

# Disclosure of Good Manufacturing Policies and their Effect on Total Quality Management through Strategic Innovation: An Analytical Study at SDI in Samarra, Iraq

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The objective of this paper is to explore good manufacturing policies (GMP) and their effect on Total Quality Management (TQM) through strategic innovation (SI) as an intermediate variable. It addresses the apparent tension between quality management and strategic innovation within the total quality management model in SDI, Samara, Iraq. This paper explores the relationship between good manufacturing policies, total quality management and strategic creativity. Also, the effect of all stakeholders on TQM has been assessed. **Design / Methodology / Approach** - A survey was conducted for the pharmaceutical plant in Samarra and the resulting data were analysed using statistical analysis (SPSS) to determine how good manufacturing policies affect TQM. A 40-question survey tool was developed, organised into three groups: questions on good manufacturing policies, strategic innovation, and Total Quality Management. The number of participants was 125. **Originality/Value** - The perception of TQM by experts in pharmaceutical companies and organisational power is broader than the definition of TQM. From the point of view of pharmaceuticals, TQM is a holistic approach to the long-term success of the organisation, addressed to all stakeholders, with a focus on public health.

**Key words:** *Good Manufacturing policies (GMP), Total Quality Management (TQM), and Strategic Innovation (SI).*

## **Introduction**

GMP is one of the most modern management topics that has attracted the interest of pharmaceutical companies and researchers in the field of production and operations management policies and TQM. The recent global trend is giving increasing attention to the interest of pharmaceutical companies in international standards including (GMP, ISO). The pharmaceutical industry in Iraq is one of the most influential sectors in this aspect, because of the importance of the fact that these products involve human health and safety. Therefore, the pharmaceutical companies must strive to implement Total Quality Management, in line with good manufacturing policies through strategic innovation to achieve excellence in performance and quality of pharmaceutical products at an appropriate price. This is sought by the producing companies and international and regional regulatory organisations specialised in this aspect, such as (WHO), the European Drug Agency (EMA), and the US Food and Drug Administration (USFDA) by issuing internationally recognised standards, assurance, guidelines, and guarantees, to regulate the industry, quality of production and circulation of medicines locally and internationally. Based on the above, this study sheds light on this important aspect to know the extent of good manufacturing policies in the pharmaceutical industry in Iraq and the relationship of this with providing the requirements of the application of quality management through strategic innovation.

## **Literature Review and Research Background**

### ***The Emergence of the Concept of Good Manufacturing Policies***

Good manufacturing policies in the pharmaceutical industry are important and necessary to ensure that pharmaceutical products are allowed to be traded in the local, regional or international markets. Most countries do not allow the circulation, export or import of any pharmaceutical product unless it is manufactured in accordance with good manufacturing policies. The manufacturer must have a certificate of good manufacturing policies by the state authority or from a global organisation such as the US Food and Drug Administration (USADA), the World Health Organisation (WHO), or by the Australian Department of Therapeutic Goods (TGA) The importance of these practices is that most of the countries of the world, including Iraq, have passed laws and regulations regulating the work of pharmaceutical factories and obligate them to policies of good manufacturing. The most developing countries, as well as the Arab countries, including Iraq, apply the guidelines and instructions of the good manufacturing policies of the World Health Organisation (WHO-GMP) (Nally, 2007, 339). Good manufacturing has a number of policies, including the following (Nally, 2007: 235), (Sharam, 2015:163) :-



### ***Human Staff***

A competent and qualified human staff is the decisive and essential element in the organisation's success or failure. It is mandated to carry out all the activities of the organisation, including activities related to the application of systems related to the quality of products and processes, as well as on how to optimise the use of machinery and equipment according to the work or function in which he or she is employed, to be able to carry out the functions of the position he/she occupies and the responsibility he/she bears.

### ***Production and Manufacturing Areas***

The processes of manufacturing pharmaceutical products must follow clear and specific methods according to the authorisation of manufacturing and marketing in order to obtain the required products. This can only be achieved through following procedures and instructions for all operations, such as quarantine, sampling, storage and labelling on all materials, manufacturing processes and finally packaging and distribution after the authorisation of the operational license by authorised persons has been made. This is done so that there is no room for omission of any step or process that may affect the pharmaceutical product and safety, and requires the practice of good manufacturing to take the necessary steps in the manufacturing areas in order to avoid any contamination or for mixing through the sources of pollution control.

