



The Relationship Between Quality Assurance Structure and Profitability in Iranian Pharmaceutical Industries



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ABSTRACT

Background: Quality Assurance Structure (QAS) plays an essential role in the profitability and market size of pharmaceutical companies. Accordingly, this study aimed to evaluate the quality certificates and QAS of pharmaceutical companies in Iran. Quality principles can increase consumer satisfaction, leading to elevated sales and profitability for companies. Besides, they have always been accompanied by growth and development. A well-established quality would be greatly valuable; if properly managed, it could influence the development of pharmaceutical companies.

Methods: In this study, the data of sales, operating profit, quality certificates, organizational chart, and quality staff were received by companies. Moreover, we made appointments with each company and received the real data directly from the relevant officials. The quality certificates and relative percentage of quality staff were collected and compared with the domestic sales, exports, and operating profit of companies. Finally, the achieved results were analyzed to determine the relationship between financial and qualitative parameters.

Results: The relationship between QAS and sales and corporate profitability was determined. The present study data indicated a relationship between the qualitative and financial sectors of pharmaceutical companies.

Conclusion: Prior surveys and the obtained data suggested that quality structure and quality certificates significantly increase the domestic sale, export, and profitability of companies. However, numerous other parameters can also be involved in the sales volume of companies that require further investigations.

Keywords: Sale; Pharmaceutical industry; Quality assurance; Quality; Pharmaceutical; Drugs; Iran

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1. Introduction

Quality is among the key factors in the pharmaceutical industry. Ample evidence supports the crucial role of quality in the final outcomes of a given country's health system. Adequately implemented quality in the pharmaceutical industry affects the reputation of the pharmaceutical manufacturer. Besides, it impacts all society members' health, and the overall health system wellness [1-3].

The exact definition of quality and its scope of action has been rapidly changed; they were concurrently updated to provide a better and more harmonized definition. Due to its exact definition, quality has always been a changing matter; its rich history in pharmaceutical science stems from a considerable set of trials and errors. Sometimes, it resulted in unforgettable tragedies (as in the thalidomide scenario) and the lessons learned through those experiences [4, 5].

The diversity in countries' experiences toward quality issues also contributes to the fast-evolving nature of quality. Accordingly, each country defines its version with its specific statements and regulations. Therefore, more than ever, the need for better-integrated identity of quality has been sensed. Such a gap has led to the first raw idea of implementing a worldwide agreed set of regulations. Subsequently, it created the establishment of current desirable manufacturing practices; therefore, the world has observed a growing awareness of the significance of good quality [6, 7].

Such awareness is associated with the generation of various definitions precisely describing the quality of the pharmaceutical product. Besides, newer aspects, such as the patient's needs, preferences, and customer satisfaction have emerged. This growing awareness also in part owes to the significant role of the regulatory bodies in meeting the legal procedures. Furthermore, these processes are linked with pharmaceutical development methods and subsequent scale-up steps, making pharmaceutical productions among the most extremely regulated industries [1, 8-10].

However, in recent decades, quality has emerged as a competitive edge for companies to achieve their financial goals [11, 12]. There exist numerous companies providing the medical needs of the society; as a newer aspect of quality in targeting patient's preferences and loyalty, it has been highlighted that patients have a broader set of options to choose from [13]. Pharma-

ceutical companies are functioning in an environment where even slight differences are certain and can determine advantages. Thus, the customer is in the limelight of the whole organization. As a result, customer satisfaction is a vital component of the companies' driving business. Studies evaluated the contributory role of quality in achieving customers' loyalty, as a business value. Moreover, almost all the resultant data approved the significance of the quality [14, 15].

By increasing the quality, the customer's satisfaction is enhanced; in turn, it facilitates repeating higher sales to customers, while reducing the cost of marketing [16]. For this purpose, pharmaceutical companies tend to acquire international quality standards as references for the quality of their products and services [17]. Among the mentioned standards, the International Standard Organizations (ISO) and current Good Manufacturing Practice Certifications (GMPCs) are the utmost quality standards that pharmaceutical companies attempt to acquire [18, 19].

This study aimed to investigate the impact of quality on sales as well as export value. Thirteen companies were chosen for the study. Moreover, the national and international quality certifications and the frequency of personnel in the quality department were selected as the indicators of the overall quality of the companies. The obtained results indicated a direct relationship between quality and overall domestic and foreign sales.

