UNIVERSITI TEKNOLOGI MARA
Cawangan Kedah
Kampus Sungai Petani

Voice of Academia

Academic Series of Universiti Teknologi MARA Kedah

BUSINESS MANAGEMENT AND ENTREPRENEURSHIP

SPECIAL ISSUE

VoA
Volume 15 Issue 1
August 2019

COMMITTEE PAGE

e-ISSN: 2682-7840

© Voice of Academia is jointly published by the Universiti Teknologi MARA Caawangan Kedah, Malaysia and Penerbit UiTM (UiTM Press), Universiti Teknologi MARA Malaysia, Shah Alam, Selangor.

TABLE of CONTENTS

Voice of
Academia
e-ISSN: 2682-7840

Ling et al. / Voice of Academia 15 Special Issue August (1) 2019, 120-130

Voice of Academia
Academic Series of Universiti Teknologi MARA Kedah
Available online at http://voa.uitm.edu.my

Investigating the Influence of Lean Six Sigma Practices on Quality Performance in Medical Device Manufacturing Industry

Sim Choon Ling[1*], *Muhammad Shahar Jusoh*[1], *Noormaizatul Akmar Ishak*[2]

[1] *School of Business Innovation & Technopreneurship, University Malaysia Perlis, Malaysia.*

[2] *School of Human Development & Technocommunication, University Malaysia Perlis, Malaysia.*

ARTICLE INFO

Article history:
Received June 2019
Received in revised form
Accepted June 2019
Published August 2019

Keywords:
Lean Six Sigma practices, quality performance, medical device manufacturing industry

Corresponding Author:
clsim89@gmail.com

ABSTRACT

With the growing pressure to gain optimum level of quality and speed, Lean and Six Sigma practices have been acknowledged as viable alternatives for process improvement. Separately, both methodologies were unable to drive process improvement to its full potential thus recent years have witnessed greater tendency for Lean and Six Sigma practices to be implemented in an integrated way. This paper attempted to highlight the key strengths, weaknesses and criticisms of Lean and Six Sigma practices as a separate methodology as well as an overview on how the two methodologies complement each other into a more robust and comprehensive approach. Furthermore, although there is a growing body of anecdotal evidence in supporting the positive linkage of Lean Six Sigma (LSS) practices in enhancing quality performance nevertheless the abundance of non-empirical evidence on whether the integration of Lean and Six Sigma practices is tied to superior performance improvement than either on a standalone basis has triggered the needs to further verifying this issue. The objective of this paper is to define and develop an agenda for future research to investigate the impact of LSS practices on quality performance in medical device manufacturing (MDM) industry.

1. Introduction

Aging population and the mounting of lifestyle diseases have given rise to the growing demand for sophisticated medical devices (WHO, 2015). Patients' life is dependent on the performance and reliability of the medical devices hence there should be no room for errors and failures as product failures may cause serious harm or even death to patients (FDA, 2011). Medical device manufacturing (MDM) companies make products intended to save lives and improve the quality of life hence the ability of MDM companies to offer better life-enhancing and life-saving technologies at lower price points is crucial. Malaysia has the potential in becoming a hub for Asia's growth region, placing itself as a developer, manufacturer and supplier of medical devices (MIDA, 2015). Nevertheless, MDM industry does not appear to have being able to drive quality and reliability through the medical device value chain neither did the growing pressure to eliminate quality issues (Fuhr, George & Pai, 2013). In light of this, adopting best quality practices are essential to accomplish this goal as this will ensure the building of quality into the medical device throughout its product lifecycle. With the growing pressure to attain optimum level of quality and speed, Lean and Six Sigma practices have been acknowledged as viable alternatives for process improvement. Originated from different conceptual bases, Lean manufacturing practice seeks to eliminate waste, loss and inefficiency in processes, whereas Six Sigma practices aims to improve the overall quality, eliminate defects, failures and errors via the reduction of process variation achieved from the data-driven decision making (Pacheco et al., 2015). Both methodologies shown significant improvements when used in isolation however there is an enormous potential for process improvement from the integration of Lean manufacturing practices and Six Sigma methodologies (Marhani et al., 2013). This is due to Six Sigma practices emphasized on reducing variation and defects however it does not address on how to optimize the process flow and does not attempt to develop a link between quality and speed (Su, Chiang & Chang, 2006; Albliwi, Antony & Lim, 2015; Pacheco et al., 2015). Moreover, the analytical nature of Lean concept does not possess the quality tools to perform statistical control and reduce process variation thus would be of no use if being executed in situation with high variation (Chan, Kamaruddin & Azid, 2014; Pacheco et al., 2015). Therefore, stand-alone Lean has been criticized for its lacking in the practical side of quality excellence since management tend to concentrate on tools and practices in process improvement activities (Pepper & Spedding, 2010; Albliwi et al., 2015; Sunder, 2016).

