

FACTORS OF QUALITY MANAGEMENT SYSTEM INFLUENCING ORGANIZATIONAL PERFORMANCE: A STUDY OF PHARMACEUTICAL FACTORIES GETTING GMP CERTIFICATE IN VIETNAM

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(Received: April 05, 2016; Revised: April 20, 2016; Accepted: May 17, 2016)

ABSTRACT

A study objective is to identify key factors of QMS (Quality Management System) influencing the organizational performance in pharmaceutical factories getting GMP (Good Manufacturing Practices) certificate. The original research model consists of eight independent factors (leadership, process management, education and training, supplier management, customer focus, employee involvement, product design, and continuous improvement) and three dependent factors related to organizational performance (productivity, product quality and customer satisfaction). The study collects 265 suitable questionnaires filled by middle managers or the top managers of the pharmaceutical factories getting GMP in Vietnam. The results identify key factors of QMS as leadership, employee involvement towards customer focus, and continuous improvement towards product design have positively impact to organizational performance that is represented by productivity and product quality, customer satisfaction. The study then suggests managerial implications to top management of pharmaceutical factories in improving performance through enhancing key factors of QMS implementation.

Keywords: GMP; organizational performance; QMS; pharmaceutical factories.

1. Introduction

Quality management philosophy in business practices is to satisfy customers, reduce costs, increase productivity, and enhance quality of outputs. Quality management practices help enhance business excellence (Lee et al., 2001). A number of quality management baselines exist that can result in an effective quality management system (QMS). They consist primarily of custom designed total quality management (TQM) programs, and programs built upon a nationally and internationally recognized standard (Schlickman, 2003). National standards

consist of Malcom Baldrige in USA, Deming Award in Japan, and European Quality Award in Europe and so on. International standards are ISO 9001:2008, ISO 14000, Good Manufacturing Practices (GMP), SA 8000, and so on. GMP for pharmaceutical products is another practice of QMS that ensures that products are consistently produced and controlled to the quality standards based on the marketing authorization and product usage purpose. GMP is aimed primarily at diminishing the risks inherent in pharmaceutical production. In the concepts of quality assurance, GMP and quality control

are interrelated aspects of quality management which are described and emphasized their relationship and fundamental importance to the production and control of pharmaceutical products (WHO, 2007).

After more than 15 years of GMP application, Vietnamese pharmaceutical industry has proved to be relatively competitive in the region. Many multinational pharmaceutical corporations have joined in Vietnam to expand their markets and supply chain. Vietnamese pharmaceutical industry recently developed rapidly, however it was lack of planning and less attention to upgrade high-tech industry for good quality products. Currently, getting GMP certificate of pharmaceutical factories is a mandatory requirement of the Vietnam Ministry of Health (Bo Y Te, 2010). To understand the role of GMP certificate in business practices, the objective of this paper is to identify the QMS factors influencing organizational performance of pharmaceutical factories getting GPM in Vietnam. This will support management to improve organizational performance in managing the key factors of QMS.

2. Literature review and methodology

2.1. Literature review

QMS Factors

A quality management system (QMS) is a company's objective and process that design to meet the customer satisfaction. It contents organizational structure, procedures, processes, resources and continuous improvement. Quality management system is a powerful tool, which enables every organization to increase quality of products and/or services offered through continuous improvement of processes (CERCO, 2000).

The underlying principles of QMS consist of eight core principles as Customer focus, Leadership, Involvement of people, Process approach, System approach to management, Continuous improvement, Factual approach to

decision making, Mutually beneficial supplier relationships (Jaafreh et al., 2012; Jorgensen et al., 2013). The study of Arumugam et al. (2011) identified that there are many factors of TQM that are effective factors in improving performance: leadership, customer focus, training, supplier quality management, product design, process management, and teamwork. The GMP is a part of QMS and good safety and hygiene to control the condition of facility, people and control the process. Eight basic factors about quality management in GMP are defined customer focus, leadership, employee contribution, process approach, system method, continuous improvement, supplier management and factual based decision.

Organizational performance

There were many different ideas regarding the organizational performance. The productivity and product quality were indicators of organizational performance (Ali et al., 2013). Besides that, customer satisfaction was also measured as organizational performance (Abdullah et al., 2009; Agus et al., 2009). Profitability, cost reduction and market share growth were measurement of organizational performance (Jorgensen et al., 2013; Kaynak, 2003). The success of implementing quality management system leads improving organizational performance as product quality, productivity and customer satisfaction (Demirbag et al., 2006; Feng et al., 2008; Nekoueizadeh et al., 2013; Yuparkon et al., 2013). Thus, organizational performances in this paper are measured by productivity, product quality and customer satisfaction.

