Reduce Customer Complaints on Packaging Counting Discrepancy Units

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Abstract *— This research discusses the root causes and the possible solutions to a packaging counting discrepancy units on a manufacturing packaging area. The packaging area currently use balances to count the quantity of blisters inside the box. Multiple customer complaints have been received in relation to not meet the minimum quantity of blister per box consistently. This research goes through the Six Sigma methodology to identify all the possible causes and the solutions to this issue. The Six Sigma methodology move the process to identify solutions that reduce the internal non conformances and to reduce the customer complaints related to the quantity discrepancy in relation to the current specification.*

Key Terms *— Customer Complaints, Manufacturing Packaging, Quantity Discrepancy, Six Sigma.*

INTRODUCTION

A medical device industry manufactured a blood transfer device that is a single use, sterile product to provide safe and convenience transfer of venous blood. The final assembly product is packaged in blisters, being the blister wall is part of the sterilization barrier. Then the blisters are packaged on a process box that are labeled as 200 units each and then transferred to a pallet. Finally the products are sent for sterilization process. Currently, there is a manual process were operators use scale balance to discriminate when the box complied the specific quantify required plus one extra unit. The extra unit is to compensate by the inherent process variability.

This research aim to identify possible solutions to the customer complaints describe incorrect quantity of blisters per box, under 200 blisters and the non-conformances identified on the manufacturing floor with incorrect quantity of blisters per box.

Research Description

The purpose of this research is to identify the root causes and possible solutions to reduce the non-conformances and customer complaints related to the quantity of blisters per box, 200 blisters per units. The verification with the product was performed with the products impacted and was observed a weight variability in the blisters per boxes. The weight variability in the blisters can be generated due to weight variability in product components.

Research Objectives

The objective to this research is identify possible corrective actions to reduce or eliminate the customer complaints and the non-conformances on the manufacturing floor related to the incorrect quantity of blisters per box. For the possible solutions identify the most cost effective process.

Research Contributions

The contributions expected by this research is reduce the customer complaints and improve the customer satisfaction related to miscounted blisters inside the boxes. Nevertheless, reduce the non-conformances and internal re-work on the manufacturing floor related miscount. This research should have an economic benefits on the raw materials and company revenues. Nevertheless, also should have regulatory compliance benefits since on the internal audits and with the domestic and international regulatory agencies audit none audit finding will be perform to the plant related to this issue.

LITERARY INFORMATION

This section contain the information necessary to the understanding of this research. A review of the regulations around the medical devices regulation agencies around the world and the concepts need it to a better understanding of this research.

FDA Customer Complaints Requirements

There are several regulatory agencies that manage customer complaints related to medical devices and pharmaceutical products.

Hilkings (2005) indicates the following on relations to the FDA customer complaints. The FDA regulated the customer complaints through the Quality System Regulation (Title 21 Code of Federal Regulations [CFR] Part 820) that includes specific requirements for the handling of complaints by medical device manufacturers. A complaint is defined as "any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution" [21 CFR 820.3(b)] [1].

Medical Device Reporting

The U.S. Food and Drug Administration (FDA) use a medical device reporting for manufacturers. "The United States (US) Medical Device Reporting (MDR) regulation specified in 21 Code of Federal Regulations Part 803, requires deaths, serious injuries and certain malfunctions related to medical devices to be reported to the US Food and Drug Administration (FDA)" [2]. In the US, the MDR applies to the company that actually manufacturers a medical device and the company that is responsible for initiating the specifications for a device, which is manufactured by another company [2]. As part of the regulations the manufacturers are obligated to identifying any customer complaint that could represent an MDR event. In addition, the company must ensure that complaints and MDR events are properly investigated in a timely fashion.

Since 1984, medical device manufacturing are required to established processes to respond and report to the FDA any device-related death, serious injuries or certain malfunctions [3]. The FDA part 822 in general provide the requirements when a post market surveillance plan is required [4].

The requirements are:

(a) Failure of the device would be reasonably likely to have serious adverse health consequences;
(b) The device is intended to be implanted in the human body for more than 1 year; or
(c) The device is intended to be used outside a user facility to support or sustain life. If you fail to comply with requirements that we order under section 522 of the act and this part, your device is considered misbranded under section 502(t)(3) of the act and you are in violation of section 301(q)(1)(C) of the act".