2. Methods

The statistical population of this study consists of the top 10 pharmaceutical companies concerning export and the top 10 pharmaceutical companies respecting domestic sale. These companies were evaluated and compared from 2014 to 2017. The list of the companies involved in the study is mentioned below.

The selected companies with the highest domestic sale were Dr. Abidi, Darou Pakhsh, Exir, Dana, Zahravi, Alborz Darou, Jaber Ebne Hayyan, CinnaGen, Tehran Chemie, and Farabi pharmaceuticals; top companies with the highest export values included CinnaGen, Farabi, Exir, AryoGen Pharmed, Caspian Tamin, Zahravi, Darou Pakhsh, Dana, Aboureyhan, and Alborz Darou pharmaceuticals.

The obtained data from the explored companies were classified into quality, sales, and profit. The required data were obtained using the companies' official published records or by conducting semi-structured inter-

Table 1. The classification of the percentage of staff working in quality department

Company	The Percentage of the Staff Working in the Quality Department
105	High
102	High
109	High
104	High
101	High
106	Medium
112	Medium
108	Medium
103	Medium
110	Medium
111	Medium
107	Low
113	Low



views with the authorized staff. Concerning the quality-related data, companies were assessed regarding the acquisition of the national and international certifications as well as the relative frequency of quality department staff (the total number of Quality Management (QM) and Quality Assurance (QA) departments) per total number of companies' personnel. To classify the percentage of the quality department of companies, semi-structured interviews were conducted with the members of the Department of Pharmacoconomics and Pharmaceutical Management of the Faculty of Pharmacy, Tehran University of Medical Sciences, and top pharmaceutical industry experts. According to their statements, the percentage of quality staff of companies was divided into 3 groups of low (5%-10%), medium (10%-13%), and high (13%-18%). The companies were compared in each of these levels regarding such indicators, as sales and profitability.

Numerical codes were used instead of the companies' names to observe the confidentiality of companies' information, as follows in the related [Table 1](#).

ISO certifications, as one of the crucial elements reflective of a given company's quality, were categorized into two groups as follows.

This classification's goal was to assess the potential relationship between the sale or profit parameters of any of the defined groups of the ISO standards.

A qualitative parameter evaluated in this study was the Iran National Quality Award (INQA). This qualitative evaluation model originated from several fundamental foundations, including the ISO 9004 standard; technical content covers the main and sub-criteria of the award. Furthermore, the points of each sub-criterion were formulated according to ISO 9004 requirements. Another source of INQA is the European Foundation for Quality Management (EFQM) model and the edited format of the NQA model is adapted from the EFQM model. The distribution of scores similar to EFQM is equally divided between empowerment criteria and outcome measures. The next entry for the INQA Award model was the RADAR logic (The RADAR logic is a dynamic assessment framework and powerful management tool that provides a structured approach to questioning the performance of an organisation, it states that an organisation needs to: Determine the Results, Plan and develop Approaches, Deploy the approaches, Assess and refine) used in the evaluations, especially the EFQM model evaluation. Besides, it was found to be highly appropriate for evaluation in the Iran National Quality Award (INQA). The last entry criterion for the INQA is

Table 2. The classification of ISO standards

Group No. 1: Production and Operation Management	Group No. 2: Strategic Management
Quality management standard (e.g. ISO 9001, 18001, 10013, 13485, & 17025)	Customer satisfaction standard (e.g. ISO 10004 and 10002)
Education Management Standard (e.g. ISO 10015)	Social responsibility (e.g. ISO 26000)
	Information security (e.g. ISO 27001)



the 10-segment classification of products based on the United Nations' CPC method. Companies were grouped according to the number of stars they have acquired. Considering the defined strategy in INQA [20, 21], it ranges from a one-star (the lowest degree) to a 4-star grade (the top grade). Companies included in the study were categorized based on the INQA model. Additionally, their possible correlation with revenue parameters was assessed.

The organizational chart of each company was received; accordingly, we compared them to explore the relationship between Good Manufacturing Practices (GMP) and Chief Executive Officer (CEO).

The GMP certifications awarded to the companies were grouped into two categories based on the certifying country. If the GMP certificate of the company was approved by a member of Organisation for Economic Co-operation and Development (OECD) countries, it would have been added into the regulated group. Moreover, if the GMP certificate was confirmed by a non-OECD country, its owner was grouped as semi-regulated [22]. The aim was to investigate the potential relationship between the defined classification and the sale/profit values of the companies.

The sales and profitability indicators were as follows:

1. Average domestic sales over 3 years;
2. The growth rate of domestic sales over 3 years;
3. Average export sales over 3 years;
4. The growth rate of export sales over 3 years;
5. Average operating profit over 3 years;
6. The growth rate of operating profit over 3 years.