### ***Documentation***

All successful and productive organisations are concerned with the documentation process for all activities and processes that take place within them, whether documents, instructions, specifications, or records, so that these documents are a reference for the organisation in the event of any defect, deviation or complaint in the product (Khawaja, 119, 2007).

### ***Raw Materials and Packaging Materials***

The practice of making pharmaceutical products requires the use of effective raw materials as well as packing and packaging materials. It is necessary to take unusual procedural policies in the handling, testing, and storage of these materials. The first of these procedural policies is the development of specifications for raw materials, packaging materials, purchase, and withdrawing samples at the time of receipt, and ensuring compliance with these specifications.

### ***Buildings and Equipment***

The selection, construction, and installation of the construction site shall be appropriate for the purposes of the manufacturing practices; the operating place shall be of sufficient space to prevent the risk and the transmission of pollution and keep any other errors to the minimum. The equipment should be designed to suit the implementation of the processes, and that planning and design should reduce errors, and allow cleaning and maintenance effectively, in order to avoid any negative effect on the quality of the pharmaceutical industry.

### ***The Concept of Total Quality Management***

During the last couple of decades, a number of studies demonstrate that TQM has benefited organisations through improving quality of products and services, thus offering superior quality products to their customers and enhancing the firm's performance. In recent years, the level of awareness towards TQM has increased considerably due to intense global competition, increasing consumer consciousness of quality, rapid technology transfer, and trends towards achieving world class status. In response to these challenges and to facilitate the organisations in achieving higher quality levels, many companies are implementing the TQM approach and quality initiatives for achieving sustainable competitive advantage and enhanced company performance (Rami & et, al., 2015:1071). TQM is one of the most prominent intellectual and philosophical concepts that has attracted wide attention by researchers interested in developing and improving production performance or service in various organisations (Azher, el al, 2013: 2). Described by OakLand, (2000: 57) as a comprehensive approach to improve competition, efficiency and flexibility through planning, organisation, understanding of each activity, and involving all employees at all levels and focusing on prevention rather than addressing problems. The dimensions of TQM are as follows (Goetsch & Davis, 2006) & (Gouveia, 2015):-

### ***Top Management Support***

Top management is one of the most important vital principles in TQM that has a very imperative role in creating an organisational climate that motivates employees. Organisations which rely more on team-based work structures have results in greater productivity and employee performance as teams have been argued to potentially overcome complex problems at work (Khawka, 2016:234).

The decision to implement TQM must be issued by top management as a long-term strategic decision. It is necessary to change the culture of the employees and to inform them of the importance of this new philosophy and it's benefits to the organisation and the society, and to determine the period required to implement it through the formulation of a declared and

written policy known to all the workers in the organisation, as this requires sufficient time, plans and short- and long-term programs. Ayed, (2012: 172) states that most failures in the application of TQM are due to the lack of faith and commitment of senior management. These departments should define their orientations and priorities in order to reach customers, work to meet their expectations and needs, and encourage all employees to participate, learn, train, and innovate. This can only be achieved through the conviction and belief of senior management (Nasser, 2016: 23).

### ***Creating the Work Environment and the Culture of the Organisation***

Before embarking on the introduction of the philosophy of TQM and putting it into practice, it is necessary to create the work environment and the culture of the organisation by educating employees and introducing them to the concept of this philosophy, by holding seminars, lectures and education and training programs to reach the stage of conviction. A convenient atmosphere must be attained that includes all amenities and safety and explains the policies, procedures, laws and regulations of the organisation (Isa, 2014,20).

### ***Quality Measurement System***

For the purpose of applying TQM successfully, it is necessary to establish standards to measure the level of application of TQM and control as it helps to detect deviations in performance in a timely manner and to take appropriate corrective measures (Ayed, 2012: 178). These tools are an intelligent means of gathering information and ideas to help get good results and sound decision-making solutions (Goetsch & Davis, 2006: 484). Different quality systems require measuring tools to ensure the effectiveness and efficiency of these systems.

### ***Information Systems for Total Quality Management***

The successful implementation of TQM requires the availability of good information related to the daily reports on the existence of the products and their conformity with the predefined specifications, as well as reports on the performance of the employees and the opinions of the customers about the products that will form the basis for continuous improvement Obaidat, (2007:224). Najjar (2013: 24) notes that decision making processes under TQM are not random, but based on factual information and facts about the organisation's activity.

