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PERFORMANCE EFFICIENCY OF QUALITY CONTROL LABORATORY THROUGH IMPLEMENTATION OF LEAN OPERATION

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Abstract

Lean operation is the common method to increase operational's efficiency, but it is still rarely implemented for Quality Control Laboratory. This paper used Value Stream Mapping to identify added value and non-added value activities from raw material analysis in Quality Control Laboratory of pharmaceutical industry. Efficiency was measured by reducing the turnaround time for raw material analysis and then converted into labor cost efficiency. Our research renders a decrease of 42.7% in turnaround time for the top 20 raw materials sample that received in 2020. In addition, it reduced the cost of labor by IDR 130,193,977 per year. These results showed us the importance of implementing lean operations in the laboratory to support pharmaceutical industries in producing quality and affordable drug products.

Keywords: Lean, value stream mapping, efficiency, quality control laboratory, pharmaceutical industry.

Introduction

Lean is defined as a process that focuses on waste elimination, meaning that each production or service process should provide value to the customer (Jacobs & Chase, 2018). Lean tools are extremely desirable for identifying and eliminating waste (Gupta, Kapil, & Sharma, 2018). Furthermore, according to Gupta *et al.* (2018), lean principles could help companies to improve their work process, saving time and money. It can achieve since the lean principles enable companies to make process more visible, so people can use them to enhance their organization performance (Stadnicka & Ratnayake, 2017). According from Natakusuma, Hidayatullah, and Purba (2018), lean implementation benefits were minimizing waste, including human effort, space, tools investment, and process improvement to develop a new product. From several lean tools, Value Stream Mapping can be highlighted since it had good ability to provide view of manufacturing process (Suhardi, Anisa, & Laksono, 2019). For simple manufacturing environments, Value Stream Mapping are straightforward and relatively less complicated, but it still needs some modifications for complex environments to keep attained the benefit of lean operations (Seth, Seth, & Dhariwal, 2017). Value Stream Mapping will visualize the flow of value added and non added value activity which do not contribute anything to the result that can satisfy customers in material flow, thus, it will be easier to eliminated non added value activity from the process and redesign process for improvement (Suhardi *et al*., 2019).

Pandemic is epidemic that initially infected a few of human communities, but it spreads and become global (Adriatama & Rahadi, 2021). COVID-19 is one of the pandemic that was first discovered in Wuhan, China but then infected all of people in other countries (Siahaan & Robiyanto, 2021). This pandemic has had a global economy impact in various sector and it negatively affect Indonesian economy (Marwanti & Robiyanto, 2021). One of sector that also had an impact of COVID-19 pandemic in early 2020 is pharmaceutical industries. The existence COVID-19 pandemic caused demand for drug production to increase. The mentioned condition is also experienced by a multinational pharmaceutical industry located in Depok, Indonesia, which had a demand increase for drug products due to the COVID-19 pandemic. This paper is focused on quality control laboratories, particularly in the raw material analysis division, which had a 14.6% increase in samples received due to the rise in demand for drug production. These raw materials need to be analyzed to ensure their quality before they are used in production. An increase did not follow the increase in the number of raw material samples in the number of laboratory personnel for the raw material analysis division, which could cause delays in the analysis results.

This paper's objective is to analyze lean implementation in a quality control laboratory of pharmaceutical companies to solve that problem. Improvements in pharmaceutical companies are an important, they should improve their service level, flexibility, cost and quality at the same time satisfy demanding regulatory and economic factor (Sieckmann, Ngoc, Helm,

& Kohl, 2018). Furthermore, according to Sieckmann *et al*. (2018), lean philosophy was the appropriate approach to address this issue. Lean approach has an opportunity to improve pharmaceutical industry performance through the adoption of process excellence program (Garza-Reyes, Betsis, Kumar, & Radwan Al-Shboul, 2018). Lean operations in manufacturing is a system that aimed to minimize production cost and maximize the profit by eliminating waste (Khairi, Rahman, & Rusdi, 2016). This system already implemented in various organizations and have certainly demonstrated the advantages and benefit (Hamilton, 2018). According to Myers and Anthos (2018), lean operations designed to improve manufacturing operations can also be applied by a quality control laboratory. Quality control laboratory has several differences with manufacturing environment, and then some changes are needed to adapt lean operations with laboratory environment. Implementing lean operations in the laboratory will improve productivity and speed, while management will gain cost and time efficiency (Myers & Anthos, 2018).

