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Improving Work System by Reducing Setup Time Activity in Drying Room in Pharmaceutical Industry with Single Minutes Exchange Die (SMED)

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ABSTRACT

Pharmaceutical industry especially that move in generic products, have many kinds of products to be manufactured in its production lines with the shortest possible time. This condition causes the frequent of changeover process. This cause requires the company to further improve the effectiveness of the machine by reducing the time of changeover process in terms of setup and clean-up machine. In order to reducing the time of setup and clean-up activity use the method of approaches the SMED analysis method to reduce unnecessary motion waste (value added and non-value added derived from lean manufacturing). Before conduct the research, in the 5th production line was not in the Kanban system. So, it often occurs the changeover process. The longest changeover time is in the drying room. After that conduct the Time and Motion Study in order to know the detail setup activities in the drying room. This is due to problems in the working methods and environment factors. Based on data from observations made on the engine FBD, there are 49 activities comprising 44 internal activities and 5 activities that can be converted to an external. Then from 44 internal activities, only 43 were able to be combined activity of up to 11 activities. Results from this study is able to decrease setup time and clean-up on the machine FBD by 62.18%. Based on this result also, this can increase the productivity of the production line.

Keywords: Unnecessary motion waste, Lean Manufacturing, Value added, Non-value added, Changeover process, SMED.

ABSTRAK

Industri farmasi khususnya yang bergerak dalam produk generik, memiliki banyak jenis produk yang akan diproduksi di lini produksinya dengan waktu sesingkat mungkin. Kondisi ini menyebabkan sering terjadi perubahan proses. Hal ini mengharuskan perusahaan untuk lebih meningkatkan efektivitas mesin dengan mengurangi waktu perubahan proses dalam hal pengaturan dan pembersihan mesin. Adapun metoda yang digunakan dalam pendekatan penyelesaian masalah tersebut digunakan metode analisis SMED dengan tujuan untuk mengurangi gerakan yang tidak perlu yang berasal dari *lean manufacturing*. Sebelum melakukan penelitian, di jalur produksi ke-5 yang tidak menggunakan sistem Kanban, dimana sering terjadi perubahan proses. Waktu pergantian terlama terjadi di ruang pengeringan. Setelah itu dilakukan analisis *Time and Motion Study* untuk mengetahui detail pengaturan aktivitas di ruang pengeringan, dan diperoleh masalahnya disebabkan oleh metode kerja dan faktor lingkungan. Berdasarkan data dari pengamatan yang dilakukan pada mesin FBD, ada 49 kegiatan yang terdiri dari 44 kegiatan internal dan 5 kegiatan yang dapat dikonversi menjadi eksternal. Kemudian dari 44 kegiatan internal, hanya 43 yang mampu menggabungkan aktivitas sampai dengan 11 kegiatan. Hasil dari penelitian ini mampu menurunkan waktu setup dan pembersihan pada mesin FBD sebesar 62,18% dan berdampak pada peningkatan produktivitas lini produksi.

Keywords : gerakan yang tidak perlu, lean manufacturing, perubahan proses, SMED

1. Introduction

PT. HJ is a pharmaceutical company. The vision is to be a sustainable leading company in budgeted therapy segment enable by agility, innovation, and operational excellence and the mission is to build a healthier society through economical quality health products. Because of produced the generic product, this product very needed by the people. So, this company must be able to fulfil the market's demand. In order to fulfil the demand, the company must be improved to become more productive. There are some factors that influence the company productivity: machine condition, setup time, processing time, and etc. Setup time and processing time are very influence to the cycle time in production process. In order to become more productive, the company must decrease the setup and processing time. So, the company can fulfil the market's demand in generics pharmaceutical.

PT. HJ has 5 production lines. The 5th production line of PT. HJ is one of the production line that produce 10 kind of products in one month. This happen can cause more changeover process. In the 5th production line, there are 4 machines that operated by the operators. Based on the data (confidential) from the production department, the time that required in order to conduct the setup process or changeover process in the 5th line production especially in the drying room that use FBD machine is the longest one than the others. Changeover process is a setup process between after produce the product "A" and before produce the product "B" in order to prevent the contamination of the product quality.