Lean manufacturing practices and Six Sigma practices complement one another and together both methodologies overcome individual shortfalls with Six Sigma focus primarily on reducing variation, whilst Lean focuses on improving the flow in value stream and reduction of lead time to sustain the organization in the long term (Albliwi et al., 2015; Pacheco et al., 2015; Sunder, 2016). In this regards, recent years have witnessed greater tendency for Lean and Six Sigma practices to be implemented in an integrated way (Jeyaraman & Teo 2010; Antony, 2011; Corbett, 2011; Campos, 2013; Muthukumaran et al., 2013; Saini & Sujata, 2013; Bhat, Gijo & Jnanesh, 2014; Chan et al., 2014; Niu & Fan, 2015; Sunder, 2016). Over and above, although LSS practices is widely acknowledged as a successful methodology for continuous improvement in process efficiency and quality performance, yet, this field of study remains in exploratory stage seeing as majority of prior studies merely contingent on anecdotal evidence in supporting the positive linkage of LSS implementation in enhancing performance outcomes (Ngo, 2010; Habidin & Yusof, 2013; Saini & Sujata, 2013). The abundance of non-empirical evidence on whether the integration of Lean and Six Sigma practices is tied to a superior quality performance improvement has triggered the needs to further verifying this issue empirically (Zu et al., 2008; Ngo, 2010; Corbett, 2011; Campos, 2013). Moreover, the comparatively low volume of LSS publications in manufacturing sector had suggested that this field of study has not been adequately studied thus this called for the need to weight the effective benefits of combined LSS practices on quality performance across different sectors especially with the growing popularity of LSS practices (Campos, 2013; Albliwi et al., 2015; Pacheco et al., 2015). MDM industry is strongly emphasis on quality thus LSS practices may exhibit an enormous potential for process improvement and productivity improvement (Nepal et al., 2011). Hence, the objective of this paper is to identify the gaps in the current LSS literatures and develops an agenda for future research to investigate the impact of LSS practices on quality performance in MDM industry. The remainder of this paper is organized as follows. Section two presented the reviewed literature on Lean, Six Sigma and Lean Six Sigma practices and followed by the hypothesis development for the proposed model where the supporting arguments for relationship between LSS practices and quality performance are presented. In the subsequent section, further discussion on research implications and future research directions are presented.

2. Literature Review

2.1 Lean Manufacturing Practices

Lean manufacturing practices aims at eliminating waste, losses, processes inefficiency and simultaneously improves the speed and flow of the value stream (Campos, 2013). Lean directs a firm to achieve continuous waste reduction and improve work flow to ensure on time delivery of right quantity and product quality to satisfy the customers (Salah, Rahim & Carretero, 2010). In general, Lean is a cost-reduction mechanism that strives to make an organization more competitive via improving process efficiency, optimizing human capital as well as elimination of non-value-added steps (Lawless, 2016). Lean production seeks to increase product flow velocity through the elimination of all non-value added activities by purging out unnecessary processes, aligning the whole processes in a systematically continuous flow and optimizing the utilization of resources (Shah & Ward, 2003; 2007; Ngo, 2010; Agus, & Hajinoor, 2012).