Value Stream Mapping and War of Waste are lean operation tools used in this paper. Value Stream Mapping is a lean operation tool that can help identify value-added activities and waste of the process (Jacobs & Chase, 2018). By using this tool, companies could visualize the material and information flow in order to find solutions to reduce or eliminate waste in their value flow (Ana, 2019). Value Stream Mapping was chosen as a tool in this paper due to the ability to quickly visualize every process, including material and information flow. Current stream mapping has been developed for the analytical parameter of the top 20 raw materials sample that received in 2020. Then, the war of waste method was used to help identify waste in the current stream mapping. Last, future stream mapping has been developed, and waste has been eliminated to make the raw material analysis process more efficient.

Turn around time is an important performance parameter for laboratory (Gupta *et al*., 2018). Case study in clinical laboratory at Seattle showed that implementing lean in laboratory could decrease turn around time from 54 to 23 minutes (Rutledge, Xu, & Simpson, 2010). Another study of CBC lab and Bio-Chemisty lab that implemented lean tools were able to reduce turn around time to 94.70 minutes and 208 minutes (Gupta *et al*., 2018). Thus, for this study, the efficiency was measured by the decrease in turnaround time before and after lean implementation. The reduction in turnaround time is then converted into raw material labor cost efficiency. Furthermore, this study can be used as a reference for implementing lean operation in the quality control laboratory of pharmaceutical industries. This study can be continued by using other lean operation tools and with other variables to expand the application of lean in pharmaceutical industries' quality control laboratory.

Lean Operation

Lean operation is a method of waste reduction by identifying and reduce or eliminate non-added value activities (Suhardi *et al*., 2019). Lean concept focuses on eliminating waste as much as possible. The basis of lean concept comes from Japan after World War II when Japanese manufacturers realized that they unable to invest in big scale to rebuild the destroyed facilities as a result of war. Toyota produces their cars with inventory, investment and fewer product defects, but still introduce products that are varied to the market (Bhamu & Sangwan, 2014). This lean concept can be used by manufacturing to improve quality and productivity by reducing variations and manufacturing defects (Blecker-Shelly & Mortensen, 2008). The quantitative benefit of lean implementation is an increase in efficiency in lead time production, processing time, cycle time, set up time, inventory, defects, and increasing the effectiveness of machines and equipment. While the qualitative benefits of the application of lean is to increase employee morale, increase effectiveness communication, job satisfaction, and increase the speed of decision making (Bhamu & Sangwan, 2014).

Value Stream Mapping

Value stream is a business management concept introduced by Porter in 1985 to define end-to-end stream activities that deliver particular results for external and internal customer (Ben Fredj-Ben Alaya, 2016). Value Stream Mapping can be defined as a visual management method used to analyse a process in its current state and design the ideal future state (Sales-Coll, de Castro, & Hueto-Madrid, 2021). This method shows the time required for each activity, including waiting time or delay in processing. The main objective of Value Stream Mapping is the identification, demonstration, and reduction of waste in the process. In the context of manufacturing process, value stream mapping used to identify all activities that provide value and does not provide value, from the arrival of raw materials until product delivery to the customer. Value in the context of lean production is something that is willing paid by the customer. Meanwhile, activities that do not provide value will only consume resources and do not directly contribute to the result that desired by customer.

Value stream mapping is divided into two process, current state mapping and future state mapping. The current state mapping should be developed based on data collected directly from floor using the set of icons (Seth *et al*., 2017). In current state mapping, waste will be identified, then a future state mapping will create. The future state mapping created based on the answer of the issues regarding process efficiency and lean implementation (Natakusuma *et al.*, 2018). In future state mapping, the process flow will be modified or eliminated to improve the process flow more efficiently.

