PPAP Process and Correlation Study for Vision Systems

John Arevalo Mercado
Master in Manufacturing Engineering
Carlos Gonzalez, PhD.
Industrial and Systems Engineering
Polytechnic University of Puerto Rico

***Abstract* —** *The Production Part Approval Process (PPAP) is being adopted by Medical Device companies to qualify raw material. To standardized qualification processes between multiple supplies and help manufactures communicate requirements effectively. This research process will focus in the new product implementation of a membrane components and the completion of its PPAP requirements. The supplier must demonstrate through a several statistical analysis like process capability and measurement system analysis that can produce the membrane component.*

Key Terms *— Production Part Approval Process, Gage R&R, Process Capability, T-Test.*

INTRODUCTION

Medical device companies have numerous challenges when introducing new products due how complex their supply chain is and having a large number of suppliers. The need to standardize and streamline the new product implementation (NPI) has let the Medical Device companies to adopt what is known as from Automobiles and Aerospace companies. This research project will be focused in a new product implementation to qualify a membrane component and it's PPAP.

PROBLEM STATEMENT

The final products for our company is assembled with a membrane component. This component is manufactured by cutting a membrane to the desired diameter of Ø 1.732 with an equipment known as Aquaflex. The validation of the membrane component must ensure that the process is capable of meeting the specification tolerance limits of ± 0.015". In addition, the supplier must establish the necessary controls to maintain the quality and mitigate any risk in the process. The supplier was provided a drawing of the component with the desired specification for its manufacturing. (See Figure 1).

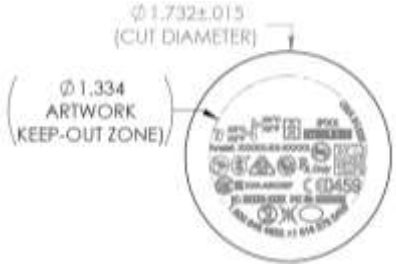

Figure 1
Membrane Component Drawing

RESEARCH DESCRIPTION

This research is about the Production Part Approval Process (PPAP) and its requirement. The PPAP is a standardized process in regulated industries (medical device, automobile, aerospace, etc…) that helps manufacturers and suppliers communicate and approve production designs and processes before, during, and after its manufacture [1]. The PPAP defines requirements for qualifying externally purchased components intended for human use.

RESEARCH OBJECTIVES

The objective of this research is to complete Production Part Approval Process (PPAP) for the Membrane component.

The PPAP documentation requirements for the membrane are [1]:

- MSA – Measurement System Analysis
- IQ – Installation Qualification
- OQ – Operational Qualification
  - Excluded if process operates under a set point and has not operating window.
- PQ – Performance Qualification
- PFD – Process Flow Diagram

- PFMEA – Process Failure Mode Analysis
- CP – Control Plan

RESEARCH CONTRIBUTIONS

This project seeks to validate the component through the PPAP process and increase the inspection capacity output to keep with product demand.

LITERATURE REVIEW

The Production Part Approval Process (PPAP) defines generic requirements for production part approval. It ensures that manufacturers document their capability to consistently meet product specifications [2]. Through these guidelines, suppliers and customers understand the requirements to obtain part approval. Application of these principles reduces delays and non-conformances during part approval. Medical device companies have begun to incorporate the medical device ISO 13485 standards into the PPAP format. ISO 13485 represents the requirements for a quality management system to design and manufacture, medical devices. It was published by the International Organization for Standardization (ISO) for the first time in 1996 and updated recently in 2016. A quality management system is set up by an organization to achieve high levels of customer satisfaction and continual improvement, focusing on common requirements and the reduction of variation and waste in the supply chain. This can be performed by establishing quality policies, quality objectives and establishing the means to achieve those objectives.

Measurement Systems Analysis (MSA)

MSA is defined as an experimental, statistical and/or mathematical method of determining the amount of variation that exists within a measurement processes. MSA is used to certify the measurement system for use by evaluating the system's accuracy, precision and stability.

- Gage R&R: Refers to the variation that exist between the interactions of instrument, operator and parts.
- Correlation: Determines how much variation exist between multiple equipment.