### ***The Concept of Strategic Innovation***

Schlegilimlihy (2003: 118) defined strategic innovation as reshaping markets by breaking the rules of the game of competition to achieve changes in the value of customers and achieving an exponential growth of organisations. Govindarajan & Gupta (2001: 1) affirm that

strategic innovation must change the rules of the game and be within a system that works for targeted action events (Martin 1998: 1). He notes that the concept of strategic innovation is part of the state of mind of the organisation's management and philosophy and is a cornerstone of the overall strategy, and when innovation within the strategic pathways will certainly create basic rules for the application of quality in an organisation that is difficult for competitors to imitate. (Demian & Vandebish, 1993: 176) Strategic innovation is a new form of organisation that results from new practices and skills that have been modified first by the possibility of modifying production rules in an industry. While the direction (Jones: 2002: 13) was even more so when it was a substitute for the establishment of the business strategy through creativity and extraordinary new design or extraordinary product, in order to fulfill the strategic intent (Koivisto 2005: 34). Strategic innovation is enhanced growth through continuous innovations through science and knowledge and the creation of new ideas for the benefit of both customers and the organisation. Jonse (2002: 24) argues that strategic innovation is a process that makes the organisation look beyond its open mental models, creating new business models that include a new value, creating new markets, reshaping existing markets, creating or increasing value for each from the customer and the organisation or to all of these goals combined (Drejer 2008: 144).

### **Research Methodology**

After reviewing the research background, it was easy to choose the methodology for our research as following:

#### ***Research Problem***

Business organisations are faced with many challenges under the international and electronic trading system and the revolution of communications and informatics that have made the world markets open to all. These factors have increased the volume of competition. The operation of the market mechanisms has made much more supply than demand in many international markets. In meeting market needs with high-quality products to gain a larger market share, business organisations have tended to adopt good manufacturing policies and strategic innovation which is an effective means to manage the requirements of the application of total quality management of organisations. The pharmaceutical industry in Iraq is one of the most influential sectors in this aspect because of the competition of imported medicines, some of which may not be in accordance with specifications. Therefore, the pharmaceutical companies working in Iraq, including Samarra pharmaceutical industry that is affiliated with the Iraqi Ministry of Health, should focus on good manufacturing policies and creativity in the management of total quality by controlling the manufacturing policies in the production of pharmaceuticals. This is because they affect the health and safety of citizens and it is the role of the national manufacture of medicine to reduce the importing of

medicines, prevent trafficking in non-conforming pharmaceutical products and to supply the local market with national products. Based on the above, the problem of research can be formulated through the following question: - How good manufacturing practices contribute to the management of total quality through creativity. This branches out to the following sub-questions:

- Does the company's management recognise the importance of good manufacturing policies in the safety of pharmaceutical products before they are applied?
- What is extent the company's management is aware of the importance of strategic innovation in improving manufacturing processes and the quality of its products?.
- Is there an effect of good manufacturing policies in Total Quality Management through the role played by strategic innovation in the company being investigated?
- What is the role played by the strategic innovation in the management of the total quality of Samarra pharmaceutical company?

### ***Research Objectives***

The research aims at achieving a number of objectives, namely:

- To identify the reality of the practices of the application of good manufacturing in the General Company for the manufacture of medicines at the factory Samarra – Iraq, and to determine the overall indicators of the level of interest and awareness of it's departments to the dimensions of good manufacturing.
- To identify the level of application of total quality management and the level of policies of strategic innovation in the pharmaceutical factory.
- To determine the nature of the relationship between the good manufacturing practices and the total quality management of the company in question.
- To determine the effect of good manufacturing policies on Total Quality Management through strategic innovation.

### ***The Importance of the Research***

The importance of the research is shown mainly by the importance of it's variables, which are good manufacturing policies, total quality management and strategic creativity in Samarra for the production of medicines, which may produce positive results for the advancement of the pharmaceutical industry, which is one of the main pillars to support the needs and pharmacological requirements of the Iraqi citizen. As well as the importance that is reflected in the following points:

