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***Research paper***


# Investigating the Impact of Quality Management Practices on Quality Performance in Medical Device Manufacturing Industry: An empirical study

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**Abstract**

Quality has become a top priority to all manufacturing industries hence recent years had witnessed the growing popularity of quality management practices (QMPs) adoption in developing countries. Nevertheless with the fallen short of QMPs initiatives, a debate into its effectiveness was set in motion. In this regard, this paper aims to empirically re-examine the ambiguity in the relationship between QMPs and quality performance. This paper reveals that QMPs have a significant and positive effect on quality performance in medical device manufacturing (MDM) industry. Furthermore, the findings of this paper shown that QMPs enhances quality performance more effectively when it is introduced in an integrative manner rather than in a piecemeal approach.

***Keywords:*** *Quality management practices, socio-technical system theory, quality performance*

## 1. Introduction

Quality has become a top priority to all manufacturing industries especially with the escalating demands of consumers in getting better products at lower price points (Islam & Karim, 2011). With the growing pressure to achieve optimum level of quality, the adoption of quality management practices (QMPs) have received greater attention due to its critical role in sustaining firm's internal quality performance (Niu & Fan, 2015). However, previous QM-performance literatures had shown contradictory findings (Mellat-Parast et al., 2011; Abdullah & Tarí, 2012; ALNasser et al., 2013; Talib et al., 2013; Psomas et al., 2014; Patyal & Koilakuntla, 2015; 2017). For instance, some scholars that investigated the link between QMPs and performance concluded that only infrastructure QMPs was found to be positively contributed to quality improvement whereas core QMPs do not (Psomas et al., 2014). In contrary, other studies revealed that core QMPs have positive impact on performance measures (ALNasser et al., 2013; Zeng et al., 2015), while infrastructure QMPs were insignificantly related to performance (Talib et al., 2013). Moreover, some of the previous works shown that soft and hard QMPs are either directly or indirectly related to performance (Abdullah & Tarí, 2012; Patyal & Koilakuntla, 2017). The contradictory findings shown in the existing QM literatures had raised doubts as to whether QMPs able to attain and sustain promising quality performance and do QMPs always lead to improved quality performance across different industries. In this regard, previous studies had stressed on the importance of investigating the influence of QMPs on quality performance across different industries (Mellat-Parast, 2013; Schniederjans & Schniederjans, 2015). The existing QM literatures had paid little attention in examining the effect of QMPs on quality performance in MDM industry thus this field of study remains in its infancy stage. Hence, this paper aims to re-examine the ambiguity in the relationship between QMPs and quality performance in MDM industry.

## 2. Literature Review

Quality management practices can be described as a set of complementary management practices in supporting all components of business to fulfill customer's quality requirements (Fernandes et al., 2014). Management by quality has stimulated quality improvement activities, making resources readily available and systematically works with statistical tools and quality-related techniques to support the basis of QM implementation (Lagrosen et al., 2012). In the pursuit of successful QM implementation, both people and technology aspects are critical to enhance quality performance (Mehra & Coleman, 2016) hence this paper proposed that grounding on sociotechnical system (STS) theory will allow a better understanding of people at work co-operates and used the technology which was being introduced to get their collective work done. Grounding on sociotechnical system theory, QM is viewed as an integrated socio-technical system at which quality performance improvement is contingent upon the jointly optimization of infrastructure QMPs (social subsystem) and core QMPs (technical subsystem) rather than independent of each other (Nair, 2006; Zu, 2009; Kim, Kumar & Kumar, 2012). In consistent with STS theoretical perspective, the effectiveness of QM in improving quality performance involves the integration of a set of complementary management practices and not a subset of them as there is a strong interdependence of relationship between the QMPs (Zu, 2009; Kim et al., 2012). Moreover, notwithstanding the abundance of literatures on QMPs, the overall consensus for the list of QMPs dimension remains lacking and inconsistently executed (Mosadeghrad, 2015; Barouch & Kleinhans, 2015). For the purpose of this study, six dimensions of QMPs that had been frequently cited in previous QM/TQM literature as the critical factors of QMPs in influencing quality performance namely leadership, process management, employee management and training, customer relationship management, supplier quality management and product design and control were selected to build the framework of QM (Sila & Ebrahimpour, 2003; Zu, 2009; Kim et al., 2012). To boot, these dimensions are consistent with the enablers of Malcolm Baldrige National Quality Award (MBNQA) criteria and EFQM Excellence Model hence would constitute a valid representation of QM (Escrig-Tena et al., 2011; Elshaer & Augustyn, 2016; Gómez et al., 2017).

