Case Study: Application of SMED on a Packaging Line in a Pharmaceutical Industry

Estudo de caso: Aplicação do SMED numa Linha de Embalagens de uma Indústria Farmacêutica

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ABSTRACT

Corporate organizations are constantly facing competitiveness in the business environment. In the pharmaceutical sector, this search for advantages over other sectors occurs mainly through the reduction of drug production costs. The strategic objective is to reduce sales prices and increase product acceptance by the target audience. In this context, the SMED methodology emerges as an essential tool to promote improvements in production processes. Its purpose is to optimize time and increase operational flexibility. This study presents a case analysis in a large pharmaceutical industry, seeking to evaluate the effectiveness of SMED in the standardization and optimization of configuration activities (SETUP) in a solid drug packaging line. The application of the four steps proposed by Shingo, creator of the method, showed conclusive results. SETUP time was reduced by 73.8% compared to the initial period, increasing the availability of equipment for production and demonstrating the efficiency of the system.

KEY-WORDS: Optimization, operational efficiency, SMED methodology and pharmaceutical industry.

RESUMO

Organizações corporativas enfrentam constantemente a competitividade no ambiente empresarial. No setor farmacêutico, essa busca por vantagens sobre outros setores ocorre principalmente através da redução dos custos de produção de medicamentos. O objetivo estratégico é diminuir os preços de venda e ampliar a aceitação dos produtos pelo público-alvo. Nesse contexto, a metodologia SMED surge como uma ferramenta essencial para promover melhorias nos processos produtivos. Seu propósito é otimizar o tempo e aumentar a flexibilidade operacional. Este estudo apresenta uma análise de caso em uma indústria farmacêutica de grande porte, buscando avaliar a eficácia do SMED na padronização e otimização de atividades de configuração (SETUP) em uma linha de embalagem de medicamentos sólidos. A aplicação das quatro etapas propostas por Shingo, criador do método, mostrou resultados conclusivos. O tempo de SETUP foi reduzido em 73,8% em comparação ao período inicial, aumentando a disponibilidade dos equipamentos para produção e evidenciando a eficiência do sistema.

PALAVRAS-CHAVE: Otimização, eficiência operacional, metodologia SMED e indústria farmacêutica.

1 INTRODUCTION

The pharmaceutical market is increasingly competitive and demanding. This, in view of their need and interest in complying with the parameters of quality, safety, and good manufacturing practices, thus guaranteeing the safety of their products. These factors drive companies to look for new tools, such as Heijunka, Andon, and Jidoka. This is because the use of such tools brings greater credibility to the products available on the market, especially in terms of quality **[1]**. However, the implementation of such tools is not always enough to balance the production process in terms of cost and quality.

In fact, it is evident that this sector has a great need to optimize its production processes, thus aiming to reduce waste, such as equipment failures, security failures, losses with reprocessing, and setup time. The latter can be divided into activities that could only be performed when the machine is stopped (internal setup) and activities that could be performed with the machine running (external setup) **[2]**.

The reduction in the execution time of SETUP activities has become one of the focuses of industrial processes with the perspective of increasing their productive capacity. The intimate relationship between the reduction of production costs and sales costs makes the continuous search for the optimization of production processes essential. Therefore, it is necessary to identify and eliminate bottlenecks that limit production in production systems **[3].**

In addition to issues related to production quality, it is worth emphasizing the importance of production capacity in terms of product variety within an industrial sector. In the pharmaceutical industry, there are several types of drugs available on the current market, with different formulations, packaging, and physical forms. If, however, there were a specific production line for each type of medicine, its survival in the field would become unfeasible.

Thus, in this type of industry, a single production line can be used to produce different types of drugs. For this purpose, at each setup period, stops are made to configure production parameters and change machine tools. Stops that become points of concern in terms of financial losses related to equipment availability and productivity.

In this context, the SMED (Single Minute Exchange of Die) or TRF (Rapid Tool Exchange) methodology emerges as a great ally in optimizing the time allocated to changing machinery tools in the respective. In this way, a greater variety of products is possible, reducing one of the main sources of losses within the productive sector of the pharmaceutical industry. Invented by industrial engineer Shigeo Shingo, the SMED method was recognized for its success in reducing setup time when implemented in Japanese companies **[2]**.

Due to the problem related to the losses related to the setup time and the variety of drugs produced in the pharmaceutical industry, the objective of this work is to analyze the performance of the application of the SMED method, aided by the standardization and optimization of the internal and external setup activities, in line with solid medicine packaging for a large pharmaceutical industry located in the state of Pernambuco. This objective will be achieved through the collection of data from activities carried out during setup, the application of SMED, and the evaluation of setup times before and after the application of SMED.