Notwithstanding the abundance of literatures on Lean manufacturing practices, the overall consensus for the overarching nature of Lean measurement remains lacking in fact varying leanness measures had been adopted by different scholars to measure lean practices (Ngo, 2010; Rahman et al., 2010; Wahab et al., 2013). Hence, this paper attempted to group-related Lean manufacturing practices into four distinct dimensions that are most commonly cited from previous studies as just-in-time (JIT), pull production system, flow management and setup time reduction (Shah & Ward, 2003; 2007; Jayaram et al., 2008; Rahman, Laosirihongthong & Sohal, 2010; Agus & Hajinoor, 2012). JIT originates from concept of reducing inventory holding, allowing the synchronization of production with demand rate so as to ensure each process is provided with the right parts and components in the exact quantity and at the right time (Jayaram et al., 2008; Rahman et al., 2010; Agus & Hajinoor, 2012).

Pull-production systems are highly supported by JIT (Levy, 1997), emphasizing on small and frequent deliveries of raw materials from suppliers or work-in-progress to be delivered JIT when the downstream workstation needs it (Agus & Hajinoor, 2012). Pull-production system regulates the flows on the factory floor driven by the demand from downstream (customer) unlike traditional batch-based production where production is pushed from upstream to downstream by a production schedule (Agus & Hajinoor, 2012). Next, flow management deals with optimizing materials flow on the factory floor with small lot production and the ideal being one piece flow to ensure the works-in-progress between processing stages can be minimized (Agus & Hajinoor, 2012). Last of all, setup time reduction aims at minimizing the changeover, setup time or downtime (Agus & Hajinoor, 2012). Machine downtime is a significant source of unnecessary waste hence setup time reduction allows the optimization of the conversion period for a given process into a different product in most efficient manner. In brief, Lean is composed of highly inter-related practices that work together synergistically to reduce the lead time in work-in-process inventories and at production site to produce finished products at the pace of customer demand with little or no wastes (Shah & Ward, 2003; 2007).

2.2 Six Sigma Practices

Six Sigma practices deals with continuous effort in reducing process variation and eliminates product defects which ultimately lead to enhanced product quality (Campos, 2013). Six Sigma practices rely on extensive set of statistical tools and supporting software to understand the fluctuation of a process (Corbett, 2011; Muthukumaran et al., 2013). Six Sigma practices is a data-driven decision making methodology that facilitates the application of statistical tools and techniques in a disciplined manner (Chakrabarty & Tan, 2009). In line with the previous works, this paper defined Six Sigma practices as multi-dimensional construct with three distinct dimensions namely Six Sigma Role Structure, Six Sigma Structured Improvement Procedure and Six Sigma Focus On Metrics (Zu et al., 2008) which is later agreed, supported and adopted by numerous scholars (Parast, 2011; Shafer & Moeller, 2012; Patyal & Koilakuntla, 2015). Six Sigma practices have a well-defined hierarchy of process improvement specialist which is typically referred as champions, master black belts, black belts, and green belts (Linderman et al., 2003; Zu et al., 2008). The hierarchical coordination mechanism of work also known as Six Sigma role structure is a distinctive characteristic of the Six Sigma practices where specialists are assigned to take different levels of roles and responsibilities in leading the continuous quality improvement efforts (Sinha & Van de Ven, 2005). Next, Six Sigma structured improvement procedure supports product design and process management with combination of well-defined set of tools that are applied at various phases (Zu et al., 2008). For instance Six Sigma problem-solving algorithms in support for process improvement consist of five phases as Define–Measure–Analyze–Improve–Control (DMAIC). Alternatively, for new product design improvement, the acronym DMADV refers to five phase of Define–Measure– Analyze–Design–Verify (Linderman et al., 2003). DMAIC/DMADV procedures provides a standardized methodological framework to guide the teams in adopting appropriate systematic tools during the conduct of planning and carrying out improvement projects subsequently enhances their problem-solving ability (Zu et al., 2008). Last of all, Six Sigma focus on metrics established a baseline that defined explicit quality goal in guiding the process improvement activities via tracking and providing feedback on product quality and process variability throughout its entire life cycle (Sin, Zailani & Ramayah, 2010). Six Sigma focus on metrics relies on the availability of accurate and timely quality information to reliably gauge processes and to set improvement goals, allowing the process improvement teams to closely monitor the process over time (Zu et al., 2008).

