Implementing Lean Manufacturing in Malaysian Small and Medium Startup Pharmaceutical Company

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Abstract. Domestic pharmaceutical industry has been identified by the Malaysian government as an industry to be developed under its 11th economic development plan. Most homegrown pharmaceutical companies fall under the category of small and medium enterprises (SME) and therefore need to be highly efficient in their operations to compete with the multinationals. Though lean manufacturing is a well-known methodology to achieve an efficient operation, only a small percentage of the local SMEs implement it. The study aims to determine the real success factors in lean implementation through systematic review of relevant literature on lean manufacturing implementation in local companies, onsite observation of a selected SME company, Global Factor Sdn. Bhd. (GFSB), that successfully implemented lean manufacturing followed by actual implementation of lean project at IKOP Sdn. Bhd., a small startup pharmaceutical company. Lean tools like Gemba, value stream map (VSM) and spaghetti diagram were used to analyze and improve a process at IKOP Sdn. Bhd. The literature review showed that the implementation of lean manufacturing at Malaysian SMEs involved in pharmaceutical industry is at its infancy. Study at GFSB indicated that successful implementation of lean manufacturing stems from management support, employee's commitment, government support and knowledge on lean among employees. Application of lean tools in IKOP Sdn. Bhd. to improve the process cycle efficiency of hand sanitizer, i-Hand 4.0, has shown that the GMP guidelines are not jeopardized. The Kaizen improvement project resulted in 46.3% reduction in lead time. It may be concluded that implementing lean manufacturing in any small local startup pharmaceutical company is beneficial in reducing operational costs and increasing the efficiency and effectiveness and does not conflict with the existing GMP guidelines.

1. Introduction

The cost of developing drugs is very high as pharmaceutical companies are required to invest approximately 3-4 times more than other manufacturing companies [1]. This high cost is due to higher failure rates, longer times required for clinical trials, and increasing drug complexity [2]. To offset these costs, pharmaceutical companies are now facing increasing pressure to reduce manufacturing costs through improving operational efficiencies. Lean manufacturing is a manufacturing system that aims to minimize production cost and maximize the profit by eliminating waste or non-value added

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activities [3]. Derived largely from the Toyota Production System, the practices have been implemented widely in many industries [4].

Pharmaceutical industry, however, has been slow in adopting LM [5,6,7]. And this may be more so in small and medium enterprises (SME) and especially so in the Malaysian context [8,9,10]. The domestic pharmaceutical industry has been identified by the Malaysian government as an industry to be developed under its new 11th economic development plan. Most of the homegrown companies within the industry fall under small and medium enterprise (SME) and therefore need to be highly efficient in their operations in order to compete with the multinationals. Therefore, this study aimed to achieve better understanding of the success factor(s) of LM implementation in Malaysian startup pharmaceutical SMEs through a systematic review of relevant literatures, an onsite observation at a local SME which successfully implemented LM and a case study implementation at another local small pharmaceutical startup company.

2. Literature Review

One approach to achieve an efficient operation is through implementing lean manufacturing. Exploratory inquiry however indicated that relatively a small percentage of the local SME companies implements lean manufacturing as also found by previous studies on this issue [10,11]. This is true for pharmaceutical companies due to their focus on establishing themselves in the initial market since for many drugs, the first to market captures the majority market share [6]. The complexity of designing operational procedures to incorporate LM into the existing system highly controlled and regulated by the current Good Manufacturing Practices (cGMP) may also be an issue.

Barriers and difficulties in the implementation of lean in pharmaceutical industry may come from the cGMP guidelines. The cGMP requires a lot of paper works; documentations and standard operation procedures (SOP) that affects the lead time [12]. cGMP are the guidelines formulated by the US Food and Drug Administration (FDA) that pharmaceutical industries in the entire world should follow in the drug production. At times, the rules and regulation in cGMP may not be applicable and become waste in pharmaceutical production process [13]. Lean manufacturing is a manufacturing system that has aimed to minimize production cost and maximize the profit by eliminating waste or non-value added activities [3]. This system was invented and implemented by Toyota Production System successfully and the practices have since been implemented widely in many industries [4].