The rankings of each company per the above-mentioned 6 parameters were extracted. Subsequently, these data were compared with the certificates and

qualitative structures of the companies. The relationship between the quality certificates and each of the financial mentioned indicators were separately analyzed.

The Kolmogorov-Smirnov test data indicated that the distribution of data was not normal. Thus, nonparametric tests were implemented in this study. Accordingly, all data were analyzed by the Kruskal-Wallis test and Mann-Whitney U test (non-parametric t-tests). The current study used the rankings of companies concerning sales, export, and operating profit. As a result, the appropriate method for checking the data correlation was the Spearman correlation coefficient, i.e., applied for ranking and nonparametric data.

3. Results

Data regarding the quality standards of the companies and the corresponding revenue information are summarized in Table 1 and Table 2, respectively.

Companies that had obtained GMP certification from regulated countries presented a better performance in exports growth rate and export mean rank. The operating profit of these companies was unavailable. Furthermore, the obtained data indicated no relationship between quality parameters and domestic sales in these companies.

According to the comparison findings of organizational charts, no relevant relationship was found and most of the charts have resembled.

Companies that participated in the NQA evaluation and received at least two-star quality accreditation certificates provided better rankings, compared to other companies respecting domestic sales mean and domestic growth rate. Additionally, no relationship was found between the NQA and corporate exports and operating profit.

The ISO certificates obtained by the companies were divided into the following groups: strategic management as well as production and operations manage-

Table 3. The national and international certificates of the companies as a representative of quality assessment

Companies	ISO Certificates	GMP Certificate	National Quality Award
105	Group No.1 (9001-18001-17025)	Semi-regulated	None
102	Group No.1 (9001)	Semi-regulated	2-star
108	Group No.1 (9001-18001) Group No.2 (10668)	Semi-regulated	3-star
113	Group No.1 (9001-18001-10015-10013) Group No.2 (10004-10002-26000)	Semi-regulated	4-star
109	Group No.1 (9001-10015)	Semi-regulated	3-star
106	Group No.1 (9001-18001-10015) Group No.2 (27001-10002)	Semi-regulated	2-star
112	Group No.1 (9001-18001-10015)	Semi-regulated	1-star
101	Group No.1 (9001-18001-13485-10015) Group No.2 (10002)	Regulated	2-star
103	Group No.1 (9001-18001)	Semi-regulated	1-star
110	Group No.1 (9001-18001)	Semi-regulated	1-star
104	None*	Regulated	None
107	Group No.1 (9001-18001)	Semi-regulated	1-star
111	Group No.1 (9001-18001-10015) Group No.2 (10004)	Semi-regulated	1-star

*The company obtained no ISO standards.



ment. Five companies had obtained both groups of certificates. The rest of the companies had only obtained ISO certificates of production management and operations. Examining the export growth rate of companies has suggested that out of the top 6 companies in terms of export growth rate, 4 companies achieved both groups of ISO certificates. Such findings indicated the positive impact of ISO certificates on the export growth rate. Examining the average domestic sales of companies revealed that 4 of the top 6 companies had an ISO certificate in strategic management. Such data highlighted the positive impact of these certificates on the domestic sales of companies. Overall, the financial indicators of all of the explored companies that had both groups of ISO certificates were better than those of the others.

Data analysis demonstrated that companies with a high percentage of staff working in QC obtained better ranks in all financial parameters, compared to the others. Among the 5 companies, i.e., superior to other companies concerning this quality index; 3 companies, ranking first to third regarding the average domestic sales, might indicate a relationship between the frequency of quality staff and the domestic sales of firms. No rela-

tionship was observed between this quality index and exports rates according to Mann-Whitney U test results.

4. Discussion

This study linked the types of quality certificates with sales and profit in pharmaceutical companies. As per Tables 3 and 4, companies that performed better in the NQA have also been more successful in the domestic market (concerning average sales & sales growth rates). This relationship seems logical. This is because INQA is a national evaluation model and the impact of this award is greater than other standards on the domestic sales of the companies. However, this model originated from EFQM. In practice, the companies that gained more points in this quality model presented no significant improvement in their exports; however, further research is recommended to explore this relationship.