2.3. Lean Six Sigma Practices

Lean Six Sigma practices stand for the integration of Lean and Six Sigma practices which is underpinned by value-maximizing philosophy of Lean in removing non-value added process and enhanced by data-driven Six Sigma methodology (Saini & Sujata, 2013). Lean Six Sigma (LSS) practices are acknowledged as a more robust and comprehensive methodology that integrates Lean concept and Six Sigma practices by exploiting on the strengths of both methodologies (Niu & Fan, 2015). Lean Six Sigma practices incorporate Lean‘s speed and waste reduction characteristics as well as integrate Six Sigma‘s statistical decision making and quality standard for process improvement.

The fundamental of Lean Six Sigma integration is to blend the two methodologies into one approach in getting things done faster, better, cheaper, safer and greener (Pacheco et al., 2015). Nevertheless, the integration of LSS concepts varies among scholars and industrial practitioners as some would perceive LSS as a fully integrated system at which both are applied simultaneously while others would perceive LSS as two different concepts that are implemented in isolation and in stages (Chan et al., 2014). The adoption and blending of two methodologies as Lean and Six Sigma practices are not without challenges, however, this paper agreed with previous studies whereby it is the nature of the problem that defines the selection of methodology and tools to be used so that two approaches are aligned to achieve efficacious outcomes at appropriate quality level and speed (Snee, 2010; Sareen, Laux & Marshall, 2014; Pacheco et al., 2015). Henceforth, the integration of LSS practices would take into consideration the strength, weaknesses and effective aspects of each practice with respect to the nature of the problem, for instance in a high variation environment, Six Sigma practices should lead the initiatives to reduce, eliminate and control the process variation followed by executing Lean tools in the latter part to eliminate waste, loss and inefficiency in processes. Contrariwise, if a company's strategic priority is to run its operations at the lowest cost and continuously improve and shorten the production cycle time as well as controlling waste to the absolute minimum hence Lean manufacturing practices should be the backbone of the framework. By having Lean manufacturing practices leading the initiatives this will ensure firm resources are utilized wisely, waste eliminated, improved process flow and subsequently followed by Six Sigma practices will allow the process of eliminating variation to speed up reasonably and spotted more easily (Sareen, Laux & Marshall, 2014). Solely dependent on either Six Sigma practices or Lean thinking are unable to drive process improvement to its full potential (Antony, 2011; Muthukumaran et al., 2013; Sunder, 2016). Therefore, this paper argued that integrating two most popular tools as Lean and Six Sigma practices will allow the organizations in getting the best of both worlds to address both quality (reduction of variation and defects rate) and speed simultaneously (elimination of waste and cycle time). Consecutively, the dimensions of Lean Six Sigma practices proposed in this paper are shown in Table 1.

Table 1: Dimension of Lean Six Sigma Practices

Lean Six Sigma Practices		Supporting Literatures
Lean Manufacturing Practices	Just-in-Time (JIT)	Shah & Ward, 2007; Jayaram et al., 2008; Ngo, 2010; Rahman et al., 2010; Furlan et al., 2011; Yang et al., 2011; Agus & Hajinoor, 2012; Hofer et al., 2012; Habidin & Yusof, 2013; Nawanir et al., 2013; Khanchanapong et al., 2014; Büyüközkan et al., 2015; Pachecho et al., 2015; Habidin et al., 2016
	Pull Production System	Shah & Ward, 2007; Ngo, 2010; Rahman et al., 2010; Furlan et al., 2011; Agus & Hajinoor, 2012; Hofer et al., 2012; Chavez et al., 2013; Nawanir et al., 2013; Khanchanapong et al., 2014; Büyüközkan et al., 2015; Susilawati et al., 2015
	Flow Management	Shah & Ward, 2007; Ngo, 2010; Rahman et al., 2010; Furlan et al., 2011; Agus & Hajinoor, 2012; Hofer et al., 2012; Nawanir et al., 2013; Khanchanapong et al., 2014; Büyüközkan et al., 2015; Susilawati et al., 2015
	Setup Time Reduction	Shah & Ward, 2007; Bhasin, 2008; Ngo, 2010; Rahman et al., 2010; Furlan et al., 2011; Agus & Hajinoor, 2012; Hofer et al., 2012; Nawanir et al., 2013; Khanchanapong et al., 2014; Büyüközkan et al., 2015; Susilawati et al., 2015
Six Sigma Practices	Six Sigma Role Structure	Linderman et al., 2006; Snee & Hoerl, 2003; Schroeder et al., 2008; Zu et al., 2008; Ngo, 2010; Shafer & Moeller, 2012; Patyal & Koilakuntla, 2015
	Six Sigma Structured Improvement Procedure	Linderman et al., 2006; Zu et al., 2008; Schroeder et al., 2008; Ngo, 2010; Sin, Zailani & Ramayah, 2010; Shafer & Moeller, 2012; Habidin & Yusof, 2013; Pacheco et al., 2015; Patyal & Koilakuntla, 2015; Habidin et al., 2016
	Six Sigma Focus on Metrics	Linderman et al., 2006; Zu et al., 2008; Schroeder et al., 2008; Ngo, 2010; Sin, Zailani & Ramayah, 2010; Shafer & Moeller, 2012; Habidin & Yusof, 2013; Patyal & Koilakuntla, 2015; Habidin et al., 2016