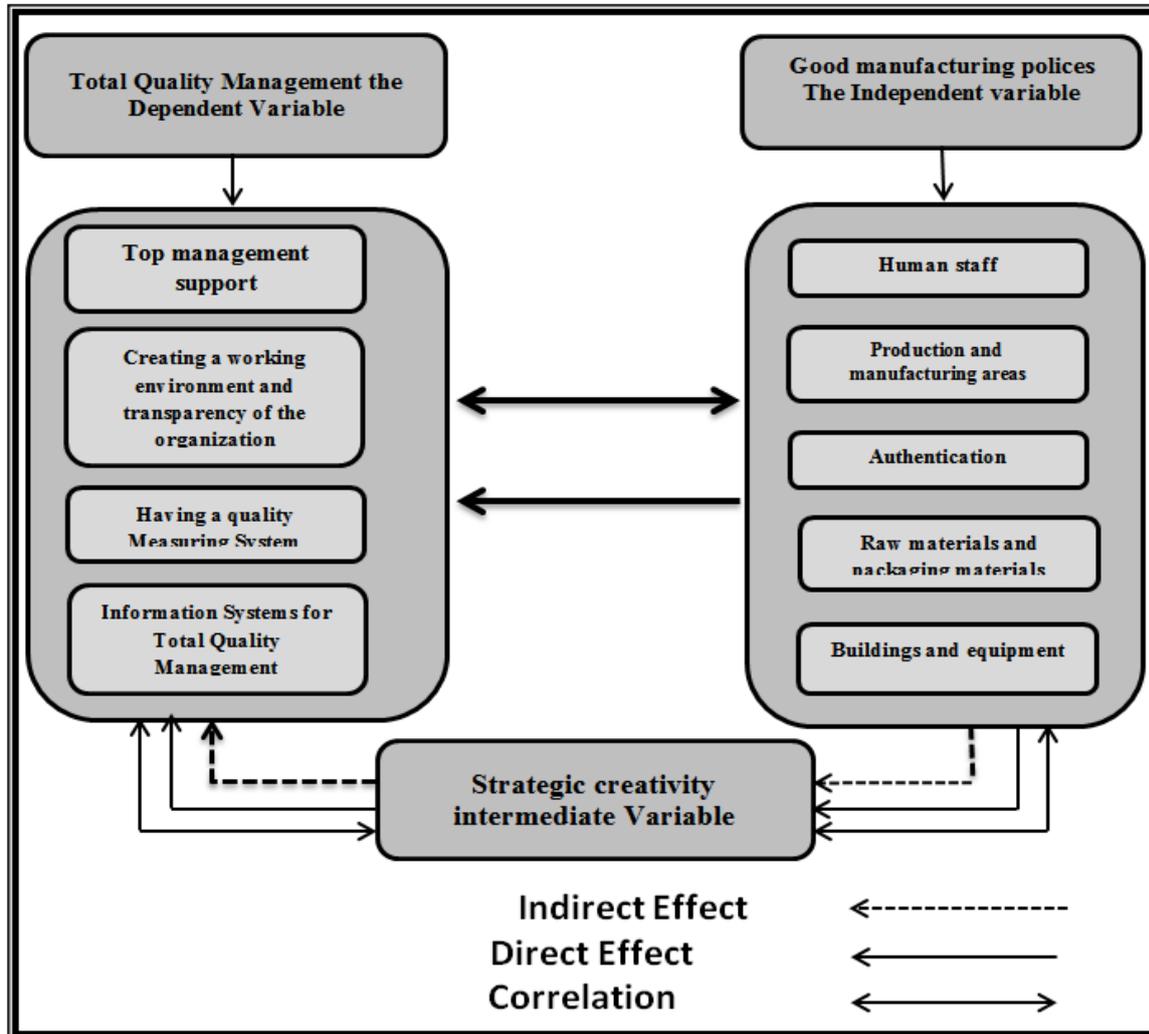


- To clarify the importance of good manufacturing policies and total quality management in modifying the practices adopted by the factory management in the pharmaceutical industry and to promote this vital industrial sector in Iraq.
- The research provides an explanation of the importance of good manufacturing policies and the nature of the relationship (**correlation and effect**) in the management of total quality through strategic innovation.
- This research represents the first attempts in the Iraqi environment, which provides the subject of good production policies in the pharmaceutical factory in Samarra in a simple attempt by researchers to provide new concepts and results on the possibility of working these practices to achieve total quality management of the company surveyed.

### ***Research Hypotheses and Conceptual Research Framework***

In order to complete the analytical treatment of the research methodology and in light of the variables and the problem of research and to achieve its objectives, a model was constructed to demonstrate the nature of the correlative and influential relationships between the independent and intermediate research variables, which are represented in good manufacturing policies, total quality management and strategic innovation.

**Figure 1.** Conceptual research framework



**The First Main Hypothesis:** There is a significant correlation between good manufacturing practices and the requirements of Total Quality Management implementation.