Relationship between QMS factors and organizational performance

Leadership

Leadership is a strong commitment from the top management in quality management and leading to higher quality performance. Their commitment is one of the

critical determinants of successful TQM implementation. Leadership practices promote quality and high performance through creating and maintaining the involvement of both internal (staff) and external (customers and suppliers) people to achieve the organization's goals (Nguyen, 2004). Leadership can be communication of the mission and vision throughout the entire organization, acceptance of quality responsibility by top management, evaluation of top management on quality, participation by top management in quality improvement efforts, specificity of quality goals. It can also be importance attached to quality in relation to cost and schedule, comprehensive quality planning, management's commitment to quality through communication with employees, participation of managers in quality activities and contribute improvements (Saraph et al., 1989). The leadership was the strongest significant predictors of operational performance (Samson et al., 1999; Kanapathy et al., 2012; Jaafreh et al., 2012). Thus, the following hypothesis was suggested:

H1: Leadership positively influences organizational performance.

Process management

A desired result is achieved more efficiently when activities and related resources are managed as a process (Nguyen, 2004). In the EFQM Excellence Model and King Abdullah II Award, the process management is defined as "how the organization designs, manages and improves its processes in order to support its policy and strategy and fully satisfy, and generate increasing value for, its customers and other stakeholders" (KAAPS, 2010; EFQM, 2010). According to Saraph et al. (1989), the activities of process management are clarity of process ownership, boundaries, and steps, less reliance on inspection, use of statistical process control, employee self-inspection, automatic testing. Process management will reduce process variation for increasing output

consistency, reducing rework and waste and resulting in an increased percent-passed final inspection with no rework. The process management influences the operational performance, especially in improving product quality, productivity of the firms (Nekoueizadeh et al., 2013, Kanapathy, 2008). Thus, the following hypothesis is offered:

H2: Process management positively influences organizational performance.

Education and training

Training is one of the most important requirements in a successful TQM implementation. Delivery of high quality services and products requires that employees be equipped with knowledge and skills. All management personnel, supervisors, and employees should accept quality education and training. Training helps employees at all levels to understand the quality management system and their roles and responsibilities within it. General training level in the basic aspects of quality includes both managers and employees. There are provision of statistical training, trade training, and quality-related training for all employees (Jamali et al., 2010). Many authors conducted the research of identifying the success factor in implementing quality system as TQM, ISO and QMS in which resulted that education and training are one of the most important elements in a successful implementation and organizational growth (Agus et al., 2009). Therefore, it is hypothesized that:

H3: Education and training positively influence organizational performance.

Supplier management

Quality is more important factor than price in selecting suppliers. Long-term relationship with suppliers has to be established and the company has to collaborate with supplier to help improve the quality of products/ services (Nguyen, 2004). The effective supplier management is fewer dependable suppliers, reliance on supplier

process control, strong interdependence of supplier and customer, purchasing policy emphasizing quality rather than price, supplier quality control and assistance in product development (Saraph et al., 1989). The providing feedback on quality performance to supplier is highly concentrated to identify the corrective action and preventive action that resulted to improve the organizational performance (Saraph et al., 1989; Demirbag, 2006). Therefore, it is hypothesized that:

H4: Supplier management positively influences organizational performance.

Customer Focus

The organization is driven by customer's needs. It is necessary to identify these needs and their level of satisfactions. The establishment and maintenance of customer relationship is very important missions to organization (Nguyen, 2004). The involvement of employee in term of customer focus is able to respond and adapt to changing customer demand and expectations, it shows the important of all employees in the organization to give their commitment to establishing and sustaining a high level of customer satisfaction. Understanding, satisfying and surpassing customer needs and expectations is the primary goal of each organization (Jamali et al., 2010). Therefore, it is hypothesized that:

H5: Customer focus positively influences organizational performance.

Employee Involvement

Employee involvement is of crucial importance to TQM as a vital means to achieve customer satisfaction, delight and commitment through continuous quality improvement. Employee involvement shows the participants and contributions of all people in the organization, from top to bottom direction (Nguyen, 2004). It can be implementation of employee involvement and quality circles, open employee participation in quality decisions, responsibility of employees for quality, employee recognition for superior

quality performance, and effectiveness of supervision in handling quality issues, ongoing quality awareness of all employees (Saraph et al., 1989). Employee participation in monitoring, detecting, and correcting quality problems requires decentralization and delegation in organizations (Kaynak, 2003). By personally participating in quality improvement activities, employees acquire new knowledge, see the benefits of the quality disciplines, and obtain a sense of accomplishment by solving quality problems (Abdullah et al. 2009). Thus, a hypothesis is proposed as:

H6: Employee involvement positively influences organizational performance.

