQM and organizational performance, indicating that TQM has a significant indirect impact on organizational performance through innovation.

Also, in Pakistan, Hafeez et al. (2018) investigated the relationship between TQM and the performance of textile companies, considering the mediating role of innovation. A fully structured questionnaire collected the primary data from 219 textile companies, and AMOS software data analyzed the structural equation modeling (SEM) technique.

The study results confirmed that TQM has a significant positive effect on corporate performance (i.e., production, market, and financial performance). Also, TQM was found to affect innovation positively. In addition, it is concluded that innovation has a significant positive effect on both market performance and financial performance. Lastly, the results proved that the relationship between TQM and financial performance is mediated by innovation.

In Portugal, Antunes et al. (2017) examined the structural relationships between TQM, innovation, and organizational performance of SMEs. To this end, the quantitative research approach was employed, and primary data were collected, via an online survey, from 287 respondents. Data have analyzed the technique of structural equation modeling (SEM).

The study results confirm that TQM has a significant positive effect on product innovation and process innovation. The results also indicate that process innovation improves SMEs' operational and financial performance, whereas product innovation only improves financial performance.

In Malaysia, Honarpoura et al. (2017) investigated the association between total TQM and knowledge management and their effect on process innovation and product innovation. The quantitative hypothesis-testing method was adopted. The primary data were gathered using a questionnaire from 190 managers of R&D units. Factor Analysis was utilized to evaluate the measurement model, and structural equation modeling (SEM) was carried out to evaluate the structural model. AMOS was employed in data analysis.

The study's main result confirmed a significant positive relationship between TQM and organizational innovation (i.e., process and product innovation). Moreover, it was found that there are no significant differences in the levels of process innovation and product innovation due to the age or size of the R&D units.

In India, Farish et al. (2017) investigated the influence of TQM application on manufacturing companies' financial performance and innovation. The quantitative hypothesis-testing research design was adopted, and primary data were collected using a structured questionnaire from a sample of 260 companies. The primary data analysis

technique was the structural equation modeling (SEM), carried out using AMOS software.

The results of path analysis confirmed that TQM application has a significant direct effect on both financial performance and innovation. In addition to this direct effect, the results indicated that the TQM application has a significant indirect effect, through innovation, on financial performance. Finally, the results identified supplier quality management, continuous improvement, quality information analysis, quality assurance, and knowledge management as the most influential TQM dimensions on financial performance and innovation.

In Turkey, Akgun et al. (2014) investigated the influence of TQM on both the financial and operational performance of companies, with the two variables of learning capability and innovation as potential mediators. The quantitative research design was employed whereby the primary data were collected, via a questionnaire, from 193 companies that were randomly selected.

The results of the study confirmed that: (1) TQM has a significant favorable influence on organizational innovation, (2) organizational innovation has a significant favorable influence on financial performance, and (3) organizational innovation plays a mediating role in the relationship between TQM and financial performance.

Finally, it is worth mentioning that some previous empirical studies investigated TQM and organizational performance in the Palestinian context. For instance, Baidoun et al. (2018) assessed the level of TQM application in governmental and non-governmental hospitals in Gaza Strip using the Malcolm Baldrige National Quality Award (MBNQA) framework. The population of the study comprised all healthcare personnel (12,937). The

sample size of 374 was calculated at a confidence level of 95%. Respondents belonged to different groups in the healthcare organizations including physicians, nurses, technicians, and management. To get a high response rate, 450 questionnaires, translated into Arabic, were personally distributed to respondents (75% and 25% to governmental and non-governmental hospitals, respectively) in the main three areas of Gaza Strip (i.e. Gaza, North Gaza, and South Gaza). A total of 363 questionnaires were found to be completed and valid with a response rate of nearly 81%. The questionnaires were analyzed using descriptive statistics. The study results show that hospitals operating in Gaza Strip have an acceptable level of performance. In addition, the results indicate that non-governmental hospitals have a higher level of TQM application than governmental hospitals.

In addition, Sabella et al. (2015) assessed the quality of TQM application in hospitals operating in the West Bank using the Malcolm Baldrige National Quality Award (MBNQA) framework. Questionnaires, interviews, and focus groups were used to collect data from 51 hospitals, and data were analyzed using descriptive statistics. The study results indicate that hospitals in the West Bank have a relatively acceptable level of performance. Moreover, the results confirmed that private and NGO hospitals have the highest level of TQM application, whereas public and UNRWA hospitals have the lowest level. Finally, process management is found to be the most implemented TQM dimension among all, whereas human resource focus is the least applied dimension.

Furthermore, Sabella et al. (2014) investigated the impact of TQM application on the organizational performance of hospitals in Palestine using the Malcolm Baldrige National Quality Award (MBNQA) framework. Primary data were collected, using a survey, from 51 hospitals operating in the West Bank and subsequently analyzed using descriptive

statistics and multiple linear regression analysis. The study's main result confirmed that the four TQM dimensions of leadership, information and analysis, human resource management, and process management have a significant positive impact on hospital performance.

Finally, Herzallah et al. (2014) investigated the structural relationships between TQM, competitive strategies (i.e., cost leadership and differentiation), and performance in the Palestinian industrial SMEs. To collect primary data, 202 Palestinian industrial SMEs were surveyed. The structural equation modeling (SEM) technique was utilized to test the structural relationships. The study results confirmed that TQM practices have a significant, direct, and positive impact on financial performance. The results also showed that TQM has a significant, indirect, and positive impact on financial performance via competitive strategies. Finally, it is found that there is a significant, direct, and positive relationship between competitive strategies and financial performance.

Having reviewed the previous empirical studies that investigated the potential effect of TQM on organizational performance, it is worth clarifying that this study contributes to the existing body of knowledge in three ways.

First, most of the previous empirical studies, excluding one study that was carried out in Palestine, examined the direct effect of TQM on organizational performance while mediating variables are ignored. However, this study fulfills this gap by including organizational innovation as a mediating variable when examining the relationship between TQM and organizational performance.

Second, most previous empirical studies measured TQM using models other than the MBNQA framework and measured organizational performance mainly using financial

indicators. Yet, this study fulfills this gap by using six dimensions of the well-known MBNQA framework to measure TQM and the business results dimension to measure organizational performance.

Finally, the previous empirical studies, including those carried out in Palestine, were applied to contexts other than pharmaceutical companies. Thus, this study fulfills this gap in the previous literature by investigating the relationship mentioned above, specifically in the Pharmaceutical Industry in the Palestinian context.

CHAPTER THREE

RESEARCH METHODOLOGY

3.1 Overview

In this chapter, the research methodology is discussed. More specifically, the research approach is selected, the study's population is identified, the corresponding sample size is determined, the data collection method is chosen, the research instrument is described, the statistical analysis techniques are outlined, and some ethical issues are highlighted.

3.2 Research Approach

Empirical studies could be qualitative, quantitative, or mixed. Qualitative studies are typically undertaken when data collected are exploratory. In this type of study, data are usually generated from interviewees' answers, responses to open-ended questionnaires, observations, or secondary sources (Sekaran and Bougie, 2016).

In contrast, quantitative studies are usually carried out when theories are available, and hypotheses are formulated accordingly regarding the phenomena of interest. Large amounts of primary quantitative data are generally collected through structured questionnaires in this type of study. Finally, mixed studies are carried out to answer research questions utilizing qualitative and quantitative approaches (Sekaran and Bougie, 2016).

In this study, the quantitative hypothesis-testing empirical approach is adopted. More specifically, primary data on the main variables of the study (i.e., TQM, organizational innovation, and organizational performance) are collected using purposive sampling from middle- and top-level managers. Participants work in any of the five pharmaceutical

companies in the West Bank using a fully-structured questionnaire and personally distributed.

3.3 Population and Sample of Study

This section identifies the study population, and the appropriate minimum sample size is determined accordingly.

3.3.1 Population of Study

According to Sekaran and Bougie (2016), the population of a given study is the complete set of individuals, events, things, countries, and so on that the researcher is interested in studying.

As stated previously, this study aims to assess the level of TQM and investigate its effect on the organizational performance of the Palestinian pharmaceutical companies, using organizational innovation as a mediating variable. Accordingly, the study population comprises all middle- and top-level managers working in any of the five pharmaceutical companies that operate in the West Bank, Palestine.

The middle- and top-level managers are purposively selected as respondents in this study, as proposed in previous empirical studies, because they have critical positions in their companies that qualify them to provide reliable data (e.g., Hung et al., 2010; Yusr et al., 2013).

3.3.2 Sample of Study

According to Sekaran and Bougie (2016), a given study sample is a subset of the entire population. Unfortunately, there are no statistics on the total number of middle- and top-level managers who work in the five Palestinian pharmaceutical companies. Thus, the

rule of thumb stating that sample sizes larger than 30 and less than 500 are appropriate for most research (Sekaran and Bougie, 2016) is used to determine the study's sample size.

As explained later in this chapter, the partial least squares structural equation modeling (PLS-SEM) technique is employed to investigate the structural relationships between the study variables (i.e., TQM, organizational innovation, and organizational performance).

One of the many advantages of the PLS-SEM technique is that it achieves high levels of statistical power even with small sample sizes. However, this does not imply that PLS-SEM's sample size issues are unnecessary. In detail, the ten times rule of thumb is used in the context of PLS-SEM to determine the minimum sample size. This rule requires that the minimum sample size be ten times the maximum number of arrowheads pointing at a latent variable anywhere in the PLS path model (Hair et al., 2017). The minimum sample size, in PLS-SEM context, is given by the following formula:

$$\text{Minimum sample size} = 10 \times \text{Maximum number of items}$$

In this study, 5 items are used to measure the dimensions of leadership, 7 items are used to measure the dimension of strategic planning, 7 items are used to measure the dimension of customer focus, 5 items are used to measure the dimension of information and analysis, 8 items are used to measure the dimension of human resource focus, and 5 items are used to measure process management. In addition, 7 items are used to measure the variable of organizational innovation. Finally, 10 items are used to measure the variable of organizational performance.

Thus, the maximum number of arrowheads pointing at a latent variable in the PLS path model is 10 (i.e., the ten items that are used to measure organizational performance). Accordingly, the minimum sample size in this study is 100 (i.e., 10 × 10).

3.4 Data Collection Method

According to Sekaran and Bougie (2016), there are three main data collection methods when primary data need to be collected: (1) observations, (2) interviews, as well as (3) questionnaires. Personally-administered, mail and electronic questionnaires are three types of questionnaires, and each of these has its advantages and disadvantages.

In this study, the questionnaire instrument is used as a data collection method to collect the primary data since it is more efficient than the other methods in terms of time, effort, and money. Specifically, fully-structured questionnaires are personally-administered to a purposive sample of middle- and top-level managers working in any of the five pharmaceutical companies in the West Bank, Palestine.