**The Second Main Hypothesis:** There is a significant correlation between the strategic creativity and the requirements of the application of Total Quality Management and its dimensions.

**The Third Main Hypothesis:** There is a significant correlation between good manufacturing practices and strategic innovation.

**The Fourth Main Hypothesis:** Good manufacturing policies have a significant effect on the application of Total Quality Management.

**The Fifth Hypothesis:** The strategic innovation has a significant effect on the application of Total Quality Management.

**The Sixth Hypothesis:** Good manufacturing policies have a significant effect on strategic innovation.

**The Seventh Hypothesis:** Good manufacturing policies have a significant effect on the requirements of Total Quality Management (TQM) by centralising strategic innovation. In light of this, the following hypotheses emerged:

- Human staff influences the requirements of TQM through strategic innovation.
- The documentation affects the requirements of TQM through strategic innovation.
- Buildings and equipment affect the requirements of TQM through strategic innovation.
- Production and manufacturing areas affect TQM requirements through strategic innovation.
- Raw materials and packaging materials affect the requirements of TQM through strategic innovation

## Results

### *Good Manufacturing policies*

The value of the general arithmetic mean of the good manufacturing policies (3.439), which is higher than the satisfactory mean of 3 and good level with a standard deviation of (0.671) and coefficient of difference (19.509). This variable came second level in terms of the relative importance of the variables either at the level of dimensions reached the highest general account after raw materials and packaging materials reached (3.499). The company is keen to deal with suppliers with quality certificates - certificates of conformity to the raw materials of packaging (the highest mean of this dimension of (3.56) and deviation (0.797) (19.794)). This dimension was the first level in terms of relative importance, and paragraph (17) of it (the company is keen to deal with suppliers with quality certificates - which are suitable for raw materials and packaging materials) and a standard deviation (0.797) and a difference coefficient of 22.388. The most significant contribution to the formation of this dimension was the lowest general accounting mean; it was at the post production and manufacturing areas at (3.392) with a standard deviation of (0.800) and coefficient of difference (23.583) In the fourth level in terms of relative importance. Paragraph (12) was used with the closed system when transporting and manufacturing raw materials to prevent pollution and according to the procedures of the blog (the most important contribution to the formation of this dimension with a mean of 3.48) and a standard deviation of (0.876) and the coefficient of difference (25.172).

**Table 1:** Arithmetic mean, standard deviation, and coefficient of variation of dimensions of the variable good manufacturing policies

Relative Importance	Coefficient of variation	standard deviation	Arithmetic mean	Paragraphs
<b>After the human Staff</b>				
	30.143	1.052	3.49	The company has an efficient human staff that meets the manufacturing requirements and responsibilities
	29.260	0.989	3.38	The company integrates human staff into our training program including GMP
	31.250	1.05	3.36	The company operates with an organisational structure that defines the duties, responsibilities and responsibilities of the human resources department.
5	26.434	0.901	3.408	The general arithmetic mean of human staff
<b>After authentication</b>				
	29.636	1.058	3.57	The company has an authentication system that assures the safety of all activities, procedures, review and withdrawal documents
	29.970	1.001	3.34	Documents are kept for reference when needed.
	26.243	0.887	3.38	The company maintains manufacturing and packaging records for each batch of pharmaceuticals.
	24.734	0.883	3.57	There are documented specifications for materials used in manufacturing and final preparations.
2	22.030	0.764	3.466	The general arithmetic mean of documentation
<b>After the buildings and equipment</b>				
	25.029	0.866	3.46	The interior design of the buildings is executed in a way that makes it is easy to clean.
	28.665	0.923	3.22	There is a heating and fitting system for each operational area

	25.903	0.904	3.49	The equipment is designed and fitted in a suitable way to carry out manufacturing operations
	30.028	1.066	3.55	Equipment is regularly maintained according to reliable programs
3	20.756	0.712	3.432	General arithmetic mean of buildings and equipment
<b>After production and manufacturing areas</b>				
	25.172	0.876	3.48	The closed system is used when transporting and manufacturing raw materials to prevent pollution and is carried out according to the Procedures Code
	32.485	1.085	3.34	During the manufacturing process, adhesives are placed on all the main containers and equipment and the rooms with the product name, pharmaceutical form, concentration and batch number (operational)
	28.393	0.954	3.36	Before starting manufacturing, make sure that the work area and equipment are clean and free of any related products (other payments)
4	23.583	0.800	3.392	<b>General arithmetic mean of production and manufacturing areas</b>
<b>After raw materials and packaging materials</b>				
	27.851	0.972	3.49	Only raw materials allowed by the quality control department are used in manufacturing (laboratory) and this permission is issued with clear instructions.
	26.928	0.929	3.45	Imported materials are imported according to the specifications specified in the quality control department
	22.388	0.797	3.56	The company is concerned with dealing with suppliers with quality certificates (certificate of conformity of raw materials, and packaging materials)
1	19.794	0.693	3.499	<b>Raw materials and packaging materials</b>
	19.509	0.671	3.439	<b>The general arithmetic mean of good manufacturing practices</b>