Based on the data collection, the setup time for FBD machine in 5th production line needs 2.66 hours. Which means in available working hour per shift, in the setup time elements, FBD machine needs 33.25% of total available working hour in one shift (available working hour is 8 hours/shift). There are 2 shift over day in this company, and also 3 times of changeover process. It means the setup time for FBD machine in 5th production line needs up to 50% of total available working hour in a day.

By this problem, PT. HJ must decrease the time for setup and clean-up process in the production lines to make the production process become faster and also to maximize the using of available man hour to produce the product. Which mean, when the setup time can be decreased, the productivity of the company can be increased. By maximize the productivity of company also can reduce the labor cost. Single-Minute Exchange of Die (SMED) analysis method is one of the right methods to decrease the setup and clean-up time.

2. Methods

2.1 Time Study

Time Study is the method of settling up an allowed time standard in order to perform a given job or task based on the measurement of work content of the prescribed method with some allowance for ennui, personal, and unavoidable delays (go to the toilet, and so on). Meyers & Stewart (2002) states that there are three conditions that required to produce a product at work station (time standard): (1) a well-trained, qualified operator, (2) working at a normal rate, and (3) doing a specific task. There are some methods in the time study theory. One of them is about stopwatch time study method.

There are so many techniques that used by some practices in the time study aspect from 1980 – 2003. Table 1. shows time study techniques.Work study is divided in two groups in order to gain higher productivity. First group is a group of method studies which are used to simplify the job and develop more ergonomic methods of doing it. Second group is a group of work measurements which are used to find the time required to carry out the operation at a defined level of activity (Russell, Taylor, 2005)

Stopwatch time study is to measure how long it takes an average worker to complete a job at a normal procedure. A "normal" operator is defined as the qualified one, entirely experienced operator who is working under the standard regulation that prevail at the workstation, at a procedure that is neither slow nor faster, but representative of an average. According to Nakayama (2002), performance rating is a prevalent technique to determine the time required in order to perform a task by the qualified operator after the observed values of the operation under study been recorded.

Frederick W. Taylor is the father of Time and Motion Study. He developed it in 1881 when he started measuring time at a machine shop at home by clipboard and stopwatch. Now, the tools can change by digital stopwatch, barcodes, computers, and Accustudy Software (Izetbegovic, 2007).

Table 1. Time Study Techniques by Source

No.	Source	Time Study Techniques
1	Barnes, (1980)	• Standard Data • Work Sampling • Predetermined Time Standard System (PTS) • Stopwatch Time Study
2	Niebel, (1993)	• Stopwatch Time Study • Computerized Data Collection • Standard Data • Fundamental Motion Data • Work Sampling and Historical Data
3	Lawrences, (2000)	• Time Study • Standard Data Systems • Predetermined Time Systems (PTS) • Work Sampling • Physiological Work Measurement • Labor Reporting
4	Meyers and Stewart, (2002)	• Predetermined Time Standard System • Stopwatch Time Study • Work Sampling • Standard Data • Expert Opinion and Historical Data
5	Niebel and Freivalds, (2003)	• Time Study • Standard Data and Formulas • Predetermine Time System • Work Sampling • Indirect and Expense Labor Standards

Source: Nor Diana Hashim, '*Time Study Method Implementation in Manufacturing Industry*', A B.E Report, Universiti Technikal Malaysia, Melaka, 2008, P.10.

2.2 The Procedure to Conduct the Stopwatch Time Study

Generally, the following procedure is described in conducting stopwatch time study method:

1. Define the task that will be observed in order to measure the time to perform the task and also tell the purpose of the project to the operator that already chosen to help the project.
2. Choose the expert operators to perform the task that will be observed in order to make the similarity of variables.
3. Prepare all the equipment to conduct the time study analysis such as stopwatch, calculator, observation board, observation sheet, and stationary (pen, pencil, and eraser).
4. Notes all of the information that is closely related to the completion of work such as layout, machine specification, or other work equipment that used to perform the task, etc.
5. Record all of the work elements in detail using some technique in the stopwatch time study method.