Voice of Academia
e-ISSN: 2682-7840

3.0 Hypothesis Development

Lean Six Sigma (LSS) practices were positively associated with enhancing the quality and reliability of products (Arnheiter & Maleyeff, 2005). LSS practices accomplished a near perfect quality level through systematic removal of variability and causes of the defect (Choi et al., 2012). Integrating Lean and Six Sigma practices directs firm towards realizing better quality performance via the removal of waste, non-value added activities, elimination of defects and decrease cycle time efficiently (Muthukumaran et al., 2013; Chan et al., 2014). LSS practices contributed in the reductions of waste, process variability and errors which leads to the reduction of rework time, increased system flexibility, reduced inventory levels and improved productivity (Bendell, 2006; Chen, Li, & Shady, 2010; Zhang et al., 2012). Moreover, Knapp (2015) described Lean Six Sigma practices as an effective quality and process improvement initiative that improves overall performance.

Lean Six Sigma practices are designed to minimize losses, eliminating defects, failures and errors hence improving overall quality in the production environment (Pacheco et al., 2015). Besides, LSS practices is a rigorous, data driven and result-oriented approach which serves to improve processes, elimination of defects and reduces cycle time which lead to improved quality performance (Psychogios, Atanasovski & Tsironis, 2012; Saini & Sujata, 2013). Additionally, Habidin and Yusof (2013) revealed that LSS practices have a direct and strong relationship on organization performance in Malaysian automotive industry. Drohomeretski et al. (2014) implied that LSS practices were significantly associated with speed, quality, flexibility, reliability and cost as compared to the adopting the models independently as it allows the organization to attain superior quality performance and offer greater reliability at faster rate. Building on the above arguments, this study hypothesized that;

H1: Lean Six Sigma practices have positive effect on quality performance.

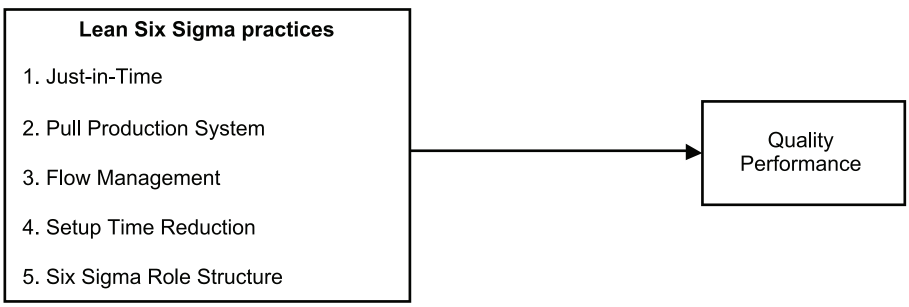

Figure I: Proposed Conceptual Model

4. Conclusion

Although LSS is acknowledged as the most well-known hybrid methodology however due to its relative newness it has not been studied in great detail besides there are limited published articles concerning its effectiveness in developing country thus it is important to expand the knowledge in this area (Campos, 2013). The objective of this paper is to identify, define and propose a conceptual model that captures the integrated nature of two methodologies into single model LSS practices. The conceptual model proposed in this paper may serve as a foundation for future research in LSS practices, nevertheless, further empirical testing on the proposed model will be needed to validate and verify the effect of LSS practices on quality performance. In conclusion, this paper argued that separately Lean and Six Sigma practices often fail to achieve process improvements in its full potential that the organizations desired hence both methodologies should be used in a complementary fashion.