### ***Requirements for the Application of Total Quality Management***

The value of the general arithmetic mean for the requirements of the application of Total Quality Management (3.410), which is higher than the satisfactory mean of (3) and good level, with a standard deviation of 0.605 and 17.750. In terms of the relative importance of the variables, at the level of dimensions, they reached the highest general mean when the existence of a **system of quality measurement** was (3.470), which is higher than the satisfactory mean of (3) and a good level with a standard deviation of (0.680) and coefficient of difference (19.595) This dimension came at the first level in terms of relative importance. All the activities of the company and it's products (the highest value of the mean of 3.53) and standard deviation (0.848) and (24.023). The lowest general mean was at the level of (3.352), average and standard deviation (0.804) And the difference coefficient (23.973) as this dimension came at the fourth level in terms of relative importance. Paragraph (31) (TQM) information system managers can make their decisions correctly; the most important in the formation of this dimension as the value of the mathematical mean (3.54), (0.955) and 26.977.

**Table 2:** Arithmetic mean, standard deviation and coefficient of variation to the dimension of the variable requirements of the application of TQM

<b>Relative importance</b>	<b>Coefficient of variation</b>	<b>standard deviation</b>	<b>Arithmetic mean</b>	<b>Paragraphs</b>
<b>After supporting senior management and supporting the philosophy of TQM</b>				
	<b>27.515</b>	<b>0.93</b>	<b>3.38</b>	The senior management of the company is committed to providing all necessary requirements for the application of total quality.
	<b>28.324</b>	<b>0.98</b>	<b>3.46</b>	The company has a written policy on TQM.
	<b>27.836</b>	<b>0.952</b>	<b>3.42</b>	The company's senior management assists in all efforts that contribute to the implementation of TQM
<b>3</b>	<b>21.309</b>	<b>0.728</b>	<b>3.416</b>	<b>The general arithmetic mean to support senior management and it's support for the philosophy of Total Quality Management</b>

<b>After creating the work environment and the culture of the organization</b>				
	<b>26.057</b>	<b>0.912</b>	<b>3.50</b>	Quality measures include all the company's activities and products.
	<b>24.769</b>	<b>0.857</b>	<b>3.46</b>	The company applies the system of tests for the intermediate products during the production processes.
	<b>26.587</b>	<b>0.888</b>	<b>3.34</b>	The company has a system to measure the quality of products according to the quality requirements of each.
	<b>28.606</b>	<b>0.944</b>	<b>3.30</b>	The company has a department specialised in quality control.
<b>2</b>	<b>20.713</b>	<b>0.704</b>	<b>3.400</b>	<b>The general arithmetic mean for the creation of the work</b>
<b>After having a quality measurement system</b>				
	<b>24.023</b>	<b>0.848</b>	<b>3.53</b>	Quality measures include all the company's activities and products.
	<b>26.928</b>	<b>0.929</b>	<b>3.45</b>	The company applies the system of tests for the intermediate products during production processes.
	<b>24.229</b>	<b>0.848</b>	<b>3.50</b>	The company has a system to measure the quality of products according to the quality requirements of each.
	<b>28.152</b>	<b>0.96</b>	<b>3.41</b>	The company has a department or department specialised in quality control.
<b>1</b>	<b>19.595</b>	<b>0.680</b>	<b>3.470</b>	<b>The general arithmetic mean of a quality measurement system</b>
<b>After the TQM information system</b>				
	<b>29.088</b>	<b>0.957</b>	<b>3.29</b>	The company has a comprehensive quality management information system.
	<b>27.544</b>	<b>0.931</b>	<b>3.38</b>	The TQM Information System provides all units and levels of management with quality information
	<b>26.977</b>	<b>0.955</b>	<b>3.54</b>	TQM information system managers can make their decisions correctly.
<b>4</b>	<b>23.973</b>	<b>0.804</b>	<b>3.352</b>	<b>The general arithmetical mean of a total quality management information system</b>
	<b>17.750</b>	<b>0.605</b>	<b>3.410</b>	<b>The general arithmetic mean of the application of TQM</b>