Quality is the responsibility of all employees nonetheless full commitment to quality is an example that needs to be driven from the top. Leadership is widely held by many scholars as a prerequisite for effective QM implementation (Wu, 2015). Leadership can be defined as leaders with clarity of quality goals and vision, actively partake in process improvement and lead the firm by creating a sense of coherence among employees in pursuing a common quality goal to achieve optimal quality performance. Next, process management controls and monitors manufacturing process through the use of statistical process control tools and techniques to reduce process variation so that it operates under optimized condition (Kristal et al., 2010; Zeng et al., 2013). The arrangement of effective employee training programs, job enlargement, teamwork and other similar initiatives are of tremendous importance in the pursuit of successful QMPs implementation (Mehra & Coleman, 2016). Training is the key for effective QM implementation to ensure the employees are aware of all requirements and the know-how to incorporate the quality system procedures into optimizing production processes (Luczak, 2012). Customer relationship management involves attending to customer feedback in designing products, monitoring customer satisfaction, responding to customer complaints and evaluating the success rate (Shan et al., 2013). Next, supplier quality management deals with evaluating suppliers' quality capabilities, and developing long-term relationships with suppliers seeing as the complexity of purchased parts increased dramatically thus interdependencies with suppliers and their reliability became crucial (Weckenmann et al., 2015). Lastly, product design and control is an important dimension of QM seeing as product design has to do with designing quality characteristics into a product with the intention of meeting the different wants and needs of customers (Shan et al., 2013). The value of QM is contingent on a set of QM practices thus QMPs should be measured in a multidimensional scale (Nair, 2006; Kim et al., 2012; Molina-Azorín et al., 2015; Zeng et al., 2015). In this paper, QMPs were measured as second-order construct which is represented by six dimensions of first-order QM constructs as leadership (L), process management (PM), customer relationship management (CRM), supplier quality management (SQM), employee management and training (EMT) and lastly product design and control (PDC).

## 3. Hypothesis Development

QMPs is a set of practices that engaged in the identification and administration process of quality improvement activities including prevention and appraisal with the focal intention of attaining quality objectives of an organization (Leong et al., 2012). Majority of the enterprise acknowledged the significant role of QM in improving product quality (Tang, 2013). Besides, an in depth investigation on QMPs in China via grounded theory approach by Niu and Fan (2015) has revealed that the utmost internal driver of TQM adoption by firms is to attain internal quality improvement, quality control and assurance. Moreover, Nair (2006) performed a meta-analysis on previous QM empirical studies over the period of 1995–2004 had found that QMPs are positively related to aggregate performance. Empirically, large body of literatures indicated that QMPs have a significant and strong impact on quality performance (Mellat-Parast et al., 2011; Abdullah & Tarí, 2012; Kim et al., 2012; Barros et al., 2014; Molina-Azorín et al., 2015; Basu & Bhola, 2016; Bolatan et al., 2016). Thus, this study hypothesized that;

*H1*: *Quality management practices have a significant positive effect on quality performance.*

## 4. Research Methodology

Given the settings and nature of quantitative study, purposive sampling method is adopted as it allows the scholar to determine eligible respondents and decide what needs to be known (Tongco, 2007). Purposive sampling method is a practical and efficient sampling technique when used properly can be just as effective as and even more efficient than random sampling (Tongco, 2007; Rowley, 2014). In line with previous QM studies, the target respondents are those who have first-hand knowledge in QM, in charge of QM activities as well as those who directly involved in the process of QM implementation such as management representatives (MR) or those who possess equivalent role as quality/operations managers, QA/QC engineers or process engineers within the manufacturing floor (Patyal & Koilakuntla, 2017). A total of 164 copies of self-administered questionnaires were distributed to MDM companies in Malaysia with 103 returned and usable questionnaires. The sample size was deemed adequate as it able to detect medium effect size at a statistical power of 80% using G*Power statistical tool (Hair et al. 2014). Given that the emphasis of this paper is on prediction hence PLS–SEM is appropriate for data analysis (Hair et al. 2014). PLS-SEM algorithm uses a two-stage approach to evaluate the measurement model and structural model.

## 5. Findings and Discussions

### 5.1. Preliminary Study

Content validity of the instrument was made certain via a thorough reviews of literature and followed by a pre-test administered to three academics to evaluate the content validity of questionnaire (Bazera 1996). All participants were asked to fill in the questionnaire and provide constructive feedback with respect to the relevant of the items in representing the constructs and all comments received were modified accordingly. For pilot test evaluation, respondents were chosen from the same pool of participants from which the sample for full study will be drawn to attain valuable insights (Bradburn et al., 2004). Questionnaires were distributed to forty eligible respondents who hold sufficient knowledge working at MDM companies in varying position.