Product design

Design is recognized as a major determinant of quality (Fynes et al., 2005). Effective design leads to high level of customer satisfaction. The activities relating to product design are involvement of all affected departments in design reviews, emphasis on productivity, clarity of specifications, and emphasis on quality, not roll-out schedule, avoidance of frequent redesigns (Saraph et al., 1989). Product design requires a wide range of information, design teams are comprised of people from purchasing, design, production, suppliers and customers. The product development by creative/quality innovation significantly and positively impacts organizational performance (Flynn et al., 1995). The consumer perception on the product innovation as stronger, more favourable and unique are found to be important moderators in the relationship between product development by innovation and organizational performance. The study of Udegbe et al. (2013) mentioned that product development had a positive influence organizational performance. Thus, the following hypothesis is offered:

H7: Product design positively influences organizational performance.

Continuous improvement

Continuous improvement means a commitment to constant examination of the technical and administrative process in search of better methods. Continuous improvement is a permanent objective of the organization (Nguyen, 2004). This factor has showed a significant and positive effect on increasing market opportunities and reduction in waste of resources. The continuous improvement and innovation, which is the most important part of services, means searching for never-ending improvements and developing processes to find new or improved methods in the process of converting inputs into useful outputs (Talib

et al., 2010). Therefore, it is hypothesized that:

H8: Continuous improvement positively influences organizational performance.

Research model

Based on the relationships above, a research model is shown in Figure 1. There are eight independent factors as leadership, process management, education and training, supplier management, continuous improvement, customer focus and employee involvement, product design. The dependent factor is organizational performance measured by productivity, product quality and customer satisfaction.

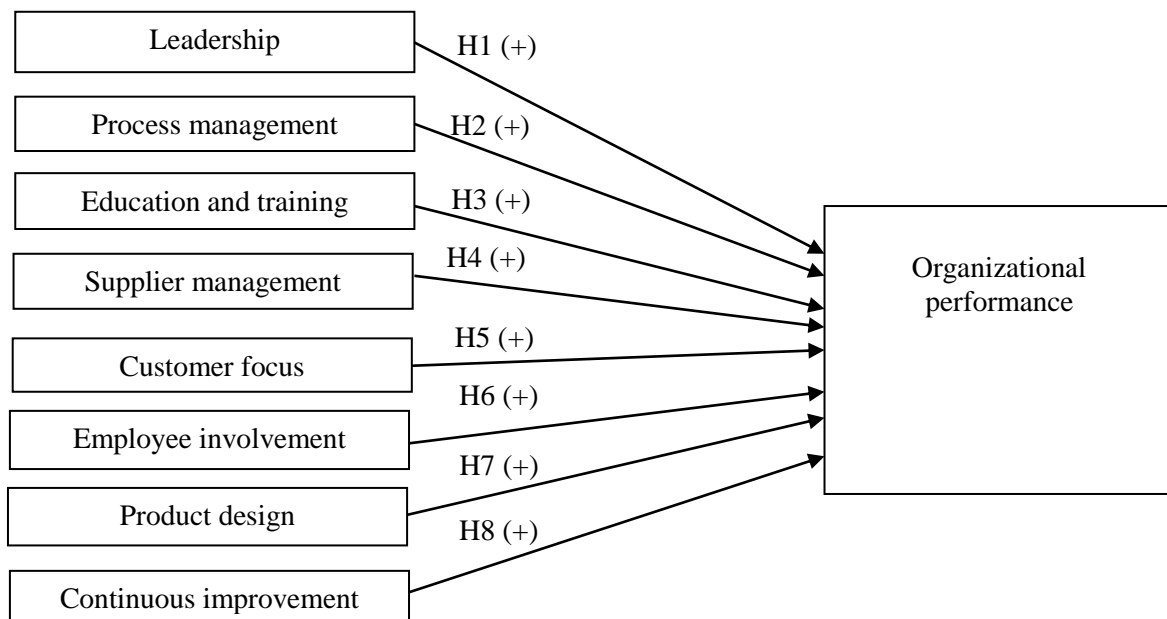


Figure 1. Research model

2.2. Methodology

The study consists of two stages: preliminary study and formal study. Preliminary study was conducted using the qualitative approach. The draft questionnaires were developed from literature review to find out the relevant constructs. The in-depth interview with the preliminary questionnaire was conducted on top directors and managers of the Vietnamese pharmaceutical factories. In fact, five respondents of five pharmaceutical factories (Savipharm, Stada, Nhat Nhat, BV

Pharma and Imexpharm) were selected for in-depth interviews to adjust the content and wording, and to add more items of constructs relevant to Vietnamese context. After qualitative research, the questionnaires were revised to suitable for survey at pharmaceutical factories in Vietnam.

