INTERNATIONAL JOURNAL OF RESEARCH SCIENCE & MANAGEMENT

RESEARCH ON EFFECTIVENESS EVALUATION OF QUALITY MANAGEMENT SYSTEM IN PHARMACEUTICAL COMPANIES

Bo Liu[*1], Huihui Sun[2], Yun Li[3] & Kewei Tan[4]
[*1,2&3]Department of Accounting and Financial Management, Ginling College, Nanjing Normal University
[4]Department of Civil Engineering, Chengxian College, Southeast University

Abstract

Under the background of increasing competitive pressure at home and abroad, it is an important task for pharmaceutical companies to improve their competitiveness by strengthening internal management. Based on defining the concept of pharmaceutical quality management system and the effectiveness of management system, this paper constructs the evaluation index system and evaluation model of the effectiveness of quality management system, and verifies the feasibility of theoretical research by case analysis, which supports the improvement of management systems such as pharmaceutical companies.

Introduction

As a substance that can prevent and treat human diseases, medicines can play an important role in maintaining human health and regulating human physiological functions. It is precisely because of the important role of medicines that all countries have put forward strict management requirements for pharmaceutical enterprises that produce medicines [1]. For pharmaceutical companies, among the many contents of the company management system, the quality management system is one of the most important contents and the key to the survival and development of the company. Therefore, pharmaceutical companies must pay more attention to the quality management system to ensure the effectiveness of the quality management work.

For pharmaceutical companies, it is far from enough to have a perfect quality management system. This is mainly because its own pharmaceutical companies are in the process of continuous development. The external environment of the company is always in constant development and change including macro environment, industry environment and regional environment [2]. Therefore, for pharmaceutical companies, it is of great significance to adjust the quality management system timely according to the external environment and its own changes to ensure the effectiveness of the quality management system and meet the development. However, when a company decides whether it needs to carry out its own quality management system decision, it needs to judge according to the implementation effect of the existing quality management system [3]. As that effectiveness of the quality management system is embodied in many aspect, it is necessary to build a comprehensive and systematic evaluation index system for the effectiveness of quality management system and a effectiveness evaluation model that can deal with multi-index problems on the basis of analyzing the characteristics and the influencing factors of the effectiveness of quality management system, and construct a comprehensive and systematic evaluation index system for the effectiveness, and a comprehensive and systematic evaluation model for the effectiveness of quality management system

Method

Effectiveness evaluation of quality management system in pharmaceutical companies is such an activity, which is an analysis of the positive impact of the quality management system in the normal operation of pharmaceutical companies. Through the formulation of evaluation standards, the evaluator carries out a strategic process according to the evaluation standards according to the size of the positive impact value of the quality management system, and finally obtains a specific judgment activity [4]. According to the definition of the concept of effectiveness evaluation of quality management system, the evaluation of the effectiveness mainly involves two aspects. One is the construction of the evaluation index system of the effectiveness of the quality management system, and the other is the construction of the evaluation model of the effectiveness of the quality management system.

INTERNATIONAL JOURNAL OF RESEARCH SCIENCE & MANAGEMENT

Index System

The purpose of carrying out the effectiveness evaluation of the quality management system of pharmaceutical companies is to evaluate the effectiveness of the quality management system in time, to support pharmaceutical companies to find out the problems and deficiencies existing in their own quality management system in time [5]. Considering that National Medical Products Administration requires domestic pharmaceutical companies to implement Good Manufacturing Practice (GMP) production quality management system. Therefore, the establishment of the evaluation index system for the effectiveness of the quality management system should be carried out reasonably based on following relevant principles by combining the contents of the quality management system of pharmaceutical companies and the contents of the national GMP production quality management system [6].

Therefore, this study determines the Level 1 index system for evaluating the effectiveness of the quality management system of pharmaceutical companies based on analyzing its contents according to the provisions of the "Medicine Production Quality Management Standard" of the People's Republic of China. The First-level index system for evaluating the effectiveness of quality management system in pharmaceutical companies consists of seven First-level indexes: The effectiveness of confirmation and verification of production conditions, the effectiveness of document management, the effectiveness of production management, the effectiveness of quality control and quality assurance, the effectiveness of commissioned production and commissioned inspection, the effectiveness of product shipment and recall, and the effectiveness of self-inspection [7].

According to the above analysis, the evaluation index system for the effectiveness of the quality management system of pharmaceutical companies is shown in Table 1.

