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Relationship between Strategic Management and Quality Assurance of Research and Development Processes in the Pharmaceutical Industries

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Authors' contributions

This work was carried out in collaboration between both authors. Author AN conceived and designed the study. Authors AN and MAA designed the experiments. Author MAA performed the experiments and wrote the first draft of the manuscript. Author MAA performed the samplings and the statistical analysis. Author AN reviewed the first draft of the manuscript and made the final manuscript. Both authors read and approved the final manuscript.

Original Research Article

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ABSTRACT

One of the major goals of firms is maintaining and increasing market share, yet there are some barriers to achieving this important goal. It can improve those barriers using on time managing of opportunities and market needs, and the internal and environmental factors' analysis. So, one of major way in the internal and external successes of organizations is maintaining and improving the current quality level of the products and creating the new products. Therefore, they must have the appropriate plan for the quality assurance and R & D. Our aim in this paper is presenting a hybrid approach to strategic management and quality assurance for quality assessment of the R & D processes in the pharmaceutical industries. Therefore, we used the descriptive and survey based research method and hypotheses and based on the data collection method through the distributed questionnaires in the Ex sir pharmaceutical industry.

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1. INTRODUCTION

It is necessary implementing a comprehensive program for dealing with environmental rapid changes and complex organizational decisions. It is nothing but the strategic plan. Strategic management based on the dynamic mentalities, holistic and Contingency is a solution for many problems of the modern organizations [1]. Foundation of strategic management is based upon the managers understanding of competing firms, Markets, prices, raw material suppliers, distributors, governments, creditors, shareholders, and customers around the world and these factors are determinant for business success in the today's world [2]. Strategic management is allowing the organization to act in creative and innovative ways, and does not shape their future in the passive way. This style of management leads that organization can influence over their activities, so that can determine their fate and come their future under control. So, one of the most important tools is the strategic management that organizations can use to achieve future successes. Strategic management is having strategic thinking. It is an approach that human answers the opportunity and Locations in the organization using that approach [3].

Quality assurance is the control system based on the internal documentation of organizations so that did not lose their customers. In other words, quality assurance eliminates the risk of errors that cause to harm the organization and its customers [4]. That harm may reduce customer benefits or eliminate reputation. One of the most important conditions to company's success in a competitive market is to maintain and improving the product's quality and creating new products [5]. However, what immediately comes to our mind will be how to achieve the quality and how to maintain it and also improve it. This will not work unless based on the proper management of quality, and this management will not do so unless they to implement a system that would control the production process from beginning to end; not only, it can prevent the occurrence of any error during the manufacturing process, but also it converts an occurred error to an opportunity with the interesting mechanism for improving of the process [6].

Today's, in the technology-based industry lack of movement and innovation are the agent of backwardness and death. Especially when every day the competition is tighter and harder and more complex, research and development units has an effective role for technology development, product creation, customer needs analysis and creating wealth. Because of the customers are the pressure factors for development of technology and hence R & D units meet customers' needs [7].

Research and development in briefly R & D that means increasing knowledge of human and promoting culture until human welfare increasing through to design new products in the different companies [8,9].

Strategic management and quality assurance emphasize the aspects of managing, and improving of organizational performance Strategic planning is seeking to develop organizational performance to achieve the strategic objectives through the organizational vision. These strategic options may lead to the fundamental successes in the main performance of organization and its processes [1,6]. Therefore, we seek to present a hybrid approach to strategic management and quality assurance for quality assessment of the Pharmaceutical R & D Processes in the Pharmaceutical Industries. Main questions of this research are: How can evaluate R & D processes in the food industries? How can apply

quality assurance in qualitative assessment based on strategic thinking?, and can present hybrid algorithm in qualitative assessment?

1.1 Literature Review

There are some related literature reviews on this issue, and we present theirs in follows:

Jabnoun (2003) is defined QA as follows: There are basically two approaches to quality management (quality assurance and total quality management). Quality assurance is considered as an initial step in the evolution of quality, and therefore it more extensively used the quality management. It corrects especially in the Europe, Africa and Asia. Implementation of any strategy is largely depends on the culture, structure and leadership in the organization. His proposed model is regarding with the above three dimensions, In addition to, national culture plays an important role in the success of the quality plans. His works also shows fitness level within the dimensions and main quality assurance principles. Peters and Waterman (1982) also has demonstrated the importance of relationship between the seven S's strategy, structure, systems, shared values, skills, style, and staff [10].

Elhami and Maleki [8] design a pattern of drug quality assurance for Iran. They were investigated the issue of quality assurance by using a comparative study and survey using Delphi method, and determined the proposed pattern for drug quality assurance (GMP) for Iran. For achieving good-quality medicines, it should establish a comprehensive system of quality assurance, including GMP (Good Manufacturing Practice). For this purpose, the patterns of drug quality assurance in the United States, Europe and the World Health Organization were reviewed [11].

