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DOES QUALITY PAY IN THE PHARMACEUTICAL INDUSTRY? THE MEDIATING ROLE OF TRAINING OF PERSONNEL BETWEEN QUALITY MANAGEMENT AND PERFORMANCE

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ABSTRACT

The study aims to contribute to the quality and training-related literature by considering the later as a mediating variable between quality and company performance. Drawing on quality management literature, we demonstrate that quality plays still an important role in the pharmaceutical industry, where legal quality control related regulations ensure a minimum level of product quality, customer service's largest part falls on other stages of the value chain (i.e., physicians), and reputation is apparently guaranteed by strict legal requirements. Similarly, we include training of personnel in the analysis, which is a key element supporting successful performance in the pharmaceutical industry. The results suggest that training personnel does positively mediate the quality management-performance link in the pharmaceutical industry.

Keywords: quality management, pharmaceutical, training, performance, mediation.

JEL classification: M1 Business Administration; L1 Market Structure, Firm Strategy, and Market Performance.

RESUMEN

Este trabajo tiene por objeto contribuir a la literatura relacionada con la calidad y la formación, considerando a esta última como variable mediadora entre la calidad y el desempeño empresarial. Basándonos en la literatura sobre gestión de la calidad, demostramos que la calidad todavía juega un papel importante en el sector farmacéutico, donde la regulación legal sobre el control de la calidad asegura un nivel mínimo de calidad de producto, la mayor parte del servicio al cliente descansa sobre otras áreas de la cadena de valor (esto es, los facultativos) y la reputación está –al menos aparentemente– garantizada por estrictas exigencias legales. Así, incluimos en el análisis la formación de la mano de obra, que es un elemento fundamental para aumentar el desempeño empresarial en el sector farmacéutico. Los resultados sugieren que, en el sector farmacéutico, la formación de la mano de obra media positivamente en la relación entre la gestión de la calidad y el desempeño empresarial.

Palabras clave: gestión de la calidad, farmacéutico, formación, desempeño, mediación.

Clasificación JEL: M1 Administración de empresas; L1 Estructura de mercado, estrategia empresarial y funcionamiento del mercado.

1. INTRODUCTION

Prior research indicates that quality plays a key role in enhancing an organization's performance (Dahlgaard-Park, Chen, Jang & Dahlgaard, 2013). Improved quality reduces waste, increases productivity (Kumar, Choisne, de Grosbois & Kumar, 2009) and is critical to achieve long-term competitive advantages (Zhang & Xia, 2013). Nevertheless, the evolution of quality management has not happened without controversies (O'Neill, Sohal & Teng, 2016). Even if there are some studies that have not been able to prove the quality management-performance relationship (e.g., Foster, 2007; Goldman, 2005; Harari, 1993; Kober, Suraamanniam & Watson, 2012; McCabe & Wilkinson, 1998; Yeung & Chan, 1998), numerous studies have proven a positive impact of quality management on performance (e.g., Abdullah & Tarí, 2012; Al-Dhaafri, Al-Swidi & Yusof, 2016; Brah, Tee & Rao, 2002; Corbett, Montes-Sancho & Kirsch, 2005; Duarte, Brito, Di Serio & Martins, 2011; Evans & Lindsay, 2011; Flynn, Schroeder & Sakakibara, 1995; Hendricks & Singhal, 2001; Huang, Wu, Lu & Lin, 2016; Joiner, 2007; Kaynak, 2003; Klingenber, Timberlake, Geurts & Brown, 2013; Lo, Yeung & Cheng, 2009; Martínez-Costa, & Jiménez-Jiménez, 2009; Naveh & Marcus, 2005; O'Neill et al., 2016; Terziovski & Samson, 1999; Zatzick, Moliterno & Fang, 2012; Zu, 2009).

Nonetheless, the results reported in prior studies are not consistent, which can at least partly be explained by the fact that the analyzed quality management practices vary among studies. Furthermore, there is a need to study how quality management is important in industries where quality is wrongly often taken for granted. In this vein, some studies have analyzed some general quality management practices in the pharmaceutical industry, mainly related to Total Quality Management (TQM) philosophy (e.g., Al-Qudah, 2012; Cheroigin, 2014; Friedli, Goetzfried & Basu, 2010; Marinkovic et al., 2016; Mazumber, Bhattacharya & Yadav, 2011; Mehralian, Nazari, Rasekh & Hosseini, 2016; Mittal & Singh, 2012; Poongothai, Ilavarasan, Karthikeyan & Arul, 2011; Wangai, 2015). Nevertheless, in the last few years the study of quality

management has shifted away from TQM to focus on determinants of establishing positive quality-performance relationships (Dahlgaard-Park et al., 2013). Within this context, this work extends the quality management literature by empirically examining to what extent training of personnel mediates the quality management-performance link in the pharmaceutical industry.