Questionnaires are decided to be personally distributed for three main reasons: (1) they are less expensive when administered to groups of respondents, (2) doubts can be clarified to respondents, and (3) they yield in high response rate.

During the seven weeks from 24/03/2022 till 14/05/2022, 104 completed questionnaires were received. All the received responses are valid for the descriptive and inferential statistical analyses.

3.5 Research Instrument

As mentioned previously, a fully-structured questionnaire is used as an instrument to collect the primary data. The Malcolm Baldridge National Quality Award (MBNQA) framework, a well-known American award in TQM, is mainly used in developing the

questionnaire. The developed questionnaire begins with an introduction where the study's main objective is clearly stated, and the privacy of data provided is assured to respondents. The questionnaire consists of five parts as follows:

Part One: Respondents' Characteristics

This part is developed to collect data on respondents' characteristics. It includes the following five items:

1. Gender: (2 categories).
2. Age: (2 categories).
3. Highest completed level of education: (4 categories).
4. Total years of experience: (2 categories).
5. Job responsibilities: (8 categories).

Part Two: Companies' Characteristics

This part is developed to collect data on companies' characteristics. It includes the following six items:

1. Company age: (4 categories).
2. Paid-in capital: (3 categories).
3. The number of employees: (4 categories).
4. Types of markets: (3 categories).
5. The number of pharmaceutical products: (4 categories).
6. Accreditation: (4 categories).

Part Three: Total Quality Management (TQM)

This part is developed to collect data on respondents' perceptions concerning the level of TQM application in Palestinian pharmaceutical companies. It consists of 37 items that capture six dimensions of the Malcolm Baldridge National Quality Award (MBNQA) framework as follows:

1. Leadership: (5 items).
2. Strategic planning: (7 items).
3. Customer focus: (7 items).
4. Information and analysis: (5 Items).
5. Human resource focus: (8 items).
6. Process management: (5 items).

A five-point Likert scale is used in this part, with one denoting "Strongly Disagree" and five denoting "Strongly Agree." All of the 37 items are positively phrased. Consequently, no items need to be reverse coded. A higher score on the scale (i.e., moving from 1 to 5) indicates a higher perceived level of TQM application in the Palestinian pharmaceutical companies.

Part Four: Organizational Innovation

This part is developed to collect data on respondents' perceptions concerning the level of organizational innovation in the Palestinian pharmaceutical companies. This part, which is mainly developed based on the work of Calantone et al. (2002) and Prajogo and Sohal (2006), consists of the following seven items:

1. The number of new product introductions compared to competitors.
2. Speed of bringing new products into the market compared to competitors.

3. Encouraging new ideas that are presented to develop performance.
4. Increase in new product introductions over the last five years.
5. Changing production methods at great speed compared to competitors.
6. Level of technological competitiveness.
7. Developing new management approaches over the previous five years.

A five-point Likert scale is used in this part, with one denoting "Strongly Disagree" and five representing "Strongly Agree." All of the seven items are positively phrased. Consequently, no items need to be reverse coded. A higher score on the scale (i.e., moving from 1 to 5) indicates a higher perceived level of organizational innovation in the Palestinian pharmaceutical companies.

Part Five: Organizational Performance

This part is developed to collect data on respondents' perceptions with respect to the level of organizational performance in the Palestinian pharmaceutical companies. It is developed based on the business results dimension of the Malcolm Baldridge National Quality Award (MBNQA) framework. This part consists of the following ten items:

1. Customer satisfaction with the company's products.
2. Company's ability to meet financial obligations.
3. Employees' satisfaction with the company's system of remuneration and benefits.
4. Employees' satisfaction with their departments.
5. Expansion of the company's products.
6. Improvement in the company's product quality.

7. The rise in the company's productivity.

8. Improvement in the company's reputation.

9. Availability of technical support when needed.

10. Cooperation between administrative employees and technicians.

A five-point Likert scale is used in this part, with one denoting "Strongly Disagree" and five representing "Strongly Agree." All of the ten items are positively phrased. Consequently, no items need to be reverse coded. A higher score on the scale (i.e., moving from 1 to 5) indicates a higher perceived level of organizational performance in the Palestinian pharmaceutical companies.

Finally, it is worth noting that the levels of TQM application, organizational innovation, and organizational performance in the Palestinian pharmaceutical companies are all qualitatively evaluated according to the scale shown in Table 3.1.

Table 3.1: Qualitative Evaluation of Study Variables

Mean Range	Qualitative Evaluation
1.00–1.80	Very Low
1.81–2.60	Low
2.61–3.40	Moderate
3.41–4.20	High
4.21–5.00	Very High

The validity and reliability of the research instrument are discussed in the next chapter. A copy of the research instrument is attached in Appendix A.

3.6 Statistical Analysis Techniques

This study uses two types of statistical analysis techniques: descriptive and inferential statistics. More specifically, descriptive statistics (namely frequencies and percentages) are used to analyze, in a descriptive way, respondents' and companies' characteristics. In addition, descriptive statistics (namely standard deviations and means) are used to assess the levels of TQM, organizational innovation, and organizational performance in the Palestinian pharmaceutical companies.

On the other hand, inferential statistics are used to test the four hypotheses of the study that are already developed. More specifically, the partial least squares structural equation modeling (PLS-SEM) technique investigates the structural relationships between TQM application, organizational innovation, and organizational performance in the Palestinian pharmaceutical companies.

In this context, it is worth remembering that structural equation modeling (SEM) is one type of multivariate technique that integrates factor analysis and regression analysis features. Thus, it enables researchers to instantaneously examine relationships between items and latent variables (i.e., measurement model) and between latent variables themselves (i.e., structural model) (Hair et al., 2017).

To conduct structural equation modeling (SEM), there are two main approaches: covariance-based structural equation modeling (CB-SEM) and partial least squares structural equation modeling (PLS-SEM) (Hair et al., 2017).

This study uses the PLS-SEM technique for several reasons instead of the alternative CB-SEM technique. First, the PLS-SEM technique can be used even with small sample sizes instead of the CB-SEM technique, which requires large sample sizes. Second, the PLS-SEM is a non-parametric technique that does not require assumptions about data

distribution compared to the CB-SEM technique, which assumes that data are normally distributed. Third, the PLS-SEM technique can examine complex models involving many indicators and relationships. Finally, the PLS-SEM technique results in greater statistical power than the CB-SEM technique, which means that it is more likely to conclude that a given relationship is significant when it is significant in the population (Hair et al., 2017).

Conducting PLS-SEM involves three main steps. The first step is assessing the measurement model (i.e., the outer model), representing the relationships between the variables and their items. The second step is hypotheses testing using path analysis. The last step is assessing the structural model (i.e., the inner model), representing the relationships between different variables (Hair et al., 2017). Each of these steps is carried out in the next chapter.

In this study, a hierarchal component model (HCM) is estimated. One of the three variables in the model is complex in that it is operationalized at more than one level of abstraction. TQM is measured using six first-order dimensions (i.e., leadership, strategic planning, customer focus, information and analysis, human resource focus, and process management). These six dimensions form the second-order variable (i.e., TQM).

To estimate hierarchal component models (HCMs), the two-stage approach is one of the methods that can be used. According to this approach, the latent variable scores for the lower-order constructs (LOCs) are obtained in the first stage without the higher-order constructs (HOCs). In the second stage, these scores are used as indicators of the HOCs (Hair et al., 2017).

Finally, it is worth saying that two statistical software packages are used to carry out statistical data analysis. The statistical package for social sciences (SPSS) is used to carry

out descriptive statistical analysis, whereas the SmartPLS is used to analyze inferential data.

3.7 Ethical Issues

Five ethical issues concerning this study are worth highlighting. First, the study's main objective is explained to respondents on the questionnaire's cover page. Second, respondents are granted the right to answer the questionnaire or decline it. Third, respondents are assured that the researcher treats the data they provide as strictly confidential. Fourth, no intentional misrepresentation of data or results is made. Finally, the researcher declares no conflict of interest with any other party.

CHAPTER FOUR

DATA ANALYSIS AND DISCUSSION

4.1 Overview

In this chapter, data analysis and discussion are presented. More specifically, descriptive statistics and inferential statists are carried out in the following pages.

4.2 Descriptive Statistical Analysis

In this section, descriptive statistics are carried out. Respondents' characteristics and companies' characteristics are analyzed descriptively. Also, the levels of TQM, organizational innovation, and organizational performance in the Palestinian pharmaceutical companies are assessed using descriptive statistics.

4.2.1 Respondents' Characteristics

In this section, respondents' characteristics are analyzed, in a descriptive way, concerning gender, age, education, years of experience, and job responsibilities.

Descriptive statistics of respondents' characteristics are presented in Table 4.1. The results indicate that 61.5% of respondents are males, whereas 38.5% are females. 27.9% of respondents are 30 years or less, while 72.1% are over 30 years. Moreover, the results indicate that 9.6% of respondents hold a Diploma degree, 69.2% have a BA (Sc.) degree, 20.2% hold a Master's degree, and only 1% hold a Ph.D. degree. In addition, the results indicate that 37.5% of respondents have ten years or less of work experience, whereas 62.5% of them have over ten years of work experience. Finally, the results indicate that

4.8% of respondents have finance or administrative responsibilities. 1% have purchase or procurement responsibilities, 25% have production or operation responsibilities. and 29.8% have R&D or product development responsibilities. 7.7% have sales or marketing responsibilities, 1% have logistics or distribution responsibilities, 25.9% have quality management responsibilities, and the rest have other job responsibilities.

Table 4.1: Respondents' Characteristics

Variable	Category	Frequency	Percentage (%)
Gender	Male	64	61.5
	Female	40	38.5
Age	30 years or less	29	27.9
	More than 30 years	75	72.1
Education	Diploma	10	9.6
	BA	72	69.2
	Master's	21	20.2
	PhD	1	1.0
Years of experience	10 years or less	39	37.5
	More than 10 years	65	62.5
Job responsibilities	Finance / administration	5	4.8
	Purchase / procurement	1	1.0
	Production / operation	26	25.0
	R&D / product development	31	29.8
	Sales / marketing	8	7.7
	Logistics / distribution	1	1.0
	Quality management	27	25.9
	Other	5	4.8

4.2.2 Companies' Characteristics

In this section, companies' characteristics are analyzed, in a descriptive way, with respect to age, paid-in capital, number of employees, types of markets, number of pharmaceutical products, and accreditation.

