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DEVELOPMENT OF A QUALITY CHECK STATION IN A PHARMACEUTICAL INDUSTRY TO ACHIEVE ZERO DEFECT PRODUCTION USING PDCA CYCLE

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ABSTRACT

This paper reports the result of a research in a pharmaceutical industry in Malaysia. The data have been collected and analyzed because of the some issues occurred in company X. There is need of adding a check station in the company. Moreover, the issues on the health of human eyes sight that required to be considered during quality check. In order to avoid the rejection of capsule, the quality check station is developed. The inspection table and the standard light intensity on the inspection table must be taken into account for better capsule production result. This also directly affects the health of human eyes and should be considered. The objective of this research is to enhance the production and avoid the rejection parts. There is one strategy for the continuously improvement. The lean manufacturing approach has been carried out in problem solving using the PDCA technique. The finding reveals that application of lean manufacturing using PDCA helps in solving the problem in the process. Thus, the inspection table has two sides of lights. The inspection table has to be equipped with a reflector in order to achieve the standard light intensity for human eyes. Consequently, this will reduce rejection of parts and aids in faster inspection.

Keywords: standard light intensity, reflector, PDCA cycle, lean manufacturing system.

INTRODUCTION

In the manufacturing process, quality means an excellent size and condition free from any defects, deficiencies and significant variation. This is because, there is a consistent commitment and control on certain standards in order to achieve a uniform product to meet customer needs in specific requirements. The overall characteristics of the product or service that bears its ability to satisfy, stated or implied needs are contained in the Standards of ISO 8402-1986. For example, there is a defect in one of the cars at an automobile company, the withdrawal and the customer will be reduced reliability. Therefore, confidence in the quality of the car will be gone.

In manufacturing, the physical product is produces to a set a criteria or specifications and delivered for consumption. The functional quality is measured by pass or fails inspection process. It is also based on the set of criteria and specification with the goal of defects. In the other perspective of quality is perceived or subjective quality. It based on a set of attributes or characteristic of a product that are observed.

In this research, achieving the zero defects is the goals of a pharmaceutical company X. The way to improve the quality inspection is the primary focused in manufacturing settings. So that, the needs is to improve the quality performance for a pharmaceutical company. Currently, in the pharmaceutical company X, the quality check stations are not available. The quality check process also not well managed. The way of measurement of quality is on right after the process without a specific station to inspect. A pharmaceutical industry of company X produces food supplement based on apricot seeds have been chosen in project research. The capsuling process in the factory has been identified as the inappropriate quality check process. In the beginning of the process, the raw apricot seed which is in powder stated will be weighing to be put in the 100 capsules. The semiautomatic capsule machine can produce 100 capsules in one cycle as shown in Figure-1.

Figure-1. Semiautomatic capsule machine.

The finish capsule will be tightened and at the same time the quality and condition of the capsule will be checked by the manpower. The following Figure-2 is the untight capsule after filling the apricot seed powder.

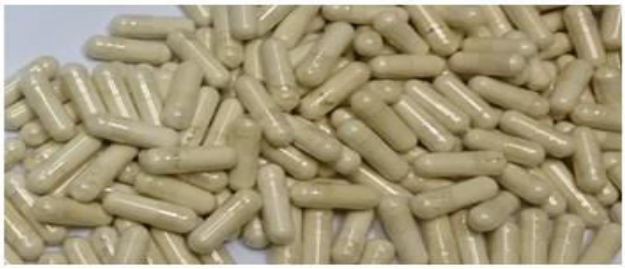

Figure-2. Untight capsule.

The capsule tend to be dented and porosity due to unfulfilled well of the apricot powder. After that, the powder will be polished and counted to be put inside the bottle. The polishing process also manually polished by the manpower by using the tissues paper. Polishing is crucial in order to remove the dust from the powder during the filling process.

Figure-3. Polishing capsule.

In order to fulfill the demands, the manpower requires fastening the process of producing one bottle of the apricot capsule.

Figure-4. Process of inserting the capsule in a bottle.