According to [8], lean implementation is still new to SMEs. This is true in the Malaysian context; the implementation is still low within them [9,10]. Malaysian SMEs are categorized based on two categories: (i) manufacturing sectors and (ii) services and other sectors [14]. A company in manufacturing sector that operates with less than 200 full time workers and obtains annual income of RM50 million is considered as an SME. In services and other sectors, for a company to be considered as an SME, the number of full time workers must be less than 75 and the annual income must be less than RM20 million. There are 60,158 companies listed by SME Corp Malaysia as SMEs. SME Corp Malaysia is the authorized government agency entrusted to improve, support and advice SMEs in competing in the global business environment. The agency has been recommending SME to apply lean manufacturing concept due to its contribution towards company's efficiency and competency [15].

Although Toyota shared the knowledge of lean concept, companies need to run and implement it using their own style [16]. The implementation of lean without right understanding will create more waste and decrease in employees' morale [17]. The level of success of lean implementation was directly determined by the understanding of lean concept by top management responsible in the organization [18]. To succeed in implementing lean, the organization must understand the lean concept really well through actual implementation [19,20]. Researchers [10,15,21,22,23,24], found that, the main barriers to the successful lean implementation in Malaysian SMEs are lack of understanding of lean concept and the employees' attitude.

3. Methodology

Multiple case study concept [25] was used to collect the data. Review of literature relevant to the implementation of LM in Malaysia was carried out. Special focus was given to the LM implementation in Malaysian SMEs and pharmaceutical companies. The main aim was to gain a better understanding of the level of lean implementation in Malaysia as well as establish the factors behind the successes and failures of LM implementation.

An onsite observation was carried out at a small manufacturing company; GF Sdn. Bhd. (GFSB) which successfully implemented lean manufacturing. Data collection was done through interviews, process observation and document analysis [26] in order to evaluate the real factors behind the successful implementation of lean manufacturing in GFSB.

Subsequently, onsite observation was done at a small local startup pharmaceutical company, IKOP Sdn. Bhd. to identify the benefits of implementing LM in this company and whether or not the cGMP poses a hindrance to successful LM implementation. Two (2) lean tools namely, value stream map (VSM) and spaghetti diagram were used in a lean project at a selected process. The implementation process at IKOP Sdn. Bhd. began with gathering data to develop the current VSM (cVSM) of the production process. Spaghetti diagram was utilized to represent flow paths of items and activities through a stream in order to identify opportunities to expedite process flow. Future VSM (fVSM) was later developed to identify improvement opportunities.

4. Results and Discussion

Exploratory study in the initial phase showed that GFSB was the one and only company which implemented lean manufacturing system in east coast region as recorded from interview with a Malaysian Productivity Corporation personnel [11]. Through systematic literature review, a total of 39 papers relevant to the lean implementation within the Malaysian context were collected. It was found that the lean implementation in the Malaysian pharmaceutical sector was in the infancy. Figure 1 indicates the percentage of reviewed papers by industries in which pharmaceutical industry was included in the “Others” category, with only one (1) paper published in 2015.

Data were collected in two SME companies, one in manufacturing (GFSB) and another one in pharmaceutical (IKOP). The lean implementation activities were successfully implemented in GFSB while in IKOP lean manufacturing was to be implemented. Table 1 describes the two main lean tools used namely, VSM and Kaizen, and success factors identified at GFSB. Top management support was found to be the starting point of this achievement as they were responsible to provide the direction of the company. Employees’ attitude was found to be the second factor behind the successful lean implementation. Only with positive attitudes of the workforce can improvement program such as lean manufacturing be successful. The third factor came in the form of training prior to the implementation; it was found that the employees were given an intensive training by an appointed lean consultant. With this knowledge, they could implement the concept correctly. Lastly, an external factor in the form of government support was the ignition point for this company to implement lean. The government authority such as SME Corporation, that offers manufacturing grants, requires the company to implement lean manufacturing system. This indirectly introduced the company to lean implementation. The analysis of this observation was used in the case of a newly established pharmaceutical company in term of success factors, effects on the implementation and performance of lean manufacturing system for the company.