### ***Strategic Innovation***

The general arithmetic mean of the variable of **strategic innovation** reached 3.347, which is higher than the mean of 3 and at an average level with a standard deviation of 0.746 and a coefficient of difference 22.294. This variable came at the third level in terms of relative importance. The company has been successful in adopting creative strategies (the most significant contribution to the formation of this variable with a mean value of 3.54), a standard deviation 0.996 and a coefficient of variation of 28.136. Paragraph (37) encourages the employees to attend training sessions that are dedicated to the innovations adopted by the company. The least contribution to the formation of this variable was worth (3.10) and a standard deviation (1.128) and the coefficient of variation (36.387).

**Table 3:** Arithmetic mean, standard deviation and coefficient of variation to distance the strategic innovation variable

<b>Coefficient of variation</b>	<b>standard deviation</b>	<b>Arithmetic mean</b>	<b>Paragraphs</b>
32.422	1.044	3.22	<b>Employees have consistently sought to excel with their colleagues by finding new methods of manufacturing</b>
29.249	0.974	3.33	<b>Our creative ideas are respected and appreciated by our management</b>
26.842	0.918	3.42	<b>The company provides facilities to apply new ideas.</b>
28.257	0.989	3.50	<b>The company seeks to speed up the solution of problems that stopped in the case of creativity by developing personal contacts in the field of work.</b>
29.120	0.993	3.41	<b>The preoccupation of employees with their tasks does not give them enough time to implement innovative ideas.</b>
36.387	1.128	3.10	<b>The management of the company encourages employees to attend meetings devoted to training in the implementation of their creations.</b>
31.981	1.033	3.23	<b>Dealing with the company's resource management crisis to implement creative ideas.</b>
28.136	0.996	3.54	<b>The company has successful experiences in adopting innovative strategies.</b>

28.576	0.963	3.37	<b>The company's management believes that new ideas will improve the company's good manufacturing practices.</b>
22.294	0.746	3.347	<b>The general arithmetic mean of strategic creativity</b>

### Postulations

- The correlation coefficient between good manufacturing policies and the requirements of the application of total quality management was (0.849) at the level of significance (0.000). The value of t-test calculated (17.783) is greater than the value of (t) (1.984). This means that there is a very good and significant correlation relationship between good manufacturing policies and Total Quality Management implementation requirements.
- The correlation coefficient between the strategic innovation and the requirements of the application of total quality management (0.818) at the level of significance (0.000), where the value of the test (t) calculated (15.773), which is greater than the value (t). This means that there is a very good and significant correlation relationship between the strategic innovation and the requirements of applying Total Quality Management.
- The value of the coefficient between good manufacturing policies and strategic innovation (16.966), which is greater than (1.96) at the level of significance (0.000) and is smaller than the level of significance at (0.05). This means that there is a significant effect of good manufacturing policies (0.836). This indicates that the increase of the good manufacturing policies (X) by one unit will lead to an increase in strategic innovation by (83%). The variable of good manufacturing policies is capable of explaining (69%) of the variables in the variable application requirements of Total Quality.
- The value of the coefficient between the strategic innovation and the requirements of the application of total quality management (4.494), which is greater than (1.96) at the level of significance (0.000) and is smaller than the level of significance at (0.05). This means that the effect of moral creativity is (0.691). This indicates that the increase in strategic innovation (M) by one unit will lead to an increase in the requirements of the application of Total Quality Management (Y) by (69%). The coefficient of determination ( $R^2$ ) of (0.669) The strategic innovation variable is capable of explaining (66%) of the variable. (34%) is due to other variables not included in the research model.
- The value of the coefficient between good manufacturing policies and the requirements of the application of total quality management is (6.809), which is greater than (1.96) at the level of significance (0.000) and is smaller than the level of significance at (0.05) (0.547). This indicates that increasing good manufacturing policies (X) by one unit will lead to an increase in the requirements of the application of Total Quality Management (M) by (54%). The value of the coefficient of determination ( $R^2$ ) (0.720) shows that the variable of good manufacturing practices is capable of explaining (72%) of the variables that

apply to the Total Quality Management implementation requirements, while the remaining (28%) is due to other variables.