Failure Mode and Effects Analysis (FMEA)

FMEA is a methodical approach used for identifying risks on process changes. The Process FMEA initially identifies process functions, failure modes their effects on the process. If there are design inputs, or special characteristics, the effect on end user is also included.

- Failure modes: Means the ways, or modes, in which something might fail. Failures are any errors or defects, especially ones that affect the customer, and can be potential or actual.
- Effects analysis: Refers to studying the consequences of those failures.

Process flow diagram (PFD)

Process Flow Diagram is a diagram commonly used in process engineering to indicate the general flow of plant processes and equipment. The PFD displays the relationship between major equipment of a plant facility.

Control Plan (CP)

Control Plan is a table that outlines the methods taken for quality control of critical inputs to deliver meet customer requirements. It also provides a written description of the measurements, inspections, and checks put in place to control production parts and processes.

Installation Qualification (IQ)

Installation Qualification (IQ) verifies that an instrument or unit of equipment being qualified (as well as its sub-systems and any ancillary systems) has been installed and configured according to the manufacturer's specifications or installation checklist. For example, a physical instrument or tool may require a specific amount of floor space, certain operating conditions, and an assurance that no damage exists on the unit. For software, IQ typically involves the user requirements and verifies that the minimum system requirements are met. The overall goal of the IQ is to document that a newly installed or modified equipment has the necessary prerequisite conditions to function as expected

Operational Qualification (OQ)

Operational qualification (OQ) is performed after completing the IQ. OQ's purpose is to determine that equipment performance is consistent with the user

requirement specification within the manufacturer-specified operating ranges. When a process is fully verifiable or doesn't have an operating window of parameters it doesn't required an OQ. It consists of two lots, one testing the process on high parameter and one lot for the low parameters.

Performance Qualification (PQ)

The last step of qualifying a process is the PQ. In this phase, the qualification and validation team verifies and documents that the user requirements are verified as being met. These user requirements should test the nominal operating parameter that the equipment is going to use during a normal manufacturing run. It usually consists of three independent lots run at the same parameters to test the consistency of the process.

PROJECT METHODOLOGY

The first step in the PPAP is to bring the equipment into the facilities and document the installation qualification (IQ). The installation IQ consist in the following requirements:

- **Utilities:** Verifies the basic necessary services needed to operate the equipment are in place.
- **Installation:** Makes sure the location and the space requirements are suitable to install the equipment.
- **Calibration:** Checks, graduate and rectify the equipment outputs to a known standard.
- **Maintenance**: Establishes key spare parts needed to perform repairs and determines the period when care and upkeep are needed for the equipment.
- **Safety:** Verifies the equipment complies with regulatory and company standards such an ergonomics, health and hazards procedures.
- **Documentation:** Record keeping of any equipment operating manuals, custom modifications, software backups and software revision.

The results and all documentation needed to complete are summarized in an installation qualification report (IQR) and a checklist summarized the execution and results of the validation. Refer to Figures 2 for the manufacturing equipment installation checklist and Figure 3 for the measurement equipment installation checklist.


Installation Checklist

UTILITIES	REQ.	ACCEPT	REJECT	CORRECTIVE ACTION
Electricity	Y	Y		
Compressed air	Y	Y		
Chill	N	N/A		
Water	N	N/A		
Steam	N	N/A		
Hot oil	N	N/A		
Ethernet	Y	Y		
Other	N	N/A		
INSTALLATION				
Machine location	Y	Y		
Machine leveled	Y	Y		
Machine condition	Y	Y		
Machine secured	Y	Y		
Machine appearance	Y	Y		
Functional check	Y	Y		
CALIBRATION				
Pressure gauges	N	N/A		
Temperature controls	N	N/A		N/A
Dwell timers	N	N/A		
Tension Meters	Y	Y		
Speed indicators	N	N/A		
Footage Meters	Y	Y		
Other	N	N/A		
MAINTENANCE				
Spare parts identified	Y	Y		
Electrical PM	Y	Y		
Mechanical PM	Y	Y		
Tech. training	N	N/A		
SAFETY				
Guarding	Y	Y		
Interlocks	N	N/A		
Electrical safety	Y	Y		
Power disconnect	Y	Y		
Insulation (Vest)	N	N/A		
Noise level	Y	Y		
Housekeeping / trash bin	Y	Y		
Ergonomics	Y	Y		
Restart/power loss	Y	Y		
Restart/E-stop	Y	Y		
Environmental	Y	Y		
DOCUMENTATION				
Machine description	Y	Y		
Drawing package	Y	Y		
OEM manuals avail.	Y	Y		