Mohammad zadeh et al. [9] are investigated model for quality assurance in the higher-education system in Iran. According to the results from the research, Ministry of Science, Research and Technology should be creators and administrator for quality assurance structure at the national level. The NGOs should determine standards (requirements) and participate in an external evaluation process. It should establish an office in each university to ensure quality. In addition, it should be uses the volunteers – encourage, participatory and soft procedures rather than mandatory - punitive, judgmental, centralized and hard procedures, until to become quality culture as available for higher education in Iran [12].

Canvar et al. [5] describes quality assurance in higher-education institutions using the strategic information systems. There ceived results show that the quality assurance is a comprehensive approach to help students and other stakeholders in an institution of higher education in order to the qualified standards. Quality assurance system success depends on management support. Thus, quality assurance must also cover strategic management, process management and the measurement system monitoring together to enable organizations interact in order to improve their processes [13]. In addition, information systems must be implementing for integrating quality assurance systems with management processes in order to increase the overall success and to evaluate the information on the quality assurance system. Any organization requires a common strategy, and action plan to integrate their activities and to create cost savings and competitive advantage. Strategic Information System also should consider integration of strategic management, process management & monitoring and measurement systems as well as international, national and regional external factors. Finally, the conceptual model for quality assurance using the strategic information systems is presented [14,15].

Rezić et al. [12] has been reviewed strategic management of universities based upon the quality assurance system. The received results show that quality assurance is a very important part of the Bologna Process. Quality assurance should be recognized as a formal tool for strategic management of higher-education institutions. Planning means a change on: a) The way in which the world -where there are universities- must changes, b) The way in which universities will change. However, more important is the fact that planning also means preserving and improving quality through the whole process of change. Without proper planning, change control cannot be more than a "crisis control," and it is impossible to ensure quality. Good quality assurance system to the universities can introduce the strategic plan as a reference for deciding to introduce budgeting and allocation of funds [16,17].

1.2 Methodology

It was carried out the descriptive–survey research methodology in this paper. Data collection method is general based in the library, and case based research. Interviews and questionnaires were used to collect data as a research instrument. The following steps are performed in order to conduct the survey: Formulation the framework, formulation a research hypothesis, design the questionnaire, analysis and suggestions. This study was used the questionnaire based on the Likert scale (five-point), also it applies the Cronbach alpha for reliability and validity of questionnaires. Sampling was cluster sampling method, This cross sectional was conducted on a total 40 persons (managers and experts) from the Exsir Pharmaceutical industry. Descriptive and inferential statistics were used for data analysis (in SPSS 19 Software). The following formula is used to determine the sample size for estimating p and the maximum error of B [18]:

$$n = \frac{Npq}{(N-1)D + pq}, \quad D = \frac{B^2}{4}, \quad q = p - 1, \quad (1)$$

Equation(1) is used for determining the sample size in $\hat{p} = 0.5$ and $B = 0.1$.

$$D = \frac{B^2}{4} = \frac{(0.1)^2}{4} = 0.0025,$$

$$n = \frac{Npq}{(N-1)D + pq} = \frac{(130)(0.5)(0.5)}{(129)(0.0025) + (0.5)(0.5)} = 84.76$$

Thus, 90 persons were selected from the Exsir company (officers and managers). Regression analysis was used to test the main hypotheses of the study. First of all, data analyses in frequency tables and pie charts. After that, Cronbach's alpha was used in the reliability of the questionnaire to confirming the study, and then it was used various statistics to test research hypotheses.

1.3 Results Analysis

Following statistical tests are used to test the research hypotheses and implement the regression model:

- Durbin – Watson Test: It was used to check positive and negative correlation between the errors. If the value is between 1.5 to 2.5, that shows there is the lack of correlation between errors and it confirmed using the regression model.
- Model significant test: It uses the ANOVA table and F-statistic.
- Coefficients significant test: Coefficient's significance of the regression model variables used the T test.
- Determination coefficient test: It uses the squared multiple correlation (R²) to examine to what extent the independent variables are able to explain the variations of the GFR of (R²).

2.3.1 Validity test

For reliability test, Cronbach's alpha coefficient of the questionnaire is sufficient that the correlation coefficient between the amount of questions to get to calculate each variable. The results from this test are shown in Table 2.

According to Table 2, the results indicated that the questionnaire and data are used in the research are valid.

2.3.2 Research hypotheses test

this study has three hypotheses. The regression model was used to test the research hypothesis according to equation (2).

$$Y = \sum_{i=1}^3 \beta_i \cdot X_i + \epsilon_0 \tag{2}$$

Y = status of quality of R&D process; X₁= Independent Variables; ε₀=regression error

Hypothesis 1: To perform this test, variables and questions were used related to the Table

The output from running the regression models is given in Tables (3) to (5).