Table 1 Evaluation Index System of Effectiveness of Quality Management System in Pharmaceutical Companies

Target Layer	First-level index	Second-level index
Effectiveness of Quality Management System in Pharmaceutical Companies	Confirmation and Verification of Production Conditions Validity X_1	Confirmation and verification of institutions and personnel X_{11}
		Confirmation and verification of plant and facilities X_{12}
		Confirmation and verification of equipment X_{13}
		Confirmation and verification of materials and products X_{15}
	File Management Validity $X2$	Quality standard X_{21}
		Process specification X_{22}
		Batch production record X_{23}
		Batch packaging record X_{24}
		Operating procedures and records X_{25}
	Production Management Effectiveness X_3	Prevention of contamination and cross-contamination X_{31}
		Production operation management X_{32}
		Packaging operation management X_{33}
	Quality Control and Quality Assurance Effectiveness X_4	Quality control laboratory management X_{41}
		Material and product release X_{42}
		Continuous stability investigation X_{43}
		Change control X_{44}
		Deviation treatment X_{45}
		Corrective and preventive measures X_{46}
		Supplier evaluation and approval X_{47}
		Product quality review analysis X_{48}
		Complaints and adverse reaction reports X_{49}
	Validity of Commissioned Production and Commissioned Inspection X_5	Commissioned production X_{51}
		Entrusted inspection X_{52}
	Product Shipping and Recall Validity X_6	Product shipping X_{61}
		Product recall X_{62}
	Self-checking validity X_7	Self-inspection plan X_{71}
		Self-inspection report X_{72}

As you can see intuitively from Table 1, the effectiveness evaluation index system of pharmaceutical quality management system constructed in this paper includes the validity of confirmation and verification of production conditions, the validity of document management, the validity of production management, the validity of quality control and quality assurance, the validity of commissioned production and commissioned inspection, the validity

INTERNATIONAL JOURNAL OF RESEARCH SCIENCE & MANAGEMENT

of product shipment and recall, and the validity of self-inspection. Each First-level index can be reflected by several specific Second-level indexes. Finally, an index system including 7 First-level indexes and 27 Second-level indexes, which can comprehensively reflect the effectiveness of the quality management system of pharmaceutical companies.

Evaluation Method

After constructing the effectiveness evaluation index system of the quality management system, the following problem is to construct the effectiveness evaluation model of the quality management system. Considering that there are many mathematical models that can be used to evaluate the effectiveness of the quality management system, it is necessary to select the most suitable mathematical model among the many evaluation models as the model for evaluating the effectiveness of the quality management system. Based on comprehensive analysis and comparison of various mathematical models, the fuzzy comprehensive evaluation (FCE) model is finally selected as the model for evaluating the effectiveness of the quality management system.

Considering that the traditional FCE has certain limitations, it is mainly reflected in: (1) In the FCE, the index weight is generally determined by AHP. Because AHP itself has certain limitations, it can only make single decision, and the determination of "1-9" value cannot well reflect the relative importance between the two indexes, so it needs to be improved. (2) The traditional method of determining the index eigenvalue in the FCE is to score by experts and then take the arithmetic average value. Because experts' views on a certain thing may be fuzzy, it is difficult to accurately describe their views with a numerical value, so improvement is needed.

Therefore, the process of building the effectiveness evaluation model of pharmaceutical quality management system based on the improved FCE is as follows:

Determine index weight

Considering that AHP weight determination method commonly used in FCE can only be made by a single person, it is not scientific enough for index weight determination. This study introduces Group Analytic Hierarchy Process (GAHP) into it. Based on the AHP, GHAP can be used by many experts to determine the weight of the index, which makes up for the problem that the traditional AHP can only determine the index weight by a single person. In GAHP, experts determine the weight of the index system according to the steps and requirements of AHP respectively, and then take the arithmetic average of the results determined by the index weight of experts as the final weight of the index.

Although GAHP can achieve the goal of multiple decision weights, only the "1-9" relative importance comparison value between the two indexes can be simply realized considering that in AHP. When experts subjectively judge the relative importance of the two indexes, they cannot be expressed by a single number, but the interval value can better reflect the opinions of experts. Moreover, in the process of determining the index weight, different experts may have different importance in the process of determining the weight due to their own experience, industry status, etc. It is necessary to clarify the weight of each expert.

This study improves the traditional GAHP to form an improved GAHP, which would be applied to the determination of the weight of the effectiveness evaluation index system of the quality management system of pharmaceutical companies.

Since the core content of GAHP is the determination of the relative importance comparison value of the two indexes by experts, the determination method of the relative importance comparison value of the two indexes is mainly discussed.