Descriptive statistics of companies' characteristics are presented in Table 4.2. The results indicate that 14.4%, 7.7%, 4.8%, and 73.1% of respondents work at pharmaceutical companies less than ten years old, 10-20 years old, 20-30 years old, and over 30 years old, respectively. With respect to paid-in capital, the results indicate that 32.7%, 20.2%, and 47.1% of respondents work at pharmaceutical companies whose paid-in capital is less than $10 million, $10-20 million, and more than $20 million, respectively. Moreover, the results indicate that 2.9%, 22.1%, 1.9%, and 73.1% of respondents work at pharmaceutical companies whose employees are less than 50, 51-100, 101-150, and more than 150, respectively. In addition, the results indicate that 97.1%, 55.8%, and 48.1% of respondents work at pharmaceutical companies that have local, regional and international markets, respectively. The results indicate that 18.3%, 34.6%, 8.7%, and 38.5% of respondents work at pharmaceutical companies with less than 50, 51-100, 101-150, and more than 150 pharmaceutical products, respectively. Finally, the results indicate that 94.2%, 72.1%, 54.8%, and 2.9% of respondents work at pharmaceutical companies with the ISO, GMP, FDA, and other accreditations.

Table 4.2: Companies' Characteristics

Variable	Category	Frequency	Percentage (%)
Company age	Less than 10 years	15	14.4
	10–20 years	8	7.7
	20–30 years	5	4.8
	More than 30 years	76	73.1
Paid-in capital	Less than $10 million	34	32.7
	$10–20 million	21	20.2
	More than $20 million	49	47.1
Number of employees	Less than 50	3	2.9
	50–100	23	22.1
	101–150	2	1.9
	More than 150	76	73.1
Types of markets	Local	101	97.1
	Regional	58	55.8
	International	50	48.1
Pharmaceutical products	Less than 50	19	18.3
	50–100	36	34.6
	101–150	9	8.7
	More than 150	40	38.5
Accreditation	ISO	98	94.2
	GMP	75	72.1
	FDA	57	54.8
	Other	3	2.9

4.2.3 Assessment of Total Quality Management

In this section, the level of TQM application in the Palestinian pharmaceutical companies, measured using six dimensions of the Malcolm Baldridge National Quality Award (MBNQA) framework, are assessed using descriptive statistics.

Dimension 1: Leadership

The descriptive statistics of the leadership dimension of TQM in the Palestinian pharmaceutical companies are presented in Table 4.3. The results indicate that this dimension of the MBNQA framework comprises five items. Overall, this dimension has a high application level, with a mean value of 3.88 on the five-point scale. When looking at each of the five items capturing this dimension, it is evident that Leadership 2, "Top management is dedicated to quality improvement," is the most implemented item. In contrast, Leadership 5, "Top management regularly shares the company vision with employees," is the least implemented item.

Table 4.3: Descriptive Statistics of Leadership Dimension of TQM

Item	Standard Deviation	Mean Value	Qualitative Level
Leadership 1	0.826	4.09	High
Leadership 2	0.724	4.50	Very High
Leadership 3	0.798	4.43	Very High
Leadership 4	1.109	3.38	Moderate
Leadership 5	1.136	2.99	Moderate
Total		**3.88**	**High**

Dimension 2: Strategic Planning

The descriptive statistics of the strategic planning dimension of TQM in the Palestinian pharmaceutical companies are presented in Table 4.4. The results indicate that this dimension of the MBNQA framework comprises seven items. Overall, this dimension has a high application level, with a mean value of 4.04 on the five-point scale.

When looking at each of the seven items capturing strategic planning, it is evident that Strategic Planning 5 "The policies and plans of the company take occupational safety into account" and Strategic Planning 6 "The strategies and plans of the company are focused on quality improvement" are the most implemented items.

Whereas Strategic Planning 3 "Top management provides adequate resources and support to achieve short-and-long-term goals," and Strategic Planning 4, "The company's policies and plans consider employees', customers' and other stakeholders' needs," are the least implemented items.

Table 4.4: Descriptive Statistics of Strategic Planning Dimension of TQM

Item	Standard Deviation	Mean Value	Qualitative Level
Strategic planning 1	0.694	4.06	High
Strategic planning 2	0.724	4.00	High
Strategic planning 3	0.767	3.93	High
Strategic planning 4	0.743	3.83	High
Strategic planning 5	0.645	4.14	High
Strategic planning 6	0.678	4.21	Very High
Strategic planning 7	0.618	4.08	High
Total		**4.04**	**High**

Dimension 3: Customer Focus

The descriptive statistics of the customer focus dimension of TQM in the Palestinian pharmaceutical companies are presented in Table 4.5. The results indicate that this dimension of the MBNQA framework comprises seven items. Overall, this dimension has a high application level, with a mean value of 3.94 on the five-point scale. When looking at each of the seven items capturing this dimension, it is evident that Customer Focus 1 "The company designs its products by considering customers' requirements" and Customer Focus 2 "The company regularly provides information about its new products to its customer" are the most implemented items whereas Customer Focus 4 "The information about customers' experiences and expectations is widely used by management to improve products" and customer focus 5 "Managers support employees' initiatives to improve customers' satisfaction" are the least implemented items.

Table 4.5: Descriptive Statistics of Customer Focus Dimension of TQM

Item	Standard Deviation	Mean Value	Qualitative Level
Customer focus 1	0.645	4.03	High
Customer focus 2	0.595	4.23	Very High
Customer focus 3	0.715	3.88	High
Customer focus 4	0.752	3.84	High
Customer focus 5	0.830	3.67	High
Customer focus 6	0.673	3.88	High
Customer focus 7	0.607	4.02	High
Total		**3.94**	**High**

Dimension 4: Information and Analysis

The descriptive statistics of the information and analysis dimension of TQM in the Palestinian pharmaceutical companies are presented in Table 4.6. The results indicate that this dimension of the MBNQA framework comprises five items. Overall, this dimension has a high application level, with a mean value of 4.12 on the five-point scale. When looking at each of the five items capturing this dimension, it is evident that Information and Analysis 1 "The company has effective information and reporting system for all products" and Information and Analysis 5 "All departments coordinate with each other to implement and monitor quality improvement programs" are the most implemented items whereas Information and Analysis 2 "Management regularly provides quality data (errors, complains, defects, etc.) to the workers" and Information and Analysis 3 "Workers, supervisors, and managers can easily retrieve information about different products" are the least implemented items.

Table 4.6: Descriptive Statistics of Information and Analysis Dimension of TQM

Item	Standard Deviation	Mean Value	Qualitative Level
Information and analysis 1	0.534	4.21	Very High
Information and analysis 2	0.806	3.99	High
Information and analysis 3	0.816	4.07	High
Information and analysis 4	0.690	4.10	High
Information and analysis 5	0.653	4.22	Very High
Total		**4.12**	**High**

Dimension 5: Human Resource Focus

The descriptive statistics of the human resource focus dimension of TQM in the Palestinian pharmaceutical companies are presented in Table 4.7. The results indicate that this dimension of the MBNQA framework comprises eight items. Overall, this dimension has a high application level, with a mean value of 3.64 on the five-point scale. When looking at each of the eight items capturing this dimension, it is evident that Human Resource Focus 4 "Management regularly takes employees' views and consider them to improve product quality" and Human Resource Focus 7 "The company treats its employees as assets and regularly measure their satisfaction" are the least implemented items whereas Human Resource Focus 6 "Quality is treated as the responsibility of all employees" and Human Resource Focus 8 "Management is concerned about the well-being of its employees (e.g. health and security)" are the most implemented items.

Table 4.7: Descriptive Statistics of Human Resource Focus Dimension of TQM

Item	Standard Deviation	Mean Value	Qualitative Level
Human resource focus 1	0.810	3.82	High
Human resource focus 2	1.014	3.52	High
Human resource focus 3	1.066	3.40	Moderate
Human resource focus 4	1.002	3.25	Moderate
Human resource focus 5	0.955	3.48	High
Human resource focus 6	0.601	4.41	Very High
Human resource focus 7	0.937	3.23	Moderate
Human resource focus 8	0.870	4.02	High
Total		**3.64**	**High**

Dimension 6: Process Management

The descriptive statistics of the process management dimension of TQM in the Palestinian pharmaceutical companies are presented in Table 4.8. The results indicate that this dimension of the MBNQA framework comprises five items. Overall, this dimension has a high application level, with a mean value of 4.06 on the five-point scale.

When looking at each of the five items capturing process management, it is evident that Process Management 2 "Most of the processes in the company are automated, fool-proof, and minimizes human error chances" and Process Management 4 "The system allows management to inspect and track key processes that are critical to the company" are the most implemented items.

In contrast, Process Management 1, "The company has standardized operational processes that are clear and well understood by employees and customers" is the least implemented item.

Table 4.8: Descriptive Statistics of Process Management Dimension of TQM

Item	Standard Deviation	Mean Value	Qualitative Level
Process management 1	0.841	3.97	High
Process management 2	0.799	4.11	High
Process management 3	0.774	4.06	High
Process management 4	0.670	4.09	High
Process management 5	0.694	4.06	High
Total		**4.06**	**High**

Summary of TQM Dimensions

The descriptive statistics of the six dimensions of TQM in the Palestinian pharmaceutical companies are summarized in Table 4.9. The results indicate that TQM is measured using six dimensions of the Malcolm Baldridge National Quality Award (MBNQA) framework. Overall, TQM has a high application level, with a mean value of 3.95 on the five-point scale. Specifically, the dimensions of information and analysis, process management, and strategic planning are the most implemented among the six dimensions capturing TQM. On the other hand, customer focus, leadership, and human resource focus are the least implemented dimensions.

Table 4.9: Descriptive Statistics of TQM Dimensions

Dimension	Mean Value	Qualitative Level	Dimension Rank
Leadership	3.88	High	5
Strategic planning	4.04	High	3
Customer focus	3.94	High	4
Information and analysis	4.12	High	1
Human resource focus	3.64	High	6
Process management	4.06	High	2
Total	**3.95**	**High**	

4.2.4 Assessment of Organizational Innovation

In this section, the levels of organizational innovation in the Palestinian pharmaceutical companies, measured using seven items, are assessed using descriptive statistics.

The descriptive statistics of organizational innovation in the Palestinian pharmaceutical companies are presented in Table 4.10. The results indicate that this variable is made up

of seven items. Overall, organizational innovation has a very high level, with a mean value of 3.61 on the five-point scale. When looking at each of the seven items capturing this variable, it is clear that Organizational Innovation 4 “The new product introductions have increased over the last 5 years” has the highest mean value whereas Organizational Innovation 2 “Compared to competitors, the company is faster in bringing new products into the market” has the lowest mean value.