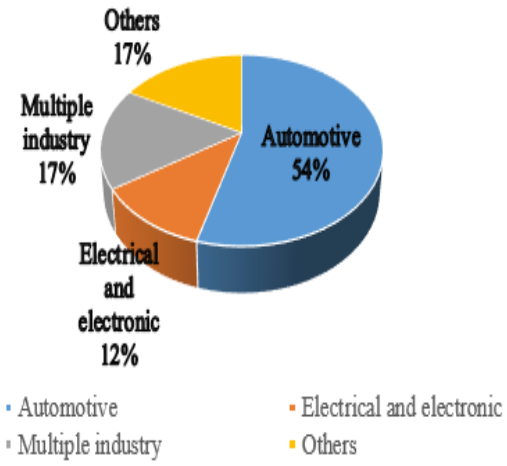


Figure 1. Papers distribution by sector.

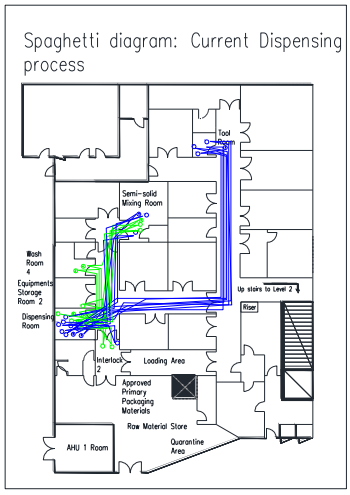


Figure 2. Current spaghetti diagram.

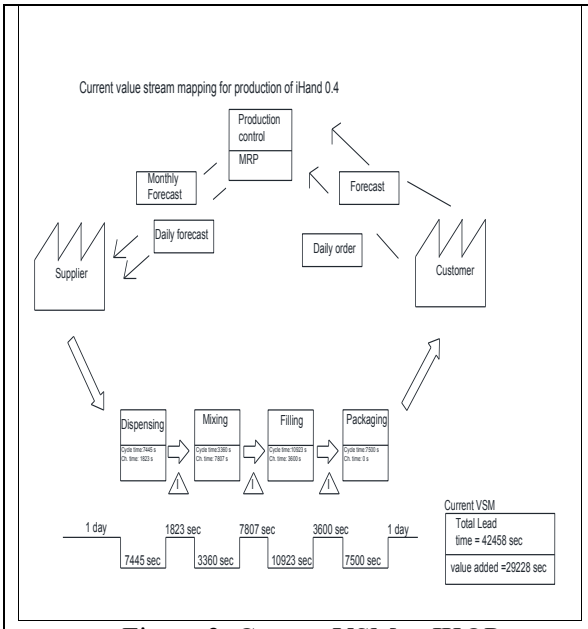


Figure 3. Current VSM at IKOP.

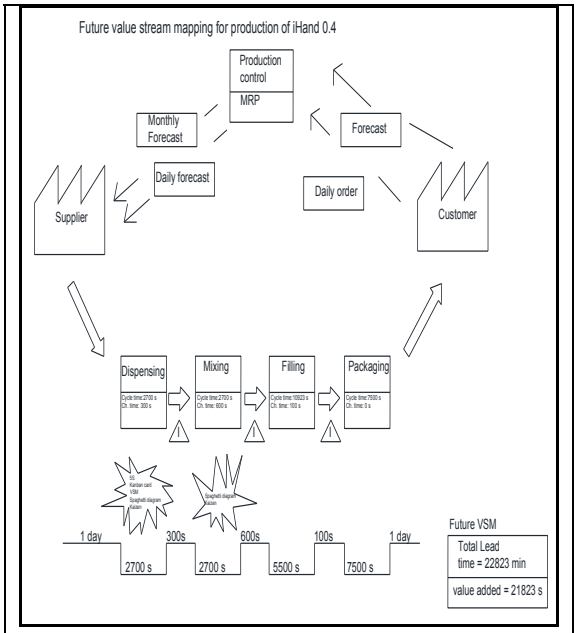


Figure 4. Future VSM at IKOP.