Sometimes, the manpower needs to do overtime in order to deliver the product on time. Some issues has been identified while the process. One of the issues is, the manpower avoiding the quality check of the capsule.

In the factory, the manpower works in sitting posture under normal lightning of the room. The position causes the seating posture in not good condition. So, the idea in development of quality check station has been thought in order to ensure the manpower will not avoid the quality check inspection at the same time can continue the process well.

An inspection table will be produced with bright light intensity measurement for human eyes. Since the process of producing capsuling is semiautomatic process the quality check will be done carefully with bare eyes, the light in the room need to consider. So, in order to care the eyes, the use of the right light intensity is very important.

LITERATURE REVIEW

Lean manufacturing

Lean manufacturing consists of various ways of achieving the vision and mission of the concerned manufacturing plants in terms of inventory and raw material consumption by systematically implementing a smooth manufacturing process. In manufacturing, raw material wastage is strictly prohibited because it can increase costs and lead to loss for the company.

Therefore, the application of lean manufacturing improves the performance of an industrial unit or production plant by increasing the productivity and enhancing the efficiency. On the other hand, lean manufacturing is defined as the elimination of waste and this approach is very useful when applied to many small and medium manufacturing factories, especially in Malaysia.

Lean manufacturing consists of various ways of achieving the vision and mission of the concerned manufacturing plants in terms of inventory and raw material consumption by systematically implementing a smooth manufacturing process. In manufacturing, raw material wastage is strictly prohibited because it can increase costs and lead to loss for the company. In reality, lean manufacturing is a good technique and is a way of thinking. Moreover, it is a way for the entire system that is capable of creating a culture for improving the operation of the organization. On the other hand, Lean Manufacturing System is a system that has been established in the manufacturing sector which is focused on minimizing cost, maximizing profit, and adding more value to the products. Moreover, the lean process has been described by [1] as the process which aims to reduce the non-value added activities and redirects them into value added activities. This is the reason why lean manufacturing is applicable to most industry and service sectors of a country's economy. Nowadays, Toyota is succeeding in many countries of the world and its secret is the application of lean manufacturing tools [1].

The implementation of lean manufacturing can change the world and help in the rapid expansion of global manufacturing and economy by helping to save money through elimination of waste. The elimination of these non-value-added activities reduces cycle time and costs, which results in more competitive, agile, and customer-responsive organizations [2].

The added benefit derived from lean manufacturing strategies is that along with reduction of costs and wastes it can help to improve the quality of the product or service. In spite of the various merits of lean manufacturing, its implementation is often met with resistance due to the misleading performance measures frequently used [3]. In manufacturing engineering, the operations of different products depend on the customers' demands.

The essence of lean thinking is that all business processes and functions integrate into a unified, coherent system with the purpose of using lean principles and tools to provide better value to customers through continuous improvement and elimination of waste [4]. If a particular product is in high demand from the customers, it generally means that the product is of very good quality. Thus, the operations involved in the manufacturing of a product require the application of lean manufacturing for ensuring better quality, fast delivery, and low production costs.

Pharmaceutical industry

The layout in pharmaceutical industries differs from in the other industries such as automotive industries. In pharmaceutical industries, they have to follow several procedures in order to maintain their high quality of the products. The standards followed by all pharmaceutical industries known as Good Manufacturing Practices (GMP). In Malaysia, GMP governs by the National Pharmaceutical Control Bureau (NPCB) to enhance the implementation of the standards.

In pharmaceutical industry the GMP is crucial to ensure the manufacturing under health and safety during production. GMP also monitoring in ensure the process of the production of the pharmaceutical / food product are under control and good condition. Due to the great increase in demand, their production has been centralized and moved to industrial manufacturing sites in which Good Manufacturing Practice.