Table 4.10: Descriptive Statistics of Organizational Innovation

Item	Standard Deviation	Mean Value	Qualitative Level
Organizational innovation 1	0.858	3.54	High
Organizational innovation 2	0.841	3.39	Moderate
Organizational innovation 3	0.835	3.55	High
Organizational innovation 4	0.759	3.79	High
Organizational innovation 5	0.721	3.57	High
Organizational innovation 6	0.762	3.70	High
Organizational innovation 7	0.650	3.75	High
Total		**3.61**	**High**

4.2.5 Assessment of Organizational Performance

In this section, the level of organizational performance in the Palestinian pharmaceutical companies is assessed using descriptive statistics.

The descriptive statistics of organizational performance in the Palestinian pharmaceutical companies are presented in Table 4.11. The results indicate that this variable is made up of six items. Overall, organizational performance is very high, with a mean value of 4.07 on the five-point scale. When looking at each of the ten items capturing this variable, it is evident that Organizational Performance 6, “The company’s product quality is

improving steadily," has the highest mean value, whereas Organizational Performance 4, "Generally, employees are satisfied with their own departments" has the lowest mean value.

Table 4.11: Descriptive Statistics of Organizational Performance

Item	Standard Deviation	Mean Value	Qualitative Level
Organizational performance 1	0.545	4.12	High
Organizational performance 2	0.586	4.12	High
Organizational performance 3	0.836	3.78	High
Organizational performance 4	0.806	3.72	High
Organizational performance 5	0.608	4.13	High
Organizational performance 6	0.603	4.25	Very High
Organizational performance 7	0.645	4.14	High
Organizational performance 8	0.664	4.12	High
Organizational performance 9	0.730	4.14	High
Organizational performance 10	0.604	4.18	High
Total		**4.07**	**High**

4.3 Inferential Statistical Analysis

In this section, inferential statistics are carried out using the partial least squares structural equation modeling (PLS-SEM) technique. This involves three steps: (1) measurement model assessment, (2) hypotheses testing (i.e., path analysis), and (3) structural model assessment. Each of these steps is carried out in the next pages.

4.3.1 Measurement Model Assessment

The first step is to assess the measurement model to test the first three hypotheses already formulated using the partial least squares structural equation modeling (PLS-SEM) technique.

To do so, the two-stage approach is used to estimate the hierarchy component model (HCM). Based on this approach, the latent variable scores for the lower-order constructs (LOCs) are first obtained without the higher-order constructs. In the second stage, these scores are used as indicators of the HOCs (Hair et al., 2017). More specifically, the scores for each of the six TQM dimensions (i.e., first-order constructs) are first obtained while omitting TQM (i.e., higher-order construct) from the model. In the second stage, the scores of the TQM dimensions are used as indicators of TQM.

First Stage of Measurement Model

In the first stage, all constructs are reflective in nature, which means that the arrows' direction is from the constructs to the indicators. It is essential to assess both convergent validity and discriminant validity in this case, and each of these is briefly discussed below.

Convergent Validity of First Stage of Measurement Model

Convergent validity is the extent to which items used to measure a specific construct are in agreement. To assess this type of validity, three criteria are usually used: (1) factor loading, (2) composite reliability (CR), and (3) average variance extracted (AVE) (Hair et al., 2017). Each of these criteria is briefly discussed below.

Factor loading is the proportion of item variance explained by the latent variable. Its value ranges between a minimum of 0 and a maximum of 1. Typically, items with factor loadings below 0.70 are deleted from the measurement model. Nevertheless, in social

sciences studies, it is normal to have weak factor loadings (i.e., less than 0.70). Instead of automatically deleting the item, the effect of deleting such an item should be carefully examined. Usually, items with factor loadings in the 0.40-0.70 range should be deleted only when their deletion increases composite reliability (CR) or average variance extracted (AVE) above the minimum acceptable values. Finally, items with factor loadings below 0.40 should always be removed (Hair et al., 2017).

On the other hand, composite reliability (CR) is typically interpreted as Cronbach's alpha. Its value ranges between a minimum of 0 and a maximum of 1. Generally, higher values indicate higher levels of reliability. Typically, values between 0.60-0.70 are acceptable in social sciences studies (Hair et al., 2017).

Finally, the average variance extracted (AVE) is equivalent to the proportion of variance explained in the context of factor analysis. Its value ranges between a minimum of 0 and a maximum of 1. To establish convergent validity, the average variance extracted (AVE) should exceed 0.50 (Hair et al., 2017).

Convergent validity assessment of the first stage of the measurement model is shown in Table 4.12. The results indicate that all items included in the measurement model to capture the different constructs have factor loadings according to the previously-discussed criteria (i.e., greater than 0.70). Moreover, the results indicate that each of the different constructs has composite reliability (CR) value that is well above the minimum acceptable level of 0.70. Finally, each of the different constructs has an average variance extracted (AVE) well above the minimum suggested threshold of 0.50. So, it is concluded that the convergent validity of the first stage of the measurement model is established according to the above three criteria.

Table 4.12: Convergent Validity of First Stage of Measurement Model

Construct	Item	Loading	CR	AVE
Leadership	L1	0.819	0.878	0.643
	L2	0.842		
	L3	0.828		
	L4	0.710		
Strategic planning	SP1	0.905	0.950	0.732
	SP2	0.857		
	SP3	0.842		
	SP4	0.810		
	SP5	0.838		
	SP6	0.882		
	SP7	0.851		
Customer focus	CF1	0.729	0.922	0.631
	CF2	0.708		
	CF3	0.862		
	CF4	0.867		
	CF5	0.839		
	CF6	0.810		
	CF7	0.729		
Information and analysis	IA2	0.915	0.954	0.838
	IA3	0.920		
	IA4	0.931		
	IA5	0.895		
Human resource focus	HRF1	0.820	0.948	0.724
	HRF2	0.924		
	HRF3	0.912		
	HRF4	0.800		

Table 4.12: Convergent Validity of First Stage of Measurement Model

Construct	Item	Loading	CR	AVE
	HRF5	0.904		
	HRF7	0.799		
	HRF8	0.784		
Process management	PM1	0.871	0.959	0.825
	PM2	0.913		
	PM3	0.903		
	PM4	0.941		
	PM5	0.912		
Organizational innovation	OI1	0.838	0.929	0.653
	OI2	0.854		
	OI3	0.758		
	OI4	0.711		
	OI5	0.875		
	OI6	0.840		
	OI7	0.766		
Organizational performance	OP1	0.789	0.947	0.668
	OP2	0.708		
	OP4	0.772		
	OP5	0.795		
	OP6	0.870		
	OP7	0.812		
	OP8	0.899		
	OP9	0.880		
	OP10	0.814		

Note: Four items are deleted due to weak loadings (L5, IA1, HRF6, and OP3).

Discriminant Validity of First Stage of Measurement Model

Discriminant validity is the extent to which a specific construct is really distinguished from the other constructs empirically. This type of validity ensures that a given construct is distinct and measures a phenomenon not measured by any other construct in the model (Hair et al., 2017).

Two criteria are typically used to establish discriminant validity: the cross-loadings and the Fornell-Larcker Criterion (Hair et al., 2017). Each of these two criteria is briefly discussed below.

The cross-loadings criterion requires that the loading of a specific item on its assigned construct be higher than its cross-loadings with all of the other constructs included in the model (Hair et al., 2017).

The cross-loadings of the first stage of the measurement model are shown in Table 5.13. The results indicate that all of the items used to capture the different constructs load higher on their constructs and lower on the other constructs in the model. Consequently, the cross-loadings analysis provides evidence of discriminant validity of the first stage of the measurement model.

Table 4.13: Cross Loadings of First Stage of Measurement Model

	L	SP	CF	IA	HRF	PM	OI	OP
L1	**0.819**	0.568	0.430	0.558	0.533	0.574	0.337	0.518
L2	**0.842**	0.703	0.481	0.602	0.503	0.581	0.266	0.467
L3	**0.828**	0.700	0.490	0.662	0.562	0.658	0.282	0.397
L4	**0.710**	0.539	0.479	0.463	0.483	0.493	0.410	0.476
SP1	0.726	**0.905**	0.555	0.656	0.539	0.638	0.392	0.555
SP2	0.666	**0.857**	0.512	0.612	0.551	0.569	0.406	0.543
SP3	0.701	**0.842**	0.580	0.607	0.564	0.558	0.366	0.453
SP4	0.650	**0.810**	0.566	0.635	0.645	0.595	0.439	0.464
SP5	0.599	**0.838**	0.724	0.675	0.404	0.541	0.327	0.491
SP6	0.693	**0.882**	0.683	0.689	0.511	0.574	0.418	0.644
SP7	0.630	**0.851**	0.579	0.678	0.609	0.710	0.468	0.644
CF1	0.294	0.451	**0.729**	0.407	0.228	0.190	0.321	0.456
CF2	0.350	0.432	**0.708**	0.395	0.281	0.258	0.333	0.316
CF3	0.543	0.599	**0.862**	0.533	0.359	0.391	0.376	0.410
CF4	0.597	0.601	**0.867**	0.516	0.374	0.444	0.407	0.417
CF5	0.644	0.673	**0.839**	0.653	0.548	0.567	0.463	0.542
CF6	0.446	0.594	**0.810**	0.486	0.341	0.412	0.483	0.554
CF7	0.340	0.487	**0.729**	0.412	0.287	0.235	0.360	0.454
IA2	0.672	0.729	0.492	**0.915**	0.731	0.741	0.391	0.553
IA3	0.634	0.675	0.529	**0.920**	0.642	0.709	0.358	0.505
IA4	0.663	0.693	0.601	**0.931**	0.609	0.696	0.294	0.536
IA5	0.625	0.686	0.642	**0.895**	0.625	0.624	0.403	0.592
HRF1	0.565	0.584	0.404	0.669	**0.820**	0.623	0.334	0.486
HRF2	0.598	0.594	0.420	0.649	**0.924**	0.689	0.546	0.532
HRF3	0.577	0.523	0.281	0.566	**0.912**	0.642	0.521	0.535