Table 1. Variables

Variables	Details
Independent Variables	1. <u>Strategic factors (x₁)</u> Hypothesis1: questions 25,27 Hypothesis2: questions 1, 2,3,4,5,7,8,9,10,11 Hypothesis3: questions 13,14,17,19,20,21 2. <u>Monitoring factors (x₂)</u> Hypothesis1: question 26 Hypothesis2: questions 4,6,12 Hypothesis3: question 18 3. <u>R & D factors (x₃)</u> Hypothesis1: questions 22,23,24,26,27 Hypothesis3: question 15,16
Dependent Variable	Status of quality of R&D process (Y) : Hypothesis1: question 22,23,24,25,26,27 Hypothesis2: question 12 Hypothesis3: questions 16, 18,21

Table 2. Results of cronbach's alpha

Variables	Questions	Cronbach's alpha
Strategic process	19	0.786
Monitoring process	5	0.767
R & D process	5	0.854
status of quality of R&D process	10	0.879

Table 3. Summery of Hypothesis 1

Durbin – Watson	Standard error of estimated	Adjusted the coefficient of determination	coefficient of determination	Correlation coefficient
1.891	.134	.968	.931	.922 ^a

Table 4. Anova for Hypothesis 1

Model	Sum of squares	Df	Mean square	F	Sig
Regression	155.312	3	51.77	56.35	.000 ^a
Residual	115.757	126	.919	-	-
Total	271.069	129	-	-	-

Table 5. Coefficients table for Hypothesis 1

Model	Non Standardized coefficients		Standardized coefficients	T	Sig
	B	Standard error	Beta		
Fixed value	-.0131	.138	-	-.107	.879
Strategic process	.1367	.098	.133	1.546	.102
Monitoring process	-.0591	.041	-.086	-1.334	.205
R & D process	.911	.093	.933	9.356	.000

It can be concluded the relationship between R & D factors, and dependent variables are significant.

Therefore, the following regression model can be proposed to test this hypothesis (Equation 3).

$$Y = 0.901X_3 \tag{3}$$

Hypothesis 2: Output tables running the regression model (6) to (8) is given.

So, according to Table 6, hypothesis 2 is confirmed. It can use quality assurance approach based on the strategic view and thinking in the qualitative assessment.

Table 8 shows that only monitoring process and dependent variable has significant relationship. Therefore, the model is proposed based upon the results from the test.

Table 6. Summary of Hypothesis 2

Durbin – Watson	Standard error of estimated	Adjusted the coefficient of determination	coefficient of determination	Correlation coefficient
2.311	.547	.733	.757	.866 ^a

Table 7. Anova for Hypothesis 2

Model	Sum of Squares	df	Mean Square	F	Sig
Regression	138.12	2	69.06	78.23	.000 ^a
Residual	112.11	127	.88	-	-
Total	150.23	129	-	-	-

Table 8. Coefficients table for Hypothesis 2

Model	Non Standardized coefficients		Standardized coefficients	T	Sig
	B	Standard error	Beta		
Fixed value	-.064	.633	-	-.1380	.867
Strategic process	-.445	.454	-.155	-1.673	.145
Monitoring process	1.343	.132	.967	8.761	.000

$$Y = 1.254X_2 \quad (4)$$

3. DISCUSSION AND CONCLUSIONS

Analysis of the results based upon the performance with the regression model, it was shown that there are three main acceptable hypothesis of this study. According to that, one of the problems of organizations and companies is lacked of comprehensive and integral international units to achieve the overall objectives throughout the organization. First, it can use the strategic management system for determining mission, Vision and Goals of organization, So that, it can use methods for analysis of the internal and external factors based on results from the analysis. They are defined projects and methods for achieving objectives in the long and short-term goals. For best results, it must determine budget and methods of each project for monitoring the status of each project. So it can use the process management to determine inputs, outputs and organization processes based on the ISO 9001: 2008 standard. The process can also be classified as the main and encouraging processes (For example, example production and sales processes belong to the main processes and R & D. Education processes belong to the supporting processes). Finally, it can monitor parameters for achieving long-term and short-term strategic objectives using monitoring and measuring of processes. And based upon the results from the monitoring plan, it should present a good plan until by planning short and long-term goals can achieve ultimately the organization's vision.

Since this study has been implemented about R & D process Pharmaceutical industry according to the too much competition from local companies and foreign products in the market, these companies should be to maintain quality of products and create new products.

This requires too many relationships between strategic management, process management, monitoring and measurement with accurate and timely identification of opportunities and threats in markets, customers and the competitors' strengths and weaknesses by creating new products and services.

4. RESEARCH PROPOSAL FOR FUTURE RESEARCH

According to the research variables and the results obtained following topics for future research is suggested:

- The study can be applied in the research and development of manufacturing industries and service sectors.
- It can reviews for other organizational processes, such as educational processes, service and support for all manufacturing and industries service.

5. LIMITATIONS OF THE STUDY

Like any other research, this study has limitations, some of them are mentioned:

One of the limitations in research includes lack of adequate information on a particular subject. Research equipment's are very hard to acquire leading to formulation mere assumptions. Another hindrance is poor or inaccessibility to the region of study.

This research was proceeding in the years 1392-1391 was conducted by Mino Company. It is possible that if the study be done at a later date due to changing local circumstances and environment, it be achieved with varying results.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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