2.3 Motion Study

Motion study is a body motion analysis when perform a task or job. The purpose of motion study is to eliminate or reduce the waste motion (Niebel, 2009). Motion study consists of dividing work into the most basic elements possible, analyze those elements separately and its relations one to another, and aimed to develop the method of least waste.

2.3.1 Macro Motion Study

Macro motion study conducted for factory flow or process. Any process can be studied by dividing it into process activity. The improvement can be found in the process by recognize those activities. The table 1 below shows the activities of macro motion study.

Table 1. Macro Motion Study Activity

Symbol	Activity	Definition
	Operation	Changes in the properties of the product
	Transportation	Changes in the location of the product
	Storage	Wait until needed
	Delay	Wait for start of operation, transportation or inspection
	Inspection	Confirmation that changes fits to specifications

2.4 Single Minute Exchange Die (SMED) Analysis

Single-Minute Exchange of Die (SMED) is one of the improvement method from Lean Manufacturing that used to accelerate time that takes to setup while changeover the product. Setup changeover time is one of the forms from waste in Lean concept that should be eliminated. Because it does not a value added to the customer and resulted in inefficient processes. SMED can called as QCO (Quick Change Over), 4SRS (Four Step Rapid Setup), OTS (One Touch Setup), and OTED (One Touch Exchange of Die) that all of them refer to the same thing, a strategy to accelerate setup and clean up time while in product turnover. All of this theory especially in SMED, it has an objective to reduce setup times in less than ten minutes, that is a number of minutes can be expressed by a single digit. According to the Shingo (1985), meanwhile not all setups can be literally reduced to this time, between one and nine minutes, this is goal of the SMED methodology.

Setup time can be defined as the length of time required when the last finished product was out until the production room able to continue to produce the other products. So, in the setup time there are several activities like stop the machine, maintenance, preparation the equipment for setup, changeover, and start-up. These activities are likely to be accelerated with the result that the setup changeover process more efficient.

2.4.1 The Procedure to Conduct the Stopwatch Time Study

There are four key steps in SMED analysis, as shown in figure 1 :

1. Internal and External
   From the field observation to get the data about time from the process activity. The process activity consists of set up, process, and clean up. After get the data, then the next is to separate the activity become internal and external activity.
2. Combine the Internal activities
   The next is to merge the waste internal activity. For example, make two activities become one activity or improve the workflow.
3. Improvement
   The final is to reduce the time in the internal activity using the creativity to make the tool, new process, and etc.
4. Standardization
   The final is to make the work procedure standard. The purposes of work procedure standard are to minimize the variability activity when conduct the setup and clean-up activity and also to prevent the misunderstanding in conduct the setup and clean-up activity.

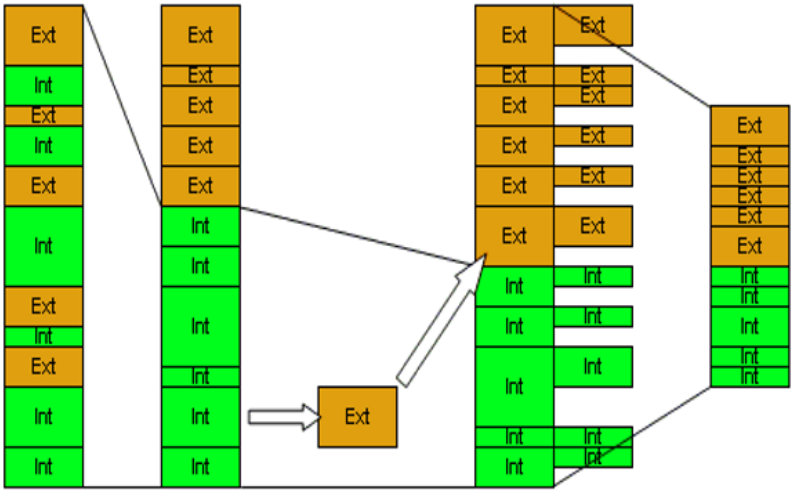

Figure 1. SMED Analysis by Shigeo Shingo, 1985

3. Result and Discussion

There are 5 lines production and 6 kinds of production rooms in the PT. HJ. The differences between the line 1 until line 5 are the product is coated or not and, for all lines will produce the product in tablet form except line 1 will produce the product in caplet form. Line 1 will produce caplet and do the film coting activity. Line 2 will produce tablet with the diameter less than 10mm and do the film coating or sugar coating activity. Line 3 will produce tablet with the diameter more than 10mm and do the film coating activity. Line 4 and 5 are plain production. That means there are no coating activity. Line 4 will produce the tablet with the diameter less than 10mm and line 5 will produce the tablet with the diameter more than 10mm.