2 THEORETICAL REFERENCE

SMED is one of the main methods of lean manufacturing for reducing waste in manufacturing processes. This method provides a fast and efficient way to convert a manufacturing process from running the current product to running the next product. Quick changeover is essential for reducing production batch sizes, thereby improving workflow. The need for implementing SMED and quick changeover programs has become more relevant than ever, due to the increasing demand for product variability, reduced product life cycles and the need to significantly reduce inventories **[4]**.

According to Cusumano **[5]**, Ohno, one of the creators of the Toyota Production System, came across Danly Machine's quick setup presses in Chicago in the mid-1950s and discovered the great solution that reducing setup time offered for production in small batches and reduction of inventories. He hired Shingo to develop the methodology at Toyota. **[6;7].**

The original application of SMED was summarized in the book SMED _ revolution in -manufacturing _ **[8]**. According to the author, the method must be applied in phases, with the three phases that compose it being: PHASE 0 – There is no distinction between internal and external operations PHASE 1

– Separation of internal and external operations PHASE 2 – Conversion of internal operations into external ones PHASE 3 – Improvement of exchange operations. The correct identification of internal and external operations is a critical success factor in the implementation of the SMED methodology, being **[9]**:

• Internal Operations: activities that have to be carried out while the machine is stopped, that is, when it is not producing.

• External Operations: these are, in turn, activities that can and should be carried out while the machine is in operation, that is, producing.

According to Braglia et al. **[10]**, the question of how to operationally apply the SMED concept to different industrial settings and situations has received great attention from scholars. As a result, the development of tools to support and improve SMED analysis and implementation at all stages is embraced by practitioners and researchers.

3 METHODOLOGY

The application of the SMED method was carried out in the primary packaging line, which focuses on solid medicines. The line is made up of high-performance equipment, such as the thermoforming machine, for example, which is the object of study in this work. On this equipment, various types of pills are produced, which represent 40% of the monthly production volume of the site under study. The equipment chosen for the study was the thermoformer, which is responsible for forming the packaging in the machine itself. After analyzing the setup time of the subsets of this line, the thermoformer was identified as the biggest bottleneck.

The primary packaging line is defined as being where the operator has direct contact with the formulated product still in bulk; that is, the medicine does not yet have packaging. Therefore, the protective equipment to be used, as well as the cleaning process to be carried out, are well defined and controlled, following safety and hygiene standards.

After the arrival of the formulated product, still in bulk, in the primary area, the equipment is filled by the operator, and the product is inserted into a funnel, moving by gravity. The primary phase of the packaging process and its steps, which occurred in the thermoforming machine, can be seen in the flowchart shown in figure 1.

Each step of this process proceeds as follows:

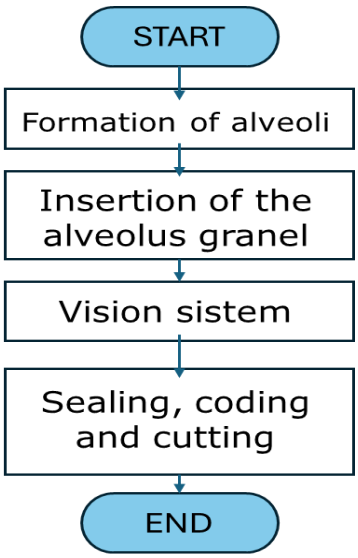
• Formation of the alveoli: this is where the formation of "holes" occurs in a polymeric base, containing the final form of the pills that will be allocated in the packaging process.

• Insertion of the bulk formulation into the alveoli: in this step, the tablets, already pressed in the respective format, are inserted into the alveoli. The tablets are directed to a vibrating sieve from a funnel and are subsequently taken to the alveolated polymeric mold, known as a blister. With the aid of a rotating brush, the filling of each alveolus is guaranteed.

• The vision system: is a very important step in the process. It is responsible for verifying and guaranteeing the total filling of the alveoli in the polymer mold. If the system perceives one or more empty blisters, the equipment stops automatically, and the defective blister is expelled from the production sequence. An audible alarm is echoed for the operator to make the appropriate adjustments, continuing the process.

• Sealing, coding, and cutting: this is a very important stage, not only for the production process but also for after-sales. The sealing procedure is carried out through the thermoforming process, which essentially consists of heating a sheet of thermoplastic material that, when flexible, is forced against the contours of a mold. In this way, the blister is finally sealed, allowing the coding process to be carried out. In this step, the product batch is marked on each blister and then cut.

Figure 1 – Flowchart of the primary packaging process.



Source: prepared by the authors.