Figure 2 and Figure 3 show the current spaghetti diagram at dispensing process and current VSM for the whole production of i-Hand 4.0 respectively. The current lead time recorded was 42,458 seconds or more than 11 hours. Figure 4 shows the suggested future VSM with the application of lean tools such as 5S, VSM, spaghetti diagram and Kaizen. Kanban card application was to be implemented. With this integration, the future lead time was expected to be reduced to 22,823 seconds or less than 7 hours.

Table 1. Lean implementation program in GFSB.

Item	Description
Lean tools	VSM and Kaizen were used. cVSM was developed and studied. Future VSM then produced and implemented. The implementation required small cost with the highest amount was RM50.
Success factor	1. Top management support 2. Employees' attitude 3. Implementation knowledge 4. Government support

Table 2. Lean implementation in IKOP.

Item	Description
Lean tools	VSM, spaghetti diagram and Kaizen was used. cVSM was developed and studied. Future VSM then produced.
Success factor	1. Top management understanding 2. Employees' attitude 3. Implementation knowledge

Table 2 shows the lean implementation in IKOP. In this implementation, three lean tools were used; VSM, spaghetti diagram and Kaizen. A spaghetti diagram could visualize the overall motion of employees in their activities. From the results three factors were identified. Firstly, top management understanding through briefing and explanation session which resulted in the top management agreeing to lean implementation with certain conditions such as no conflict with current good manufacturing practices (cGMP) and minimum cost required in the implementation. The second factor was employees' attitude in which they believed this system can generate better results thus may increase the company's income through better understanding the benefits of lean manufacturing system. Lastly, the implementation knowledge; after a few training sessions on lean and VSM, they understood their functions in the organization.

5. Conclusions

It may be concluded from the study that the implementation of lean manufacturing at Malaysian SMEs involved in pharmaceutical industry is at its infancy. Successful implementation of lean manufacturing stems from management support, employee's commitment, government support and knowledge on lean among employees. Application of lean tools in IKOP Sdn. Bhd. to improve the process cycle efficiency of hand sanitizer, i-Hand 4.0, has shown that the GMP guidelines are not jeopardized with the Kaizen improvement project resulted in 46.3% reduction in lead time. It may be further concluded that implementing lean manufacturing in any small local startup pharmaceutical company is beneficial in reducing operational costs and increasing the efficiency and effectiveness and does not conflict with the existing GMP guidelines.

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References

[1] F.J. Cohen. Macro Trend in Pharmaceutical Innovation, Nature Review: Drug Discovery, January 2005, Volume 4. Retrieved from www.nature.com/reviews/drugdisc
[2] M.E. Lawler, Improving Shop Floor Visualization and Metrics. (MSc. Thesis), 2010. Massachusetts Institute of Technology.
[3] J.P. Womack, D.T. Jones, and D. Ross, The Machine that Changed the World, Rawson Associates, New York, NY, 1990.
[4] M. Holweg, The Genealogy of Lean Production, J. Operation Management. 25 (2007) 420 – 437.