### 5.2.Measurement Model

Validity and reliability are two fundamental criterions in the evaluation of an instrument as despite having good level of reliability, the lacking of validity does not reflect in goodness of measurement (Sekaran, 2003). The evaluation of measurement model aims to ensure that all the constructs are reliable and valid for the testing of structural relations (Hair et al., 2011). Measurement model's internal consistent reliability at item level is assessed using PLS-SEM by means of composite reliability (CR). Reliability test shown that all constructs have satisfactory inter-item consistency with CR value recorded at between 0.879 and 0.953. Consecutively, two approaches were used to measure measurement model's validity namely convergent validity and discriminant validity (Hair et al., 2017). Discriminant validity measures the extent to which indicators discriminate across constructs. Henseler et al. (2015) implied that HTMT criterion able to achieve higher specificity and sensitivity rates as compared to cross loadings criterion and Fornell and Larker's (1981) criterion. HTMT criterion is an estimate of the correlation within construct to correlation between the construct. Table 2.0 shown that the values of HTMT criterion is lower than the required threshold value of HTMT.85 (Kline, 2011) thus in referring to HTMT criteria there was no discriminant validity issues for inter-construct correlations of 0.803 and lower.

**Table 1:** Assessment of Measurement Model

| Construct | Item | Loading | CR | AVE |
|---|---|---|---|---|
| Leadership | L1 | 0.827 | 0.953 | 0.772 |
| | L2 | 0.895 | | |
| | L3 | 0.908 | | |
| | L4 | 0.894 | | |
| | L5 | 0.917 | | |
| | L6 | 0.825 | | |
| Process Management | PM1 | 0.639 | 0.895 | 0.553 |
| | PM2 | 0.592 | | |
| | PM3 | 0.744 | | |
| | PM4 | 0.846 | | |
| | PM5 | 0.767 | | |
| | PM6 | 0.782 | | |
| | PM7 | 0.804 | | |
| Employee Management and Training | EMT1 | 0.745 | 0.906 | 0.582 |
| | EMT2 | 0.652 | | |
| | EMT3 | 0.774 | | |
| | EMT4 | 0.802 | | |
| | EMT5 | 0.823 | | |
| | EMT6 | 0.777 | | |
| | EMT7 | 0.754 | | |
| Customer Relationship Management | CRM1 | 0.863 | 0.879 | 0.647 |
| | CRM2 | 0.875 | | |
| | CRM3 | 0.763 | | |
| | CRM4 | 0.702 | | |
| Supplier Quality Management | SQM1 | 0.741 | 0.893 | 0.629 |
| | SQM2 | 0.591 | | |
| | SQM3 | 0.826 | | |
| | SQM4 | 0.875 | | |
| | SQM5 | 0.895 | | |
| Product Design and Control | PDC1 | 0.880 | 0.939 | 0.720 |
| | PDC2 | 0.719 | | |
| | PDC3 | 0.856 | | |
| | PDC4 | 0.779 | | |
| | PDC5 | 0.909 | | |
| | PDC6 | 0.928 | | |
| Quality Performance | QP1 | 0.766 | 0.918 | 0.650 |
| | QP2 | 0.797 | | |
| | QP3 | 0.848 | | |
| | QP4 | 0.796 | | |
| | QP5 | 0.760 | | |
| | QP6 | 0.865 | | |

**Table 2:** HTMT criterion

| | CRM | EMT | L | PM | PDC | SQM |
|---|---|---|---|---|---|---|
| CRM | | | | | | |
| EMT | 0.754 | | | | | |
| L | 0.628 | 0.620 | | | | |
| PM | 0.751 | 0.733 | 0.531 | | | |
| PDC | 0.500 | 0.407 | 0.365 | 0.674 | | |
| SQM | 0.803 | 0.589 | 0.571 | 0.789 | 0.426 | |

In addition, attributable to the subsequent phase of structural model evaluation involved the exploring of QMPs at a higher level of abstraction thus required a detailed assessment on the measurement model at both item level and higher-order level. The reliability and validity for higher level of QM construct appeared to be significant and in acceptable range. Above and beyond, significant test statistically shown that the correlation weights for six dimensions of first-order QMPs constructs in representing QM appeared to be significant with p-value less than 0.01 and t-value larger than 1.645 as shown in Table 3.