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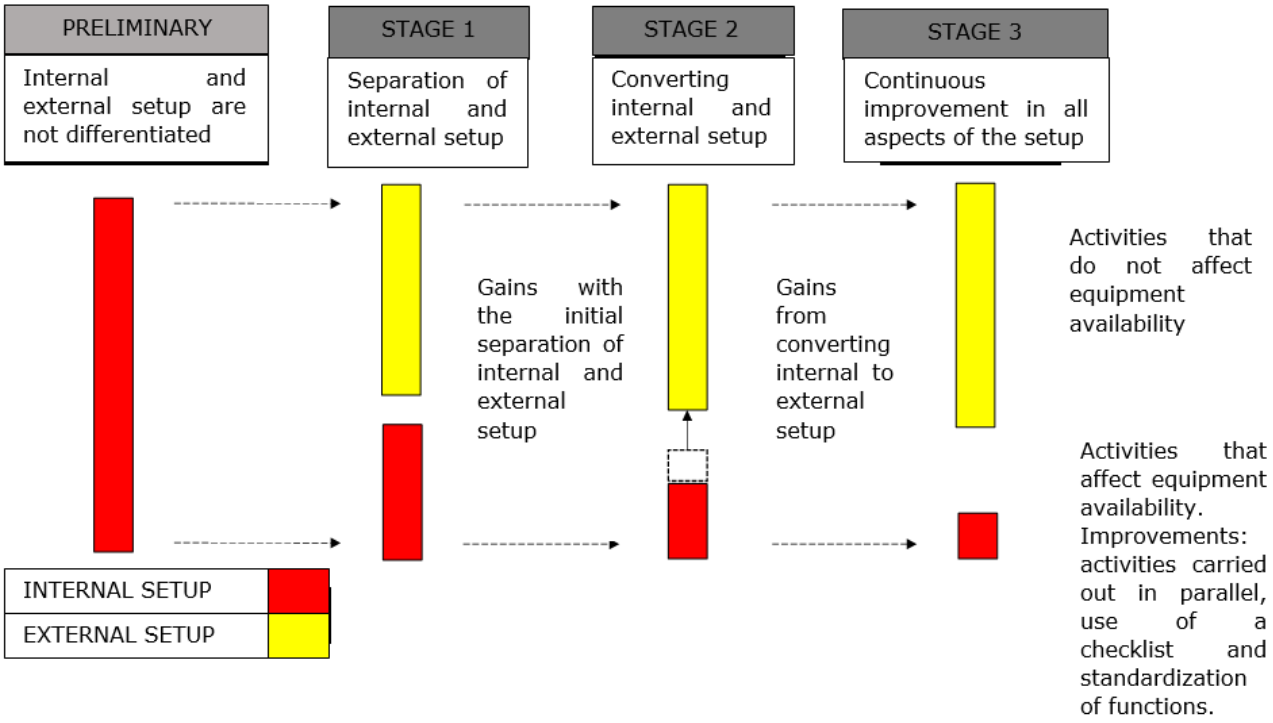

Figure 2 – SMED application stages
Source: Shingo **[2]** Adapted.

Considering each of the steps described the application of the SMED methodology was carried out using the internship techniques listed by Shingo **[2]**, as shown in figure 2 and described below.

3.1 PRELIMINARY STAGE - INTERNAL AND EXTERNAL SETUP CONDITIONS

Once the preliminary period in the need for tool exchange was defined, the internal and external setup conditions could be defined. It is worth noting that the internal setup has delimited the stages of the procedure that can only be carried out on the stalled production line. The external setup delimited the activities that could occur with the line in operation. Periods of operators' travel to the production area, as well as production cycle data-pointing activities, are also adhered to during setup time.

According to Shingo **[2]**, the determination of the time of performance of setup activities is made possible using a timetable, the conduct of the study of the method, the interview with operators, or the analysis of the filming of the operation. In addition, the holding of routine meetings with the workers of the production line is important in the decision-making process related to internal and external setup tasks.

Data collection was carried out using the mean setup time on the line before applying the SMED as a reference. This survey was carried out over a period of three (03) months before the implementation of the method. The data were obtained through the history of information from the beginning and end of all tool changes that occurred on the line under study. In this way, field research was carried out through the monitoring and observation of the setup execution carried out by the line operators. All activities performed related to tool changes were considered and timed.

3.2 STAGE 1 - SEPARATING INTERNAL AND EXTERNAL SETUP

This phase corresponds to the organization of activities, with the respective classification in internal or external setup. Shingo **[2]**, stated that an in-depth study should be carried out and directed so that a maximum number of activities can be carried out during the external setup process, aiming to minimize non-productive periods.