2. LITERATURE REVIEW AND CONCEPTUAL MODEL

2.1. Quality management

Quality can be defined as the degree to which a set of inherent characteristics fulfils requirements (O'Neill et al., 2016). The achievement of economic advantage began with the analysis of quality control techniques and lead to the notion that quality can be pursuit in every aspect of an organization. Quality has been since then a cornerstone providing inspiration for a broad range of strategies under the umbrella of quality management. In essence, quality management is a multidimensional phenomenon and a very broad concept that can be considered a holistic management philosophy. Quality management has led to other concepts such as just-in-time (JIT), Lean Manufacturing, Total Productive Maintenance (TPM), Six Sigma and specially the Total Quality Management (TQM), which has been one of the most dominating managerial approaches over the last years (Dahlgaard-Park et al., 2013; de Sena, 2011; Sila & Ebrahimpour, 2002).

Nevertheless, in the last few years the study of quality management has shifted away from TQM to focus on determinants of establishing positive quality-performance relationships (Dahlgaard-Park et al., 2013). In this sense, we focus on three of the quality signals that have received the greatest attention in the literature, namely quality control, customer service, and reputation of the firm within the industry.

Quality control is the process that provides stability to prevent adverse change (Juran & Godfrey, 1999). At first, researches focused only on product and operational quality but nowadays quality can be applied to every part of the organization. Top management should ensure that companies have a system to audit all departments for quality control and results (Chang & Lu, 1995), being the information obtained often interesting for external stakeholders too (Van de Heuvel, Niemeijer & Does, 2013).

Customer service is everything what a company does for satisfaction of its customers (Kanovska, 2015). Organizations have long realized that providing superior customer service is a good way to enhance quality and thus distinguish from competitors (Collier, 1987). In addition to it, focusing on customer service has a strong impact on customer satisfaction (Innis & La Londe, 1994), which has been a key issue in management research since customer satisfaction is crucial to long-term performance (Szymanski & Henard, 2001).

Reputation is an intangible element that is difficult to imitate (Roberts and Dowling, 2002). Reputation is a signal of underlying quality (Jin & Kato, 2006; Roberts & Dowling, 2002) which has received much attention in the literature (Dawar & Parker, 1994). In short, reputation clearly reflects the importance of quality management too.

2.2. Training of personnel

Training is defined as a systematic development of competences needed by employees to perform their work (Dermol & Cater, 2013), which would, in turn, improve firm's performance (Manoharan, Muralidharan & Deshmukh, 2012). Training of personnel is essential to continuously improve the quality of human capital (Zheng, Hyland, & Soosay, 2007) and human resource development (Manoharan, Muralidharan & Deshmukh, 2012; Taylor & Davies, 2004), and it is used mainly in bigger firms (Smith & Hayton, 1999; Van Smoorenburg & Van der Velden, 2000) based in developed countries (Dermol & Cater, 2013). Hence, Training of personnel is a key element supporting successful performance (e.g., Blandy, Dockery, Hawke & Webster, 2000; Dimovski, Škerlavaj, Kimman & Hernaus, 2008; Tharenou, Saks & Moore, 2007). Just as firms usually recoup their investments in training many times over (Blandy et al., 2000), limited investments in training may in turn result in lower knowledge and skills (Minbaeva et al., 2014). As stated by Kirkpatrick (2006), training and performance appraisals are close relatives.

The success of training depends on two factors: quality and volume (Dermol & Cater, 2013). With properly trained employees the firm can develop, and as employees develop, so will the company (Williams, 1997). Trainees must be reliable and effective (Nikandrou et al., 2009), and they should in turn obtain appropriate incentives (Dermol & Cater, 2013). Training can be formal or informal, existing a strong correlation between the likelihood of receiving both types (Ng, 2005). In any case, training should be well designed and established in a way that works for the specific firm it was designed to (Pluta & Fugate, 2009) and it must be relevant to the job (Nikandrou et al., 2009). The majority of training an employee receives is normally informal (Blandy et al., 2000), which is unplanned, not documented and largely unstructured (Smith & Hayton, 1999). Some decades ago training targeted only upper levels in businesses, but nowadays the majority of employees are trained (Blandy et al., 2000; Jarvis, Holdford & Griffin, 2003), even if it is true that the ratio between costs and benefits of training is more favorable for employees with higher education levels (Blunch & Castro, 2005).