**Table 3:** Establishment of Second-Order Construct

| 2nd Order | 1st Order | Factor Loading | AVE | t-value | P value |
|---|---|---|---|---|---|
| QMPs | CRM | 0.842 | 0.618 | 27.592 | 0.000 |
| | EMT | 0.808 | | 20.334 | 0.000 |
| | L | 0.748 | | 13.283 | 0.000 |
| | PM | 0.862 | | 25.747 | 0.000 |
| | PDC | 0.609 | | 6.653 | 0.000 |
| | SQM | 0.819 | | 21.826 | 0.000 |

## 5.3. Goodness-of –Fit Index

Following the assessment of higher order measurement model, the next step was to estimate goodness of fit (GoF) as an overall measure of model fit for PLS-SEM. Henseler et al. (2014) introduce the SRMR as a goodness of fit measure for PLS-SEM. The SRMR refers to the root mean square discrepancy between the observed and model-implied correlations (Hair et al. (2017). A value of SRMR less than 0.08 represents a good fit (Hu & Bentler, 1998) hence a SRMR value of 0.073 would indicate a good fit.

## 5.4. Structural Model

Having ensured that the measurement model exhibit satisfactory in both reliability and validity, this paper proceeds with assessing the structural model to examine the significance and relevance of inner model relationships in describing the relationships between latent variables (constructs). The testing of structural relationship was performed in five stages as testing of collinearity issues, the level of $R^2$, effect size $f^2$, predictive relevance of model ($Q^2$) and assessing the significance of inner model relationship. To test the proposed hypotheses, a bootstrapping procedure was executed at 1000 subsample to examine the effects of QMPs have on quality performance. The result shown that there is significant and positive relationship between QMPs and quality performance thus the hypothesis $H_1$ is accepted. In estimating the predictive relevance of the model, $Q^2$ is calculated using cross-validated redundancy (CVR) approach. As seen from Table 5.0, the $Q^2$ value estimated are larger than 0 thus this can be concluded that QMPs have predictive relevance over quality performance ($Q^2$ = 0.404). Next, the effect size ($f^2$) assesses the relative impact of predictors on endogenous construct, measuring how strongly exogenous constructs contributes to explaining an endogenous construct in terms of $R^2$. According to Cohen (1988), the value of $f^2$ at 0.35 and above is considered as large effect sizes thus the computed $f^2$ of 0.755 would indicate that QMPs have a large effect size on quality performance.

**Table 4:** Collinearity issues

| Model | | Collinearity Statistics | |
|---|---|---|---|
| | | Tolerance | VIF |
| CRM | Quality Performance | 0.422 | 2.367 |
| EMT | | 0.446 | 2.242 |
| L | | 0.571 | 1.752 |
| PM | | 0.300 | 3.331 |
| PDC | | 0.607 | 1.648 |
| SQM | | 0.408 | 2.450 |

**Table 5:** Determination of Level of $R^2$, $Q^2$ and $f^2$

| | $R^2$ | $Q^2$ | $f^2$ | Side of effect |
|---|---|---|---|---|
| QMPs → QP | 0.430 | 0.404 | 0.755 | Large |

**Table 6:** Path Coefficients and Hypothesis Testing

| Hypothesis | Relationship | Path Coefficients | Std. Deviation | t-value | p-value | Decision |
|---|---|---|---|---|---|---|
| $H_1$ | QMPs → QP | 0.656 | 0.083 | 7.905*** | 0.000 | Supported |

## 6. Discussion and Conclusion

Medical device manufacturing companies make products intended to save lives and improve quality of life hence the quality of medical devices cannot be compromised since it is closely related to the patient's safety and well-being. The finding of this paper shown that QMPs has a statistically significant and positive influence towards the quality performance in MDM industry. Results revealed that the effectiveness of QM is dependent on the integration of a set of six complementary dimension of QMPs as leadership, process management, employee management and training, customer relationship management, supplier quality management and product design and control. Furthermore, this study contributes by providing an ample empirical evidence in supporting the theoretical arguments of STS theory whereby the success of QM implementation in improving quality performance is contingent upon the jointly optimization of both infrastructure QMPs and core QMPs instead of solely dependent on either one. Unlike previous studies, the finding of this paper has stressed on the importance of implementing QMPs in an integrative manner rather than in a piecemeal approach seeing as each of QMPs dimension served different purposes and functions in enhancing the quality performance of an organization hence embracing the dimensions separately may failed to attain the full benefits of QM as a whole thus perhaps may explained the reasons of inconsistent findings shown in previous QM literatures. In conclusion, this study presents a significant value to industrial practitioners in MDM industry by allowing them to foresee the significance of incorporating all six dimensions of QMPs and not a subset of them to sustain and improve the product quality performance. As suggestions for future work, the authors would like to suggest the use of mixed method approach to investigate the organizational phenomena given that heavily reliance on quantitative approach had failed to address the problems of production. Future study may also consider the indirect influence of other variables as technological capability especially with inevitable infiltration of technology into MDM companies which would be critical to QM on quality performance.

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