This stage is considered the most important in relation to the others due to its power of reduction

in the non-productive period of the line, which can be from 30% to 50% **[11; 12; 2]**. To guarantee an efficient setup process, techniques of analysis of SETUP tasks were used, according to SHINGO **[2]** and SUGAI et al **[7].**

Among these are: a checklist of components and execution steps; verification of components and tools used, as well as the operating conditions in the respective areas; and observation of opportunities for improvement in the transport of matrices and other components. Having defined the activities after the field research, they could be properly classified according to the type of setup.

3.3 STAGE 2 - CONVERTING INTERNAL SETUP TO EXTERNAL

In the second stage, the activities defined in the first stage must be examined again to ensure that there is no external setup activities defined as internal and vice versa. New perspectives on traditional processes must be adopted. It is important to point out that, in stage 2, the focus is on reducing the total setup time: it aims to guarantee the earliest return of the productive period of the production line under study **[12;2]**.

3.4 STAGE 3 - SYSTEMATIC IMPROVEMENT OF EACH ACTIVITY

Shingo **[2]** knew that the pursuit of the single minute (single digit) could not be achieved in the previous stages, requiring continuous improvement of each element, both internal and external setup. So, he proposed a last stage, which would induce continuous improvement of the operating tasks involved in the process.

Thus, the standardization of TRF activities initiated the last stage of SMED: the ECRS analysis (Delete, Combine, Reorganize and Simplify). This analysis aims to find and propose ideas so that the activities that are carried out during setup could be done in a faster and simpler way, to optimize their duration. After the analysis, the activities of the new setup pattern could be defined and standardized. A small group of operators were trained so that the activities could be put into practice.

Monitoring of the execution of the tasks of the new setup model was carried out, with the objective of supporting the operators involved and verifying its success. The new standard focused on improving the tooling assembly and disassembly pattern, as well as related activities. It was also observed that there was a need to include people in the execution of the tasks involved. This evaluation allowed for the revision and improvement of the proposed activities.

All the operators on the study line could receive training on the new SETUP model after all the adjustments had been made. The operators were split up into groups according to their activities, where they became experts in those tasks. Greater learning agility during training was attained in this method. Both internal and external activities were included in the activities, which reduced the unproductive time. Finally, the production data could be analyzed after the implementation of SMED, focusing on the average setup time and equipment availability period. A comparison was made between the data obtained before and after the implementation of SMED.

4 RESULTS AND DISCUSSION

The results presented were analyzed before and after the implementation of SMED in the packaging line of a pharmaceutical industry. The objective of this analysis was to evaluate the effectiveness of the SMED methodology in reducing setup time and increasing operational efficiency.

4.1 PRELIMINARY STAGE - INTERNAL AND EXTERNAL SETUP CONDITIONS

In the second stage of SMED, the team identifies elements that can be performed off-site while the machine is still in operation. These include cleaning, inspections, quality checks, tool preparation and material recovery. Performing these tasks off-site minimizes downtime and increases changeover efficiency **[13].**

During the field research, the activities performed during the setup were observed and timed during their execution. Three (03) setup procedures were monitored, one (01) per shift, and the information from Table 1 was obtained. In this table, thirty-three (33) activities are identified, which are carried out during the tool change, taking a total of 382 minutes.

It is important to highlight that the setup time is understood as the period between the last unit produced in one cycle and the first unit of the subsequent cycle **[14]**. It was observed that there was no defined sequence for the execution of tasks. Only one (01) operator performed the setup activities per shift, in the order he found most convenient.

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Table 1 - SETUP activities before the application of SMED.