References

Agus, A., & Hajinoor, M.S. (2012). Lean production supply chain management as driver towards enhancing product quality and business performance: Case study of manufacturing companies in Malaysia. International Journal of Quality & Reliability Management, 29(1), 92-121.

Albliwi, S. A., Antony, J., & Lim, S. A. H. (2015). A systematic review of Lean Six Sigma for the manufacturing industry. Business Process Management Journal, 21(3), 665-691.

Antony, J. (2011). Six Sigma vs Lean: some perspectives from leading academics and practitioners, International Journal of Productivity and Performance Management, 60(2), 185-190.

Arnheiter, E. D., & Maleyeff, J. (2005). The integration of lean management and Six Sigma. The TQM magazine, 17(1), 5-18.

Bendell, T. (2006). A review and comparison of six sigma and the lean organisations. The TQM magazine, 18(3), 255-262.

Bhat, S., Gijo, E. V. & Jnanesh, N. A. (2014). Application of Lean Six Sigma methodology in the registration process of a hospital, International Journal of Productivity and Performance Management, 63(5), 613-643.

Bhasin, S. (2008). Lean and performance measurement. Journal of Manufacturing Technology Management, 19(5), 670-684.

Büyüközkan, G., Kayakutlu, G., & Karakadılar, İ. S. (2015). Assessment of lean manufacturing effect on business performance using Bayesian Belief Networks. Expert Systems with Applications, 42(19), 6539-6551.

Campos L. M. S. (2013). Lean manufacturing and Six Sigma based on Brazilian model ―PNQ‖, International Journal of Lean Six Sigma, 4(4), 355-369.

Chakrabarty, A., & Kay Chuan, T. (2009). An exploratory qualitative and quantitative analysis of Six Sigma in service organizations in Singapore. Management Research News, 32(7), 614-632.

Chan R. J., Kamaruddin, S. & Azid, I.A. (2014). Implementing the Lean Six Sigma Framework in a Small Medium Enterprise (SME) – A Case Study in a Printing Company, International Conference on Industrial Engineering and Operations Management, 387-396.

Chavez, R., Gimenez, C., Fynes, B., Wiengarten, F., & Yu, W. (2013). Internal lean practices and operational performance: The contingency perspective of industry clockspeed. International Journal of Operations & Production Management, 33(5), 562-588.

Chen, J. C., Li, Y., & Shady, B. D. (2010). From value stream mapping toward a lean/sigma continuous improvement process: an industrial case study. International Journal of Production Research, 48(4), 1069-1086.

Choi, B., Kim, J., Leem, B. H., Lee, C. Y., & Hong, H. K. (2012). Empirical analysis of the relationship between Six Sigma management activities and corporate competitiveness: Focusing on Samsung Group in Korea. International Journal of Operations & Production Management, 32(5), 528-550.

Corbett, L.M. (2011). Lean Six Sigma: the contribution to business excellence, International Journal of Lean Six Sigma, 2(2), 118-131.

Drohomeretski, E., Gouvea da Costa, S. E., Pinheiro de Lima, E., & Garbuio, P. A. D. R. (2014). Lean, Six Sigma and Lean Six Sigma: an analysis based on operations strategy. International Journal of Production Research, 52(3), 804-824.

FDA (2011). Understanding Barriers to Medical Device Quality, Retrieved on 25th April 2016 from https://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM277323.pdf

Furlan, A., Vinelli, A., & Dal Pont, G. (2011). Complementarity and lean manufacturing bundles: an empirical analysis. International Journal of Operations & Production Management, 31(8), 835-850.