Lean Laboratory

Lean laboratory is a process that focuses on testing products and materials to provide the most efficient results in terms of cost or speed to increase performance and reduce costs by using less resources, effort, and time (Naik, Sharma, Naik, Lakshmana, & Devi, 2011). Compared to manufacturing, the laboratory has fewer samples but has higher complexity and variability. Thus, general approach of lean operations cannot be applied entirely in the laboratory. According to (Zevitas, 2012), the benefits of implementing a lean operation in a laboratory were:

- Increased laboratory productivity by lowering operational costs and lead time.
- Increased first-time quality, decrease rework and laboratory investigation.
- Encouraged innovative ideas for continuous improvement.

Lean operations have been implemented in several pharmaceutical manufacturing to make company operations more efficient. The research conducted by Pramadona and Adhiutama (2013) was a case study on the pharmaceutical industry in Bandung, West Java. More specifically, this study aims to reduce yield inconsistencies in the production line of OBH products. Value Stream Mapping and Seven Waste of War are lean operation tools used in this study. Value Stream Mapping was created to assist researchers in understanding the production process. Then, seven war of waste is used to identify any activity that does not provide value in the production process. Future Value Stream Mapping is then made based on process modifications to minimize non-value activities. This research shows the decrease of the total cycle time of the OBH product production process from 295 minutes to 195 minutes.

Research about lean operation implementation in the laboratory was conducted by Scharton-Kersten *et al.* (2010). The research analyzed the implementation of lean operations in the quality control laboratory of the pharmaceutical industry, Novartis-Sandoz. Novartis-Sandoz laboratory improved its lab design and layout to support the implementation of lean operations. The result of this study is the design, layout, and placement of labs can give a significant result of lean laboratory implementation. Thus, the laboratory areas should be designed to support leveling, flow, and standard work, support of the effective use of man-hour, minimize waste and support 5S implementation (Scharton-Kersten *et al*., 2010).

Another research about lean laboratory implementation was conducted by Natakusuma *et al.* (2018). This research focused on chemical laboratories in the textile industry. This chemical laboratory wants to increase customer satisfaction by giving customers a faster turnaround lead time. Value Stream Mapping and Seven War of Waste are lean operation tools used in this study. The azo dyes testing process was chosen as a process for which current state value stream mapping would be made so that researchers could more easily understand the stages of the azo dye analysis process. The process modification was developed, and additional tools were also made to reduce bottleneck process and lead time analysis. The result of this research is a reduction in the lead time of the azo dye analysis process from 8400 seconds to 5471 seconds.

Isa *et al*. (2020) also conducted research related to lean operations implementation in the laboratory. This study examines the application of lean operations in the clinical laboratory of a hospital to reduce Laboratory Turn round Time (LTAT). This research was conducted for two months, from September to October 2015. The research was started with developing current layout value stream mapping to identify the processes. Then, waste analysis was conducted to find added and non-added value activities. Future process layout was developed based on input from laboratory staff and instrument vendors. This study concludes that the application of lean operations in laboratory operations has a positive impact, such as improving team performance, reducing inventory costs, and increasing the services provided by the laboratory to customers.

Most of them use value stream mapping and war of waste as a lean operations tool from all of the studies above. Both methods are easy to use and give effective results. One of the drawbacks of the research above is there are no efficiency calculations in terms of costs. From the management point of view, cost efficiency can make lean operations more attractive to be applied in the company; thus, management can support the successful implementation of lean operations.

Research Methods

This research was conducted in the laboratory facilities of the quality control department of a multinational pharmaceutical industry in Indonesia. Quality control laboratory was chosen because there were not many studies that discussed the implementation of lean operations in the laboratory (Myers & Anthos, 2018). Meanwhile, the implementation of lean operations could improve the process flow and make the process more efficient in terms of time and finances (World Health Organization, 2011). The research began by analyzing data of raw material samples received in the laboratory during 2020. This data will be ranked for the top 20 raw materials samples obtained in 2020. Raw materials have different testing parameters according to the monographs listed in the Pharmacopoeia. According to each monograph, the top 20 raw material samples will be grouped based on the similarity of their testing parameters to obtain the top six of testing parameters.