SETUP - BEFORE SMED					
STEPS	**ACTIVITIES DISCRIPTIONS**	**TIME (min)**	**STEPS**	**ACTIVITIES DISCRIPTIONS**	**TIME (min)**
1	Operator begins SETUP by completing the documentation for the previous batch/product.	15	19	Operator performs complete cleaning of the equipment.	10
2	Operator moves from the primary area to the secondary area.	2	20	Operator moves from the primary area to the cleaning staff room.	6
3	Operator checks with the secondary area operator if the next batch/product documentation is available.	5	21	Operator requests and releases the general cleaning of the primary area line.	5
4	Operator moves from the primary area to the material stage.	5	22	Operator moves from the cleaning staff room to the primary area.	6
5	Operator checks if materials for next batch/product are available.	8	The next two (02) activities take place in parallel		
6	Operator moves from the material stage to the tool room.	5	23	Cleaning staff perform general cleaning of the room.	20
7	Operator checks if tooling for next batch/product is available.	30	24	Operator checks and assigns the parameters of the next batch/product that will be packed.	10
8	Operator moves from the tool room to the primary area.	5	The two (02) previous activities are completed		
9	Operator weighs and arranges the material from the previous batch/product on the pallet.	10	25	Operator assembles the tooling.	65
10	Operator moves from the primary area to the material lock.	3	26	Operator performs the mechanical adjustment checklist.	20
11	Operator removes all material from the previous batch/product.	15	27	Operator moves from the primary area to the material stage.	2
12	Operator moves from the material hatch to the tool room.	8	28	Operator places the next batch/product materials on the pallet.	4
13	Operator searches the cart to collect the tools from the previous batch/product.	5	29	Operator moves from the material stage to the primary area.	2
14	Operator moves from the tool room to the primary area.	8	30	Operator takes the inputs to the packaging line.	5
15	Operator disassembles the tools and places them in the designated cart.	50	31	Operator supplies the machine with inputs (PVC film and/or aluminum film and bulk).	10
16	Operator moves from the primary area to the tooling washing room.	7	32	Operator starts filling out the documentation for the next batch/product.	10
17	Operator leaves trolley with tools for washing.	4	33	Operator turns on the equipment, makes the last adjustments and closes SETUP.	15
18	Operator moves from the tool washing room to the primary area.	7			

Source: prepared by the authors.

4.2 STAGE 2 - CONVERTING INTERNAL SETUP TO EXTERNAL

During the monitoring phase, it was observed that all tasks were defined as internal configuration tasks, that is, performed with the machine stopped. To optimize the process, a detailed analysis was carried out with the area managers, identifying which tasks could be reclassified as external configuration. Only the activities that necessarily required equipment shutdown were maintained as internal configuration tasks. This distinction between internal and external configuration is essential to minimize downtime and increase operational efficiency.

Out of the thirty-three (33) setup tasks that were performed, eleven (11) were identified as external setup tasks. These include tasks numbered 1 to 8 and 12 to 14, as shown in Table 1. Thus, it is possible to observe that of the three hundred and eighty-one two (382) minutes of total SETUP, ninety-six (96) minutes could be converted into external SETUP, that is, into productive time of the study line. This accounts for 25.1% of the setup time that was previously lost in productivity due to tool change-related activities. The remaining twenty-two (22) activities continued to be classified as internal setup, representing 286 minutes.

Of activities defined as external SETUP, 34.4% are displacement activities, representing thirty-three (33) minutes. These are the activities: 2, 4, 6, 8, 12 and 14. According to Koskela **[15]** the activities of transport, waiting and inspection do not add value to the final product. In this way, the management of these is an important step in the optimization of production processes.

4.3 STAGE 2 - CONVERTING INTERNAL SETUP TO EXTERNAL

After the separation of internal and external activities, meetings were held with the operations team and production managers to assess whether there were any remaining internal activities that could be converted to external setups. After a detailed and in-depth analysis, it was decided that activities numbered 20 through 22 and activity 32 would be reclassified as external setups. This reclassification is essential to streamline the setup process, reducing machine downtime and increasing operational efficiency. Converting internal activities to external ones allows for greater flexibility and agility in production, contributing to a more continuous and efficient workflow, aligned with the principles of integrated manufacturing.

By converting these four (04) activities, an additional gain of 27 minutes was achieved, corresponding to a 9.4% reduction in non-productive time during tool change. This calculation takes into account the period assigned for internal setup at the end of stage 1. Thus, considering the total setup duration, by the end of stage 2, a conversion of 32.2% of setup time into productive period was achieved.

4.4 STAGE 3 - SYSTEMATIC IMPROVEMENT OF EACH ACTIVITY

In this step, an ECRS analysis was performed with the aim of finding faster and simpler ways to execute internal activities, optimizing setup time. The ECRS analysis aims to E - Eliminate, C - Combine, R - Reorganize and S - Simplify activities. Table 2 presents the activities analyzed together with the respective actions to be taken. Eliminating unnecessary activities, combining similar tasks, reorganizing processes for greater efficiency and simplifying complex procedures are key strategies to reduce setup time and increase operational efficiency. This systematic approach is crucial to improving performance and productivity in the manufacturing environment.

Out of the remaining eighteen (18) activities in internal setup, none could be eliminated. However, it was observed that seventeen (17) of them could be performed in parallel, except for task number 33, as presented in Table 3. Therefore, the addition of one (01) operator in the tool change execution and two (02) people in the cleaning team was necessary, resulting in a total of two (02) and four (04) team members respectively for their respective activities.

According to the ECRS analysis, five (05) activities could be simplified (activities number 15, 23, 25, 31, and 33), thus reducing the execution time. Activity number 23 (general room cleaning) saw a reduction of 10 minutes in the time dedicated to its execution.

