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Corrective and preventive actions for damage product problem on raw materials for the pharmaceutical industry

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ABSTRACT

One issue that plagues every industry is defective products, which are unintended product quality deviations during the production process. In a pharmaceutical business situated in East Jakarta, Indonesia's Raya Bogor Street, data shows that when products were received from vendors, almost 30% of imported raw materials for Pharma X were damaged or defective. We apply the root cause analysis (RCA) method to faulty or damaged items to identify the fundamental issues that arise, and we offer solutions for preventive and corrective activities. As a result, the supplier is to blame for any damage to the bulk drum container. The answer and course of action that must be followed are to make sure that fiber drum deliveries from suppliers are more protected and that there are no longer any air shipments from the vendor's warehouse to the material warehouse.

Keywords: root cause analysis; corrective action; preventive action; inbound process

1. INTRODUCTION

It is well known that, among oral dosage forms, tablets are the most popular and commonly used. This is because the administration is simple and relatively inexpensive. Defects in tablets may appear during the receipt of raw materials from vendors, the packing process, or the shipping process [1]. These aesthetic flaws could make users less likely to adopt and operate the device effectively, putting their safety at risk.

The existence of product defects released by the pharmaceutical industry can cause the product to be recalled up to the revocation of the distribution permit. In this case, quality management is needed to ensure every product received from suppliers and the products to be supplied are in good condition, safe, and maintained.

Meanwhile, according to the 1978 ANSI/ASQC Standard, "quality" is the sum of a product's or service's features and characteristics that can guarantee satisfaction or necessity. Crosby argued that Total Quality Management (TQM) is a strategy and integration of management systems that prioritize the involvement of all managers and employees while using quantitative methods [2].

Satisfaction is associated with performance that fulfills expectations, while discontent occurs when performance needs are not met, suggesting that relative rather than absolute judgments are involved in determining satisfaction. It is therefore vital for businesses to give

priority to customer satisfaction. Therefore, this research article will describe manufacturing defects or quality issues and the corrective and preventive actions in the pharmacy industry [3].

The purpose of this paper is to find the root cause of problems and give solutions as corrective and preventive actions to reduce defective products. The contribution made in this research area is to address and eliminate the root causes of incoming damaged products (Pharma X tablets), while also committing to long-term improvement of the manufacturing process. Furthermore, it can eliminate the recurring problem and reduce both the cost and manpower associated with investigation activities.

The CAPA system is the most frequently checked subsystem during regulatory audits. Inadequate investigations and CAPA systems and missing root cause analysis are the most frequently cited observations by regulators [4]. The CAPA system is an important component of an effective organization, and it must maintain a close relationship with its other quality subsystems. Any regulated company's ultimate goal should be to have a suitable, effective, and efficient CAPA system. All relevant subsystems that can generate nonconformities must be part of the process. An efficient CAPA process is a great tool for improving quality systems and processes; early attempts are worthwhile if well-planned and done right. Studies on CAPA have been widely discussed in other studies; the development of the research we are doing is that we examine up to the shipment level to ensure that all goods are free of defective products. It is preferable to use this method to refer to the paper [5].[6]. The basic question of this research is: What is the root cause of the damaged incoming product, pharma X tablets? How can we improve the current incoming goods processing and associated costs? How can I avoid recurring events?

After this introductory section, the relevant literature on solution applications and one of the seven tools and methods for these three main topics have been reviewed. In section 3, the research methodology is presented followed by results and discussion in Section 4. Section 5 discusses the limitations and conclusions of this research.

2. LITERATURE REVIEW

The organization should continually improve the effectiveness of the quality management system using quality policy, quality objectives, audit results, data analyses, corrective and preventive actions, and management considerations.

2.1 Quality Control

Quality is the most important force that gives success to an organization and drives company growth in both national and international markets. As a result, every company is constantly striving to improve its products in the face of free market competition. Along with the development of technology, many breakthroughs have been developed by manufacturers whose point is to improve product quality [7].