Other regulation that applies related to customer complaint is ISO 10002:2014. ISO This regulation provides guidance on the process of complaints handling related to products within an organization, including planning, design, operation, maintenance, and improvement. The complaints-handling process described is suitable for use as one of the processes of an overall quality management system.

International Organization for Standardization is an international standard that creates documents that provide requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose [5].

ISO 10002:2014 Complaints Handling Regulations

ISO 10002:2014 addresses aspects of complaints handling as the enhancement of customer satisfaction by creating a customer-focused environment that is open to feedback (including complaints), resolving any complaints received, and enhancing the organization's ability to improve its product and customer service. Another factor addressed is the top management

involvement and commitment through adequate acquisition and deployment of resources, including personnel training; recognizing and addressing the needs and expectations of complainants; providing complainants with an open, effective, and easy-to-use complaints process. Nevertheless, the regulation enforced to analyzed and evaluated complaints in order to improve the product and customer service quality and audited of the complaints-handling process; reviewing the effectiveness and efficiency of the complaints-handling process [5].

Other important aspect related to this investigation is the non-conformance product definition established by the regulations.

FDA Sec. 820.90 Nonconforming Product

The FDA Sec. 820.90 that govern the Nonconforming product:

(a) Control of nonconforming product. Each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements. The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product. The evaluation of nonconformance shall include a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance [6]. The evaluation and any investigation shall be documented.

(b) Nonconformity review and disposition – This is subdivided on the following:

(1) Each manufacturer shall establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product [6]. The procedures shall set forth the review and disposition process. Disposition of nonconforming product shall be documented. Documentation shall include the justification for use of nonconforming product and the signature of the individual(s) authorizing the use.

(2) Each manufacturer shall establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications. Rework and reevaluation activities, including a determination of any adverse effect from the rework upon the product, shall be documented in the device history record (DHR). Important provide a definition of the regulations related to non-conformance product [2].

Six Sigma Overview

The analysis will be perform following the Six Sigma Analysis process method. This is a common practice on the medical device industry.

Six Sigma Methodology

The Six Sigma Methodology is used to achieve statistical accuracy conclusion. Six Sigma Methodology is a deployment strategy for implementing value-added improvement projects [7]. The Six Sigma Methodology use the DMIAC methodology. DMAIC stands for Define, Measure, Analyze, Improve and Control. The methodology use a set of tools and methods including statistical (i.e., enumerative stats, statistical process control, and designed experiments), problem-solving, consensus-building, and lean tools [7]. The DMAIC problem-solving methodology typically is used to acquire data and gather information from the data in the context of a Six Sigma project.

The DMAIC methodology is designed to

- Define the problem
- Measure the extent of the problem
- Analyze the sources of variation
- Improve the process
- Control the process for sustained improvement [7].

The methodology can be summarize as followed, Rivera de Leon (2012) [8]:

(a) Define: Get a clear purpose of the project scope acquiring data. Tools used to acquire data to define the problem are voice of the customer, supplier input process output customer diagram.

(b) Measure: Focus on gathering information on the current situation. Measure the current process performance. The tools used in this phase are for stratification purposes such a time series plot, dot plot, Pareto graphs, etc.

(c) Analyze. The purpose of this phase is identify the root cause of the problem acquiring data. Tools used on this phase are fishbone diagrams, design of experiments, between others.

(d) Improve: On this phase the purpose is identify and implement solutions that could resolve the opportunity area identified. Tools used on this phase are design of experiments, project management, and others.

(e) Control: On this phase the purpose is that the solutions identified on the previous phase are maintain through the process. On this phase could be implemented Standard Operating Procedures and established controls to assure that the key variable identified are established on the process consistently [7].

Six Sigma Tools

The cause and effect diagram is used to establish all the possible root causes to the situation under investigation. Cause and Effect Analysis gives you a useful way you to consider all possible causes of a problem, rather than just the ones that are most obvious [7].

Montgomery (1991) notes that "A designed experiment is a test in which some purposeful changes are made to the input variables of a process or system so that we may observe and identify the reasons for changes in the output response. Experimental design methods play an important role in process development and process improvement [9].