Table 4.13: Cross Loadings of First Stage of Measurement Model

	L	SP	CF	IA	HRF	PM	OI	OP
HRF4	0.453	0.457	0.380	0.536	**0.800**	0.577	0.576	0.493
HRF5	0.587	0.577	0.369	0.614	**0.904**	0.634	0.511	0.582
HRF7	0.425	0.404	0.361	0.517	**0.799**	0.488	0.477	0.431
HRF8	0.660	0.668	0.440	0.706	**0.784**	0.799	0.448	0.578
PM1	0.672	0.665	0.431	0.676	0.667	**0.871**	0.388	0.526
PM2	0.674	0.670	0.495	0.733	0.699	**0.913**	0.427	0.526
PM3	0.621	0.565	0.340	0.634	0.701	**0.903**	0.478	0.476
PM4	0.674	0.666	0.441	0.683	0.653	**0.941**	0.462	0.535
PM5	0.619	0.628	0.401	0.703	0.689	**0.912**	0.483	0.565
OI1	0.341	0.354	0.383	0.326	0.522	0.421	**0.838**	0.498
OI2	0.324	0.329	0.294	0.277	0.522	0.417	**0.854**	0.509
OI3	0.422	0.517	0.455	0.456	0.589	0.465	**0.758**	0.507
OI4	0.116	0.234	0.421	0.095	0.162	0.096	**0.711**	0.454
OI5	0.323	0.374	0.403	0.365	0.514	0.476	**0.875**	0.588
OI6	0.419	0.446	0.452	0.438	0.525	0.539	**0.840**	0.634
OI7	0.328	0.384	0.431	0.224	0.365	0.290	**0.766**	0.604
OP1	0.453	0.510	0.476	0.484	0.525	0.524	0.557	**0.789**
OP2	0.338	0.427	0.484	0.416	0.482	0.418	0.542	**0.708**
OP4	0.597	0.597	0.359	0.524	0.702	0.605	0.525	**0.772**
OP5	0.362	0.401	0.491	0.318	0.368	0.254	0.571	**0.795**
OP6	0.480	0.570	0.523	0.518	0.400	0.479	0.525	**0.870**
OP7	0.389	0.435	0.499	0.404	0.407	0.329	0.625	**0.812**
OP8	0.545	0.587	0.505	0.626	0.555	0.536	0.583	**0.899**
OP9	0.641	0.679	0.517	0.679	0.638	0.632	0.581	**0.880**
OP10	0.456	0.453	0.390	0.349	0.367	0.411	0.447	**0.814**

The Fornell-Larcker criterion is the second criterion used to assess the measurement model's discriminant validity. This criterion requires that the square root of the average variance extracted (AVE) of a specific construct be larger than the squared correlation with any other constructs in the model. The logic underlying the Fornell-Larcker criterion is that a construct shares more variance with its assigned items than other constructs (Hair et al., 2017).

The Fornell-Larcker criterion of the first stage of the measurement model is shown in Table 4.14. The square root of each construct's AVE is on the diagonal, and the non-diagonal entries represent the correlations between the constructs. The results indicate that the square root of each construct's AVE is larger than its correlation with other constructs in the model. Therefore, the discriminant validity is established.

Table 4.14: Fornell-Larcker Criterion of First Stage of Measurement Model

	L	SP	CF	IA	HRF	PM	OI	OP
L	**0.802**							
SP	0.779	**0.855**						
CF	0.588	0.700	**0.794**					
IA	0.709	0.761	0.620	**0.915**				
HRF	0.651	0.640	0.445	0.714	**0.851**			
PM	0.717	0.703	0.464	0.756	0.750	**0.908**		
OI	0.412	0.474	0.502	0.398	0.579	0.494	**0.808**	
OP	0.588	0.642	0.578	0.600	0.614	0.579	0.676	**0.817**

To summarize, the convergent validity and the discriminant validity of the first stage of the measurement model are established. The results of the first stage of the measurement model are depicted in Figure 4.1.

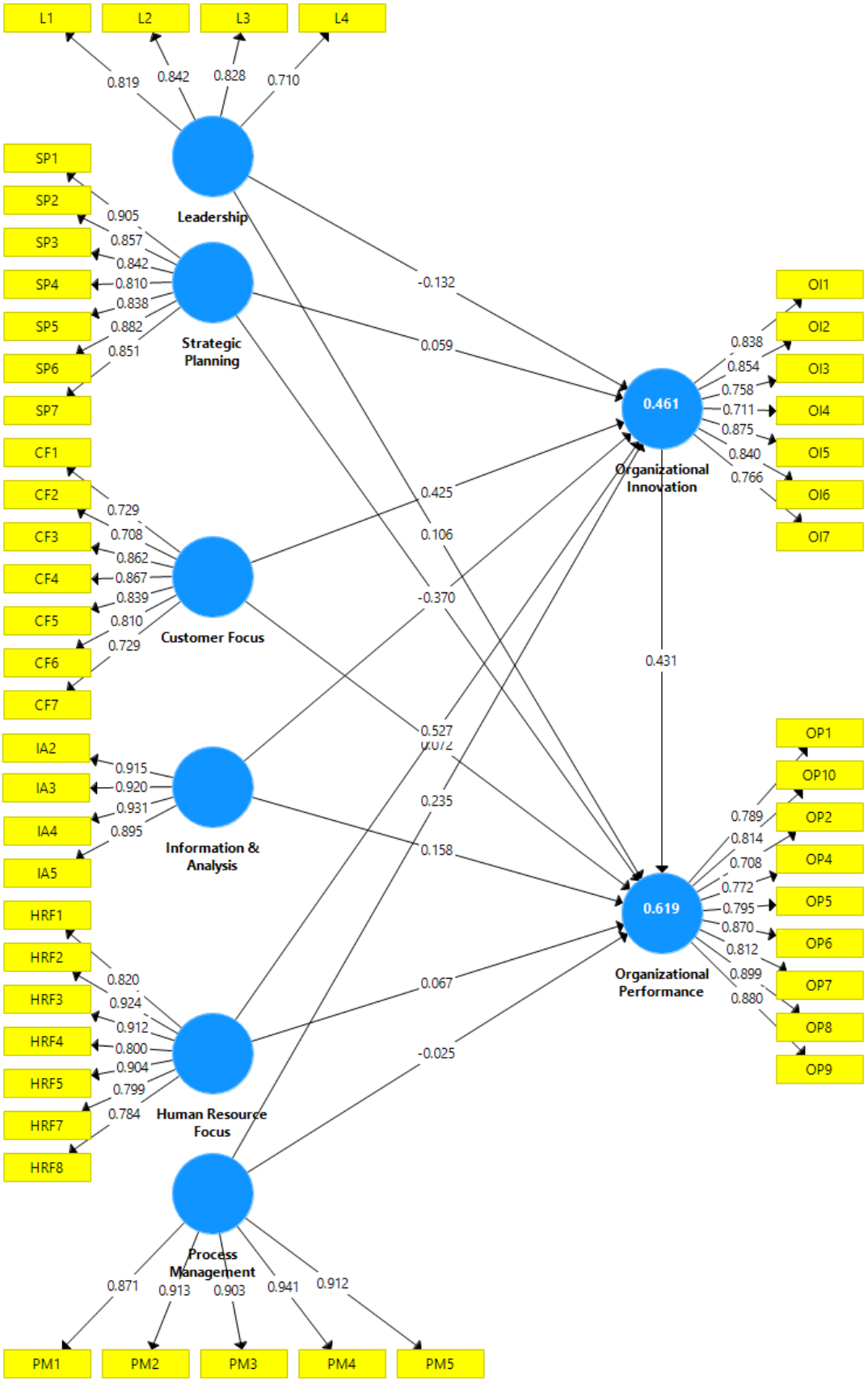

Figure 4.1: Results of First Stage of Measurement Model

Second Stage of Measurement Model

As said previously, the latent variable scores of the lower-order constructs (LOCs) extracted from the first stage are used as indicators of the higher-order constructs (HOCs). More specifically, the scores of each of the six dimensions of TQM obtained in the first stage are used in the second stage as indicators of TQM.

In this stage of the measurement model, TQM is measured using the six TQM dimensions as formative indicators. This means that the direction of the arrows is from the indicators to the construct. On the other hand, both organizational innovation and organizational performance are measured using reflective indicators. The same as in the first stage, it is important to assess both convergent validity and discriminant validity in this stage. Each of these is briefly discussed below.

Convergent Validity of Second Stage of Measurement Model

Before assessing the convergent validity of the second stage of the measurement model, it is worth mentioning that convergent validity is assessed for reflective measurement models only. In contrast, convergent validity does not apply to formative measurement models (Hair et al., 2017). In the context of this study, convergent validity is only assessed for organizational innovation and organizational performance.

The convergent validity assessment of the second stage of the measurement model is shown in Table 4.15. The results indicate that all items included in the measurement model to capture organizational innovation and performance have factor loadings according to the previously-discussed criteria (i.e., more than 0.70). Also, the results indicate that the composite reliability (CR) values for organizational innovation and organizational performance are 0.929 and 0.947, respectively. These composite reliability

(CR) values are well above the minimum acceptable level of 0.70. Finally, each of organizational innovation and organizational performance has an average variance extracted (AVE) that is above the minimum suggested threshold of 0.50 (0.653 and 0.668, respectively). Thus, it is concluded that the convergent validity of the second stage of the measurement model is established according to the above three criteria.

Table 4.15: Convergent Validity of Second Stage of Measurement Model

Construct	Item	Loading	CR	AVE
Organizational innovation	OI1	0.838	0.929	0.653
	OI2	0.853		
	OI3	0.759		
	OI4	0.710		
	OI5	0.875		
	OI6	0.841		
	OI7	0.766		
Organizational performance	OP1	0.791	0.947	0.668
	OP2	0.715		
	OP4	0.773		
	OP5	0.797		
	OP6	0.867		
	OP7	0.812		
	OP8	0.895		
	OP9	0.876		
	OP10	0.814		

Note: One item is deleted due to weak loading (OP3).

Discriminant Validity of Second Stage of Measurement Model

As in the first stage of the measurement model, it is also necessary to assess the discriminant validity of the second stage of the measurement model in terms of both cross-loadings and the Fornell-Larcker criterion.

The cross-loadings of the second stage of the measurement model are shown in Table 4.16. The results indicate that the six dimensions used to capture TQM load high on this variable and low on the other two variables. Similarly, the items used to measure organizational innovation load high on this variable but lower on the other two variables. Finally, the items used to tap organizational performance load high on this variable but lower on the other two variables. Thus, the cross-loadings analysis provides evidence of discriminant validity of the second stage of the measurement model.

Table 4.16: Cross Loadings of Second Stage of Measurement Model

	TQM	Organizational Innovation	Organizational Performance
L	**0.734**	0.414	0.586
SP	**0.819**	0.475	0.641
CF	**0.791**	0.503	0.579
IA	**0.733**	0.400	0.597
HRF	**0.874**	0.581	0.615
PM	**0.786**	0.496	0.578
OI1	0.553	**0.838**	0.500
OI2	0.518	**0.853**	0.511
OI3	0.629	**0.759**	0.507
OI4	0.337	**0.710**	0.455
OI5	0.565	**0.875**	0.590

Table 4.16: Cross Loadings of Second Stage of Measurement Model

	TQM	Organizational Innovation	Organizational Performance
OI6	0.598	**0.841**	0.635
OI7	0.487	**0.766**	0.606
OP1	0.603	0.558	**0.791**
OP2	0.568	0.543	**0.715**
OP4	0.666	0.526	**0.773**
OP5	0.487	0.571	**0.797**
OP6	0.542	0.526	**0.867**
OP7	0.512	0.625	**0.812**
OP8	0.609	0.583	**0.895**
OP9	0.683	0.582	**0.876**
OP10	0.466	0.447	**0.814**

The Fornell-Larcker criterion of the second stage of the measurement model is shown in Table 4.17. In this context, it is worth mentioning that this criterion does not apply to the formative measurement model (i.e., TQM). The results indicate that the square root of AVE for organizational innovation (i.e., 0.808) is larger than its correlation with organizational performance. In the same way, the square root of AVE for organizational performance (i.e., 0.817) is larger than its correlation with organizational innovation. Therefore, the discriminant validity is established.