Observations were then performed to develop current state value stream mapping of the top six testing parameters of raw material analysis. Value-added and waste activities are identified using war of seven waste, and process improvement is proposed to minimize waste or activities that do not provide the value. Furthermore, future stream mapping is developed for each of the top six testing parameters. Future stream mapping is a workflow of the same process that has been improved to make it more efficient by eliminating waste or activities that do not provide value. The efficiency of lean operations implementation is then calculated by comparing the turnaround time before and after applying lean operations. Time efficiency is then converted into labor cost efficiency.

This study uses primary and secondary data. The primary data were obtained from field observations and discussions with laboratory personnel about process improvement. All of the activities during the analysis of the top six testing parameters will be observed, and the time completion is logged. Secondary data used in this study are internal company data such as data on raw material samples received in quality control laboratory during 2020 and specification of testing parameters for the top 20 raw material samples.

Time efficiency in this study was calculated by analyzing the decrease of turnaround time on Current Stream Mapping and Future Stream Mapping as follow:

Turnaround time = VA + NVA

Time efficiency = TAT2 - TAT1

where:

VA : Time of added-value activities
NVA : Time of non-added value activities
TAT1 : Turnaround time of current stream mapping
TAT2 : Turnaround time of future stream mapping

The time efficiency result (min) then multiplied by the number of samples received in 2020 which have the top six parameter to get the total efficiency (min).

Total Efficiency = Time Efficiency × Total Sample

The total efficiency (min) then converted into hours. This time efficiency then multiplied by the regional minimum wages for Depok City in 2020 to determine the efficiency in terms of cost. The regional minimum wages for Depok City in 2020 IDR 4,339,514 (Mantalean, 2020), which when divided per hour becomes IDR 4,339,514/(40 hours × 4 weeks) = IDR 27,122. Then, the cost-efficiency would be calculated as follow:

Cost Efficiency (IDR) = Total Efficiency (hour) × Depok Regional Minimum Wages (per hour)

Results and Discussion

Current State Value Stream Mapping

The analysis was performed on data of raw material sample that received in the laboratory during 2020. From these data, it is known that the total number of raw material samples during 2020 was 1476 samples, dominated by the arrival of 188 samples of Acetaminophen. Data of top 20 raw material sample as follow (Table 1).

Table 1
Top 20 Raw Material Sample (2020)

Raw Material Sample	Quantity Sample Received in 2020
Acetaminophen	188
Ascorbic Acid 90% Gran	60
Empty Capsule No.0	58
Salicylamide	47
Povidone K-30	43
Corn Starch	43
Thiamine Mononitrate 98%	41
Sod. Starch Glycolate	30
Polyvinyl Acetate Phtalate	29
Ca Pantothenate	27
Riboflavin Tab Grade	27
Methylene Chloride	25
Colloidal Attapulgite	24
Mg Strearate	21
HPMC 2910 15 cps	20
FDC Yellow#5 Lake 27%	20
Acetylsalicylic Acid Crystal	20
Ca Carbonate Heavy	19
Cotton Sliver	19
Sod. Saccharin	17

Source: PT XYZ internal data, processed

Top 20 raw material sample then grouping based on testing parameter of each pharmacopeia monograph. Top six testing parameters can be sorted as follows Table 2.

Table 2
Top 6 Testing Parameter of Raw Material

Testing Parameter	Quantity
Description	20
Solubility	18
Identification	18
Residue on Ignition	12
Assay	12
Loss on Drying	12

Source: PT XYZ internal data, processed

Furthermore, Current Stream Mapping was developing for the top 6 testing parameters. The current stream mapping was developed with eight types of waste to analyze added value and waste activities from the process. Current Stream Mapping for raw material analysis as Figure 1.