All in all, as Zheng, Hyland and Soosay (2007) well state, the benefits of training of personnel have been widely acknowledged in the literature: through training individual productivity raises, employee commitment to the enterprise increases, adaptability and flexibility of the workforce is improved, changes in business strategy can be made (Smith & Hayton, 1999) and staffs' loyalty to the organization may increase (Taylor & Davies, 2004), among others. These features turn out to be especially important in industries such as the pharmaceutical industry, where to some extent there is a shortage of qualified staff in specific R&D areas (Frietsch & Neuhäusler, 2015).

As Talib, Rahman and Qureshi (2011) suggest, a successful quality management environment requires a committed and well-trained work force that is focused on quality improvement. While elevating the general knowledge base of the workforce returns many benefits (Evans & Lindsay, 2011), untrained employees will result in lack of continuous improvement culture. Training allows an organization to improve its standard and quality of service to customers (Taylor & Davies, 2004). In this sense, high quality employees who possess certain skills and competencies are the key to enhance customer service and hence customer satisfaction (Abu-ELSamen, Akroush, Al-Khawaldeh & Al-Shibly, 2011), being the combination of customer service and employee training what is effective.

Training likelihood depends not only on a country's level of development (Booth, 1991; Ng, 2005), but it also differs among industries. In this sense, the adoption of new technology is an important driver for employee training because it is vital for maintaining the absorptive capacity of innovative firms (Zheng et al., 2007). For example, in the pharmaceutical industry, where innovation is the very essence of the industry, and as a result firms' absorptive capacity needs to be developed (Cockburn & Henderson, 1998; Fabrizio, 2009; Lane, Salk & Lyles, 2001; Nooteboom et al., 2007), training plays a major role. In other words, training of employees has positive effects on new product development (Langerak & Hultnik, 2005), which is crucial in the pharmaceutical industry and especially in the German pharmaceutical industry, where companies are intensifying their investments. In short, quality is a factor that drives training in the firm (Smith & Hayton, 1999). Based on the review of the extant literature, we formulate the following hypotheses:

Hypothesis 1: There is a positive association between Quality management and performance.
Hypothesis 2: There is a positive association between Training of personnel and performance.
Hypothesis 3: Training of personnel mediates quality management's impact on performance.

3. RESEARCH METHODOLOGY

3.1. Sample and data collection

Our population comprises all the German pharmaceutical firms operating under the 2834 SIC code (928 firms); this data was obtained from the Dun & Bradstreet Database. We chose German pharmaceutical firms as the sample for this study because this German industry is a clear source of benchmarking data, that is, the results obtained using the data from the German pharmaceutical industry could be extended to other pharmaceutical industries.

Using the computer-assisted telephone interviewing (CATI) procedure, 200 valid responses were obtained from CEOs in the German pharmaceutical industry with the help of a German institute. In order to obtain 200 valid responses, 597 CEOs were interviewed; thus, the final response rate was around 33.5%. For every firm in the sample, we collected data associated with the 3-year period immediately after the enactment of the Act on the Reform of the Market for Medicinal Products (AMNOG) in 2011, which is intended to reduce the price of drugs by introducing a mandatory benefit assessment system for new drugs. The sample size is appropriate due to the low complexity of the model (Hair et al., 2011). Power analysis (Hair, Hult, Ringle & Sarstedt, 2017; Roldán & Sánchez-Franco, 2012) supports this notion.

3.2. Measures

The dependent and independent variables were measured using the means of multiple items on 5-point Likert scales, ranking from 1 ("much below the average") to 5 ("much above the average"). Training of personnel was considered a single-item construct. Based on previous research, we focused on some practices emphasized in

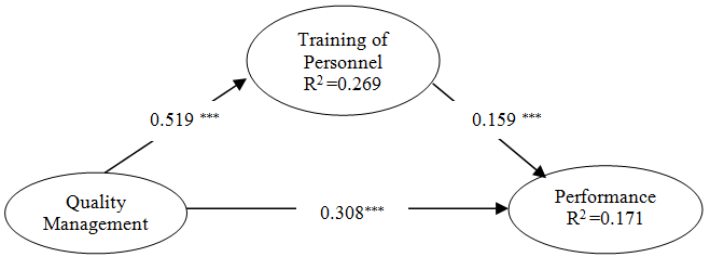
quality management literature, namely customer service, quality control, and reputation (e.g., Forker, Vickery & Droge, 1996; Mehralian et al., 2016; Powell, 1995). The measurement scale for performance was adapted from Akan, Allen, Helms and Spralls (2006) and Allen and Helms (2006).