Table 4.17: Fornell-Larcker Criterion of Second Stage of Measurement Model

	1	2	3
TQM (1)	Formative		
Organizational innovation (2)	Formative	**0.808**	
Organizational performance (3)	Formative	0.678	**0.817**

To summarize, the convergent validity and the discriminant validity of the second stage of the measurement model are established. The results of the second stage of the measurement model are depicted in Figure 4.2.

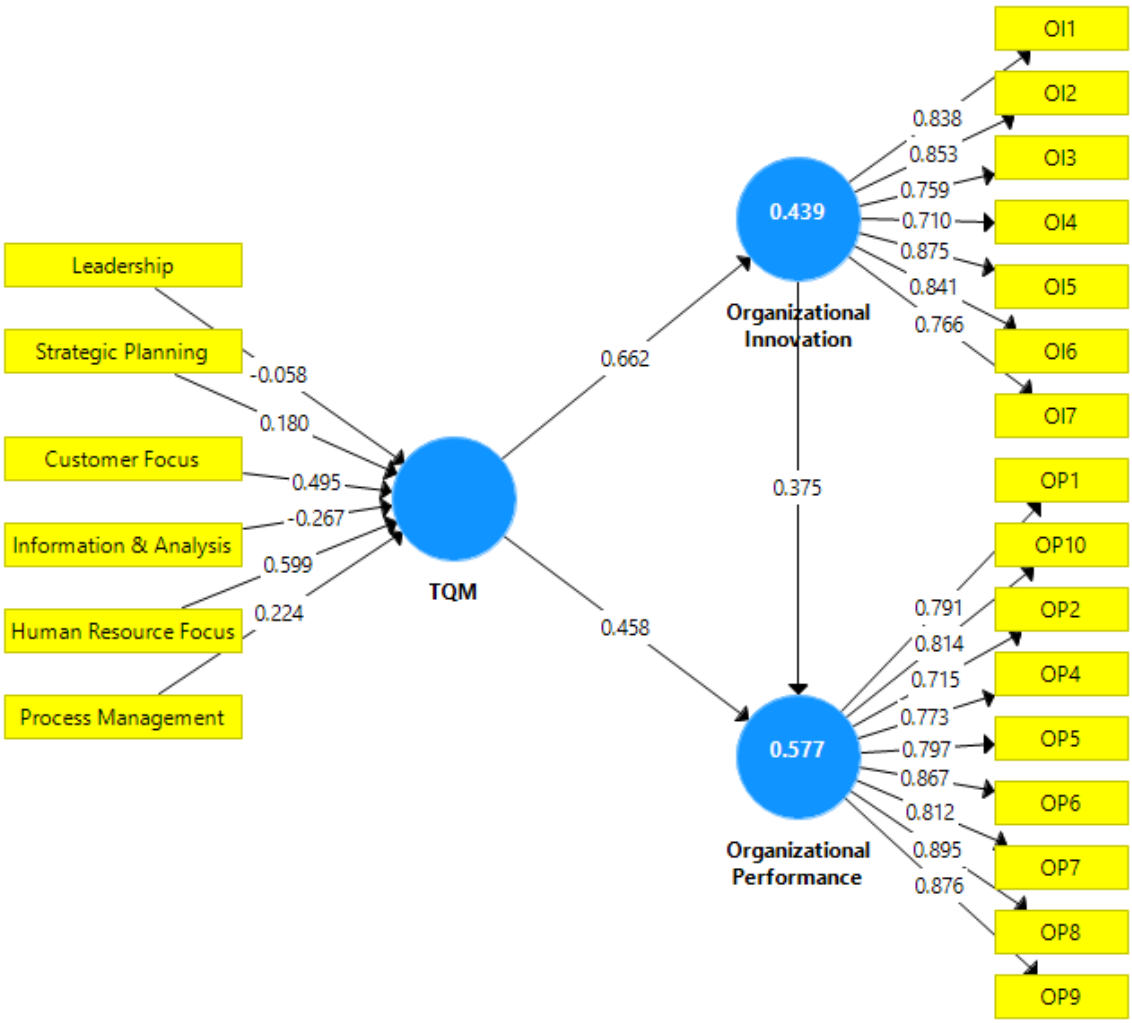

Figure 4.2: Results of Second Stage of Measurement Model

4.3.2 Hypotheses Testing (Path Analysis)

The measurement model of the study is assessed in the previous section. Now, it is time to test the hypotheses already formulated using the partial least squares structural equation modeling (PLS-SEM) technique.

Testing Direct Effects

Recall that the first three hypotheses are:

H_1: There is a significant positive relationship between TQM and organizational innovation in Palestinian pharmaceutical companies.

H_2: There is a significant positive relationship between organizational innovation and organizational performance in the Palestinian pharmaceutical companies.

H_3: There is a significant positive relationship between TQM and organizational performance in Palestinian pharmaceutical companies.

The partial least squares structural equation model (PLS-SEM) is carried out by drawing 5,000 bootstrap samples to test each of the above three hypotheses. The results of the path analysis of direct relationships are presented in Table 4.18.

Table 4.18: Path Analysis of Direct Relationships

Hypothesis and Path	Path Coefficient	Std. Error	T-Value	P-Value
TQM → Organizational innovation	0.662	0.053	12.513	0.000*
Organizational innovation→ Organizational performance	0.375	0.064	5.868	0.000*
TQM → Organizational performance	0.458	0.070	6.550	0.000*

* Significant at P < 0.001.

The results of the path analysis indicate that the coefficient of the path between TQM and organizational innovation is 0.662. This coefficient is positive and significant at the 0.001 level. The positive sign of the coefficient means that TQM has a positive direct effect on organizational innovation in the Palestinian pharmaceutical companies. In other words, better TQM application leads to enhanced organizational innovation in these companies. Therefore, the first hypothesis, which postulates a significant positive relationship between TQM and organizational innovation in the Palestinian pharmaceutical companies, is accepted. This result is consistent with the results of many previous empirical studies, which also confirmed the significance of the positive relationship between these two variables (e.g., Akgun et al., 2014; Antunes et al., 2017; Chaudhry et al., 2018; Farish et al., 2017; Hafeez et al., 2018; Honarpoura et al., 2017; Hussain et al., 2020; Sirisan, 2020; Suhendah and Brigita, 2020).

Similarly, the results of the path analysis show that the coefficient of the path between organizational innovation and organizational performance is 0.375, which is positive and significant at the 0.001 level. This positive sign of the coefficient means that organizational innovation directly affects the organizational performance in the Palestinian pharmaceutical companies. In other words, enhancing organizational innovation leads to improved performance in these companies. Thus, the second hypothesis, which postulates a significant positive relationship between organizational innovation and organizational performance in the Palestinian pharmaceutical companies, is accepted. This result is in line with the results of many previous empirical studies, which also confirmed the significance of the positive relationship between these two variables (e.g., Akgun et al., 2014; Antunes et al., 2017; Chaudhry et al., 2018; Hafeez et al., 2018; Hussain et al., 2020; Sirisan, 2020; Suhendah and Brigita, 2020).

Finally, the results of the path analysis indicate that the coefficient of the path between TQM and organizational performance is 0.458. This coefficient is positive and significant at the 0.001 level, meaning that TQM has a positive direct effect on the organizational performance of the Palestinian pharmaceutical companies. In other words, better TQM application leads to improved organizational performance in these companies. Thus, the third hypothesis, which postulates a significant positive relationship between TQM and organizational performance in the Palestinian pharmaceutical companies, is accepted. This result agrees with the results of many previous empirical studies, which also confirmed the significance of the positive relationship between these two variables (e.g., Farish et al., 2017; Hafeez et al., 2018; Hussain et al., 2020; Singh et al., 2018; Sirisan, 2020).

Testing Mediation Effect

Recall that the fourth hypothesis is:

H_4: The relationship between TQM and organizational performance in the Palestinian pharmaceutical companies is mediated by organizational innovation.

But before testing the above hypothesis, it is worth discussing the concept of mediation. According to Hair et al. (2017), mediation happens when a third variable (the mediator variable) intervenes between two other associated variables. More specifically, a change in the independent variable causes a change in the mediator variable, resulting in a change in the dependent variable in the structural model. Thus, a mediator variable governs the nature (i.e., the underlying mechanism or process) of the relationship between the two variables (i.e. the independent and dependent variables). In short, analyzing the mediation

effect allows understanding the mechanism that underlies the cause-effect relationship between the independent and dependent variables.

The two main types of mediation discussed in the literature are full mediation and partial mediation. The first type of mediation (i.e., full mediation) occurs when the direct effect is insignificant. At the same time, the indirect effect is significant, which means that only the indirect effect via the mediator exists. In other words, full mediation means that the effect of the independent variable on the dependent variable is completely transmitted with the help of another variable (i.e., mediator variable). In contrast, partial mediation occurs when the direct and indirect effects are significant. As the name suggests, partial mediation partially explains the relationship between the independent and dependent variables (Hair et al., 2017).

To test the mediation effect of organizational innovation on the relationship between TQM and organizational performance in the Palestinian pharmaceutical companies, the indirect effect is analyzed (Table 4.19). The results confirm that TQM has a significant positive effect, through organizational innovation, on the organizational performance in the Palestinian pharmaceutical companies ($\beta = 0.248, P < 0.001$).

Since TQM has a significant direct positive effect on organizational performance, as previously discussed, and also has an indirect effect via organizational innovation, it is concluded that the relationship between TQM and organizational performance is partially mediated by organizational innovation.

The above result provides empirical support for the mediating role of organizational innovation in the structural model. Specifically, organizational innovation represents a mechanism that underlies the relationship between TQM and organizational performance.

Better TQM application improves organizational performance directly and enhances organizational innovation, which leads to improved organizational performance. Therefore, some of the TQM effects on organizational performance are explained by organizational innovation.

This result concurs with the results of many previous empirical studies which also confirmed that organizational innovation mediates the relationship between TQM and organizational performance (e.g. Akgun et al., 2014; Chaudhry et al., 2018; Farish et al., 2017; Hafeez et al., 2018; Hussain et al., 2020; Sirisan, 2020; Suhendah and Brigita, 2020).