In the execution of activities number 15 (the operator performs disassembly

of tooling) and 25 (operator assembles the tools), there was no prior planning followed. This was because they were considered actions that did not affect product quality. However, they did impact the required time for tool change. The ECRS analysis allowed the identification of the significant amount of time dedicated to these activities, enabling the implementation of improvement actions. The company, as the owner of the equipment project used on the line, was consulted, and information regarding the best order and method for disassembling and assembling the tooling was obtained.

The assignment of number 31 (supplying equipment with inputs) was simplified by providing the operator with guidance: the need to supply the equipment with inputs, starting from the closest point to the machine and progressing to the furthest point, always following this sequence.

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Table 2 - Application of ECRS analysis in internal setup activities.

	DESCRIPTION OF ACTIVITIES	ANALYSIS			
		E	C	R	S
9	Operator weighs and arranges the material from the previous batch/product on the pallet.		x		
10	Operator moves from the primary area to the material lock.		x		
11	Operator removes all material from the previous batch/product.		x		
15	Operator disassembles the tools and places them in the designated cart.		x	x	x
16	Operator moves from the primary area to the tooling washing room.		x		
17	Operator leaves trolley with tools for washing.		x		
18	Operator moves from the tool washing room to the primary area.		x		
19	Operator performs complete cleaning of the equipment.		x		
23	Cleaning staff perform general cleaning of the room.		x	x	
24	Operator checks if he assigns the parameters of the next batch/product that will be packed.		x		
25	Operator assembles the tooling.		x	x	x
26	Operator performs the mechanical adjustment checklist.		x		
27	Operator moves from the primary area to the material stage.		x		
28	Operator places the next batch/product materials on the pallet.		x		
29	Operator moves from the material stage to the primary area.		x		
30	Operator takes the inputs to the packaging line.		x		
31	Operator supplies the machine with inputs (PVC film and/or aluminum film and bulk).		x		x
33	Operator turns on the equipment, makes the last adjustments and closes SETUP.			x	x

Source: prepared by the authors.

Table 3 - Internal SETUP activities after application of SMED.

INTERNAL – SETUP			
DISCRIPTION OF ACTIVITIES		TIME (MIN)	OPERATORS
3. Operator checks with the secondary area operator if the next batch/product documentation is available.	15. Operator disassembles the tools and places them in the designated cart.	30	OP1/OP2
9. Operator weighs and arranges the material from the previous batch/product on the pallet.			
11. Operator removes all material from the previous batch/product.			
16. Operator moves from the primary area to the tooling washing room.	19. Operator performs complete cleaning of the equipment.	10	OP1/OP2
17. Operator leaves trolley with tools for washing.			
18. Operator moves from the tool washing room to the primary area.			
21. Operator requests and releases the general cleaning of the primary area line.	32. Operator starts filling out the documentation for the next batch/product.		E.L./OP
24. Operator checks and assigns the parameters of the next batch/product that will be packed.	25. Operator assembles the tooling.	35	OP1/OP2
27. Operator moves from the primary area to the material stage.			
28. Operator places the next batch/product materials on the pallet.			
29. Operator moves from the material stage to the primary area.			OP1/OP2
30. Operator takes the inputs to the packaging line.			
31. Operator supplies the machine with inputs (PVC film and/or aluminum film and bulk).			
26. Operator performs the mechanical adjustment checklist.		10	OP1/OP2
33. Operator turns on the equipment, makes the last adjustments and closes SETUP.		5	OP1/OP2

Source: prepared by the authors.

Finally, activity number 33 (turning on the equipment and performing final adjustments) had its execution time reduction conditioned to the task being performed by two (02) operators together. After ECRS analysis and improvement proposals, the internal SETUP could be defined in accordance with Table 3.

During the ECRS analysis, it was found that activities number 9, 3, and 11, respectively, could be performed in parallel with activity 15. This can be achieved if one of the operators (OP1/OP2) performs the first three mentioned activities, while the other performs the number 15. The first three activities are executed outside the equipment, whereas the last one is performed on the machine.

Activities 16, 17, and 18, on the other hand, could be directed to one operator, while the second one performs activity number 19 in parallel. This execution organization follows the same reasons cited for the activities in the previous paragraph. While the cleaning team performs the general cleaning of the room (activity number 21), both operators fill out the documents for activity number 32. This is to avoid cross-contamination between medications.

Activities 24, 27-31 can be performed by one operator, while the other performs activity number 25. It is important to note that the operator added to the process was included only to assist in the SETUP. Thus, while the machine is producing, they remain on their original line. Another relevant point is that while the line operator performs activities that require more equipment knowledge, the additional operator performs more general activities. Activities number 26 and 33 occur without a sequence and are performed by both operators, reducing the total time of these activities from 35 to 15 minutes.