METHODOLOGY

The research is intended to pursue the identification of the possible corrective actions to reduce or eliminate the customer complaints and the non-conformances on the manufacturing floor related to the incorrect quantity of blisters per box. For the possible solutions identify the most cost effective process. This research will be focus on follow a Six Sigma methodology and tools to identify all the possible solutions to the aforementioned objective and established with one will be the most cost effective.

Define

In order to specific define the issue in relation to the customer perspective the Voice of the customer (VOC) tool will be used.

Measure

The data will be collected and analysis to determine the current frequency to establish a base line trend related to the customer complaints and internal non conformances triggered by the blister by box quantity discrepancy in relation to the current box label.

Analyze

The data will be analyze to determine the most cost effective way to reach the objective of this research. Customer complaints and Non-Conformance root causes will be analyze to identify the root causes. The cause and effect diagram will be used to define all the possible root causes and solutions to reduce or eliminate the customer complaints and the non-conformance on the manufacturing floor related to the incorrect quantity of blister per box. Engineering Studies will be executed to identify the best and most cost effective solution in relation to the research objective. The analysis will verify if it is possible to improve the current process to determine the quantity of blister on the box using scale or if we can also install an automation system that count the blister that goes inside the case.

AQL Criteria

The acceptable quality limit (AQL) is the worst tolerable process average (mean) in percentage or ratio that is still considered acceptable; that is, it is at an acceptable quality level. As part of the analysis it will be use the AQL criteria of 99 % reliability / 95% confidence level. The acceptance sampling plan of the engineering study required to perform this research analysis will be established following ANZI Z.4 Standard. The Acceptance Sampling plans are scheme used to assist in the decision to accept or reject lots of material based on sampling data for either variables or attributes. [10].

On this research we will be working with variable data. Crossley indicates that lot acceptance plan for attribute data are based on acceptance criteria where a specified number of non-conforming units and a specified sample size are given. If this number of non-conforming units is exceeded in a sample, a decision is made to reject the lot from which the sample were taken. Such inspection plans are predefined are predefined under MIL-STD-105E (ANSI/ASQ Z1.4-2003) [11].

Improve

Based on the Analyze phase established all the possible solutions or improvement to reduce or eliminate the customer complaints related to quantity discrepancy and determine their effectiveness following statistical methods like the ANSI/ASQ Z1.4-2003.

Control

Once is determine the best choice. The Standard Operating Procedures and forms must be in place to ensure that the system stay in control and avoid recurrence of the blister miscounted issue.

RESULTS AND DISCUSSION

In order to comply with the intended research of identify the possible corrective actions to reduce or eliminate the customer complaints and the non-conformances on the manufacturing floor related to the incorrect quantity of blisters per box a Six Sigma methology was followed.

Define

In order to define the problem the voice of the customer or VOC tool was generated to have a clear understanding of what the customer wants from us and help us to identify the issue and translate them into specific and measurable requirements.

Table 1
Voice of the Customer

VOC (What the customers want from us?)	Key Customers Issue (We need to identify the issues that prevent us from satisfying our customers)	Critical Customer Requirements (Summarize key issues and translate them into specific and measurable requirements)
The customer want that we provide our product with the correct quantity at all time.	The customer is not receiving the correct product quantity as labeled on the product package.	Received the correct product quantity as labeled on the product package at all time. Keep a trending of the customer complaints when the corrective actions were implemented. Keep a trending of any internal nonconformance related to the product counting issue.

Measure

As part of the measure step, the data it was evaluated the quantity of customer complaints that have been received in relation to quantities discrepancy by box. Also it was reviewed the quantities of nonconformance internal events identified with the situation. The data was evaluated using a quantity of customer complaint by month graph that help us to established a base line of the current frequency of the customer's complaint related to quantity discrepancy on the product received. The graph cover the data of the complaint received from March 2017 to July 2017.

Figure 1
Quantity Discrepancy Complaint

A total of twenty-six (26) customer complaints related to the same issue were received from March 2017 to July 2017. Customer complaints describe incorrect quantity of blister per box (under 200 blisters). In addition it was quantified the quantity of internal failure mode related to incorrect quantities of blister per box during the packaging process, resulting in 10 internal events non conformances.