Fuhr, T., George, K. & Pai, J. (2013).The Business Case for Medical Device Quality, Retrieved on 14th Feb 2017 from https://www.mckinsey.com/~/media/McKinsey/dotcom/client_service/Public%20Sector/Regulatory%20excellence/The_business_case_for_medical_device_quality.ashx.

Habidin, N.F. & Yusof, S.M. (2013). Critical success factors of Lean Six Sigma for the Malaysian automotive industry, International Journal of Lean Six Sigma, 4(1), 60-82.

Habidin, N.F., Yusof, S.M., & Fuzi, N.M. (2016). Lean Six Sigma, strategic control systems, and organizational performance for automotive suppliers. International Journal of Lean Six Sigma, 7(2), 110-135.

Hofer, C., Eroglu, C., & Hofer, A. R. (2012). The effect of lean production on financial performance: The mediating role of inventory leanness. International Journal of Production Economics, 138(2), 242-253.

Jayaram, J., Vickery, S., & Droge, C. (2008). Relationship building, lean strategy and firm performance: an exploratory study in the automotive supplier industry. International Journal of Production Research, 46(20), 5633-5649.

Jeyaraman, K., & Teo, L. K. (2010). A conceptual framework for critical success factors of Lean Six Sigma, International Journal of Lean Six Sigma, 1(3), 191-215.

Khanchanapong, T., Prajogo, D., Sohal, A.S., Cooper, B. K., Yeung, A.C., & Cheng, T.C.E. (2014). The unique and complementary effects of manufacturing technologies and lean practices on manufacturing operational performance. International Journal of Production Economics, 153, 191-203.

Knapp, S. (2015). Lean Six Sigma implementation and organizational culture, International Journal of Health Care Quality Assurance, 28(8), 855-863.

Linderman, K., Schroeder, R. G., Zaheer, S. & Choo, A. S. (2003). Six Sigma: a goal-theoretic perspective, Journal of Operations Management, 21(2), 193-204.

Linderman, K., Schroeder, R. G., & Choo, A. S. (2006). Six Sigma: The role of goals in improvement teams. Journal of operations Management, 24(6), 779-790.

Marhani, M. A., Jaapar, A., Bari, N. A. A., & Zawawi, M. (2013). Sustainability through lean construction approach: A literature review. Procedia-Social and Behavioral Sciences, 101, 90-99.

MIDA (2015). Malaysia, The Hub of Medical Device Manufacturing in ASEAN, Retrieved on 10th August 2016 from http://www.mida.gov.my/home/2586/news/malaysia-the-hub-of-medical-device-manufacturing-in-asean-/

Muthukumaran, G., Venkatachalapathy, V. S. K., & Pajaniradja, K. (2013). Impact on integration of Lean Manufacturing and Six Sigma in various applications - a review, Journal of Mechanical and Civil Engineering, 6(1), 98-101.

Nawanir, G., Kong Teong, L., & Norezam Othman, S. (2013). Impact of lean practices on operations performance and business performance: some evidence from Indonesian manufacturing companies. Journal of Manufacturing Technology Management, 24(7), 1019-1050.

Nepal, B., Natarajarathinam, M., & Balla, K. (2011). Improving manufacturing process for biomedical products: a case study, Journal of Manufacturing Technology Management, 22(4), 527-540.

Ngo, T. (2010). The Relationship between Lean Six Sigma and Organizational Performance: an empirical investigation (Doctorate dissertation, Lincoln University).

Niu, R. H., & Fan, Y. (2015). An in-depth investigation on quality management practices in China, International Journal of Quality & Reliability Management, 32(7), 736-753

Pacheco, D., Pergher, I., Vaccaro, G. L. R., Jung, C. F., & Caten, C. T. (2015), 18 comparative aspects between Lean and Six Sigma: Complementarity and implications, International Journal of Lean Six Sigma, 6(2), 161-175.

Parast, M. M. (2011). The effect of Six Sigma projects on innovation and firm performance. International Journal of Project Management, 29(1), 45-55.