At the end of this stage, most activities were combined or simplified, resulting in a reduction from 259 to 100 minutes. That is, what used to take 4.3 hours is now completed in 1.7 hours. These data represent a 61.4% reduction in SETUP time during stage 3. Compared to the initial setup period, there is a 73.8% reduction percentage, which is considered a very encouraging result.

According to Santos **[16]**, the internal SETUP procedure is considered one that does not add value to the process since no production occurs during this period. Thus, the ideal time for its execution is zero. The closer it is to zero, the lower the associated cost, in addition to being directly related to the time dedicated to external SETUP, resulting in greater productivity.

4.4 RESULT AFTER APPLICATION OF SMED

Based on the analyses and proposed modifications, the results of the new internal and external setup model were presented to the line operators, who underwent training for the definitive implementation of the new setup standard.

A comparison of the average setup times of the studied line was conducted before and after the application of SMED. The monitoring took place between October and December, and January to March, without and with the application of SMED, respectively. The collected data is available in Table 4.

Table 4 - Mean SETUP times before and after SMED application

Month	Nº of SETUPs	Mean SETUP time (h)
without SMED		
OCT	52	7,1
NOV	48	6,9
DEC	35	7,2
with SMED		
JAN	32	2,1
FEB	55	1,8
MAR	58	1,7

Source: prepared by the authors.

In Table 4, it can be observed that in October, the average setup time was 7.1 hours for 25 tooling changes. In November, the average dedicated time was 6.9 hours for 18 changes. In December, with 35 SETUPS, the average change time was 7.2 hours. According to the data from the respective table, it can be concluded that the average change time does not vary significantly when compared to each other, considering the number of batches produced.

Regarding the data from Table 4 obtained after the application of SMED, it can be observed that in January, the average setup time was 2.1 hours for 32 tooling changes. In February, the average was 1.8 hours for 55 changes. Finally, in March, there were 58 setups processes with an average change time of 1.7 hours.

The number of SETUP procedures performed varies according to demand and production scheduling. Figures 3 and 4 show that in December and January, the number of batches produced was the lowest. This is justified as pharmaceutical industries usually have collective vacations during these respective months, which affects the resulting production.

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When comparing the highest average time observed, in October before the application of SMED (7.1 hours), with the highest average time after the methodology was applied (2.1 hours), a reduction of 70.4% in SETUP time is observed. The same comparison can be made with the lowest average times observed (6.9 hours and 1.7 hours, respectively), resulting in a reduction of 75.4%.

When examining the average time related to the number of changes after the modifications (Table 4), variations of 0.3 hours between January and February, as well as 0.1 hours between February and March, can still be noticed. This is likely due to the operators' learning process, as it is a new routine that requires a logical and synchronized sequence of execution. In March, the average SETUP time was 1.7 hours, indicating that the theoretical time determined through SMED was achieved.

According to Campos **[17]**, there are several benefits associated with quick tool change, including:

- Increased equipment availability through reduced SETUP time.
- Enhanced flexibility in producing small and diverse batches, leading to significant inventory reduction.
- Rapid and versatile response to changes in demand, allowing for timely delivery and meeting specific requirements.

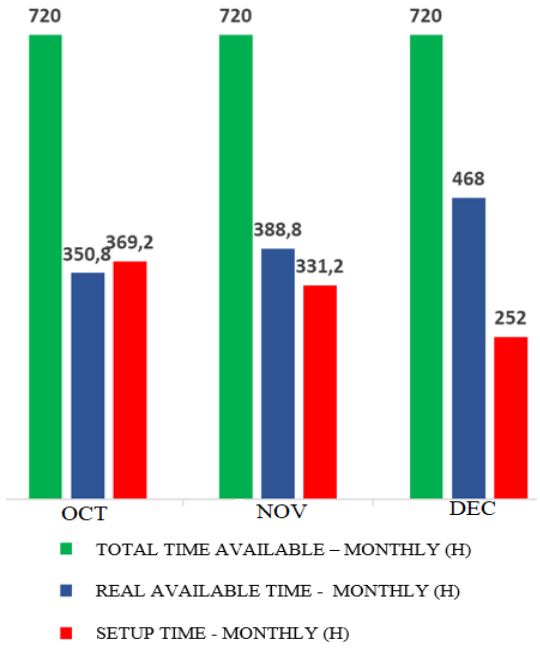
The data regarding the equipment availability in the packaging line were also collected during the same aforementioned periods and can be observed in figures 3 and 4. According to Pinto **[18]**, optimizing tool changes using SMED increases equipment availability, contributing to a more efficient production with reduced delivery times.