Quantitative research was implemented in the stage of formal study. The closed questionnaires were used to survey. Revised measurement scales consisted of 45 items, in which eight independent factors were 33 items

and three dependent variables were 12 items (Table 1). The minimum sample size was planned 225 ($= 45 \times 5$). There are about 170 pharmaceutical factories getting GMP certificate in Vietnam. Due to limitation of relationship with all factories, the study was conducted at pharmaceutical factories getting GMP certificate located in the Southern Vietnam. The respondents were middle or top

managers that have worked at different divisions of factories. Thus, the questionnaires were sent to 50 factories and about five to ten questionnaires was collected at each factory. The techniques as Cronbach's alpha, Exploratory Factor Analysis (EFA) are used to test the reliability of measurement scale. Multiple Regressions is used for hypotheses testing.

Table 1. The revised measurement scale

<i>Factors</i>	<i>Items</i>	<i>Sources</i>
Leadership		
LS1	Leaders take on the responsibility for developing quality oriented management systems.	Santos et al. (2007)
LS2	Leaders allocate resources for continuous improvement of the management system.	Santos et al. (2007)
LS3	Management team always cares to customer demand. (*)	<i>Qualitative research</i>
LS4	Senior managers actively encourage the changes and implementation about a culture of trust, involvement, and commitment in moving towards 'Best Practice'	Samson et al. (1999)
LS5	Leaders listen, support, and encourage employees to take part in deciding and managing total quality policies and plans.	Santos et al. (2007)
LS6	Top management empowers employees to solve quality problems	Santos et al. (2007)
Process management		
PR7	Processes are designed to ensure that skills and capacities meet company needs.	Santos et al. (2007)
PR8	Standardized and clear work or process instructions are given	Samson et al. (1999)
PR9	Process capability and productivity are regularly assessed the effectiveness of processes and production operation.	Zhang (1999)
PR10	Organization closely works with suppliers to improve processes.	Samson et al. (1999)
Education and training		
ED11	Employees are encouraged to accept education and training.	Zhang (1999)
ED12	Most employees are trained on how to use quality management methods.	Zhang (1999)
ED13	Specific work-skills training (technical and vocational) are given to employees.	Antony (2002)
ED14	The top management pays attention to employee training. (*)	<i>Qualitative research</i>

Supplier management		
SM15	There are technical assistances to improve the quality and responsiveness of suppliers.	Antony (2002)
SM16	Clarity of specifications is provided to suppliers.	Santos et al. (2007)
SM17	The suppliers involve in the product development process.	Antony (2002)
SM18	Organization has established long-term co-operative relations with suppliers.	Santos et al. (2007)
Customer Focus		
CF19	Organization always conducts market research in order to collect suggestions for improving products.	Zhang (1999)
CF20	The requirements of customers are effectively disseminated and understood throughout the workforce.	Samson et al. (1999)
CF21	Organization receives and responds to customer's needs and feedback on products/ services provided quickly.	Zhang (1999)
Employee Involvement		
EI22	Employees understand the importance of their contribution and role in the organization.	Samson et al. (1999)
EI23	Employees willingly share their knowledge and experience. (**)	<i>Qualitative research</i>
EI24	Employees actively seek opportunities to enhance their competence, knowledge and experience. (**)	<i>Qualitative research</i>
EI25	Employees joint in teams or groups to improve quality or solve problems. (**)	<i>Qualitative research</i>
Product Design		
PD26	Product/service specifications and procedures are clarified.	Antony (2002)
PD27	The customer requirements are thoroughly considered in new product design	Zhang (1999)
PD28	New product designs are thoroughly reviewed before production.	Zhang (1999)
PD29	Various departments participate in new product development.	Zhang (1999)
Continuous Improvement		
CI30	Improvement of products/services is based on customer demand. (**)	<i>Qualitative research</i>
CI31	There are assessment and improvement of processes and products/services.	Antony (2002)
CI32	Feedback is provided to employees on their quality performance	Antony (2002)
CI33	There are programs on waste elimination.	Antony (2002)