As per the defects graph it can be observed an increase trend (refer to figure no. 1) of complaints related to incorrect blister quantity per box and multiple Internal events (10 internal events) with the same defects resulting in nonconformance investigation.

Defect Trend: An evaluation of this defect trend of the internal non conformances was performed from March 2017 to July 2017. Ten (10) internal events were generated on that period of time.

Complaint Trend: An evaluation of the complaint trend was performed from March 2017 to July 2017. A total of twenty-six (26) complaints have been reported.

Analyze

In order to determine the most cost effective way to reach the objective of this research the customer complaint and Non Conformance root causes were analyzed to identify the root causes. A cause and effect diagram was generated to evaluate all the possible root causes and possible solutions to reduce or eliminate the quantity discrepancy customer complaints and internal non-conformance.

The criticality to quality was evaluated and there is no risk related to blister quantity discrepancy per box. It was established that the client risk severity index is considered low. As per customer complaints received, there is no adverse health consequence or device malfunction. This condition represents customer dissatisfaction. The quantity discrepancy is considered a minor defect with an AQL of 0.65% LTPD0.05.

Cause and effect diagram: The following is the results of the investigation of the possible factors for the failure:

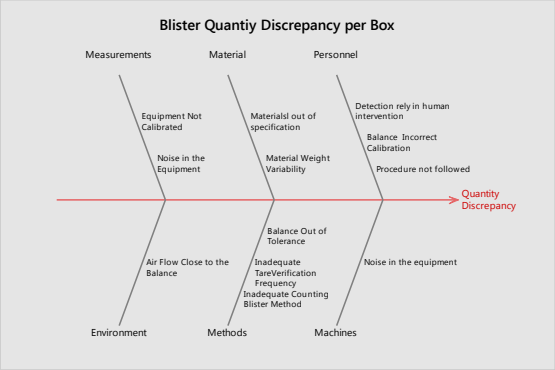

Figure 2
Blister Quantity Discrepancy per Box

(a) Measurements:

- Equipment Not Calibrated: The balances calibrations was verified and no abnormalities related to the balance Out of Tolerance (OOS) were observed. An external calibration and preventive maintenance was performed by external vendor and the balances were found in Tolerance in the ranges that are used. Therefore the balances not being calibrated can be ruled out.
- Noise in the equipment: An external preventive maintenance was performed by an external vendor and the balances were found in Tolerance in the ranges that are used. Therefore noise in the balances can be ruled out.

(b) Environment:

- Air Flow Closed to the Balance: There is not air flow on the packaging area that could impact the balance. Therefore noise in the balances can be ruled out.

(c) Material:

- Material Out of Specification: An analysis related to material incoming inspections and the materials were found in tolerance. Therefore material out of specification can be ruled out.

- Material Weight Variability: An analysis related to the material weight changes was performed. The analysis concluded that the weight variability is present in all components. Material weight variability is considered a possible root cause.

(d) Methods:

- Balance out of Tolerance: An external calibration and preventive maintenance was performed by external vendor and the balances were found in Tolerance in the ranges that are used. Balance out of tolerance by an incorrect calibration method is ruled out.
- Inadequate Tare Verification Frequency: The tare frequency standard operating procedure was evaluated and it was determine that the current frequency of the Tare Verification that is each 4.5 hours could possibly be a factor in not capturing the weight variability. Inadequate tare verification frequency is considered a possible root cause.
- Inadequate Counter Blister Method: The balance does not have the capability to manage weigh variability per boxes in a range of 200 to 203 blisters per box due to raw material weight variability. Inadequate counter blister method is considered a possible root cause.

(e) Personnel:

- Detention rely on human intervention / Procedure not followed: The training records of the people working on the packaging area were evaluated. Based on the records, the people were trained on the weight verification procedure. Therefore that the detention rely on human intervention and that the packaging personnel are not following the procedures can be ruled out.
- Balance Incorrect Calibration: Balance calibration records were evaluated and the calibration was performed as per predefine frequency. No out of tolerance were reported. Therefore balance incorrect calibration can be ruled out.

(f) Machine:

- Noise in the Equipment: It was not identified noise in the equipment. The balances are consistently verified at the beginning of each lot. Therefore noise in the equipment can be ruled out.