According to Nakajima **[19]**, one of the criteria for equipment efficiency loss is related to availability issues, such as machine breakdowns and tool changes. In the graphs shown in figures 3 and 4, the total available time represents the theoretical time that the machine would be available for production. However, it is known that SETUP procedures are necessary.

The actual available time, on the other hand, refers to the theoretical availability time of the machine, minus the time spent on tool changes. Thus, the monthly SETUP time is the sum of the time spent on all the changes. Therefore, all the time spent on SETUP affects equipment availability and, consequently, the production capacity of the factory.

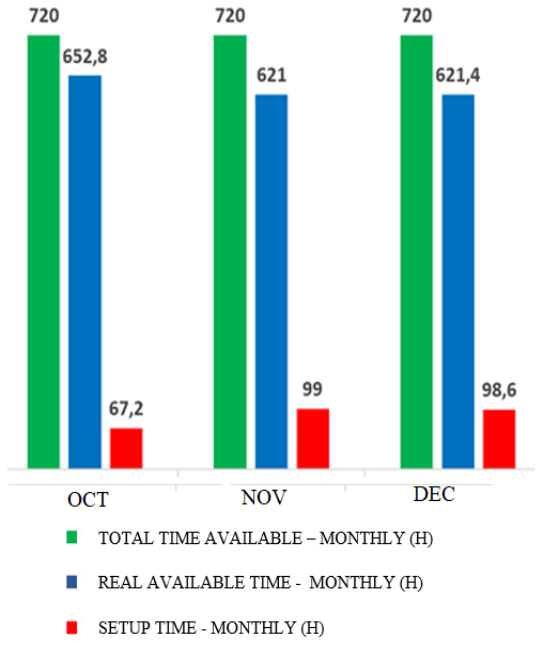
In Figure 3, during the month of October, the actual available equipment time was 350.8 hours, with a time related to tool changes of 369.2 hours. It can be concluded that, before implementing SMED, the machine spent more time idle than producing. As a result, 51.3% of its production capacity was reduced. In November, a lower nonproductive time was observed, with 331.2 hours. However, there was still a significant reduction in production capacity: 46%. In December, due to the lower number of batches produced, the loss of production capacity was 35%.

Figure 3 - Availability of equipment prior to application of SMED



Source: prepared by the authors.

Figure 4 - Equipment availability after SMED application



Source: prepared by the authors.

In Figure 4, the reduction in SETUP time is evident, resulting in increased actual machine availability. In January, there were 67.2 hours dedicated to tool changes, with a 9.3% loss in production capacity. In February, 99 hours of SETUP were performed due to an increase in the number of batches produced, resulting in a 13.8% reduction in productivity. Finally, in March, the target for tool change time was achieved, with 98.6 hours spent on internal SETUP, and a 13.7% decrease in production capacity.

Table 5 shows the respective reductions in nonproductive time during setup activities as the SMED implementation progressed through stages, categorized by type for each stage, demonstrating the significant improvement in the studied process. Before implementing SMED, the nonproductive time resulting from the three stages was 927 minutes (~15.45 hours). After implementing SMED, the nonproductive period was reduced to 282 minutes (~4.7 hours).

Table 5 - Reductions in non-productive time in activities of SETUP, according to the evolution of the SMED application.

SMED STAGE	SETUP TIME WITHOUT SMED	REDUCTION OF SMED / ACTIVITY TIME				
	MIN	TYPE OF ACTIVITY	MIN	%	TOTAL	%
Stage 1	382	Administrative	20	5,2	96	25,1
		Available material check	38	9,9		
		Displacement	38	9,9		
Stage 2	286	Administrative	15	5,2	27	9,4
		Displacement	12	4,2		
Stage 3	259	Cleaning	10	3,9	159	61,4
		Assembly / disassembly of tooling	129	49,8		
		Preparation for start of production	20	7,7		

Source: prepared by the authors.

Thus, the effectiveness of SMED implementation is confirmed, in accordance with the advantages of the methodology as described by Chiaverini (2014): increased production capacity and equipment flexibility.

5 CONCLUSIONS

The case study presented in this article demonstrated the effectiveness of applying the SMED method. The implementation of the methodology, structured in its four stages, in the drug packaging process in a pharmaceutical industry resulted in a 73.8% reduction in the SETUP time compared to the initial period observed.

This reduction in unproductive time contributed to the increase in operational availability and production capacity of the analyzed line, enabling the production of a greater variety of products. These improvements are strategic for the pharmaceutical sector, as they enable an increase in productivity combined with the diversification of the product offering, thus promoting increased competitiveness in the market.

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