Productivity		
PT34	Waste and costs in activities of production are decreased.	Santos et al. (2007)
PT35	The cycle time is reduced.	Santos et al. (2007)
PT36	Organization achieves rationalization of process and procedure. (**)	<i>Qualitative research</i>
Product Quality		
PQ37	Conformity rates of primary products are increased.	Zhang (1999)
PQ38	Failure rates of primary products are decreased.	Zhang (1999)
PQ39	Quality level of primary products is increased.	Zhang (1999)
PQ40	Reliability of primary products is increased.	Zhang (1999)
Customer satisfaction		
CS41	Satisfaction of clients is improved.	Santos et al. (2007)
CS42	Client perception is improved.	Santos et al. (2007)
CS43	The number of customer complaints is reduced.	Santos et al. (2007)
CS44	Communication with clients is improved.	Santos et al. (2007)
CS45	Consolidation and loyalty of clients is increased.	Santos et al. (2007)

Note: Items (*) are adjusted and items (**) are developed in qualitative research.

3. Result and discussion

Sample description

More than 350 questionnaires were sent for survey. There were 265 suitable questionnaires are used for analysis. The table 2 describes the main characteristics of the sample.

Table 2. Sample descriptive statistics

Description	Frequency	Percent (%)	Description	Frequency	Percent (%)
Ownership			Position of respondent		
State-owned	0	-	General manager (GM)	0	-
Foreign	6	12.0	Vice GM	1	0.4
Joint venture	3	6.0	Director	11	4.2
Joint stock	41	82.0	Vice director	7	2.6
<i>Total</i>	<i>50</i>	<i>100.0</i>	Manager	115	43.4
Number of employees			Vice manager	37	14.0
≤ 100	4	8.0	Group leader	82	30.9
101-300	32	64.0	Vice group leader	12	4.5
301-500	11	22.0	<i>Total</i>	<i>265</i>	<i>100.0</i>
>500	3	6.0			
<i>Total</i>	<i>50</i>	<i>100.0</i>			

Cronbach's Alpha and EFA Testing

The Cronbach's Alpha reliability analysis is a measurement of the internal consistency of the constructed items to assess the reliability of each factor in measurement scales. The reliability of Cronbach's Alpha shows how relation of the items in a set which are significantly correlated with the other as well. Such coefficient that is above 0.6 is acceptable for the reliability of each factor and the item-total correlation that is smaller than 0.4 is considered to be deleted (Hair et al., 2006). The result of reliability analysis in this study indicates that all of measurement scales (45 items) are reliable (Table 3).

Exploratory factor analysis (EFA) is used to test the validity of measurement scales by using the principal axis factoring with Promax rotation. The criteria for the validity of EFA are Eigenvalue ≥ 1 , The Accumulative of Total Variation Explained $\geq 50\%$, and Factor Loadings ≥ 0.50 . The summary of reliability analysis and EFA in the Table 3 proves that all of measurement scales are reliable and valid.

After refining EFA, supplier management factor was removed. This could be explained

that the involvement levels of Vietnamese suppliers in pharmaceutical industry are low. Due to almost active ingredients were imported, they were limited of sharing R&D, IP protection as well as buyer power in the context of generic product competition. Two factors as "customer focus" and "employee involvement" were extracted into one factor. It could be understand that the employees with their competency, knowledge and contribution are considered as key drivers to proactively deliver high quality of product/service to customers. Therefore, it was named *employee involvement towards customer focus*. Two other factors as "product design" and "continuous improvement" were also extracted one factor. Product design factor was understood by respondents in term of how to improvement and develop product to adapt with customer demand and expectation. Thus, this combined factor was named *continuous improvement towards product design*. For dependent factors, two factors as "productivity" and "product quality" were extracted into one factor, namely "*productivity and product quality*".

Table 3. Summary of Cronbach's Alpha and EFA results

Factors	Cronbach's alpha	After EFA		Factor loading
		<i>Eliminate</i>	<i>Accept</i>	
<i>Independent factors:</i> KMO=0.905, Cumulative %TVE = 60.279%, Eigenvalues = 1.085				
Leadership	0.831	3 (LS4, LS5, LS6)	3 (LS1, LS2, LS3)	0.542 ÷ 0.842
Process management	0.735	1(PR9)	3 (PR7, PR8, PR10)	0.533 ÷ 0.714
Education and training	0.780	1 (ED13)	3 (ED11, ED12, ED14)	0.579 ÷ 0.781
Supplier management	0.781	4 (SM15, SM16, SM17, SM18)	0	-
<i>Customer focus and</i>	0.676 and	0	7 (CF19, CF20,	0.534 ÷