- The correlation coefficient between good manufacturing policies, strategic innovation, and total quality management (0.514) was at a level of (0.000), which is below the significance level (0.05), indicating a significant correlation between good manufacturing policies, strategic innovation, and Total Quality Management (TQM) and that the relationship between the variables is a strong direct positive relationship. The calculated F value of the multiple linear regression models was (192.305) which is greater than the value (F) of the scale (2.70) at the level of significance (0.05) which means that there is a significant effect between good manufacturing policies and strategic innovation in the requirements of the application of total quality management at the level of significance (5%) (95%). The value of the ( $R^2$ ) which is (0.759) indicates that good manufacturing practices and strategic innovation together can explain (75%) of the changes in (total quality management), while the remaining (25%) are other variables not included in the research model. Through the illustration of the marginal slope coefficient of good manufacturing policies (0.493) that the increase in good manufacturing policies by one unit will lead to an increase in the requirements of the application of total quality management (49%). The strategic slope of 0.293 indicates that the increase in strategic innovation by one unit will result in an increase of (29%) in the requirements of the application of Total Quality Management. The results showed that there is a significant indirect effect between the dimensions (human cadres, documentation, production, manufacturing areas, raw materials and packaging materials) in the requirements of implementing TQM through strategic innovation. CR (2.271, 4.394, 4.135, 2.302) respectively, which is greater than the standard value of (1.96) at the level of significance (0.023, 0.000, 0.000, 0.021) respectively, which is smaller than (0.05). The statistical significance between the dimensions (human cadre, documentation, production and manufacturing areas, raw materials and packaging materials) in the application of total quality management requirements through strategic innovation and influence between research variables type, is a partial effect. The results showed that there was no indirect effect between the buildings and equipment and the requirements of applying TQM. The CR test value was (0.317) and it was smaller than the critical standard value of (1.96). Direct between buildings and equipment and the requirements of the application of total quality management through strategic innovation.

## Conclusions

The researchers emphasise the need to implement the requirements of Total Quality Management in general and the need to create a suitable working environment to promote a cultural atmosphere among the employees on the basis that quality is the responsibility of each individual in the company. The latter is working to raise the consciousness of the former

through their involvement in training and development programs to adopt the philosophy of Total Quality Management within the company investigated. There is a correlation between good manufacturing practices as an independent variable and Total Quality Management as a dependent variable. This indicates that good manufacturing practices are important in achieving Total Quality Management requirements. There is a correlation between good manufacturing policies and strategic innovation, where good manufacturing policies require the adoption of innovative strategies capable of manufacturing medicines according to quality control specifications. The issue of strategic innovation is related to the requirements of achieving Total Quality Management. This indicates the interdependence between the two variables. The requirements of Total Quality Management require the application of new ideas and the implementation of modern manufacturing methods. The survey showed that there is a significant indirect effect of the dimensions (human cadres, documentation, production, manufacturing areas, raw materials and packaging materials) in activating the requirements of applying Total Quality Management in the company through strategic innovation and the type of effect which is a "partial" effect.

The results showed that there was no indirect effect on the dimension of buildings and equipment on the requirements of the application of Total Quality Management. There was no significant effect for each of the dimensions of the independent variable (good manufacturing policies) namely, documentation and raw materials. This is an indication of the company's lack of interest in the company and the weakness of the application of good manufacturing policies within the company. The good manufacturing policies also affect directly the strategic innovation and this effect is caused by the influence of both the human cadres, buildings and equipment, production and manufacturing areas. This explains the strength of these dimensions, especially the human cadres, in enhancing the company's ability to look for sophisticated work methods towards good manufacturing policies. In addition, the search for a suitable environment for the implementation of manufacturing processes of raw materials away from pollution requires creative processes, but both after employment, raw resources and packaging materials did not show any effect on strategic innovation directly. The results also showed that the effect of good manufacturing policies has an indirect effect on the requirements of achieving Total Quality Management through strategic innovation. This effect is the result of the influence of the human staff, documentation, production and manufacturing areas, raw materials and packaging materials. Strategic innovation affects the requirements of applying Total Quality Management indirectly and has a partial but not a total effect. However, buildings and equipment do not affect the requirements of the application of total quality management with the existence or mediation of strategic innovation, and this indicates the lack of focus of the company investigated on the application and activation of good manufacturing practices in the pharmaceutical industry, which is essential in the Iraqi economy.



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