[5] A. Greene, and D. O'Rourke. Lean Manufacturing Practice in a cGMP environment. (2006). Retrieved from Pharmaceutical Technology Europe: http://www.ptemagazine.com
[6] A.D., Villa. Lean Transformation Methodology and Implementation in Biopharmaceutical Operation. (MSc. Thesis) 2008. Massachusetts Institute of Technology.
[7] V. Jaiganesh, and J.C. Sudhahar, Sketching Out the Hidden Lean Management Principles", International Journal of Scientific and Research Publications. 3(2) (2013).
[8] P. Achanga, E. Shehab, R. Roy and G. Nelder, Critical Success Factors for Lean Implementation within SMEs, Journal of Manufacturing Technology Management Vol. 17 No. 4 (2006) 460-471.
[9] A.M.N. Rose, B. Md. Deros, M.N. Ab. Rahman, and N. Nordin, Lean Manufacturing Best Practices in SMEs, Proceedings of the 2011 International Conference on Industrial Engineering and Operations Management Kuala Lumpur, Malaysia, January 22 – 24, 2011
[10] Y.C. Wong, K. Y. Wong, and A. Ali, A Study on Lean Manufacturing Implementation in the Malaysian Electrical and Electronics Industry, European Journal of Scientific Research ISSN 1450-216X Vol.38 No.4 (2009), 521-535.
[11] Sharifah Mazina Syed Mohamed, Interviewed by Author, Kuantan, Pahang, 15 October 2014.
[12] M. Khlat, A.H. Harb, A. Kassem. Lean Manufacturing: Implementation and Assessment in the Lebanese Pharmaceutical Industry. International Journal of Computing and Optimization, 1, (2014) 47 – 62.
[13] B.V. Chowdary, and D. George, Improvement of Manufacturing Operations at a Pharmaceutical Company, Journal of Manufacturing Technology Management, Vol. 23, (2011) 56 – 75.
[14] Information on www.smecorp.gov.my
[15] N. Nordin, B. Md. Deros, and D. Abd. Wahab, A Survey on Lean Manufacturing Implementation in Malaysian Automotive Industry, International Journal of Innovation, Management and Technology, 1(4), (2010) 374 – 380.
[16] J.K. Liker, The Toyota Way – 14 Management Principles from the World's Greatest Manufacturer, McGraw-Hill, New York, NY. 2004.
[17] J.H. Marvel, and C.R. Standridge, A Simulation-enhanced Lean Design Process, Journal of Industrial Engineering & Management, Vol. 2 No. 1, (2009) 90-113.
[18] R. Shah, P.T. Ward, Lean Manufacturing: Context, Practice Bundles, and Performance, Journal of Operations Management 21, (2010) 129-149.
[19] A.D. Rymaszewska, The Challenges of Lean Manufacturing Implementation in SMEs, Benchmarking: An International Journal, Vol. 21 Iss 6 (2014) 987 – 1002.
[20] Flinchbaugh, "Beyond lean: building sustainable business and people success through new ways of thinking", available at: http://mhlnews.com/archive/beyond-lean-building-sustainable-business-and-people-success-through-new-ways-thinking-2 (2005).
[21] E.N. Roslin and S.A.M. Shahadat,. A Conceptual Model for Full-blown Implementation of Lean Manufacturing System in Malaysian Automotive Industry. Proceedings of the 2014 International Conference on Industrial Engineering and Operations Management. (2014) 1309 – 1315.
[22] A.R. Rahani, M. al-Ashraf, (2012) Production Flow Analysis through Value Stream Mapping: A Lean Manufacturing Process Case Study. Procedia Engineering 41, (2012) 1727 – 1734.
[23] N. Nordin, B. Md. Deros, M.N. Ab. Rahman. Lean Manufacturing Implementation in Malaysian Automotive Industry: An Exploratory Study. Proceedings of the 2011 International Conference on Industrial Engineering and Operations Management. 4(1), (2011) 1979 – 3871
[24] R. Muslimen, S.M. Yusof, and A.S.Z. Abidin, Lean Manufacturing Implementation in Malaysian Automotive Components Manufacturer: A Case Study. Proceedings of the World Congress on Engineering 2011 Vol I WCE 2011, 1. (2011)
[25] R.K. Yin, Case Study Research: Design and Methods, 2nd Edition. (1994) Thousand Oaks, CA:

Sage.
[26] D.E. Gray, Doing Research in the Real World (2004) London: Sage Publication