(GMP) principles and guidelines for pharmaceutical products are to be applied. In Europe, EU directive 2001/83/EC requires that the industrial production of medicinal products has to comply with Good Manufacturing Practice (GMP) [5]. Specific GMP guidelines, have been set for hygienic on production products and pharmaceuticals, which both apply to the manufacture of pharmaceutical industry has always been accompanied by intense discussion regarding the difficulties in applying GMP rules, which often collide with process time frame, hygienic and safety constraints linked to operators' and environmental because the hygienic is important in pharmaceutical industry.

According to GMP, all production phases are documented and recorded in order to ensure full traceability of the manufacturing process, from raw materials to final product. The major change was the passage from a linked to the characteristics of the product, to the management of the overall product history during its entire lifecycle. So that, the product should be also designed and developed according to GMP. Therefore, besides receiving training sessions on GMP, special training has to be given on safety and radiation protection (including emergency situation preparedness) during production and QC, as well as on special rules applicable to packaging and shipping (heavy packaging handling, safety and documentation for the dispatch of radioactive goods).

Human visual inspection

The reason of using human eyes is stated in [6] which the human eye is a highly advanced instrument to rate precise graduations of surface distress and to quantify potentially harmful deposits. In this case on food supplement also can be applied in order it requires hygienic as the quality control.

Early, in the producing the apricot capsule, fully the human visual inspection has been used instead of computer visual inspection. This is the main reason in development of quality check with measure the light intensity of the inspection table. So, the long life health for the human eyes needed to be considered. The computer visual inspection has been used in many food product industries. In the paper [7] is written that the computer visual inspection has been used in food products for the quality for example in egg and lemon. However, in this company, the human visual inspection is applicable due to cost saving and job opportunities.

Other than that, in paper [8] stated that visual inspection is defined as the process of using the unaided eye, alone or in conjunction with various aids, as the sensing mechanism from which judgments may be made about the condition of a unit to be inspected. Moreover, in inspection human vision involves transformation, analysis, and interpretation of images [9]. So, the human brain also can interpret the capsule well.

In paper [10] mentioned that as with the human eye, vision systems are affected by the level and quality of illumination. So that, the human eye sight affected by certain levels and quality of lighting for example too brightness can cause dry eyes. It can be controlled by adjusting the lighting and the appearance of the object so clearly without any ambiguity. Therefore, affect the performance of the lighting can cause the system image quality turn to unclear seen. It can also affect the rate of product appropriately. Apart from that, the lighting system specially designed to help increase the number of good quality products.

Good lighting can reduce reflections, shadows of screening. There are various aspects of lighting can be considered as the location, type and quality of light colors when designing the inspection station. The light intensity measurement that perceived by human eyes is important. The sufficient light intensity enters the human eyes. The excess light intensity can dry the human eyes during inspection process especially in the food and pharmaceutical industry. The manpower works in the factory for eight hours and rest for an hour. Thus, the human eyes expose for long time under the light can cause dry and tired eyes. The tired and dry eyes can cause the manpower to do some mistake during inspection. There are also cases were inspection tends to be tedious or difficult, even for the best-trained experts.

In paper [11] mentioned that actually, humans can do the job better than machines in many cases, they are slower than the machines and get tired quickly. Moreover, human experts are difficult to find or maintain in an industry, require training and their skills may take

time to develop. In this case, one capsule has to be zero dented on the surface and no porosity of the powder inside the capsule cases. This can be proven in the paper [12] that 'Zero Defects', implemented by preventing established and known problems is an essential constituent of total quality management.

Moreover, it stated that inspection is no longer the backbone of quality, but it has an important role in preventing and identifying those problems, and in limiting their impact on the company and, even more importantly, on its customers. So, the inspector will inspect the dented part on the corner of the apricot capsule. Then, they will count the amount of the capsule to be put in the bottles.

Brightness perception has been considered in this research which the luminosity function brings standardize model of human visual brightness perception. Other than that, the interaction of light which relates to reflection model describes the interaction of light with a surface. In paper [13] mentioned that within the narrow spectrum of visible light, the human eye is more sensitive to some wavelengths than to others. This sensitivity depends on whether the eye is adapted for bright light or darkness. The method of reflection of light can be improved by improving the light intensity. In this situation, the reality is defects can then be easily perceived by the human eye, since ultraviolet light greatly enhances fluorescence [14].