Based on the daily production schedule, the materials will take into the compounding room. In the compounding room, all the raw materials will be processed by SMG (Super Mixer Granule) machine. In here the output from compounding room is wet granule. After that the wet granule will take into the drying room. In here the wet granule will dry by FBD (Fluid Bed Dryer) machine. The result from drying machine is dry granule. The dried granule will take into the final mixing room. In final mixing, the dried granule will add some lubricant, and anti-adherent in order to make the final mixing product become easy and ready to form become tablet. The half final mixing product will take into WIP room and to the Tableting room. Every process before stripping process, the inspector QC will take the sample from every result from each process to do the In Process Control (IPC). There are 2 kind of stripping machines; Chentai and Kunglong Machine. After that from stripping room, the product will have packed in the Secondary Packaging Floor and arrange the product on a pallet.

3.1 Data Collection

The collection data about the setup and clean-up activities in the compounding room and drying room in the 5th line with 3 times process of setup activities while changeover product.

The variables in collection the data are:

- The data is already normal distributed, uniform, sufficient, and homogeny.
- The operator that do the setup activities in the 5th line compounding room is one person.
- The operator that do the setup activities in the 5th line drying room is one person.
- The materials are easy to be cleaned.
- The setup activity time was counting from the last finished product out until the room machine able to start the production activity for the new type of product.

Based on the data collection, the table below shows about the comparison average between the total time of the setup activity for FBD machine. Because of the operator that conduct the setup and clean-up activity is one person, the list of activity result is all the same from the samples. So, the time in every activity can be averaged. This table below is show the detail setup and clean-up activity's average time in the drying room.

Table 2. The Average Setup Time and MLT

	Setup Time (Minutes)	MLT (2 shift)
Drying room	159.67	50%

The time average in order to conduct the setup activity in the drying room for FBD machine is 159.67 minutes. After that, the total available work in one shift is 8 hours. Then in one day there are 2 shift and 3 times in order to conduct the setup activity in the drying room 5^{th} line production for FBD machine. In the MLT (Manufacturing Lead Time) calculation, the setup time aspect is about 50% from the total of MLT.

3.2 Data Analysis

There are some steps to conduct the data analysis:

1. Doing the Cause and Effect Analysis in order to know what is the root causes that affect in 5 prominent factors. From the 5 factors, there are 2 factors that have the problems. The first is about method factor. That is no work procedure to conduct these setup activities and the work steps are not sequential and lack of technology for the cleaning tools such as Jet Cleaner and etc. After that, the second is about the environment. The problems for this factor are less number of cleaning tools and there is no the reserve of bag filter. So, it needs a lot of time to dry the bag filter using FBD machine.

2. Conduct the SMED analysis.
   - Separate the activities become internal activities and external activities.
     In this step, the initial data is consisting of 49 of internal activities. That activities separated become 44 internal activities and 5of external activities. After that the end result is the total time required to conduct the setup and clean-up activity is decreasing in 12.24 minutes from 159.67 minutes or in other words, the internal time is decreasing in 7.66%.

   - Merge the internal activities.
     In this step, the internal activities data from the last step will be combined. From 44 internal activities is combined become 11 internal activities. In this step also there are some improvement. The first one is for the long term improvement in the setup and clean-up activities will use the jet cleaner in order to accelerate the processing time and make the result is cleaner than use the common hose and provide the waterproof clothes with the models of shirts and pants. So, the operator's clothes did not become wet in the setup and clean-up process. The second one is replacing the use of chamois with the cotton waste in order to decrease the chance of contamination. The chamois can become the one factor that can cause the contamination. Because of the chamois is in the damp condition and also it can be a place to grow the fungus and bacteria. After that, change the work layout. Move the tank of maxiclean to the cleaning room not in the garbage room. So, there is no transportation waste anymore.