Assuming that K experts participate in the evaluation of the effectiveness of the quality management system of pharmaceutical companies, in the process of determining the weight of the index system, the relative importance comparison interval value of the k (k=1,2, . . . , K) expert for the two indexes x_g and x_h under the same level is $[d_{1e}^{(k)}, d_{2e}^{(k)}]$ ($d_{2e}^{(k)} \geq d_{1e}^{(k)}$). The weight of each expert is c_k (k=1,2, . . . , K) respectively, then the relative importance comparison value of the two indexes x_g and x_h is

INTERNATIONAL JOURNAL OF RESEARCH SCIENCE & MANAGEMENT

$$f_{g,h} = \frac{1}{2} \bullet \frac{\sum_{k=1}^{K} \{[d_{2e}^{(k)}]^2 - [d_{1e}^{(k)}]^2\} \bullet c_k}{\sum_{k=1}^{K} [d_{2e}^{(k)} - d_{1e}^{(k)}] \bullet c_k} \qquad (1)$$

After determining the relative importance comparison values between the two indexes under the same level according to the above methods, the weight of the effectiveness evaluation index system of the quality management system of pharmaceutical companies is determined according to the steps and requirements of AHP.

In the process of determining the weight of the evaluation index system for the effectiveness of the quality management system of pharmaceutical companies, the weight distribution of the First-level evaluation index X_i is set as a_i ($i = 1,2,\ldots,7$), the First-level index weight vector is $A = (a_1, a_2 \ldots, a_7)$, and meets the requirements of $a_i \geq 0$, and $\sum_{i=1}^{7} a_i = 1$; Set the weight distribution of the Second-level evaluation index X_{is} is a_{is} ($i = 1,2,\ldots,7$; $s = 1,2,\ldots, n_i$), and the weight vector of each Second-level indexes is $A_i = (a_{i1}, a_{i2}, \ldots, a_{in})$ and satisfies $a_{is} \geq 0$, $\sum_{s=1}^{n_i} a_{is} = 1$

Determine the characteristic values of each Second-level index

Since each Second-level index is qualitative index in the effectiveness evaluation index system of pharmaceutical quality management system constructed in this paper, the determination method of index characteristic value adopts expert scoring method.

Specifically, each expert who participates in the effectiveness evaluation of the quality management system gives an interval value to each Second-level index in the evaluation index system based on their own understanding of the effectiveness evaluation index of the specific quality management system and their attitudes and opinions on the effectiveness of the quality management system.

In order to effectively distinguish the effectiveness of the quality management system, the following definition is made: the effectiveness of the quality management system of pharmaceutical companies is divided into five grades, which are very high, high, general, low and very low, and the corresponding score ranges are [90, 100], [80, 90], [70, 80), [60, 80) and [0, 60] respectively.

Assume that the number of experts is K, each expert gives an interval value $[v_{1p}^{(k)}, v_{2p}^{(k)}]$ of (k is expert, $k = 1,2,\ldots, K$; $v_{2p}^{(k)} \geq v_{1p}^{(k)}$) for each Second-level index X_{is} in the effectiveness evaluation index system of the quality management system of pharmaceutical companies. Then the index eigenvalue x_{is} of the Second-level index X_{is} is

$$x_{is} = \frac{1}{2} \sum_{k=1}^{K} [(v_{2p}^{(k)})^2 - (v_{1p}^{(k)})^2] / \sum_{k=1}^{K} [v_{2p}^{(k)} - v_{1p}^{(k)}] \qquad (2)$$

Final evaluation

According to the above hypothesis, if the weight distribution of each Second-level evaluation index X_{is} in the effectiveness evaluation index system of pharmaceutical quality management system is a_{is} ($i = 1,2,\ldots,7$; $s = 1,2,\ldots, n_i$), and the index characteristic value is x_{is}, then the final evaluation value x of the effectiveness evaluation of pharmaceutical quality management system is

$$x = \sum_{i=1}^{7} \sum_{s=1}^{n_i} x_{is} \, \alpha_{is} \qquad (3)$$

INTERNATIONAL JOURNAL OF RESEARCH SCIENCE & MANAGEMENT

According to the size of the final evaluation value x, the specific level of effectiveness of the quality management system of pharmaceutical companies can be specifically judged [8].