From Figure 1, it can conclude that the turn-around time for raw material analysis using the top six testing parameters is 3283 minutes. Figure 1 also showed us the amount of waste that occurs in each process. Total waste or non-added activity from the raw material analysis is 1470 minutes with three categories of waste: motion (127 minutes), waiting time (1303 minutes), and over-processing (40 minutes). This waste contributed 44.8% of the total cycle time of the raw material analysis process. This non-added value activities have potential to become a bottleneck if it is not minimized properly.

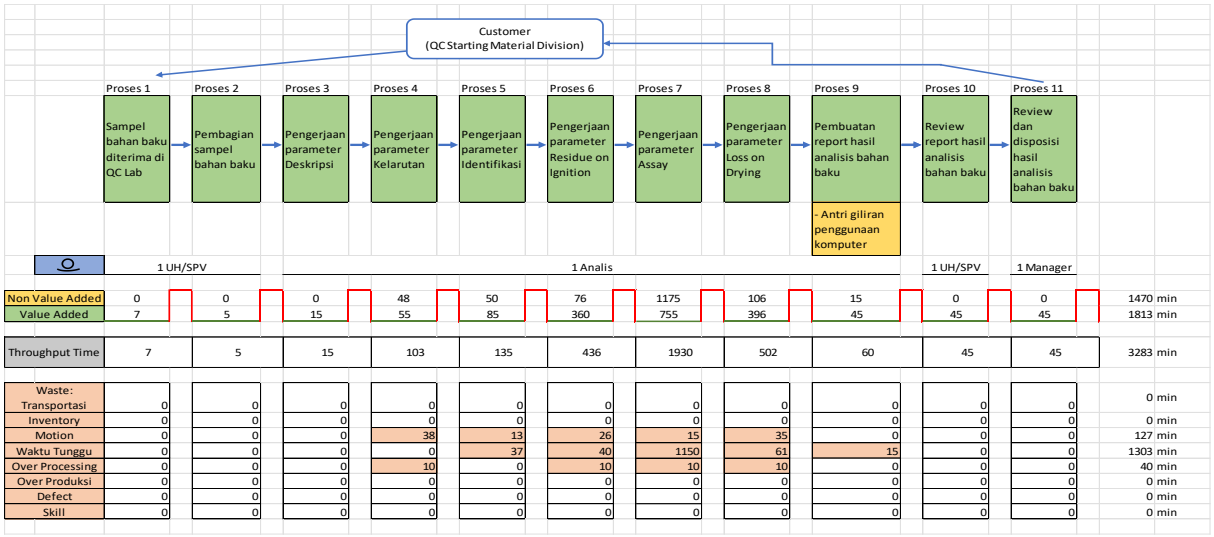

Figure 1. Current state value stream mapping

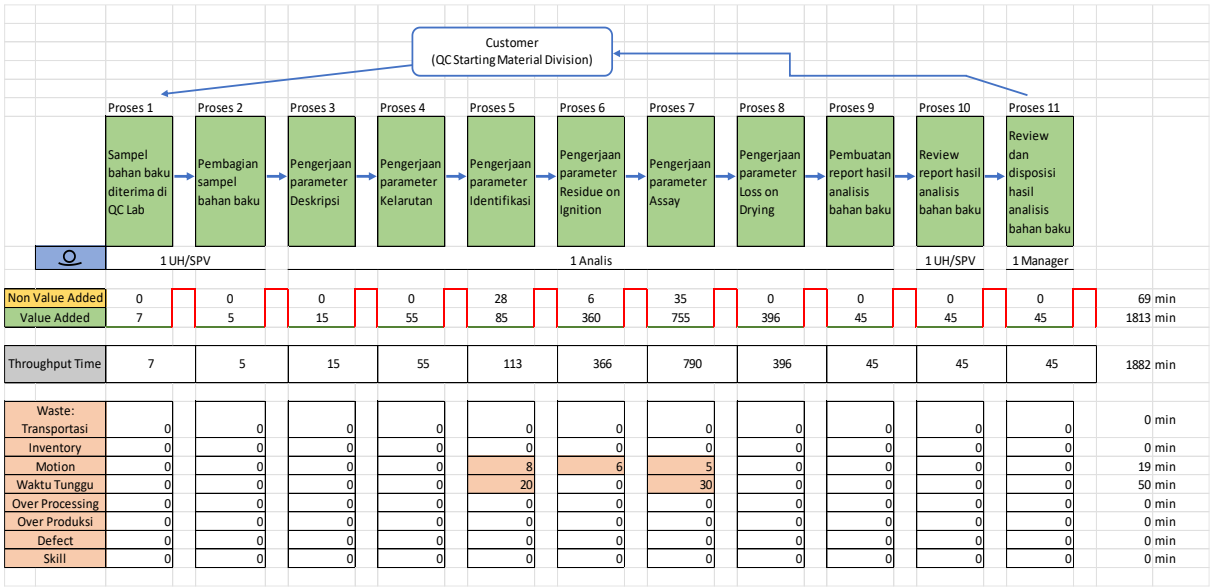

Figure 2. Future state value stream mapping

Future State Value Stream Mapping

After identifying the waste in the process, improvements then suggested to minimize the waste. As shown in Figure 2, there was a decrease in the cycle time of the raw material analysis process. This can be achieved by reducing non-value/waste activities.

By eliminating non-added value activities, the turnaround time of the raw material analysis can be up to 42.7% more efficient. The turnaround time required for raw material analysis was reduced from 3290 minutes to 1882 minutes.

Furthermore, time efficiency was calculated based on reduction in turnaround time before and after the implementation of lean operations. This time efficiency was then multiplied by the regional minimum wages for Depok to obtain the cost efficiency (Table 3).

Discussion

Value stream mapping is one of the lean operation tools that help identify materials and information flow from a product or service (Blecker-Shelly & Mortensen, 2008). The main purpose of making Value Stream Mapping is identification, demonstration, and reduction of waste in the process. Value stream mapping is divided into two parts, the first is called the "current state" process