Factors	Cronbach's alpha	After EFA		Factor loading
		<i>Eliminate</i>	<i>Accept</i>	
<i>Employee involvement</i>	0.774		CF21, EI22, EI23, EI24, EI25)	0.764
<i>Product design and Continuous improvement</i>	0.789 and 0.828	1 (PD26)	7 (PD27, PD28, PD29, CI30, CI31, CI32, CI33)	0.546 ÷ 0.760
Dependent factors: <i>KMO = 0.905, Cumulative %TVE = 60.279%, Eigenvalues = 1.085</i>				
<i>Productivity and Product quality</i>	0.734 and 0.815	0	7 (PT34, PT35, PT36, PQ37, PQ38, PQ30, PQ40)	0.518 ÷ 0.778
Customer satisfaction	0.840	0	5 (CS41, CS42, CS43, CS44, CS45)	0.521 ÷ 0.867

Revised research model

As a result, a revised research model (Figure 1) consisted of five independent factors (leadership, process management, education and training, continuous improvement towards product design, employee involvement towards customer focus) and two dependent factors (productivity and product quality, customer satisfaction).

Based on Figure 1, the revised hypotheses were adjusted as follows:

Model 1 (dependent factor: Productivity and product quality):

H1a: Leadership positively influences productivity and product quality.

H2a: Process management positively influences productivity and product quality.

H3a: Education and training positively influences productivity and product quality.

H4a: Employee involvement towards

customer focus positively influences productivity and product quality.

H5a: Continuous improvement towards product design positively influences productivity and product quality.

Model 2 (dependent factor: customer satisfaction):

H1b: Leadership positively influences customer satisfaction.

H2b: Process management positively influences customer satisfaction.

H3b: Education and training positively influence customer satisfaction.

H4b: Employee involvement towards customer focus positively influences customer satisfaction.

H5b: Continuous improvement towards product design positively influences customer satisfaction.

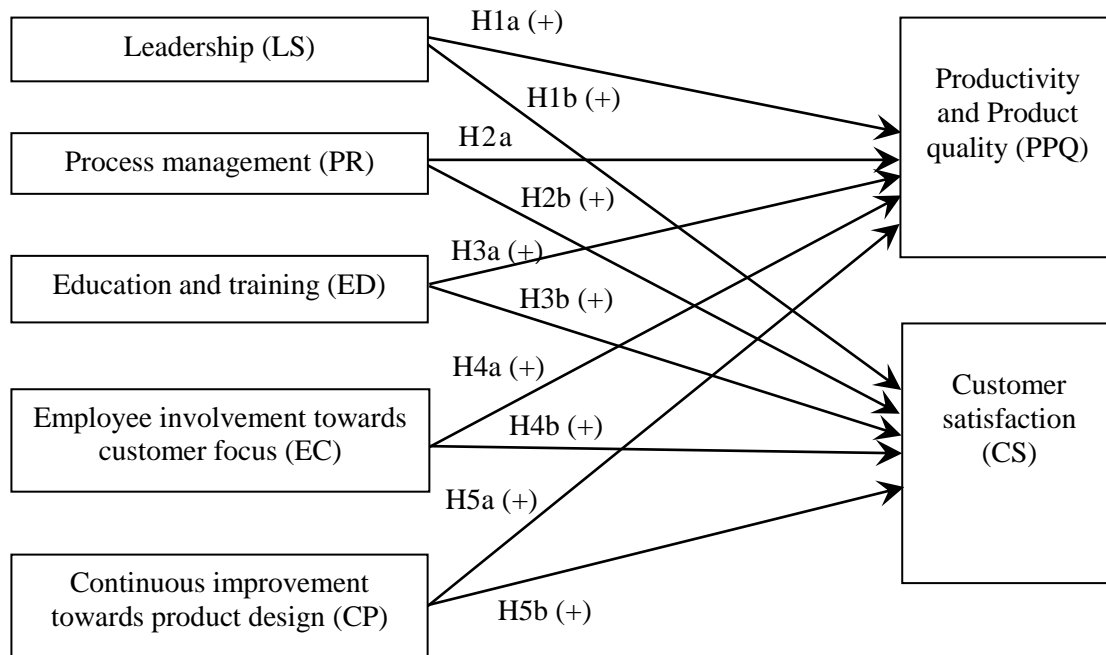


Figure 2. Revised research model

Pearson Correlation

The Pearson Correlation (Table 4) showed that independent factors (LS, PR, ED, EC, CP) have significant correlations to the dependent factors (PPQ and CS). However, a

correlation between those independent variables may influence the regression analysis results due to multicollinearity. It will be tested after regression analysis by Variance Inflation Factor (VIF).