Case Analysis

L Pharmaceutical Company takes meeting the medical needs of human beings as its starting point and always regards medicine research and development as "the core of business and the soul of company". The research mainly focuses on several core areas, including central nervous system, endocrine, tumor and cardiovascular diseases. The U.S. Headquarters of L Pharmaceutical Company has established the company's internal website to publish the latest global quality standards, which include production quality requirements for design, implementation and monitoring. The formulation of global quality standards is based on the medicine laws and regulations of the United States, the European Union, Japan, China, and other countries, as well as the standards of the pharmaceutical industry. The website provides standards, practices, resources and training in the context of collaborative space to support the integrity of the quality management system. The goal of U.S. Headquarters of L Pharmaceutical Company is to ensure that all branches around the world update their standard operating procedures according to the latest global quality standards, to ensure the consistency of the quality system of each branch. What's more, it aims to ensure that the branches of each country meet the requirements of medicine regulations and pharmaceutical industry standards.

In order to deeply understand the effectiveness of the current quality management system, L Pharmaceutical Company set up a quality management system effectiveness evaluation group in November 2020 to evaluate the effectiveness of the company's current quality management system. The specific evaluation process would not be described in detail. The evaluation results are as follows:

According to the calculation results, the final evaluation value is $x=81.5936$.

According to the classification basis of the effectiveness of the quality management system of pharmaceutical companies, the effectiveness of the quality management system of L Pharmaceutical Company is Second-level, that is, the high level.

Conclusion

In this paper, the effectiveness evaluation system of pharmaceutical quality management system is deeply studied, and a systematic evaluation index system and evaluation method are proposed to provide effective support for the improvement of pharmaceutical quality management system. Due to the limitation of research ability and research vision, there are still some deficiencies in some issues, which need to be improved in the future. These include: (1) Establish an evaluation index system for the effectiveness of pharmaceutical quality management system composed of more objective indexes [9]. The index system constructed in this research is all qualitative index. Although such index can also reflect the effectiveness of quality management in pharmaceutical companies, it is easily affected by subjective factors of experts. Therefore, we can try to construct an evaluation index system of effectiveness of quality management system in pharmaceutical companies composed of more objective indexes in the future [10]. (2) In-depth analysis of the influencing factors and mechanism of the effectiveness of the quality management system of pharmaceutical companies. The analysis of the influencing factors and mechanism of the effectiveness of the quality management system of pharmaceutical companies is of great significance for improving the effectiveness of the quality management system of pharmaceutical companies. Therefore, it is necessary to deeply analyze the influencing factors and mechanism of the effectiveness of the quality management system of pharmaceutical companies.

Acknowledgements

Conflicts of Interest

The authors declare that there are no conflicts of interest regarding the publication of this paper.

INTERNATIONAL JOURNAL OF RESEARCH SCIENCE & MANAGEMENT

References

[1] Aharoni Y. "The performance of State-owned Enterprises", in Toninelli P A, et al., The Rise and Fall of State-owned Enterprise in the Western World. New York: Cambridge University Press, 2000:49-72.

[2] Wade R. The American Parados: Ideology of Free Markets and the Hidden Practice of Directional Thrust. Cambridge Journal of Economics, 2017, 41(3):859-880.

[3] Tonurist P., Karo E. State Owned Enterprises as Instruments of Innovation Policy. Annals of Public and Cooperative Economics, 2016,87(4):623-648.

[4] Arrow K. "Economic Welfare and the Allocation of Resources for Invention", in The Rate and Direction of Inventive Activity: Economic and Social Factors. New Jersey: Princeton University Press, 1962: 609-626.

[5] Ebbinghaus H, Ruger H A, Bussenius C E. Memory: A contribution to experimental psychology. Annals of Neurosciences, 2013,20(4):155.

[6] Li Huan, Huang Xianjin, Kwan Mei-Po. Changes in farmers' welfare from land requisition in the process of rapid urbanization. Land Use Policy, 2015, 42: 635-641.

[7] Wang, RX., Wijen, F., Heugens, PPMAR., 2018. Government's green grip: Multifaceted state influence on corporate environmental actions in China. Strategic Management Journal, 2018,39(2): 403-428.

[8] Bo Liu, Ju-qin Shen, Zhao-jian Meng, Fu-hua Sun. A Survey on the Establishment and Application of Social Capital Partner Selection System for the New Profit PPP Project. KSCE Journal of Civil Engineering, 2018, (10): 3726-3737.

[9] Chuang Yating, Schechter, Laura. Stability of experimental and survey measures of risk, time, and social preferences: A review and some new results[J]. Journal of Development Economics, 2011, 117: 151-170.

[10] Li, LF., Qiu, WY., Xu, CD.,Wang, JF.. A spatiotemporal mixed model to assess the influence of environmental and socioeconomic factors on the incidence of hand, foot and mouth disease. BMC Public Health, 2018, (18):274.