and the second is called the "future state" process (Jacobs & Chase, 2018). The current stream map is a depiction of the actual existing process flow. In this current state, waste and other activities do not give value to the final product. From the current state map, waste will be identified, then a future state map will be developed. In the future state, the process flow will be modified or eliminated so the process becomes more productive.

Table 3
Efficiency of Raw Material Analysis

Raw Material Sample	Total Sample	Parameter of Analysis					
		Solubility	Identification	Residue on Ignition	Assay	Loss on Drying	Reporting
Acetaminophen	188	188	188	188	188		188
Ascorbic Acid 90% Gran	60	60	60	60		60	60
Empty Capsule No.0	58			58		58	58
Salicylamide	47	47	47	47	47		47
Povidone K-30	43	43		43			43
Corn Starch	43	43		43		43	43
Thiamine Mononitrate 98%	41	41		41	41	41	41
Sod. Starch Glycolate	30		30			30	30
PVAP	29	29		29			29
Ca Pantothenate	27	27	27		27	27	27
Riboflavin Tab Grade	27	27		27	27	27	27
Methylene Chloride	25	25	25				25
Colloidal Attapulgite	24	24				24	24
Mg Stearate	21	21				21	21
HPMC 2910 15 cps	20	20		20		20	20
FDC Yellow#5 Lake 27%	20	20	20				20
Acetylsalicylic Acid Crystal	20	20	20	20		20	20
Ca Carbonate Heavy	19	19				19	19
Cotton Sliver	19			19			19
Sod. Saccharin	17	17	17				17
Total Sample		**671**	**434**	**595**	**330**	**390**	**778**
Time Efficiency (min)		48	22	70	1140	106	15
Total Sample x Time Efficiency (min)		32208	9548	41650	376200	41340	11670
Total Sample x Time Efficiency (hour)		536.8	159.1	694.2	6270	689	194.5
Depok Regional Minimum Wages per month		IDR 4,339,514	IDR 4,339,514	IDR 4,339,514	IDR 4,339,514	IDR 4,339,514	IDR 4,339,514
Depok Regional Minimum Wages per hour		IDR 27,122	IDR 27,122	IDR 27,122	IDR 27,122	IDR 27,122	IDR 27,122
Cost Efficiency		IDR 14,559,069	IDR 4,316,008	IDR 18,827,162	IDR 170,054,705	IDR 18,687,032	IDR 5,275,222
Total Efficiency				**IDR 226,443,977**			