As per the analysis performed using the fishbone analysis the most possible root causes that were observed are:

(a) Methods:

- Inadequate Tare Verification
- Inadequate Counting Blister Methods

(b) Material

- Material Weight Variability

An analysis of the cause and effect diagram lead to identify the most significant factors that may relate to the problem that we are trying to resolve through the DMAIC process. Based on the cause and effect diagram the most significant factors are related to Measurement, Methods and Material. In relation to the material weight variability no actions will be pursued, since is part of the supplier manufacturing normal process. Other source of weight variability could be attributed to the normal manufacturing process on the product assembly. Also, the data shows that all the materials meet the acceptance criteria of Incoming Inspection Process. The analysis of the different weights limits of each raw material was perform and was confirmed that the allowed weight specification could perform variation on the quantity detected on the box by the balances, this points out that the potential root causes are related to measurement and methods. In addition the Tare Verification could be a factor in not capturing the weight variability in four (4) hours or in thirty (30) minutes approximately.

Improve

Based on the analyze phase of this research that established the most possible root causes the following improvements were identified:

As a first step it was established a new range per box in order to decrease or eliminate the Customer Complaint and internal non conformances, an immediate action was implemented through a process deviation to change the quantity specification of the product per box and increased the tare verification frequency updating the standard operating procedure from one time each (4) hours to one time each thirty (30) minutes approximately. The tare verification procedure was updated with new instructions. This helped capture weight variability.

Also the specification of the product quantity was changed from 200 - 203 blisters per box to 200 – 210 blisters per box with a target of 205 blisters. This change was performed to complied the requirement of 200 blister minimum per box and reduce the probability of have a customer complaint. As part of the evaluation it was determine that the new maximum limit do not impact the current sterilization process.

As a second step is was established pursued a new automated blister counting system: A new Counting System will be implemented to improve the actual counting process in a range of 200 to 203 blisters per box. A quotation was required from different Packaging Vendors. A customize counting system was designed by an external vendor to pack in a range of 200 - 203 blister per box.

Counter system: In order to have a successful automation program of the counter system the following quality key process output variables must be evaluated through engineering studies following statistical methods like the ANSI/ASQ Z1.4-2003 in order to have a successful automation system implementation.

(a) Blister Counter with an AQL of 0.65 LTPD0.05
(b) Blister Leak Test with an AQL of 0.065 LTPD0.05
(c) Holes in Blister with an AQL of 0.065 LTPD0.05

As part of the automation process to count the blister it must take in consideration not damage the blister itself since the blister is the sterilization barrier of the product and is considered a major defect. In order to implement the automated counter system it was decided to implement a system that will perform the following functions:

The equipment will move the blisters in 6 individual lanes that will separate and keep aligned each of the 24 blisters after the Multivac cut stations. A Slotted Track Indexing conveyor for Multivac discharge of 6ea UHMW machined slotted bed for blister alignment and Twin timing belt for each lane (6 ea.) to transport the product.

A Transfer Conveyor will take the blisters for inspection and counting. During the travel of the blisters through the individuals lanes will be inspected at the same time for missing holder.

The Transfer Conveyor will run at high speed while is receiving the blister from Multivac Machine but when the Multivac machine is at rest the system change to low speed to begin the transfer to the overhead vacuum conveyor in order to run product on the inspection and reject system allowing a smooth operation of both system.

A Reject Station will be placed in each lane after the inspections stations for immediate rejection of fail inspection Blisters. The blisters will be separated in order to allow the vision system to inspect each blister individually. One Sick LUT3-620 UV sensor will be installed in each lane to detect the presence of the product in the blisters. Each track has an individual reject station that sends the rejected blister to a stainless steel bin. Each track is provided with an Allen Bradley 42JS-P2MPA2-Y4 sensor that ensures the blister is rejected and sends a signal to the Blister Inspection and Counting equipment PLC if the sensor does not detect the rejected blister. The reject bin presence is detected by an Allen Bradley 42JS-P2MPA2-Y4. If the reject bin is full, an Allen Bradley.