According to the obtained results, the GMP certificates and the exports of the pharmaceutical companies were associated; however, there was no correlation between these certificates and the operating profit and domestic sales of the companies. In other words, the impact of GMP certificates on domestic sales was not evident in Iran; companies are denying GMP certificates, i.e., a ne-

Table 4. The revenue data of the explored companies

Companies	Domestic Sales Ranking	Domestic Sales Growth Rate Ranking	Export's Sales Ranking	Export's Sales Rate Growth Ranking	Operating Profit Ranking	Operating Profit Growth Ranking
105	3	3	NA	NA	7	1
102	1	7	5	8	2	3
108	4	9	2	12	6	5
113	5	2	9	3	4	7
109	9	6	7	9	5	11
106	6	5	11	5	1	2
112	8	8	12	7	3	4
101	2	4	1	1	NA	NA
103	10	11	10	11	11	10
110	7	13	4	10	8	8
104	11	1	3	2	NA	NA
107	13	12	6	4	10	9
111	12	10	8	6	9	6

NA: Not Available.



glected point for them. This is because it is a vital point that they can emphasize and attempt to increase their royalty, and improve sales and revenue. This is among the best leverages that such companies can make value for themselves as well as their customers. Their clients are patients; while GMP certificates from OECD member states are essential for companies that want to import pharmaceuticals from Iranian companies. GMP certificates significantly impact international pharmaceutical sales. In Iran, other parameters might present a greater impact on domestic sales.

Companies that obtained both groups of ISO certificates (production & operation management, strategic management) provided better average ranking in all 6 financial parameters, compared to the other companies according to Mann-Whitney U test results. However, due to the small number of companies studied, Spearman's statistical test revealed no relationship between ISO certificates and sales parameters. Overall, ISO's relationship with the sales and profitability of companies cannot be considered with certainty. For instance, Aryogen Pharmed achieved no ISO certificates; however, it is well ranked respecting exports and domestic growth rates. Thus, ISO certificates positively affect the sales and profitability of companies; however, they are not a

prerequisite of sales. Instead, they are more applicable for improving the organization. Gaining such standards is not directly linked to the quality criteria, i.e., valuable for the end-users (patients).

According to the Mann-Whitney U test data, in all 6 financial parameters, the average rating of companies with a high percentage of personnel in the quality sector was better than that of the others; these results indicated the positive impact of quality staff on the sales and profitability of companies. An increase in the firm's operating profit positively impacts sales. This is because sales and profitability are mostly interrelated and influence each other.

As a result, after consulting with experts, it seems that the percentage of staff working in the quality department is not an independent influential factor in the sales of companies, and can be considered a complementary factor.

5. Conclusion

The current study results revealed a relationship between quality structure and certifications, and sales and corporate profitability. However, numerous variables, including CEO performance, sales strategies, the history

of company presence in the market, etc., were involved in the overall sales and profitability of companies. However, the obtained data highlighted the relationship between the qualitative and financial sectors of pharmaceutical companies in Iran.

Ethical Considerations

Compliance with ethical guidelines

All ethical principles are considered in this article. The companies were informed of the purpose of the research and its implementation stages. The codes were used instead of the companies' names so that the companies' information would not be revealed.

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Authors contributions

Data collection: Abbas Kebriaeezadeh and Mohammad Sadegh Khoramirad; Data analysis: Abbas Kebriaeezadeh, Meysam Seyedifar and Mohammad Sadegh Khoramirad; Writing – original draft: All authors; Writing – review & editing: Mohammad Sadegh Khoramirad.

Conflict of interest

The authors declared no conflict of interest.