Table 4.19: Indirect Effect of TQM on Organizational Performance

Path	Path Coefficient	Std. Error	T-Value	P-Value
TQM → Organizational performance	0.248	0.048	5.127	0.000*

* Significant at P < 0.001.

The results of the estimated structural model are summarized in Figure 4.3.

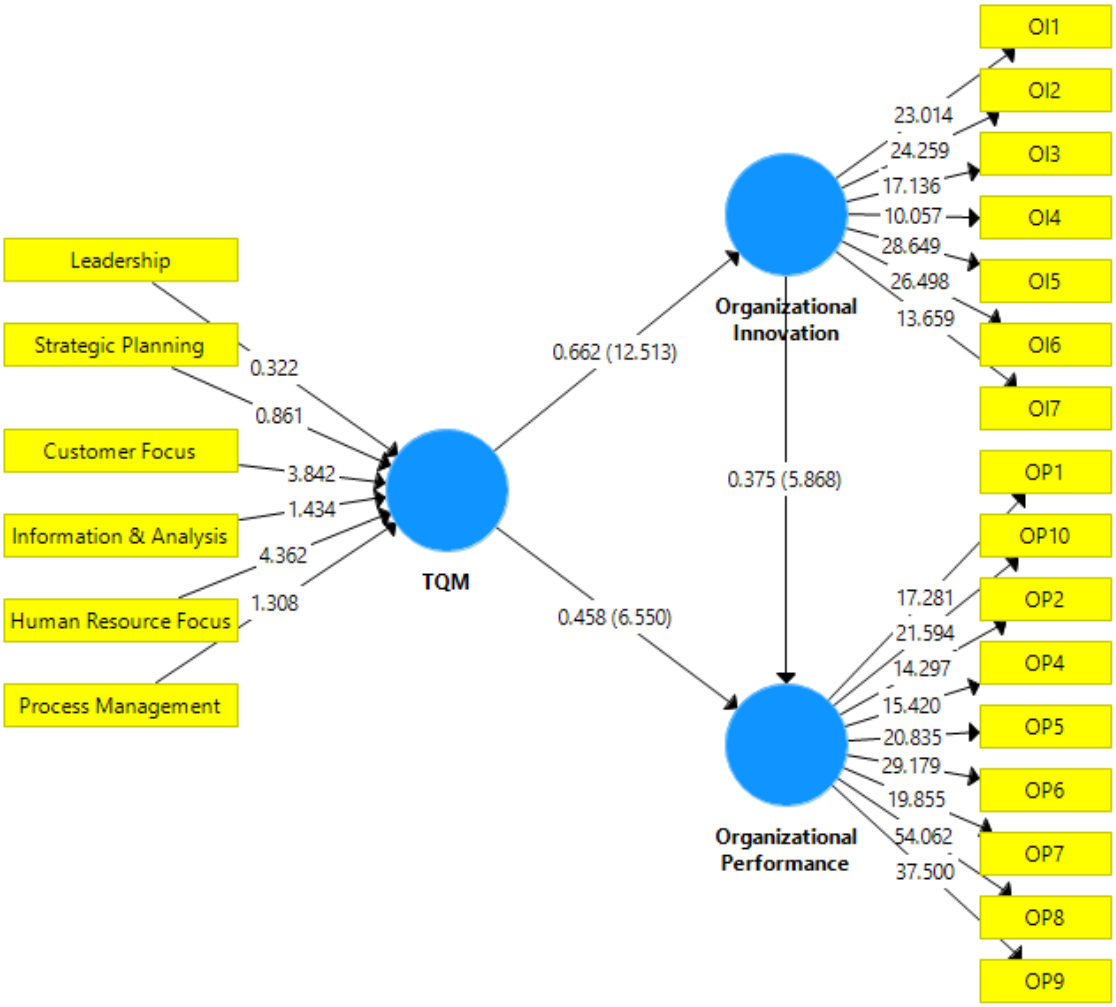

Figure 4.3: Results of Estimated Structural Model

4.3.3 Structural Model Assessment

Having estimated the structural model of the study, it is time to assess the structural model that is already estimated in terms of three criteria: (1) coefficient of determination (R^2), (2) effect size (f^2), and (3) predictive relevance (Q^2). Each of these criteria is discussed below.

Coefficient of Determination (R^2)

The first criterion used to assess the quality of the structural model is the coefficient of determination (R^2). This coefficient is interpreted in the same way as R^2 in the context of

regression analysis. It represents the percentage of the variation in the dependent variable that is explained by one or more independent variable (Hair et al., 2017).

The minimum acceptable level of the coefficient of determination (R^2) depends on the context of the research (Hair et al., 2017). However, Falk and Miller (1992) suggested that the minimum acceptable level, in the PLS-SEM context, is 0.10. According to Cohen (1988), the R^2 value is assessed as: (1) substantial (> 0.26), (2) moderate (0.13-0.26), and (3) weak (<0.02).

The coefficient of determination (R^2) of the estimated structural model is shown in Table 4.20. The results indicate that organizational innovation has an R^2 value of 0.439. This means that nearly 44% of the variation in organizational innovation is explained by TQM (i.e., the independent variable). This R^2 value exceeds the minimum acceptable level according to Falk and Miller (1992) and is substantial according to Cohen (1988).

Similarly, organizational performance has an R^2 value of 0.577, indicating that nearly 58% of the variation in organizational performance is explained by TQM and organizational innovation (i.e. the two independent variables). This R^2 value also exceeds the minimum acceptable level according to Falk and Miller (1992) and is also substantial according to Cohen (1988).

Table 4.20: Coefficient of Determination (R^2) of Structural Model

Dependent Variable	R^2	Result
Organizational innovation	0.439	Substantial
Organizational performance	0.577	Substantial

Effect Size (f^2)

In addition to the previously discussed coefficient of determination (R^2), the effect size (f^2) is used to assess the quality of the structural model in the PLS-SEM context. The effect size (f^2) measures the relative effect of a specific independent variable on the dependent variable due to changes in R^2 (Chin, 1998).

An effect size (f^2) exceeding 0.35, between 0.15 and 0.35, between 0.02 and 0.15, and less than 0.02 is considered large, medium, small, and with no effect, respectively (Cohen, 1988).

The effect size (f^2) of the estimated structural model is shown in Table 4.21. The results indicate that TQM has a large effect size of 0.781 on organizational innovation. In the same way, organizational innovation has a medium effect size of 0.187 on organizational performance. Finally, TQM also has a medium effect size of 0.278 on organizational performance.

Table 4.21: Effect Size (f^2) of Structural Model

Path	f^2	Result
TQM → Organizational innovation	0.781	Large
Organizational innovation → Organizational performance	0.187	Medium
TQM → Organizational performance	0.278	Large

Predictive Relevance (Q^2)

Finally, it is important to assess the predictive capability of the estimated structural model using the predictive relevance (Q^2) criterion. This value can be calculated using the cross-validated redundancy approach. According to Fornell and Cha (1994), an Q^2 value of

more than zero indicates predictive relevance of the structural model while a value of less than zero indicates that the model lacks predictive relevance.

The predictive relevance (Q^2) of the estimated structural model, using the cross-validated redundancy approach is shown in Table 4.22. In this context, it is worth saying that SSO stands for the sum of squared observations, SSE stands for the sum of squared prediction errors, and the last column (i.e., 1–SSE/SSO) gives the Q^2 value. The results indicate that each of organizational innovation and organizational performance has an Q^2 value that is greater than zero. More specifically, organizational innovation has an Q^2 value of 0.274 whereas organizational performance has an Q^2 value of 0.372. These above-zero Q^2 values provide evidence for the structural model's predictive relevance.

Table 4.22: Predictive Relevance (Q^2) of Structural Model

Dependent Variable	SSO	SSE	Q^2 (1-SSE/SSO)
Organizational innovation	728.000	528.743	0.274
Organizational performance	936.000	587.695	0.372

CHAPTER FIVE

CONCLUSIONS AND RECOMMENDATIONS

5.1 Overview

In this chapter, the study's main conclusions are summarized, recommendations are provided to interested parties, and some suggestions for future researchers are given.

5.2 Conclusions of Study

As mentioned previously, main objective of this study is to assess the level of TQM application in the Palestinian pharmaceutical companies and investigate its effect on their organizational performance, considering the mediating effect of organizational innovation.

The results of the study indicate that the Palestinian pharmaceutical companies apply total quality management (TQM) at a high level, with a mean value of 3.95 on a five-point scale. In addition, organizational innovation has a high perceived level, with a mean value of 3.61 on a five-point scale. With respect of organizational performance in these companies, it has a high perceived level, with a mean value of 4.07 on a five-point scale.

The measurement model assessment proves that the Malcolm Baldridge National Quality Award (MBNQA) framework is a valid and reliable tool to assess TQM application in Palestinian pharmaceutical companies.

Moreover, the results prove that among the six dimensions capturing TQM in the Palestinian pharmaceutical companies, the three dimensions of information and analysis, process management, and strategic planning are the most implemented, whereas the three

dimensions of customer focus, leadership, and human resource focus are the least implemented.

The estimated structural equation model (SEM) confirms that TQM has a significant direct positive effect on organizational innovation and performance in the Palestinian pharmaceutical companies. Also, organizational innovation has a significant direct positive effect on organizational performance.

Finally, the mediation analysis confirms that the relationship between TQM and organizational performance in Palestinian pharmaceutical companies is partially mediated by organizational innovation.

5.3 Recommendations of Study

In light of the above conclusions of the study, the following recommendations are made to interested parties:

1. The Palestinian pharmaceutical companies are encouraged to periodically employ the Malcolm Baldridge National Quality Award (MBNQA) framework to assess the TQM application-level.
2. The Palestinian pharmaceutical companies are highly recommended to design and implement TQM strategies to enhance organizational innovation and improve organizational performance.
3. The Palestinian pharmaceutical companies need to improve their TQM application further, especially in the three dimensions of customer focus, leadership, and human resource focus.

4. The Palestinian pharmaceutical companies are advised to empower their employees more and more to enhance organizational innovation, which in turn improves organizational performance.

5.4 Suggestions for Future Researchers

Some suggestions for future researchers are worth mentioning. First, future researchers are advised to include other mediating variables (e.g., learning capability and knowledge management) or moderation variables (e.g., ISO certification and organizational culture) while investigating the relationship between TQM and organizational performance. Second, researchers are recommended to use business quality models other than the Malcolm Baldridge National Quality Award (MBNQA) framework (e.g., EFQM model) to measure TQM. Third, researchers are directed to similar studies using other performance measures (e.g., innovation performance and social performance). Last but not least, researchers are endorsed to carry out similar studies to industries other than the pharmaceutical one (e.g., service industry and healthcare industry).

