Balloon Final Inspection System

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Abstract *— This paper presents an innovative and automated system to improve the current inspection process of the balloon of the catheters. The human factor could affect the product quality because the operator output and accuracy are variable. The proposed inspection process includes a Keyence system, a rotary fixture, a Zaxis system, and an additional vision system that will identify defects. The new inspection process provides consistent quality and accuracy of the products.*

Key Terms *— Advance Process Development, Automation, Innovation, Regulatory, Vision Inspection System.*

INTRODUCTION

Overview of the Project

The current inspection process for the balloons of the catheters in a medical devices company is performed by an operator who accepts or rejects the product after visual inspection. For this reason, the product quality could be adversely affected by the human factor which is not the most suitable option in the pharmaceutical industry. Emerging new technologies can improve this process to make it more effective. Using a combination of devices to capture and record product defects will make the inspection process more accurate. As a result, the use of a device with all these features will improve product quality and company profit.

The medical devices industry needs to adjust their process to maintain an innovative edge. For that reason, the current inspection process needs to be redesigned. Because of this, the company will replace the inspection of the operator for one that will be realized with a Keyence system. This device had a rotary fixture that holds the catheter and rotates the balloon when it is inflated. Also, a Zaxis system will perform the leak testing of the products, and last, a vision system will identify the defects if anyone. Parts needed to complete this system are shown in Figure 1. The result of using a more innovative and automated system to realize the inspection process will provide consistent quality and accuracy of the products.

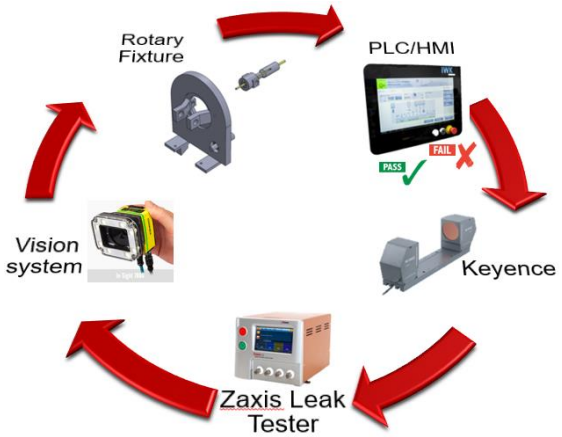

Figure 1
Parts to develop the Inspection System

Current Inspection Process

This inspection process is about identifying some defects already defined like a pinhole, abruption as well as balloon deterioration and separation into the surfaces of the balloon. The presence of primer under UV light as well as adhesive and some dimensions like gaps between the shoulder, tip exposure, and eccentricity of the balloon. The current inspection process is realized by an operator using magnification, UV light, and chronometer. In the current inspection process, the product is rejected or accepted after performing these inspections.

LITERATURE REVIEW

Innovation in Medical Devices

Innovation is one of the constant actions that arise within the medical devices industries as well as in pharmaceuticals. In the industry it was work for, seeks to innovate existing devices as well as new devices to make them non-invasive. The advantage of making non-invasive devices attracts doctors and clinicians since patients prefer alternatives that do not require operations. In this way, most of the companies have decided to make similar products and due to the results, they have increased their manufacturing in other countries. Creating new manufactures in other countries indeed helps the company's growth as a reduction in production costs. Many multinational companies have already established manufacturing facilities in new destinations, such as China, as a way of accessing the local market directly but also exploiting opportunities for lower production cost [1].

Good Manufacturing Practices and Quality System Regulations

Any product that is consumed, food, clothing, detergents as well as the products used when people are sick such as the thermometer or other instruments used by doctors for surgeries are all regulated by the federal government. Companies that manufacture pharmaceutical products are dedicated to ensuring the health and preventing products that develop harm or endanger the life of the human being. In the case of manufacturing, it is necessary to create a series of documents where there is evidence of the processes, materials, and tools used, as well as details of how the products are made. The Food and Drug Administration (FDA) is revising the current good manufacturing practice (CGMP) requirements for medical devices and incorporating them into a quality system regulation. The quality system regulation includes requirements related to the methods used in, and the facilities and controls used for, designing, manufacturing, packaging, labeling, storing, installing, and servicing of medical devices intended for human use. This action is necessary to add preproduction design controls and to achieve consistency with quality system requirements worldwide. This regulation sets forth the framework for device manufacturers to follow and gives them greater flexibility in achieving quality requirements [2].

This project investigates an innovative system to eliminate the current inspection system and to replace it with more precise equipment. Using a precise vision system to inspect defects that in turn can make measurements and make calculations and then determine some critical factors of the product. The current inspection system is performed by an operator in which it uses a 3X or 10X magnification to measure some of these factors. One of the main ideas is to standardize the inspection criteria to increase the quality of the product. As mentioned above to comply with a quality product, it is necessary to comply with FDA using a guide to inspections of quality systems (QSIT). This document guides to the FDA field staff on a new inspectional process that may be used to assess a medical device manufacturer’s compliance with the Quality System Regulation and related regulations [3].