2.2 Supplier quality management

Operational optimization is crucial. Therefore, quality management has a significant contribution to operational performance [8]. The reason is that major development and living standards have increased the point's importance. They conducted a study to investigate the influence of quality management practices, and they compared it with an Australian garment company [9]. The results showed that delivery time was one of the few factors that positively impacted the product's quality. Last but not least, it further shows that improving quality in a manufacturing or garment industry is more complex than in logistic firms [10].

2.3 Inbound process and supplier risk

Inbound supply risk is defined as the potential occurrence of an incident associated with inbound supply from individual supplier failures or the supply market, resulting in the inability of the purchasing firm to meet customer demand, and as involving the potential occurrence of events associated with inbound supply that can have significant detrimental effects on the purchasing firm [11]. These risks or supply chain failures can be costly and lead to significant delays in customer deliveries [12]. Therefore, managing supply risk is a critical component of managing the supply chain [13]. Consequently, it is important to an organization's success to understand the sources of supply risk and how to best manage them [14].

2.4 Corrective Action

A correction is an action to eliminate a detected non-conformity. A correction can be made in conjunction with a corrective action. A correction can be, for example, reworked or regraded. ISO 9000:2005 (E). Corrective action is intended to eliminate the cause of a detected non-conformity or other undesirable situation. There can be more than one cause for non-conformity. Corrective action is taken to prevent a recurrence. Corrective action may arise from manufacturing deviations, OOS (out of specification) investigations, complaints, audit findings, and recalls [15].

Organizations should take action to diminish the causes of incompatibility to prevent a recurrence. Corrective action should be compatible with the impact of unsuitability faced by the organization. Documented procedures ought to be settled to determine the requirements of incompatibility observation, including customer complaint; determination of incompatible causes; necessary action evaluation to guarantee the incompatibility won't occur; determination and implementation of necessary actions; implemented result action; observation of implemented corrective actions.

2.5 Preventive Action

Preventive action is a process to eliminate the cause of a potential non-conformity or other undesirable situation. There can be more than one cause for a potential nonconformity. Preventive action is taken to prevent its occurrence. Preventive action may result from trending of in-process data, analytical data, audit findings, trending of root causes for non-conformities or complaints, annual product reviews, and quality risk analyses.

The organization should determine actions to diminish potential causes of incompatibility to prevent such things from happening. Preventive action must be specific to the problems that might occur. Documented procedures must be determined to be necessary by the following: determination of possible incompatibilities and their causes; evaluation actions to prevent incompatibilities; necessary determination and implementation action; recording of resultant actions taken; and affectivity observation of preventive action taken.

2.6 Corrective Action & Preventive Action (CAPA) Procedure

Corrective and preventive actions (CAPAs) are an important part of pharmaceutical quality systems and industry-produced medical devices. Once it is discovered that there are weaknesses, including failures in the production and/or testing of drugs, investigations into the cause(s) should commence [16]. Actions should be taken to correct the existing product non-conformity or quality problems (corrective actions) and to prevent the recurrence of the problem (preventive actions). FDA (Food and Drug Administration) investigators and compliance officers often refer to the practice of addressing only the immediate problem as the "band-aid approach," which often results in a warning letter. CAPA is part of the overall Quality Management System (QMS) (Denise, 2001; ISO, 9000, 2005; US FDA website).

CAPA has seven general phases for pharmaceutical product industries, such as:

- Identification of the issue: It states the problem.
- Evaluation: Judge the extent and possible impact.
- Investigation: Find the main source (root cause) of the issue.
- Analysis of evaluation and investigation: Execute a detailed evaluation with relevant documents.
- Action Plan: Explain preventive and corrective action.
- Implementation of action: implementation of the action plan.
- Follow up: Confirm and evaluate the success of the plan.

Preventive actions resolve future issues. In general, it is possible to think of the preventive action method as a risk analysis process.

2.7 Root Cause Analysis (RCA)

Root cause analysis (RCA) is a process designed for use in investigating and categorizing the root causes of events with safety, health, environmental, quality, reliability, and production impacts [17]. The RCA is a four-step process involving the following:

a) Data collection.
b) Causal factor charting.
c) Root cause identification.
d) Recommendation generation and implementation.