Table 4. Pearson Correlation

		LS	PR	ED	EC	CP
PPQ	Pearson Correlation	.528**	.389**	.357**	.509**	.704**
	Sig. (2-tailed)	.000	.000	.000	.000	.000
	N	265	265	265	265	265
CS	Pearson Correlation	.565**	.437**	.387**	.540**	.572**
	Sig. (2-tailed)	.000	.000	.000	.000	.000
	N	265	265	265	265	265

Multiple regression analysis

The Model 1 is significant (Sig. value = 0.000). The adjusted R-square is 0.554. It illustrates that the independent factors explain 55.4% of the variance of dependent factor (PPQ). In model 1 (Table 5), continuous improvement towards product design has strongest impact on productivity and product quality ($\beta = 0.536$), follow by leadership ($\beta = 0.249$) and employee involvement towards

customer focus ($\beta = 0.135$).

The Model 2 is also significant (Sig. value = 0.000). The adjusted R-square is .477. It illustrates that the independent factors explain 47.7% of the variance of dependent factor (CS). In model 2 (Table 6), Leadership has strongest impact on customer satisfaction ($\beta = 0.313$), follow by continuous improvement towards product design ($\beta = 0.285$), employee involvement towards customer focus ($\beta = 0.232$).

Table 5. Regression analysis for model 1

Model 1 (Adjusted R Square = .554)	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	Collinearity Statistics	
	B	Std. Error	Beta			Tolerance	VIF
(Constant)	.600	.169		3.547	.000		
Leadership	.210	.044	.249	4.791	.000	.624	1.603
Process management	-.032	.055	-.032	-.586	.558	.558	1.791
Education and training	-.008	.046	-.008	-.164	.870	.670	1.492
Employee involvement towards customer focus	.144	.055	.135	2.599	.010	.623	1.606
Continuous improvement towards product design	.518	.050	.536	10.320	.000	.625	1.599

a. Dependent Variable: Productivity and product quality

Table 6. Regression analysis for model 2

Model 2 (Adjusted R Square = .477)	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	Collinearity Statistics	
	B	Std. Error	Beta			Tolerance	VIF
(Constant)	.646	.184		3.505	.001		
Leadership	.265	.048	.313	5.548	.000	.624	1.603
Process management	.014	.060	.014	.234	.815	.558	1.791
Education and training	.038	.050	.042	.765	.445	.670	1.492
Employee involvement towards customer focus	.247	.060	.232	4.105	.000	.623	1.606
Continuous improvement towards product design	.276	.055	.285	5.055	.000	.625	1.599

a. Dependent Variable: Customer satisfaction

According to Hair et al. (2006), the criteria used for multicollinearity testing is the VIF in the Collinearity statistic of the independent of variables are higher than 2. The result showed that all the VIFs of two models have value smaller than 2 so there was no multicollinearity in the regression analysis.

Discussion

The result of the research shows that there are three QMS factors as leadership, employee involvement towards customer focus, and continuous improvement towards product design positively influencing organizational performance as productivity and product quality, customer satisfaction. Two factors as process management and training and education do not positively influence organizational performance.

Leadership (H1a and H1b are supported). In this study, leadership positively influences productivity and product quality with standardized coefficient $\beta = 0.249$ and on customer satisfaction with $\beta = 0.313$. This result confirms again a positive relationship between leadership and organizational performance in the literature review as Samson et al. (1999), Santos et al. (2007), and Jaafreh et al. (2012). In the context of local pharmaceutical manufacturers in Vietnam, the role of top management is very important. The leadership expectation was proven the successful growth in the local company as Savipharma, Imexpharm or Hau Giang factories. The leaders of those companies exposed their leadership high performance behaviors in term of high commitment and deliverable quality mission and vision. By improving the QMS, those companies got the GMP certification from reliable quality association or agency. It is not only building their reputation, but also support them in leading growth in Vietnamese pharmaceutical industry and sustain their business in locally as foundation for exporting which met the international quality standards. Many factories

have exposed their impression of leadership by setting the quality mission and vision. They also deeply invest the resources into quality management as well as establishing the Quality Rewards to employees who can achieve the target in quality operation in their organization.

Employee involvement towards customer focus (H4a and H4b are supported). Employee involvement towards customer focus positively influences productivity and product quality with $\beta = 0.135$ and on customer satisfaction with $\beta = 0.232$. Employee involvement towards customer focus is considered as front line elements to deal with quality and concentrate to customer demand and expectation. The employees involve in usage their knowledge and competency bringing the best service to customer and in development of effective customer relationship. In general, it was found customer focus throughout employee involvement is essential which it proved to have a positive influence on the organizational performance.