Automated Inspections and Metrology

When it talks about using a vision system to inspect, it can say that it implies several necessary factors to have good results. Machine Vision is a subfield of engineering that encompasses computer science, optics, mechanical engineering, and industrial automation. Most MVS’s require digital input/output devices and computer networks to control other manufacturing equipment, such as robotic arms. Some uses of MVSs include part identification, defect inspection, presence/absence detection, dimensional measurement, positioning, and counting. One of the most common applications of MVS’s is the inspection of manufactured goods, such as semiconductor chips, automobile parts, food and pharmaceuticals [4]. An MVS is composed of a camera, an image capture

device, a lighting system, a computer, and software. The computer software converts the images into electronic signals and relays them from the image capture device to the computer, where they can be analyzed and stored. The type of analysis performed varies greatly; but, in general, the computer transforms the image into meaningful information [4].

ANALYSIS APPROACH

New Inspection Process Advantages

Due to the technology today the advantages that are getting to develop process are many. While it was walking through the assembly line of catheters it can observe that the current inspection procedure was variable even though it is validated. My approach to convinces the team as well as the manufacturing supervisor was taken the current operator and requested to pull out his glasses and performed the inspection. That means that the operator should not forget their glasses even though the supervisor used another person that shows that the process is variable. As part of this analysis, it took the equipment (Magnification) and it could see that the lens has scratches which can cause distortion in the image during the inspection. Something that helps enough to convince the team was to repeat this exercise with two other operators and the way of each operator perform the inspection it was completely different. For this reason, it has taken the current inspection process to be improved. For this balloon inspection process some of the following advantages of this improvement are: less dependence of the human factor to realize inspections, improve quality of the product, standardize the inspection process, an accurate measurement system, information are stored and available for other users, ease visual accept/reject units, ease programming and maintenance as well product cost decrease.

Equipment Featuring

Table 1 shows what the equipment is and what are their function.

Table 1
Equipment Featuring

Equipment	Featuring
Keyence	Gaps between shoulder Eccentricity Tip exposure Storage data
Zaxis	Leak Test Inflation Volume Deflation Time
Cognez Vision System	Defect (deterioration/abruption/particles) Presence of primer
PLC/HMI	Communication between equipment's Accept or Reject Units notification
Rotary Fixture	Hold Catheter Rotate 180°

RESULTS

Equipment Featuring Data for Automated Inspection

It was not established yet a test to perform a number of units to prove the variability of the process. For example, when the operators measure the gap between the balloon edge and shoulder of the tip as shown in Figure 2, the measures were different for each operator even though, it was close between them and those measurements were into the specification.

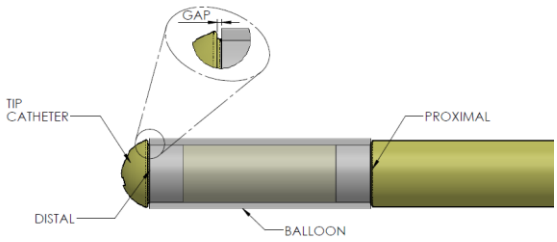

Figure 2
Gap between shoulder and balloon

DISCUSSION

Build Prototype for Automated Inspection

After showing the variability of the process and how the human factor could affect the quality of the product were discussed possible alternatives to correct and improve the inspection process. First, it captures the dimensions during the inspection it will be using the Keyence system. Some advantages of this system are that it can record the images and store them if is necessary to review them later. Also, the system saves the data into a spreadsheet that can be used to do some statistical analysis of the variability of the measurement inspected. The programming and maintenance of this was another topic that was discussed. The programming, as well as the maintenance of this equipment, is easy to learn and do it without a specialized operator. It will do a procedure to perform these actions.

Second, the Zaxis can be communicated with the system to inflates the balloon and to save the deflation time. The Cognex vision system which got the defect particles and primer presence is another system that is easy to program and do maintenance. Finally, one part of the maintenance is the calibration which is important for the quality of the product and which was mentioned during the discussions about the things that can improve the quality of the product.

CONCLUSIONS

The main goal of this project is to eliminate the human error, increase the quality and accuracy of the inspection process of the balloon into the catheters. To improve the quality is necessary to use a semi-automated or automated sophisticated equipment. Due to the new technologies is necessary to be less dependent on the humans to perform process like inspection or process in where there is needed to reject or accept any product. Some implications of the process that it was dependable of humans being rationale are: increase the price of products, poor quality and variability on the process.

An important fact while developing a system as this one is combining different factors like vision, metrology, and leak test system that makes the project an expensive one. However, the final product will have a better quality which will guarantee that the customers trusted in the product.

Recommendations

Future work that is needed is to add more complexity to the system using an automated robot that can pick the part that will be inspected and then place it into the rotary system as well as classify it when the system accepted or rejected. This needs to be investigated as well as tested to prove effectivity.

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