The result of an RCA investigation is generally an investigation report. The format of the report is usually well defined by the administrative documents governing the reporting system, but the completed causal factor chart and causal factor summary tables provide most of the information required by most reporting systems.

3. RESEARCH METHODOLOGY

This research uses root cause analysis methods and process flow analysis tools to analyze a defective problem in an incoming material product. The focus of this research is on the cylinder part produced by the die-casting section. The research methodology steps are:

a) Problem formulation

The problem formulation stage defines what should be fixed as a result of this research. In this case, the percentage of defects and dented materials from the supplier has increased.

b) Determining research objectives

This stage is to solve the research problem above. The main objective of this research is to reduce the percentage of defective products.

c) Literature review

Journals and literature studies are required for the basic theory needed to get the exact corrective method or step to be implemented and solve problems in this research. Journals and literature studies refer to book references, journal articles from the internet, or other research related to these problems.

d) Establishing research limitation

Problems must be limited to obtaining an explanation of the research guide, ensuring that the research problem and objectives are not misunderstood. The limitation of this research is that only one product is to be researched and checked at the inbound processing area, and the finishing method employs the RCA, which is a collection of seven tools and preventive and corrective actions. Problems must be limited to obtaining an explanation of the research guide, ensuring that the

research problem and objectives are not misunderstood. The limitation of this research is that only one product is to be researched and checked at the inbound processing area, and the finishing method employs the RCA, which is a collection of seven tools and preventive and corrective actions.

e) Data collection and calculation

The preliminary data is the defective product of Pharma X material data that occurred in the inbound processing area. The data was taken from a warehouse system database with high accuracy. After getting preliminary data, data tabulation was processed to determine the dominant root cause, which subsequently will be the corrective focus of this research [18].

f) Data analysis

At this point, the researcher conducted a thorough examination of all potential causes of the dominant type of defective product, in this case, the leakage of Pharma X material. Analysis was performed by using RCA methods and quality assistance instruments (seven tools) [19].

3.1 Data collection

The preliminary data is the defective product of Pharma X material data that occurred in the inbound processing area. The data was taken from a warehouse system database with high accuracy. Below is Table 1. Data on damaged products of Pharma X in 12 months.

Table 1. Damage product of pharma x tablets in 12 months

No.	Time	Event
1	20 Jun 2022	Pharma X tablets HF batch no. C029399078, C029399079 C029399080, C029399081, C029399082, C029399083, C029399084, C029399086, C029399089, and C029399090 shipped out from the supplier warehouse by air shipment for 10 batches (313 fiber drums)
2	21 Jun 2022	Pharma X tablets HF batch no. C029399085, C029399087, C029399088, C029399091, and C029399092 shipped out from the supplier warehouse by air shipment for 5 batches (152 fiber drums) for 4 batches (128 fiber drums)
3	25 Jul 2022	Pharma X tablets HF batch no. C029548570, C029548571, C029548572, and C029548578 shipped out from the supplier warehouse by air shipment for 4 batches (128 fiber drums)
4	29 Jul 2022	Pharma X tablets HF batch no. C029548573, C029548574, C029548577, C029548579, and C029548580 shipped out from the supplier warehouse by air shipment for 5 batches (152 fiber drums)
5	09 Aug 2022	Incoming pharma X tablets HF received by the warehouse for 4 batches (128 fiber drums) and defect drums (7 of 128 fiber drums have dented) were identified prior unloading process.
6	19 Aug 2022	Incoming pharma X tablets HF received by the warehouse for 5 batches (152 fiber drums) and the defect drums (18 of 152 fiber drums have dented) were identified prior unloading process
7	22 Aug 2022	Incoming pharma X tablets HF received by the warehouse for 15 batches (465 fiber drums) and defective drums (7 of 465 fiber drums have dented and 1 of 465 fiber drums has torn and damaged) were identified prior unloading process

During the incoming bulk, 32 fiber drums were identified as dented, and 1 fiber drum was torn and damaged. On August 9, 19, and 22, 2022, Pharma X tablets were air shipped from the supplier warehouse to our warehouse.