Blisters with product will be offloaded to the counting station. The station consists of a stainless steel accumulator bucket with pneumatic doors at the bottom and a diverter door. Eight Allen Bradley 42JS-P2MPA2-Y4 sensors detect the product after the reject station. Blisters will be counted at the end of the vacuum conveyor and a collating system for 6 ea. lane. Six Allen Bradley 42JT-P8LAT1-F4 sensors, one for each lane will perform the counting duties. The blisters are directly loaded into the shipper. When the shipper reaches 86 blisters or more counted, the accumulator bucket door closed while the box is taken to a compressing station. The box returns to the loading area and the accumulator door opens, resuming the loading process. When the count reaches 194 blisters or more, the accumulator door closes and the diverter door opens, allowing the loading from one lane ensuring that the count reaches the 200 blisters. The blisters of the other 5 lanes fall into the accumulator for being loaded in the next shipper. After the count reaches the 200 blisters, the diverter door closes and the shipper goes to the secondary press station while a new pre-formed shipper is placed in the loading area and the accumulator door opens. A Banner LX12R/LX12E light curtain sensor verifies that all the blisters are remaining in the accumulator.

If any alarm or power failure occurs in the counting station, that case carton will be rejected and a new one by placed and a new count will began.

If any alarms occur during counting process that can affect the accuracy of the count of blister inside the box, will be reject and alarm will be generated to advice the operator to remove the affected box.

The Counter Technology will consist of A slotted track conveyor accommodates the blisters coming out of the Multivac packaging machine into six lanes.

A Vacuums Conveyor picks up the blisters for verification and counting.

Six UV sensors, one per lane, verify the blister for holder presence using the holders UV signature; since the empty blisters do not have UV signature. If the sensor does not detect the holder in the blisters, the blister is rejected by turning off a vacuum switch in the reject area and the rejected blister falls to a bin. A sensor confirms that the blister is rejected.

The blisters are counted by individual sensors, one in each lane. The blisters fall through an accumulator and then to a carton case previously formed by the Case Erector. When the blister count reaches 200, the case moves out of the counter and a new case enters the counter.

Validation process: A validation process must be performed to assure an accurate Installation Qualification where all the parts were successfully identified and ensure that the electrical and pneumatic connections complied with the specifications and an accurate Performance Qualification where the following critical to quality key process output variable will be challenge.

1. Blister Content - Blister must be packed with correct content
2. Holes in Blisters - Blisters must be free of holes.
3. Blister Count - There are 200 blisters assemblies with correct content per case carton. There must not be empty nor double blisters. There must not be blisters with Top and/or bottom web splicing tape.

Control

To maintain the improvement that will ensure to reduce the quantity of customer complaints and internal nonconformance the Standard Operating Procedure were updated to reflect the new tare verification frequency instructions. Training to all packaging personnel in relation to the new instructions were performed. In addition the process documentation was updated to change the quantity specification for products per box from 200 - 203 blisters to 200 – 210 blisters with a target of 205 blisters per box.

The previous actions will reduce the customer complaint and avoid that the customer received boxes with less than 200 blister each. The final

corrective action to implement a counter system was identified and is currently under validation process.

Once the new automated counter system validation is completed, the process will be control through the update of the standard operating procedures and packaging personnel on the job training to ensure that the personnel know to handle the system as intended.

As part of the control phase the effectively of the first step implemented actions was confirmed through the review of the customer complaints trend of the last three months as illustrated on the figure below.

Figure 3
Quantity Discrepancy Complaint Effectiveness Verification

CONCLUSIONS

Follow the Six Sigma methodology provide the structure to identify the root causes that were generating the blister quantity issue on the box. The structure provide to identify all the possible root causes and provide evidence to rule out the causes that were not generating the issue to focus on the ones that could be generating the problem.

It was determine two different paths to resolve the problem. Established most robust standard operating procedures and change the quantity specification limits to reduce the customer complaints.

As a second step it was determined to install an automation system to count the blister. During the implementation of the Counter system automation equipment through a validation process must ensure that not damage to the sterilization barrier is perform.

After the implementation of first step through changing the SOP and provide training to all the affected personnel the customer complaint due to blister quantity discrepancy improve considerable. The actions put in place demonstrate to be effective in reduce the occurrence of the quantity discrepancy customer complaints.

Next steps after this event on the continuous improvement process is to complete the validation process of the automation counter system. That will help to practically eliminate the quantity discrepancy issue and that the product will be in compliance with the label information at all time.

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