METHODOLOGY

Firstly, in carrying out the lean manufacturing analysis, the selection of an appropriate production line in pharmaceutical industry was followed. Next, the plan, do, check and act (PDCA) methods has been used to find the solution of the problem. In paper [15] stated that the PDCA cycle can be an effective and rapid method for implementing continuous improvement. Moreover, each step: Plan, Do, Check, and Act are critical for consistent implementation. This application has been adapted from the lean manufacturing systems.

P- PLAN

The observation and recording will be done to identify the factor that influences the quality process for example in capsule production. In the research, there is one specific room for capsule and polishing room which is the capsule process has been selected to be investigated. First and foremost, the identification of the factors that influence the quality process in capsule production is required.

In carrying out the study, the first stage is Plan which is the process of planning the strategy involves the understanding of the perception of light intensity, brightness and interaction of light for human eyes. Of equal importance is the process of discussion involving manpower that worked as inspectors in the inspection station.

The quality check station will be developed to improve the quality check process. Designing the quality check of the station requires calculation in term of ergonomic for good work place to achieve the third objective. The design requires the position of the worker and the amount the light intensity during quality check process. In the other way, it benefits the worker for fast identification and inspection. Moreover, in the meantime the rejection of capsules product can be inspected. The proposed of the table of inspection station is as shown in Figure-5. The table has considered the source of light from sides in order to avoid the dust on the top of the lamp. So, the source of light can be fully focused on the capsule on the table.

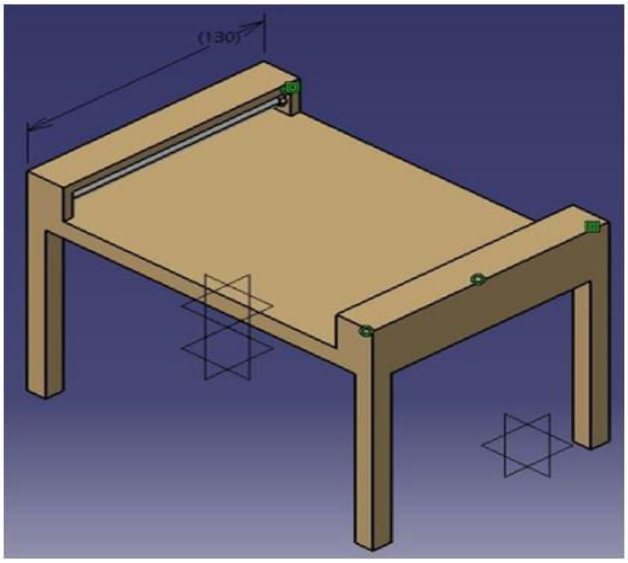

Figure-5. Proposed inspection table.

Other than that, the plan also included the propose solution base on the human eye that can accept the standard light intensity of 450 lux. There are three proposed solutions in term of light intensity. The Table-1 below shows the summary of the proposed solution.

Table-1. Proposed solutions.

Item	Remarks
1.Adjustment height	No
2.Add lamp	Cost
3.Add reflector	Cost

The suggestion on adjustment of the height is not possible because the inspection station is fixed. The solution also involved additional lamp that can be installed for example adding two lamps more. It is possible but would be costly. The third solution which involved adding the reflector is highly suitable. It is much cheaper than adding the lamp. In this case, the aluminum and white reflector has been chosen but only one of the reflectors will be used in the inspection station.

D-DO

The second stage is Do which involves scheduling the flow of the countermeasures. Figure-4 below shows the planning schedule in four steps.

Item	2015			
	Quarter 1	Quarter 2	Quarter 3	Quarter 4
Production of reflector				
Installation for mock up				
Testing				
Instalation of reflector				

Figure-6. Planning schedule.

In the Figure-6 during first quarter, the proposal preparation should be done first followed by the production of the reflector, installation for mock-up reflector, testing for the reflector and last but not least the fully installation of the reflector on all inspection station.