4. RESULTS OF DATA ANALYSIS

The data analysis was performed using the partial least squares structural equation modeling (PLS-SEM) technique, which is a useful multivariate method in strategic management and marketing (Barroso, Cepeda & Roldán, 2010; Hair, Hult, Ringle & Sarstedt, 2017; Hair, Ringle & Sarstedt, 2011; Hair, Ringle & Sarstedt, 2012; Hair, Sarstedt, Pieper & Ringle, 2012; Hair, Sarstedt, Ringle & Mena, 2012; Richter, Cepeda, Roldán & Ringle, 2016; Richter, Sinkovics, Ringle & Schlägel, 2016; Ringle, Sarstedt & Schlittgen, 2014; Sarstedt, Ringle, Smith, Reams & Hair, 2014; Schloderer, Sarstedt & Ringle, 2014). We used the SmartPLS 3 software (Ringle, Wende & Becker, 2014). Both quality management and performance were defined in a reflective way since the causality goes from the variable to the items (Hair et al., 2019; Podsakoff, Shen & Podsakoff, 2006).

Figure 1 presents the structural model resulting from the PLS analysis, displaying the variance of the endogenous variables (R^2) and the path coefficients. Table 1 shows the assessment of the measurement model, and Table 2 shows the structural model assessment.

Figure 1. Structural model: Path coefficients and R^2



Note: Lohmöller settings were used.
*** p < .01; ** p < .05; * p < .1.

The first step requires the assessment of the measurement model (Table 1). The assessment of internal consistency reliability (CR) showed that all values were above 0.7 (Henseler, Ringle & Sinkovics, 2009). Cronbach's α values were above or close to 0.7 (Hair, Black, Babin, Anderson & Tatham, 2006; Nunnally & Bernstein, 1994). We assessed convergent validity using the average variance extracted (AVE) values. All the values were above or very close to 0.5 (Henseler et al., 2009). We used the heterotrait–monotrait (HTMT) ratio of correlations to detect the lack of discriminant validity reliably (Henseler, Ringle & Sarstedt, 2014). Values range from 0.326 to 0.652, thus the values were below the threshold of 85% (Kline, 2011).

Relying on a satisfactory assessment of the measurement model, the second step is the evaluation of the structural model (Table 2). We used the bootstrapping procedure to analyze the significance of the paths. The effect size (f^2) allows the assessment of a construct's contribution to an endogenous latent variable. Examining for collinearity, each predictor construct's tolerance (VIF) value is higher than 0.2 and lower than 5 (Hair et al., 2011; Hair et al., 2019).

Table 1. Evaluation results: Measurement model

Constructs/indicators	Loading	Composite reliability	Cronbach´s α	AVE
Quality management		0.802	0.629	0.574
- Extensive customer service	0.775			
- Strict quality control	0.750			
- Reputation in industry	0.747			
Performance		0.953	0.938	0.801
- Total asset growth	0.923			
- Net income growth	0.871			
- Overall performance/success	0.908			
- Total revenue growth	0.875			
- Market share growth	0.898			

Note: AVE = Average variance extracted

Table 2. Assessment of structural model

Endogenous construct	R^2			Q^2	
Performance	0.171			0.134	
Training of Personnel	0.269			0.264	
Path	Path coefficient	Collinearity (VIF)	f^2	*t*-value	Bias corrected 95% confidence interval
Quality management→ Performance	0.308	1.368	0.084	5.749***	[0.214; 0.422]
Training of personnel → Performance	0.159	1.368	0.022	2.607***	[0.030; 0.272]
Quality management→ Training of personnel	0.519	1.000	0.368	12.495***	[0.434; 0.599]

Note: The cross-validated redundancy measure (Q^2) is derived from the blindfolding procedure with an omission distance of 7. The *t*-values are derived from the bootstrapping procedure with the pairwise deletion algorithm. VIF = variance inflation factor.

*** p < .01; ** p < .05; * p < .1

Our findings reveal that quality management has a positive influence both on performance (Table 2: path coefficient of 0.308; p < .01) and on training of personnel (Table 2: path coefficient of 0.519; p < .01). Similarly, training of personnel has also a positive effect on performance (Table 2: path coefficient of 0.159; p < .01).