Patyal, V. S., & Koilakuntla, M. (2015). Infrastructure and core quality practices in Indian manufacturing organizations, Journal of Advances in Management Research, 12(2), 141-175.

Pepper, M. P. J., & Spedding, T. A. (2010). The evolution of Lean Six Sigma, International Journal of Quality & Reliability Management, 27(2), 138-155.

Psychogios, A. G., Atanasovski, J., & Tsironis, L. K. (2012). Lean Six Sigma in a service context: a multi-factor application approach in the telecommunications industry, International Journal of Quality & Reliability Management, 29(1), 122-139.

Rahman, S., Laosirihongthong, T., & Sohal, A. S. (2010). Impact of lean strategy on operational performance: a study of Thai manufacturing companies, Journal of Manufacturing Technology Management, 21(7), 839-852.

Saini, U., & Sujata (2013). Lean Six Sigma – Process Improvement Techniques, International Journal of Recent Research and Review, 6(3), 11-16.

Salah, S., Rahim, A., & Carretero, J. A. (2010). The integration of Six Sigma and Lean management, International Journal of Lean Six Sigma, 1(3), 249-274.

Sareen, S., Laux, C., & Marshall, B. (2014). The suitability of lean, six sigma and lean six sigma for small, medium and large scale firms, In Proceedings 2014 ASEE Conference for Industry and Education Collaboration (pp. 325601-609).

Schroeder, R. G., Linderman, K., Liedtke, C., & Choo, A. S. (2008), Six Sigma: definition and underlying theory, Journal of Operations Management, 26(4), 536-554.

Shafer, S. M., & Moeller, S. B. (2012). The effects of Six Sigma on corporate performance: An empirical investigation. Journal of Operations Management, 30(7-8), 521-532.

Shah, R., & Ward, P. T. (2003). Lean manufacturing: context, practice bundles, and performance. Journal of Operations Management, 21(2), 129-149.

Shah, R., & Ward, P. T. (2007). Defining and developing measures of lean production. Journal of Operations Management, 25(4), 785-805.

Sin, A. B., Zailani, S., & Ramayah, T. (2010). Six Sigma and organizational performance: a knowledge creation perspective, Int. J. Productivity and Quality Management, 6(2), 182-212.

Sinha, K. K., & Van de Ven, A. H. (2005). Designing work within and between organizations. Organization Science,16(4), 389-408.

Snee, R. D., & Hoerl, R. W. (2003). Leading Six Sigma: a step-by-step guide based on experience with GE and other Six Sigma companies. Ft Press.

Su, C., Chiang, T., & Chang, C. (2006). Improving service quality by capitalizing on an integrated Lean Six Sigma methodology, International Journal of Six Sigma and Competitive Advantage, 2(1), 1-22.

Sunder, M. V. (2016). Lean Six Sigma in higher education institutions, International Journal of Quality and Service Sciences, 8(2), 159-178.

Susilawati, A., Tan, J., Bell, D., & Sarwar, M. (2015). Fuzzy logic based method to measure degree of lean activity in manufacturing industry. Journal of Manufacturing Systems, 34, 1-11.

Wahab, A. N. A., Mukhtar, M., & Sulaiman, R. (2013). A conceptual model of lean manufacturing dimensions. Procedia Technology, 11, 1292-1298.

WHO (2015). Systematic review of needs for medical devices for ageing populations: commissioned to the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S), Retrieved on 23rd May 2017 from http://www.who.int/medical_devices/systematic_Review_needs.pdf

Yang, M. G. M., Hong, P., & Modi, S. B. (2011). Impact of lean manufacturing and environmental management on business performance: An empirical study of manufacturing firms. International Journal of Production Economics, 129(2), 251-261

Zhang, D., Linderman, K., & Schroeder, R. G. (2012). The moderating role of contextual factors on quality management practices. Journal of Operations Management, 30(1), 12-23.

Zu, X., Fredendall, L. D., & Douglas, T. J. (2008). The evolving theory of quality management: the role of Six Sigma, Journal of Operations Management, 26(5), 630-650.

e-ISSN: 2682-7840

9 772682 784004

UNIVERSITI TEKNOLOGI MARA
Cawangan Kedah
Kampus Sungai Petani