Source: PT XYZ internal data, processed

From current state mapping, the most waste occurred in process 7 (Assay parameter) in the form of 1150 minutes waiting time. This waiting time occurs due to the HPLC (High-Performance Liquid Chromatography) instrument being used for the raw material analysis and processing samples from other divisions. Raw material samples have to wait for their turn to running on the HPLC instrument. Waste from different waiting time categories can occur because analysts must queue to take turns at weighing and queue to get their turn to use the computers during the process of making reports. The second most waste that occurs in the process of raw materials testing is motion (127 minutes). It can happen because tools and solvents to be used are stored in different area from analyst preparation table (reagent room and washing room cabinet), and glassware storage that have not applied the 5S principle. Both cause the analyst to need more time to prepare the required glassware and reagents. The last one is waste in the form of over-processing (40 minutes). This waste occurs because, during the preparation of glassware, it was found that several glasswares had not been washed properly. Thus, the analyst had to re-wash it to ensure that the glassware used was in a clean condition. These non-added activities add the time needed for the analyst to prepare the glassware that will be used for raw material analysis.

In attempt to reduce waste or non-added value activities in the laboratory, it was suggested several improvements as below:

- Glassware used for raw material analysis is stored in the cabinet of analyst preparation table. This storage implements the 5S principle. Thus, it will be easier to find.
- Develop an SOP that stated the glassware is cleaned immediately after being used by the analyst and put back in the storage, since this company does not yet have an SOP that standardize this procedure.
- Provide solvents that are commonly used in solubility parameters (alcohol, water, ether, chloroform, 1 N NaOH, and methanol) in small glass bottles. Then the tiny glass bottles are placed near the preparation table.
- Provide dedicated computer for reporting raw material analysis results.
- Provide dedicated analytical balance and desiccator that placed near the oven and furnace.
- Rent an HPLC instrument that dedicated to raw material samples. Estimated HPLC rent fee for 330 raw material samples which have assay parameter is IDR 96,250,000 per year.

If all the recommendations described above can be applied as a whole, the turnaround time of the raw material analysis can be more efficient, up to 42.7%. The turnaround time required for raw material analysis will be reduced from 3283 minutes to 1882 minutes, the details are as follows:

- Throughput time for solubility parameter reduced from 103 minutes to 55 minutes
- Throughput time for identification parameter reduced from 135 minutes to 113 minutes
- Throughput time for residue on ignition parameter reduced from 436 minutes to 366 minutes
- Throughput time for assay parameter reduced from 1930 minutes to 790 minutes
- Throughput time for loss on drying parameter reduced from 502 minutes to 396 minutes

The cost efficiency for all analysis parameters is IDR 226,443.977 per year. This value is reduced by estimated costs of HPLC rent IDR 96,250,000. Thus, the total efficiency from the implementation of lean operation in the quality control laboratory are IDR 130,193,977 per year.

Conclusion and Implication

Lean operations have a significant impact on the efficiency process in the laboratory. In this study, there is a considerable cost efficiency of IDR 130,193,977 per year. It shows that non-added value activities have a significant impact on pharmaceutical companies. For being able to implement excellent lean operations, it requires continuous support from the management of PT. XYZ to make the implementation of the proposed improvement can run smoothly. Otherwise, support from management can improve personnel motivation, thus the personnel can be more motivated to provide better performance for the company.

This research focuses on the application of lean operations in the division analysis of raw materials from a quality control laboratory of pharmaceutical industry. Suggestions for further research are:

1. The research object selected for further research can be wider, so the application of lean operations can be seen from the other divisions or other departments in the pharmaceutical industry.
2. Future research can use other tools of lean operations that different from this study, thus in the end it can be concluded which tools are more effective for implementing lean operations, especially in the laboratory quality control of a pharmaceutical industry.

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