4.1. Training of personnel as mediator

Before including training of personnel in the analysis, quality management has a positive significant impact on performance (i.e., 0.391; p < .01). In order to test the

mediating effect of training of personnel on the relationship between quality management and performance, we focused on examining the magnitude of the indirect effects (Preacher & Hayes, 2008; Rucker, Preacher, Tormala & Petty, 2011; Zhao, Lynch & Chen, 2010). After including trained personnel in the analysis, not only both indirect effects (i.e., quality management-trained personnel, and trained personnel-performance paths) are significant (Table 3), but also, considering the sample value of the bootstrapping procedure, quality management-performance path decreases (from 0.395 to 0.312). We followed Preacher and Hayes (2008), who argue that we must calculate the standard deviation of the indirect effect (the product of direct effects) of each of the 5,000 samples that have been used to conduct bootstrapping. The standard deviation is 0.013. Dividing the original value of the path coefficient obtained in the bootstrapping (0.308) by the standard deviation (0.013), we obtained the *t* value of the indirect effect (22.875, $p<0.01$), which is significant. Finally, following Hair et al. (2017), we calculated the Variance Accounted For (VAF), which was 21%. Hence, there is a *partial mediation* of trained personnel between quality management and performance.

Because it might be argued that focusing on the significance of the direct relation before and after examining a mediator may be unnecessarily restrictive, we utilized the typology proposed by Zhao et al. (2010) too. Thus, in accordance with Zhao et al. (2010, Figure 2) we conclude that there is a *complementary mediation*. This result (Table 3) demonstrates a significant indirect effect of training of personnel on the quality management-performance link. Hence, both methods lead to the same conclusion.

Table 3. Mediation

Indirect effect	*t*-value	Type of Mediation
Training of personnel between Quality management → Performance	2.494**	Complementary mediation

Note. The t-values are derived from the bootstrapping procedure with the pairwise deletion algorithm.
*** p < .01; ** p < .05; * p < .1

5. DISCUSSION

The way organizations manage quality has received considerable attention in the management literature because quality plays a key role in understanding organizations' performance. TQM has been one of the most dominating managerial approaches over the last years, but in the last few years, the study of quality management has shifted away from TQM to focus on determinants of establishing positive quality-performance relationships (Dahlgaard-Park et al., 2013).

In this sense, to the best of our knowledge there is a lack of studies that analyze quality management including training of personnel as a mediator between quality management and performance. A reason behind this apparent lack of attention might be the wrong assumption of taking quality for granted in industries such as the pharmaceutical industry. Nevertheless, we demonstrate that quality plays still an important role in an industry in which legal quality control related regulations ensure a minimum level of product quality, customer service's largest part falls on other stages

of the value chain (i.e., physicians), and reputation is apparently guaranteed just by following strict legal requirements. Apart from quality, defined by the aforementioned signals, we included training of personnel in the analysis, which is one of the most important elements of human resource development and a key element supporting successful performance.

Our first contribution lies in highlighting the importance of quality management on the performance of pharmaceutical firms. In short, pharmaceutical firms focusing on quality perform better. This result assumes particular relevance insofar as it overcomes previous doubts on the need of focusing on quality as a way of acquiring a competitive advantage in a highly regulated industry such as the pharmaceutical industry. The focus on continuous improvement over the long run can enhance pharmaceutical companies' performance.

The second contribution lies in suggesting that ensuring trained personnel has also a positive impact on pharmaceutical firms' performance. This finding corroborates previous studies (e.g., Aw, Roberts & Winston 2007; Frietsch & Neuhäusler, 2015; McGuirk, Lenihan & Hart, 2015) suggesting that having trained personnel is crucial especially in R&D-intensive sectors.

Thirdly, the results demonstrate training personnel mediates the quality management-performance link. This result goes in line with what was hypothesized too.

We focused on the pharmaceutical industry where studies in the quality management field have shifted away from TQM to focus on determinants of establishing positive quality-performance relationships. Moreover, even if it is true that the results should be extrapolated to other sectors with caution, analyzing the German pharmaceutical industry, which is often cited as one of the most profitable industries in Germany, enhances the representativeness and the importance of the results.

6. LIMITATIONS AND DIRECTIONS FOR FURTHER RESEARCH

As with any empirical research, our study is not without limitations. First, we included training on personnel as the only variable that mediates the quality-performance relation. Second, we analyzed specific aspects of performance only. Thus, our study inevitably suffers from the normal bias associated with subjective measures. Third, we used a single-item to measure training of personnel. Finally, since we studied German pharmaceutical firms, the path coefficients could differ significantly across countries and sectors, that is, researchers and managers should extrapolate the results with caution.

Our study establishes new directions for future empirical and theoretical research. First, future research could include additional variables that mediate the quality-performance relationship for a better explanation of performance. Second, researchers could conduct similar studies in different industries and/or countries with a view to analyze the different results. Third, researchers could use richer scales to measure training of personnel to better capture the meaning of the concept. Finally, analyzing the relations in a longitudinal framework would allow a better interpretation of the results. Evaluating possible variations over time would be particularly interesting for assessing the change in the mediating effect of training on the quality-performance relation.

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