The investigation to find the root cause is conducted using the RCA tool and will include a review of all circumstances related to the incident and the collection of supporting data. Supporting data can be

examples of trend analysis from data, gap analysis vs. actual procedures, field observations, interview results, and others.

3.2 Process flow analysis

Upon arrival at the warehouse, the truck container was still in sealed condition. Before unloading Pharma X tablets HF of each bulk incoming, the warehouse operator inspected the truck condition per the incoming checklist procedure, then photographed the inner container, pallet, and bulk drum container condition as part of the documentation process and reported them to the warehouse supervisor. During the inspection of the inner container.

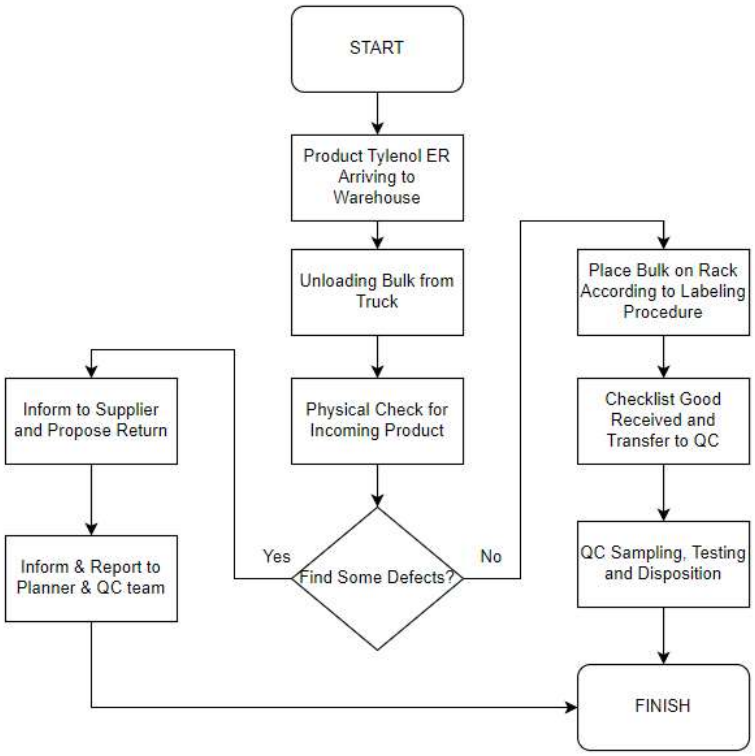

Figure 1. Diagram of the inbound process from supplier until the company's warehouse

According to the company's SOP, if any material is damaged or broken, wet, or dented during the incoming process, the warehouse operator will notify the warehouse supervisor, QA, SQM, and material planner before having an appropriate material disposition. While for import material, the defect drum could be accepted and the goods received should be performed by the warehouse, this event should be recorded on the check sheet.

After the truck inspection finished, the warehouse operator continued with the bulk unloading process and inspected individual bulk drum containers. From the individual inspection result, it was identified two bulk drums container have tear and damaged from another batch (from batch number C027694589/18L007: drum#F3 with quantity 28 Kg & batch no. C027694589/18L007: drum #F20 with quantity 34Kg). Refer to transport test study report, and cargo inspection report, it was determined that shipment by air was considered as worst case, this event was attributed to shipment way.

Refer to another inspection recorded in transport test study report, this event was attributed to supplier due to current packaging configuration being unable to guarantee the packaging integrity of Pharma X tablets bulk. **Figure 1** determines of inbound process flow from the supplier to the company's warehouse.

4 RESULT AND DISCUSSION

4.1 Problem identification.

The issue is the discovery of damage to the fiber drum in the receiving area. Based on the inspection results, it was found that 1490 units were damaged in the period from June to August 2022. The potential for issues to occur can be divided into 2 areas, namely the area in the company's warehouse due to unloading activities and the supplier area where material and shipment preparation activities are carried out (see Figure 2).