Y = YES, N = NO

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Figure 2
Installation Qualification - Aquaflex (Manufacturing)


Installation Checklist

UTILITIES	REQ.	ACCEPT	REJECT	CORRECTIVE ACTION
Electricity	Y	Y		
Compressed air	N/A			
Chill	N/A			
Water	N/A	N/A		
Steam	N/A			
Hot oil	N/A			
Ethernet	N/A			
Other	N/A			
INSTALLATION				
Machine location	Y	Y		
Machine leveled	Y	Y		
Machine condition	Y	Y		
Machine secured	Y	Y		
Machine appearance	Y	Y		
Functional check - Table movement	Y	Y		
CALIBRATION				
Pressure gauges	N/A			
Temperature controls	N/A			
Dwell timers	N/A	N/A		
Tension Meters	N/A			
Speed indicators	N/A			
Footage Meters	N/A			
Other - Dimensional	Y	Y		
MAINTENANCE				
Spare parts identified	N	N		
Electrical PM	N	N		
Mechanical PM	Y	Y		
Tech. training	Y	Y		
SAFETY				
Guarding	N/A			
Interlocks	N/A			
Electrical safety	N/A			
Power disconnect	N/A	N/A		
Insulation (Vest)	N/A			
Noise level	N/A			
Housekeeping / trash bin	N/A			
Ergonomics	N/A			
Restart/power loss	N/A			
Restart/E-stop	N/A			
Environmental	N/A			
DOCUMENTATION				
Machine description	N	N		
Drawing package	N	N		
OEM manuals avail.	N	N		

Y = YES, N = NO

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Figure 3
Installation Qualification – Micro-VU (Measurement)

The next step is to perform a test method validation or measurement system analysis to qualify the measurement equipment. The equipment used to measure the membrane component is a Micro-Vu vision system. Minitab Statistical software was used to calculate the % Tolerance of the equipment must be below 25% (See Figure 4).

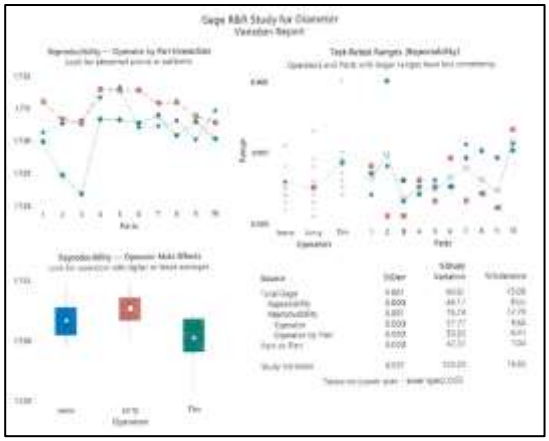

Figure 4
Micro-Vu Gage R&R Results

The operational qualification (OQ) comes after the IQ and MSA are completed. For this particular process, no OQ is required since the equipment operates in a given set point; therefore there is no variance in the parameters to challenge during OQ.

The last step for a validation is known as the performance qualification (PQ) where we test the consistency and stability of the process with multiple lots without changing the nominal parameters. The PQ consist in the analysis of normality of the data and process capability for three (3) manufacturing lots.

Normality Testing

Three (3) manufacturing PQ lots were completed and 60 samples gathered per lot. These were analyzed with Minitab Statistical Software through a probability plot to determine normality via Anderson Darling Test. All three lots failed normality with P-Values ≤ 0.05 (See Figure 5).