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APPENDIX A

RESEARCH INSTRUMENT

Dear Sir / Madam,

The researcher is carrying out a study titled "**Assessment of TQM Application: The Case of Palestinian Pharmaceutical Industry**" as partial fulfilment of the requirements for the Master's degree in Quality Management at the Arab American University, Ramallah Branch.

This questionnaire is developed to collect the primary data. The data you provide will help the researcher assess the level of TQM application in the Palestinian pharmaceutical companies and investigate its effect on their organizational performance taking into consideration the mediating role of organizational innovation.

Because you are the one who can give a correct picture in this regard, you are invited to respond to the questions honestly. Completing the questionnaire takes no more than 15 minutes.

Your responses will be dealt with as strictly confidential. They will be used for scientific purposes only.

Thank you in advance. I highly appreciate your help.

Regards,

Wafa Abduljalil

Part One: Respondents' Characteristics

Please circle the number of the appropriate response for you:

1. Gender:

1. Male.
2. Female.

3. Age:

1. 30 years or less.
2. More than 30 years.

3. Highest completed level of education:

1. Diploma.
2. BA.
3. Master's.
4. PhD.

5. Total years of experience:

1. 10 years or less.
2. More than 10 years.

3. Job responsibilities:

1. Finance / administration.
2. Purchase / procurement.
3. Production / operation.
4. R&D / product development.
5. Sales / marketing.
6. Logistics / distribution.
7. Quality management
8. Other. Specify _____

Part Two: Companies' Characteristics

Please circle the number of the appropriate response for your company:

1. Company age:

1. Less than 10 years.
2. 10-20.
3. 20-30 years.
4. More than 30 years.

5. Paid-in capital:

1. Less than $10 million.
2. $10-20 million.
3. More than $20 million.

4. Total number of employees:

1. Less than 50.
2. 50-100.
3. 101-150.
4. More than 150.

5. Types of markets (choose all that apply):

1. Local.
2. Regional.
3. International.

4. Total number of pharmaceutical products:

1. Less than 50.
2. 50-100.
3. 101-150.
4. More than 150.

5. Accreditation (choose all that apply):

1. ISO.
2. GMP.
3. FDA.
4. Other. Specify _____

Part Three: Total Quality Management (TQM)				
Please indicate the extent to which you agree with the following statements, using the scale given below, and indicate the response number on the box by each statement:				
Strongly Disagree (1)	**Disagree (2)**	**Neutral (3)**	**Agree (4)**	**Strongly Agree (5)**
Dimension 1: Leadership (L)				
1. Top management is strongly committed to the culture of change.				
2. Top management is dedicated to quality improvement.				
3. Top management allocates sufficient resources for quality improvement. (i.e. patient safety).				
4. Top management strongly encourages employees to share their views and try new things.				
5. Top management regularly shares the company vision with employees.				
Dimension 2: Strategic Planning (SP)				
6. The company has clear vision and mission statements.				
7. Top management regularly sets and reviews short- and long-term goals.				
8. Top management provides adequate resources and support to achieve short- and long-term goals.				
9. The policies and plans of the company consider employees', customers', and other stakeholders' needs.				
10. The policies and plans of the company take occupational safety into account.				
11. The strategies and plans of the company are focused on quality improvement.				
12. Company's operations are effectively aligned with the vision and mission statements.				
Dimension 3: Customer Focus (CF) (e.g. doctors, pharmacists, and patients)				
13. The company designs its products by considering customers' requirements.				

Part Three: Total Quality Management (TQM)				
Please indicate the extent to which you agree with the following statements, using the scale given below, and indicate the response number on the box by each statement:				
Strongly Disagree (1)	**Disagree (2)**	**Neutral (3)**	**Agree (4)**	**Strongly Agree (5)**
14. The company regularly provides information about its new products to its customer.				
15. The company regularly takes feedback from its customers about their experiences and expectations to measure their satisfaction.				
16. The information about customers' experiences and expectations is widely used by management to improve the products.				
17. Managers support employees' initiatives to improve customers' satisfaction.				
18. The company is keen to resolve customers' complaints via an effective mechanism.				
19. The company keeps strong relationships with its customers by providing them with an easy channel for communication.				
Dimension 4: Information and Analysis (IA)				
20. The company has effective information and reporting system for all products.				
21. Management regularly provides quality data (errors, complains, defects, etc.) to the workers.				
22. Workers, supervisors, and managers can easily retrieve information about different products.				
23. Top management uses quality data to make decisions and plans.				
24. All departments coordinate with each other to implement and monitor quality improvement programs.				
Dimension 5: Human Resource Focus (HRF)				
25. Management gives value to recruitment standards by employing "the right man at the right place".				

<u>Part Three</u>: Total Quality Management (TQM)	
Please indicate the extent to which you agree with the following statements, using the scale given below, and indicate the response number on the box by each statement:	
Strongly Disagree (1) **Disagree (2)** **Neutral (3)** **Agree (4)** **Strongly Agree (5)**	
26. The company regularly arranges training and development sessions for its employees.	
27. The company has an effective reward system to motivate the employees.	
28. Management regularly takes employees' views and consider them to improve product quality.	
29. The company has effective top-to-bottom and bottom-to-top communication process.	
30. Quality is treated as the responsibility of all employees.	
31. The company treats its employees as assets and regularly measure their satisfaction level.	
32. Management is concerned about the well-being of its employees (e.g. health and security).	
Dimension 6: Process Management (PM)	
33. The company has standardized operational processes that are clear and well understood by employees and customers.	
34. Most of the processes in the company are automated, fool-proof, and minimizes human error chances.	
35. The company has the latest technology and equipment to serve its customers more effectively and efficiently.	
36. The system allows management to inspect and track key processes that are critical to the company.	
37. The company regularly evaluates and improves business processes to ensure quality.	

Part Four: Organizational Innovation				
Please indicate the extent to which you agree with the following statements, using the scale given below, and indicate the response number on the box by each statement:				
Strongly Disagree (1)	**Disagree (2)**	**Neutral (3)**	**Agree (4)**	**Strongly Agree (5)**
1. The number of new product introductions is high compared to competitors.				
2. Compared to competitors, the company is faster in bringing new products into the market.				
3. The company encourages new ideas presented to develop the performance.				
4. The new product introductions have increased over the last 5 years.				
5. The company changes production methods at great speed compared to competitors.				
6. The technological competitiveness of the company is high.				
7. During the last five years, the company has developed new management approaches.				

Part Five: Organizational Performance	
Please indicate the extent to which you agree with the following statements, using the scale given below, and indicate the response number on the box by each statement:	
Strongly Disagree (1) **Disagree (2)** **Neutral (3)** **Agree (4)** **Strongly Agree (5)**	
1. Generally, customers are satisfied with the company's products.	
2. The company is able to meet its financial obligations.	
3. The company's system of remuneration and benefits is satisfactory.	
4. Generally, employees are satisfied with their own departments.	
5. The company's products are expanding.	
6. The company's product quality is improving steadily.	
7. The company's productivity is rising steadily.	
8. The company's reputation is improving.	
9. Technical support is available when needed.	
10. There is adequate cooperation between administrative employees and technicians.	

Thank You

APPENDIX B

GMP INSPECTION CHECKLIST

الملخص

تُعدّ قضايا الجودة في قطاع الأدوية ذات أهمية قصوى لأن هذا القطاع من بين أكثر القطاعات تنظيماً. ومن ثمّ فإن شركات الأدوية تهتم بشكل متزايد بتطبيق مبادئ إدارة الجودة الشاملة. وفي هذا الصدد، تؤكد العديد من الدراسات أن هذا التطبيق يؤثر على العديد من المتغيرات بما في ذلك، من بين أمور أخرى، الابتكار والأداء.

ولذلك، تهدف هذه الدراسة إلى تقييم مستوى تطبيق إدارة الجودة الشاملة في شركات الأدوية الفلسطينية وفحص أثر ذلك على أدائها المؤسسي، مع الأخذ في الاعتبار الدور الوسيط للابتكار المؤسسي. ولتحقيق هذا الهدف، تم اعتماد منهج البحث الكمي من خلال اختبار الفرضيات. وتم جمع البيانات الأولية، من خلال استبانة تم توزيعها بشكل شخصي، على عينة قصدية تتألف من 104 من مدراء الإدارات المتوسطة والعليا العاملين في شركات الأدوية الخمسة في فلسطين.

وتتكون الاستبانة، المعدة بناءً على إطار جائزة مالكولم بالدريدج الوطنية للجودة (MBNQA)، من خمسة أجزاء رئيسة: (1) خصائص المستجيبين، (2) خصائص الشركات، (3) تطبيق إدارة الجودة الشاملة، (4) الابتكار المؤسسي، و(5) الأداء المؤسسي. وتم تحليل البيانات باستخدام الإحصاءات الوصفية، بما في ذلك المتوسطات الحسابية والانحرافات المعيارية، وتقنية نمذجة المعادلات الهيكلية (PLS-SEM).

يُظهر نموذج القياس الخاص بالدراسة أن إطار جائزة مالكولم بالدريدج الوطنية للجودة (MBNQA) أداة ذات مصداقية وموثوقية لفحص أثر تطبيق إدارة الجودة الشاملة على الأداء المؤسسي في شركات الأدوية الفلسطينية من خلال الابتكار المؤسسي. كما تشير النتائج إلى أن هذه الشركات تتمتع بمستويات عالية من إدارة الجودة الشاملة والابتكار المؤسسي والأداء المؤسسي. بالإضافة إلى ذلك، يؤكد تحليل المسارات أن إدارة الجودة الشاملة لها أثر إيجابي مباشر ذو دلالة إحصائية على الابتكار المؤسسي والأداء المؤسسي. كما أن للابتكار المؤسسي أثر إيجابي مباشر ذو دلالة إحصائية على الأداء المؤسسي. وأخيراً، وُجد أن العلاقة بين إدارة الجودة الشاملة والأداء المؤسسي يتوسطها جزئياً الابتكار المؤسسي.

وأخيراً وليس آخراً، يجدر مناقشة ثلاثة محددات رئيسة للدراسة. بادئ ذي بدء، تقتصر هذه الدراسة فقط على شركات الأدوية وبالتالي لا يمكن تعميم نتائجها على الشركات الصناعية الأخرى. ثانياً، تم تطبيق هذه الدراسة فقط على خمس شركات أدوية عاملة في الضفة الغربية ولا تشمل الشركات

العاملة في قطاع غزة. وأخيراً، لم يتم تحديد التسلسل الزمني للعلاقات بين إدارة الجودة الشاملة والابتكار المؤسسي والأداء المؤسسي لأنه تم استخدام بيانات مقطعية بدلاً من البيانات الطولية.