References

- [1] Woodcock J. The concept of pharmaceutical quality. *Am Pharm Rev.* 2004; 7(6):10-5. https://www.researchgate.net/publication/279577343_The_concept_of_pharmaceutical_quality
- [2] Gaynor M. Competition and quality in health care markets. *Found Trends Microecon.* 2007; 2(6):441-508. [DOI:10.1561/0700000024]
- [3] Haleem RM, Salem MY, Fatahalla FA, Abdelfattah LE. Quality in the pharmaceutical industry-A literature review. *Saudi Pharm J.* 2015; 23(5):463-9. [DOI:10.1016/j.jsps.2013.11.004] [PMID] [PMCID]
- [4] Kim JH, Scialli AR. Thalidomide: The tragedy of birth defects and the effective treatment of disease. *Toxicol Sci.* 2011; 122(1):1-6. [DOI:10.1093/toxsci/kfr088] [PMID]
- [5] Rehman W, Arfons LM, Lazarus HM. The rise, fall and subsequent triumph of thalidomide: lessons learned in drug development. *Ther Adv Hematol.* 2011; 2(5):291-308. [DOI:10.1177/2040620711413165] [PMID] [PMCID]
- [6] Rågo L, Santoso B. Drug regulation: History, present and future. In: van Boxtel CJ, Santoso B, Edwards IR, editors. *Drug Benefits and Risks: International Textbook of Clinical Pharmacology.* 2nd ed. Amsterdam: IOS Press; 2008. p. 65-77. <https://books.google.com/books?id=idbvAAQAQBAJ&printsec=frontcover&dq>
- [7] Nally JD. *Good manufacturing practices for pharmaceuticals.* 6th ed. Boca Raton: CRC Press; 2016. [DOI:10.3109/9781420020939]
- [8] Crowley R, FitzGerald LH. The impact of cGMP compliance on consumer confidence in dietary supplement products. *Toxicology.* 2006; 221(1):9-16. [DOI:10.1016/j.tox.2006.01.011] [PMID]
- [9] Pandey P, Anju G. Quality management system in drug industry: A review. *Biomed J Sci & Tech Res.* 2018; 2(1):2177-9. [DOI:10.26717/BJSTR.2018.02.000653]
- [10] Reddy GTK, Reddy GNK. Significance of pharmaceutical regulatory bodies-A review. *Pharma Tutor.* 2017; 5(8):15-22. <https://www.pharmatutor.org/articles/significance-of-pharmaceutical-regulatory-bodies-a-review>
- [11] Rust RT, Moorman C, Dickson PR. Getting return on quality: Revenue expansion, cost reduction, or both? *J Mark.* 2002; 66(4):7-24. [DOI:10.1509/jmkg.66.4.7.18515]
- [12] Anderson M, Sohal AS. A study of the relationship between quality management practices and performance in small businesses. *Int J Qual Reliab Manag.* 1999; 16(9):859-77. [DOI:10.1108/02656719910289168]
- [13] Malerba F, Orsenigo L. The evolution of the pharmaceutical industry. *Bus Hist.* 2015; 57(5):664-87. [DOI:10.1080/00076791.2014.975119]
- [14] Caruana A. Service loyalty: The effects of service quality and the mediating role of customer satisfaction. *Eur J Mark.* 2002; 36(7/8):811-28. [DOI:10.1108/03090560210430818]
- [15] Kaura V, Durga Prasad CS, Sharma S. Service quality, service convenience, price and fairness, customer loyalty, and the mediating role of customer satisfaction. *Int J Bank Mark.* 2015; 33(4):404-22. [DOI:10.1108/IJBM-04-2014-0048]
- [16] Manu M. Quality and customer satisfaction perspective in organisations by gap and total quality improvement methods [PhD dissertation]. Vaasa: University of Vaasa; 2011. <https://www.semanticscholar.org/paper/Quality-and-customer-satisfaction-perspective-in-by-Manu/81d106f59c5e5903f0508336d7b169bf43db17c7>
- [17] Kai CLSCW, Khodabocus F. Quality Systems Implementation in the Pharmaceutical Industry. *Univ Maurit Res J.* 2009; 15(1):436-57. https://scholar.google.com/scholar?hl=fa&as_sdt=0%2C5&q=Quality+Systems+Implementation+in+the+Pharmaceutical+Industry.+&btnG=
- [18] Murphy CN, Yates J. *The International Organization for Standardization (ISO): Global governance through voluntary consensus.* Abingdon, Oxfordshire: Taylor & Francis; 2009. <https://books.google.de/books?id=iXAeQAAlAAJ&hl=de>

- [19] Cooper DE. Adequate controls for new drugs: Good manufacturing practice and the 1938 federal food, drug, and cosmetic act. *Pharm Hist.* 2002; 44(1):12-23. [\[PMID\]](#)
- [20] Mojdehi S. Compare the model of Iran national quality award and the EFQM model. *Chin Bus Rev.* 2010; 9(9):61-4. https://scholar.google.com/scholar?hl=fa&as_sdt=0%2C5&q=+Compare+the+model+of+Iran+national+quality+award+and+the+EFQM+model.&btnG=
- [21] Zamani M, Valmohammadi C. Evaluating the effects of the implementation of Iran National Quality Award new model (inqa) in Iranian organizations. *Int J Qual Res.* 2014; 8(3):311-22. <http://ijqr.net/paper.php?id=306>
- [22] Organisation for Economic Co-operation and Development. Member countries [Internet]. 2021 [Updated 2021 July 10]. Available from: <https://www.oecd.org/about/members-and-partners/>