RESULT AND DISCUSSION

C-CHECK

Next, the third is Check which is explained in the relocation merit that has three categories in term of investment, quality and manpower. The investment for the company which brings merit is less rejection unit but the cost will be borne by the company. Moreover, the quality will be achieved through the goal of production on time which means at the right time. Other than that, in terms of manpower, reduced inspection time can be done. This will directly result in less need for overtime which is good for the company.

A-ACT

The final stage in lean manufacturing in PDCA is Actwhich means the action that will be taken in order to achieve the result.

The lux measurement at the inspection stations will be planned in order to make a comparison with the other proposed solution. The lux meter has been used to measure light intensity. As seen in the Figure-7 below, the comparison of light intensity in average value will be collected and the table below will be fulfilled.

Type of reflector	Lux measurement
White Reflector	302
Aluminium Reflector	493
Bare Lamp	522
Standard	450

Figure-7. Comparison table of light intensity.

The Figure-7 shows, the bare lamp has the highest light intensity. Moreover, aluminum is better than white reflector compared to the standard LUX. The other reason of using the aluminum reflector is the light reflecting off of a polished or mirrored surface. It has been stated [16] that precision optical systems use first surface mirrors that are aluminized on the outer surface to avoid refraction, absorption, and scatter from light passing through the transparent substrate found in second surface mirrors. So, it is suitable to the human eyes.

Figure-8 is a lamp reflector sketch. The sketch shows the measurement of the lamp with the aluminum reflector. The design is suitable in order to reflect the light very well.

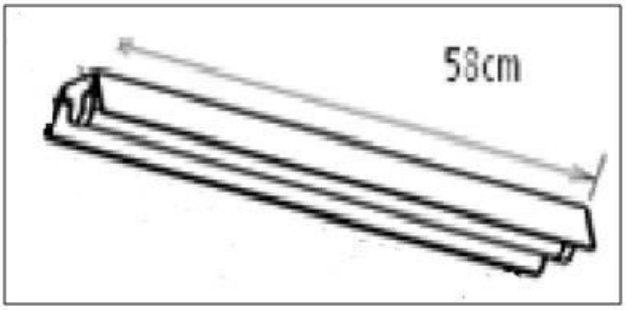

Figure-8. Lamp reflector sketch.

A feasibility study was conducted to scrutinize whether the recommended improvements to the inspection station has any development merits for management's consideration. This study identified a parameter, the investment category, seen in Figure-9.

No	Item	Investment (RM)
1	Ordering items	400.00
2	Produce Reflector (Mock-up)	200.00
3	Installation Activities	400.00
	Sub Total	**1,000.00**

Figure-9. Investment category.

The development merit which is the break even timing (ROI) versus the saving cost will be calculated. The development merit means the benefits from the installation of the aluminum reflector brings to the company. The data will be collected after the cost saving per part counted. Moreover, the saving ROI the highest from cumulative saving and investment cost will be counted in further research.

From the analysis, the information brings the great estimation in term of spending money. Other than that, it also can be refereed for the future.

CONCLUSIONS

As a conclusion, by development of the quality check station with installing the inspection table and reflectors on the inspection table, the inspection time can be saved. So, the production of the capsule per bottle unit can be increased. Moreover, by following the industry

standard for inspection station lamp height, the correct light intensity aids in providing fast and quality inspection. Other than that, the rejection from can be prevented and the target production for per unit bottle will be achieved when the inspection time can be done at the same time. Even though, manual inspection is slower than automatic inspection, the manufacturing processes tend to have high production speed these days and manual inspection cannot always fulfill these requirements. Other than that, the labor cost has become an issue in manufacturing industry as the manufacturing costs are tried to keep as low as possible [9].

Lastly, the application of PDCA cycle from lean manufacturing is helpful in finding and solving the issues in the factory. The successful application of PDCA cycle in this project could actually help motivate the management of the company to the concept that could be applied in any department in the factory. The concept is beneficial in well-organized problem solving.

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