     The last is the continued improvement from the first step of SMED analysis. Provide the cleaning tools trolley with the dimension 1.2x0.6x0.75 in meter unit that will be used to deliver the cleaning tools into the room that will be cleaned. After that the end result is the total time required to conduct the setup and clean-up activity is decreasing become 108.55 minutes from 159.67 minutes or in other words, the internal time is decreasing in 32.02%.

   - Decrease the processing time in the internal activities using some improvement.
     The activity number 11 from the previous step analysis will be improved by make it become external activity with buy the laundry dryer machine and the reserve of bag filter. The cost for the laundry dryer machine and the reserve of bag filter are confidential from the vendor. From this improvement, after the operator already wash the bag filter, the operator will assemble the reserve of bag filter to the FBD machine. And the as the last activity is to drop all the cleaning tool and the wet bag filter to the cleaning room. After that the operator can perform the drying wet bag filter activity in the cleaning room after the setup and clean-up process. After that the end result is the total time required to conduct the setup and clean-up activity is decreasing become 60.39 minutes from 159.67 minutes or in other words, the internal time is decreasing in 62.18%.

- Do the standardization.
  This step is to make the work procedure standard. The purposes of work procedure standard are to minimize the variability activity when conduct the setup and clean-up activity and also to prevent the misunderstanding in conduct the setup and clean-up activity.

3.3 Analysis of Result

3.3.1 Activity

From the data collection, there are 49 internal activities. After that, using the SMED analysis, the activities separate become 44 internal activities and also 5 external activities. After that some internal activities combined based on the part that will be cleaned. From the combination of the internal activities there are just 11 internal activities. After that all of these 11 internal activities will have some improvement and also make it become a work procedure standard in order to conduct the setup activity in the drying room that using Fluid Bed Dryer Machine. This figure below shows about the analysis of result of activity.

3.3.2 Saving Time

After conduct all the stem in the SMED analysis, from the first step about convert the internal activity become external activity can be decreasing up to 7.66% or can be decreasing 12.24 minutes from 159.67 minutes. After that the second step about merge the internal activity. From this step can decrease the time that needed to conduct the setup and clean-up activities up to 32.02% or can decrease until 108.55 minutes from 159.67 minutes. Then the third step as the last step improvement is do the improvement's plan, the time which required 60.39 minutes decreased until 159.67 minutes. In other words, the improvement using SMED analysis can accelerate the time in order to conduct the set up and clean-up activities until 62.18%. The figure below shows about the analysis of result of setup time.

3.3.3 Profit

From this research also indirectly can optimize the direct labour cost per shift. The direct labour cost per shift in this research is IDR 149.000. In other means, before this research, the operator just can produce the products in 5.3 hours or 66.25% of their salary per shift. After conduct this research, the operator can produce the products in 6.9 hours or 86.25% of their salary per shift. This mean the operator can optimize the direct labour cost per shift and also with assumption the profit of the company will be increase because of the changeover time is decrease. This figure above shows about analysis of result of profit.

4. Conclusion

There are so many external activities in setting up and clean up the Fluid Bed Dryer (FBD) Machine. Based on the Ishikawa Diagram, there are some problem in the method factor and environment factor. After conduct the steps in the Single Minute Exchange Die (SMED) analysis based on the cGMP (current Good Manufacturing Practices). From the first step about convert the internal activity become external activity can be decreasing up to 7.66% or can be decreasing 12.24 minutes from 159.67 minutes. This step also can convert 5 internal activities become external activities.

After that the second step about merge the internal activity. From this step can decrease the time that needed to conduct the setup and clean-up activities up to 32.02% or can decrease until 108.55 minutes from 159.67 minutes. Then the third step as the last step improvement is do the improvement's plan, the time which required 60.39 minutes decreased until 159.67 minutes. In other words, the improvement using SMED analysis can accelerate the time in order to conduct the set up and clean-up activities until 62.18%.