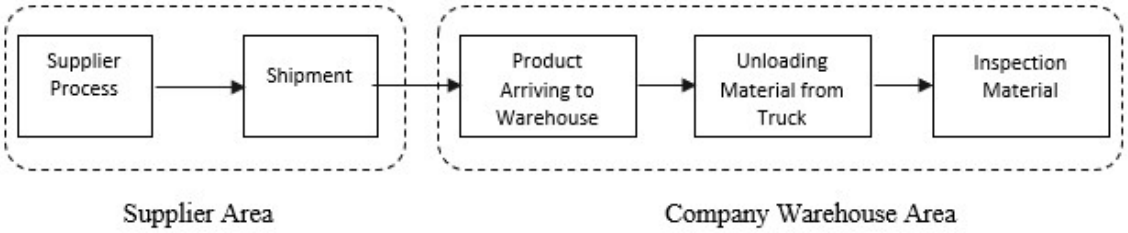

Figure 2. Potential area problem occur.

Further checks are carried out in the warehouse area with the material checking method before the unloading process is carried out to prove that no unloading process has the potential to cause material damage. Based on the inspection results before the unloading process, it was determined that the material was in defective condition. This narrows down the problems that arise in the supplier area, namely during the material preparation or shipment process.

4.2 Casual factor charting

The problems can be mapped on the casual factor chart in Figure 3 using the problem identification report.

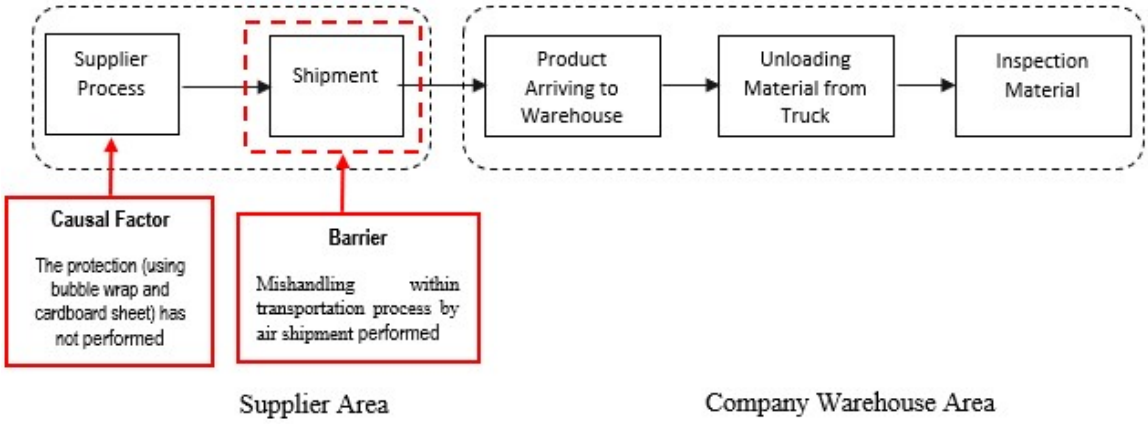

Figure 3. Causal factor chart in inbound process

4.3 Root cause analysis

Using the Root Cause Analysis (RCA) method, Table 2 and Table 3 provides additional analysis to comprehend the factors that caused the defect and dent in the Pharma X tablet. Document the results of the investigation, which includes product evaluation of the affected batch as well as other products. The root cause was obtained from the results of the investigation.

Table 2. Root cause analysis using 5-whys method

Possible Root Cause	Why 1	Why 2	Why 3	Why 4	Why 5
There were identified 32 fiber drums	Air shipment was chosen due to	Refer to transport test study report,	Based on inspection result and	There are multiple loading and	The protection (using bubble wrap and

have dented and 1 fiber drums has tear and damaged during incoming bulk Pharma X tablets shipped out from Supplier to Company's Warehouse by air shipment on 09, 19 and 22 Aug 2022	shortage Pharma X tablets bulk for production process	and Cargo inspection report, it was determined that shipment by air was considered as worst case	further observation on defect fiber drums during incoming process at Company's Warehouse, there is probable mishandling within transportation process by air shipment	unloading process performed since the bulk shipped out from Supplier to Company's Warehouse	cardboard sheet) into fiber drum was performed previously has no longer performed properly during this shipment process