Continuous improvement towards product design (H5a and H5b are supported). Continuous improvement towards product design influences productivity and product quality with $\beta = 0.536$ and on customer satisfaction with $\beta = 0.285$. Continuous improvement towards product design is one of important dimension of quality management in which product design meets or exceeds the requirements and expectations of customers better than the competitors, and then it can lead to an increased market share. The improving product design is required to have research development and marketing experiences. In the pharmaceutical industry, new formulation or new molecule can make different of strategy in term of launch and product pipelines to expand their business. Especially, they can launch the generic products to compete the branded ones as alternative treatment for population and to

follow the Ministry of Health direction.

Process management (H2a and H2b are rejected). It is indicated that process management does not positively influence organizational performance. In Vietnamese pharmaceutical industry, the processes and documentation of operating procedures are standardized. Due to sensitive of pharmaceutical formulation influencing safety of human, efficacy of treatment, any changes of the pharmaceutical manufacturing processes will need a huge investment to conduct process validation, qualification of installation, operational, and performance as well as a lot of investment for product research and development. In the other hand, the difficulties of updating new and modern technologies from developed countries into local industry also result in the limitation of process management.

Education and training (H3a and H3b are rejected). It is indicated that education and training do not positively influence organizational performance. It can be explained that the budget for education and training is the one of constrains for local pharmaceutical manufacturers that they need more external training. They are facing with the high investment to upgrade their organization's knowledge by education and training. In this stage, the objective of training just focus on the basic knowledge mandated for employees running production as GMP requirement rather than concentrating to knowledge and skills to improve quality and productivity and reduce customer complaints.

4. Conclusion

The main content of the study is to identify the key factors of QMS influencing organizational performance in Vietnamese pharmaceutical companies. The middle or top managers of 50 factories located in the Southern Vietnam were surveyed and the suitable 265 questionnaires were used to analysis. As a result, the factors as leadership,

continuous improvement towards product design, and employee involvement towards customer focus have positively influenced organizational performance (productivity and product quality, customer satisfaction). Two remaining factors as process management, training and education have not positively influenced organizational performance.

Based on the findings of the study, the following managerial implications are suggested to managers of pharmaceutical factories getting GMP in improving performance through enhancing important factors of QMS:

Leadership. The leadership is one of key factors that present the management commitment of the factory towards quality. The quality culture should be built in the organization. The management should take accountability in establishing the quality mission and vision as well as demonstrate the empowerment to employees. The leaders in the company should build the culture of coaching and giving feedback to employee and customer. In addition, management should allocate sufficient resource to support for continuous improvement.

Continuous improvement towards product design. The local pharmaceutical market is requesting the competition mainly depended on the quality of medicine, pricing and productivity. Continuous improvement towards product design is the key factor leading the factories approach the solution effectively. Management should focus on seeking the customer requirements and expectations. Not only focusing on the design, the R&D procedure and product specification should be frequently reviewed for continuous improvement. Management should motivate and inspire the employee on their achievement in new product development by developing the incentive program and bonus scheme. Management should develop the specific training program concerning research and development to upgrade the scientific

knowledge for employees. Moreover, customer requirements and production cost should be thoroughly considered during the process of product design as well. Different departments in an organization should participate in new product development. Before production, new product design should be thoroughly reviewed in order to avoid problems happening during production.

Employee involvement towards customer focus. The quality management system addresses how well the organization meets customer requirements and expectations and maintains a good relationship with customers. The management should engage the employees in the factory in building trust to customers by improving the customer service and seeking information related to customer and handling the issue in transparency and integrity. This also emphasizes the employee to discipline ethical code in pharmaceutical industry. Patient focus concept should be expanded to encourage employee engagement

towards patient. Empowerment culture should be built up to optimize the contribution and accountability of employees.

The study has certain limitations. Firstly, the scope of this study is focused on pharmaceutical factories in Southern Vietnam. It should be expanded to whole country. Secondly, the study does not include the other industry like cosmetic that have GMP certificate. It is proposed that the next research should be extended to cosmetic industry that its products also impact on human safety, and GMP certificate is also a mandatory requirement of this industry. Lastly, the organizational performance does not consist of financial measurement. Thus, further research is recommended to study the financial indicators to get a general organizational performance.

Acknowledgements

The author would like to send special thanks to Mr. Dang Anh Vu for his useful insights and supports in completing this paper.

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