From this, the fourth step is about to make it become standardize that will bring the equality method for every operator that will conduct the setup and clean-up activity in the FBD machine. So, because of the changeover processing time can decrease up to 62.18%, the company can be become more productive in order to produce their product.

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Appendix

Table before SMED Analysis

No.	Activity	Time (minutes)	Internal/ External
1	Fill the cleanliness label and Master Production Procedure	3.80	I
2	Dispose the trash from the production process	2.70	I
3	Take the hose and bucket	3.53	I
4	Take the maxiclean	2.36	I
5	take the basket	1.82	I
6	Release the mesh from the containers	2.67	I
7	Dispose the granule residue in the mesh of container	1.43	I
8	Release the silicone seal of FBD machine	0.40	I
9	Bring down the bag filter of FBD machine	0.81	I
10	Take the cotton waste	0.28	I
11	Shut down the FBD machine	0.34	I
12	Release the bag filter from the hook	0.92	I
13	Release the bag filter from the O ring	0.78	I
14	Soak the bag filter in the basket that already fill with maxiclean	1.86	I
15	Install the hose	0.57	I
16	Hose down the mesh and the container using the tap water	0.58	I
17	Hose down the inside part of the FBD machine using tap water	3.09	I
18	Hose down the outside part of the FBD machine using tap water	1.39	I
19	Hose down the shovel, mortar, and pestle using tap water	0.57	I
20	Hose down the O ring of bag filter	0.53	I
21	Scrape the containers	3.74	I
22	Clean the containers using maxiclean	4.29	I
27	Clean the O ring of the bag filter using maxiclean	0.66	I

No.	Activity	Time (min)	Internal/ External
28	Rinse the containers using tap water	2.18	I
29	Rinse the inside part of the FBD machine using tap water	2.18	I
30	Rinse the outside part of the FBD machine using tap water	1.31	I
31	Rinse the shovel, mortar, and pestle using tap water	0.90	I
32	Setup the jet cleaner	2.16	I
33	Rinse the mesh of the containers with tap water using the jet cleaner	4.28	I
34	Tidy up the jet cleaner	3.23	I
35	Wash the bag filter of FBD machine and soak it using the purified water	4.22	I
36	Tidy up the hose	0.44	I
37	Store the hose, jet cleaner, and take the chamois and wiper	2.25	I
38	Damp the chamois with the purified water	0.55	I
39	Wipe the container using chamois	5.48	I
40	Wipe the shovel, mortar, and pestle using chamois	1.48	I
41	Wipe the mesh of containers using chamois	3.60	I
42	Wipe the inside part of the FBD machine using chamois	4.00	I
43	Wipe the outside part of the FBD machine using chamois	6.57	I
44	Wash the bag filter of FBD machine	1.73	I
45	Wipe the floor using wiper	9.90	I
46	Install the silicone seal of FBD machine	0.41	I
47	Dry the bag filter using FBD machine	50.38	I
48	Mop the floor	4.91	I
49	Return all the cleaning tool	1.93	I
TOTAL		159.67	

Table after SMED Analysis

No.	Activity	Time (minutes)	Internal/ External
1	Fill the cleanliness label and Master Production Procedure	3.80	I
2	Prepare all the equipment for setup and clean-up activity	3.30	I
3	Bring down the bag filter of FBD machine and soak it with the maxiclean	3.45	I
4	Hose down and wash the shovel, mortar, and pestle with the jet cleaner using tap water and clean up them with maxiclean	3.55	I
5	Disassemble the containers, hose down and wash it with jet cleaner using tap water and clean up with maxiclean.	8.47	I
6	Hose down and wash the FBD machine with jet cleaner using tap water and clean up with maxiclean	10.60	I
7	Wipe the FBD machine, containers, and the tools (shovel, mortar, and pestle) using the cotton waste which already damp with purified water	9.42	I
8	Wash the bag filter of FBD machine and soak it with purified water	2.33	I
9	Wipe the floor and sanitized the room	10.22	I
10	Assemble the containers and install the silicone seal of FBD machine	3.03	I
11	Storage all the cleaning tools in the cleaning room	2.22	I
TOTAL		60.39	