Table 3. Root cause analysis using 5-whys method

No.	Root Causes (from the last why)	Category
A	The defect drum container comes from the supplier. The packging configuration of fiber drums and current additional protection (using cardboard sheet and bubble plastic wrap) has not been performed anymore that may has impact to bulk drum container handling during loading or unloading process occurred on air shipment. This is repeated similar issue occurrred during air shipment that cause high defect on fiber drum.	Material; bulk or finished goods: Transportation, storage, or handling issue.

4.4 Corrective Action (CA)/Preventive Action (PA)

Corrective action aims to diminish the causes of the emerging problems and prevent their recurrence. Based on the problem analysis, performing corrective action entails the main issues. step is performed to fix all factors that could initiate leaks on the drum fiber component. The corrective action is using additional protection fiber drums made of cardboard and bubble wrap to keep the product safer. Preventive action was taken by reaching an agreement with the supplier to deliver the product by sea shipment only, with no use of air shipment except in emergency situations. The summary of actions is provided in Table 4.

Table 4. PA/CA Action based on RCA results

Root Cause Code	Root Cause (Based on RCA Results)	Corrective, Preventive. Interim Control Action	Action Description	Is Action Related to Change Modification / process improvement?	PIC	Due Date (Done)	Justification for the due date
A	The defective drum container comes from the supplier. The packaging configuration of fiber drums and current additional protection to guarantee the	**Corrective Action**	Informed to supplier to use the additional protection on fiber drum (using cardboard sheet and bubble plastic wrap) as	Yes	Nurul R.	10 Oct 2022	N/A

Root Cause Code	Root Cause (Based on RCA Results)	Corrective, Preventive. Interim Control Action	Action Description	Is Action Related to Change Modification / process improvement?	PIC	Due Date (Done)	Justification for the due date
	packaging integrity (fiber drum) have not been performed anymore, which may have an impact on bulk drum container handling during the loading and unloading process during air shipment.	**Preventive Action**	Make sure the shipment plan from supplier is no further incoming of Pharma X tablet bulk shipped out from supplier warehouse to.	Yes	Nurul R./ Dewi S.	30 Oct 2022	Next shipment of Pharma X tablets bulk from Supplier's Warehouse
		Interim Control	N/A	N/A	N/A	N/A	N/A

5 CONCLUSION

Further research revealed no deviations during the warehouse operator's unloading procedure, leading to the conclusion that the supplier is to blame for the problem in the bulk drum container. The flaw was brought on by the bulk air shipment, which involved multiple handling operations (loading and unloading processes) between the supplier's warehouse and the company's warehouse. Without additional protection to ensure the packaging integrity that had already been applied to the previous shipment, the handling of the bulk drum containers during these operations may have been impacted. Every piece of material or large item needs to be contained properly. Bulk products with damaged packaging pose a contamination risk and cannot be used in the process to maintain the product's quality for the intended use.Corrective action should be taken at the company, such as notifying the supplier team of the recurrent difficulties with fiber drum defects and offering evaluation for minor dented drums (such as those dented on the upper position of the drum) during bulk sampling by QC. Bulk tablets in drum containers that have significant dents and damage are subject to rejection and cannot be utilized for packing. Corrective action and preventative action should be used by notifying the supplier to use the additional protection on the fiber drum (using cardboard sheets and bubble plastic wrap) as a previous improvement to avoid developing defective material in the future. Additionally, our warehouse must ensure that the cargo from the supplier does not include any additional bulk shipments of Pharma X tablets from the supplier's warehouse to the company's warehouse by air shipping. Limitations and Future Research: Even though this study corrected an analysis error, it still has certain limitations. First, only one of the numerous different products produced by this pharmaceutical corporation is used in the study. Since it has already evolved into semi-finished items from the provider, this product was chosen because it is the most valuable and influential when compared to others. Additionally, we use a short-term period for the three-month receiving plan.

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