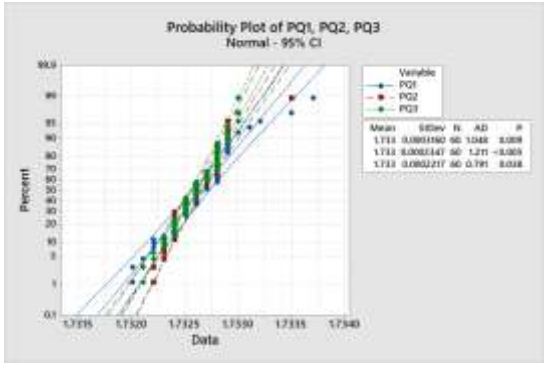

Figure 5
Normality Anderson darling PQ 1-3

Per company statistical **procedure** when normality cannot be proven with Anderson Darling Test, the next step is to evaluate the data for normality via Ryan-Joiner. All three (3) PQ lots had a P-Value ≥ 0.05 with Ryan-Joiner; therefore, we can use a normal distribution for process capability purposes (See Figures 6, 7 & 8).

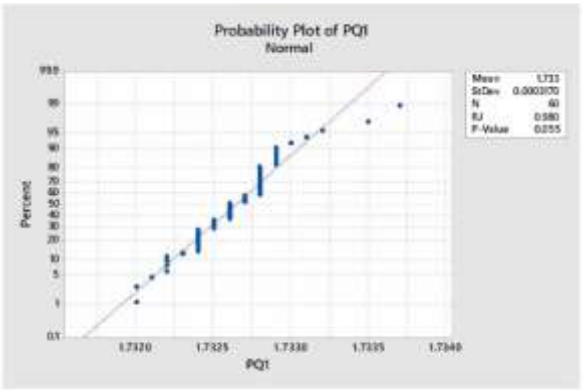

Figure 6
Normality Ryan-Joiner PQ1

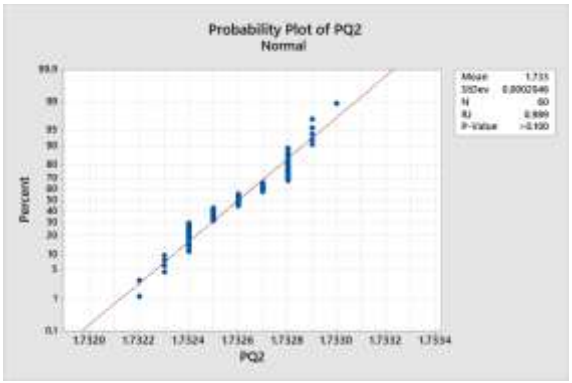

Figure 7
Normality Ryan-Joiner PQ2

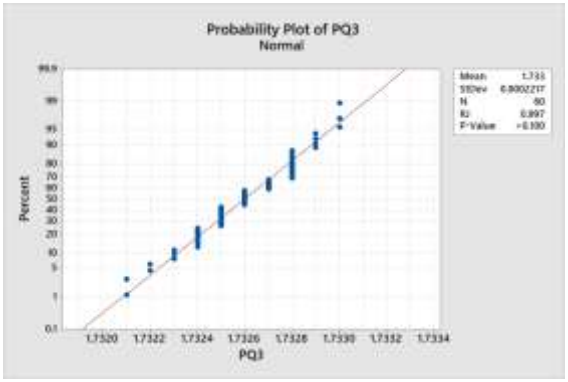

Figure 8
Normality Ryan-Joiner PQ3

Process Capability Analysis

The process capability results for dimension Ø1.735" ± 0.015" were calculated using Minitab Statistical software normal process capability report. All three (3) PQ lots met the acceptance criteria of Cpk/Ppk ≥ 1.33 (See Figures 9, 10 & 11).

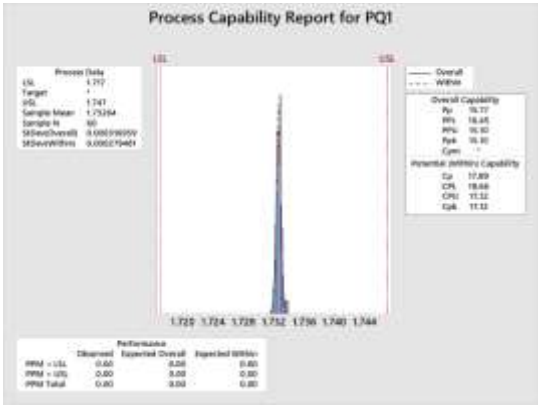

Figure 9
Process Capability PQ1

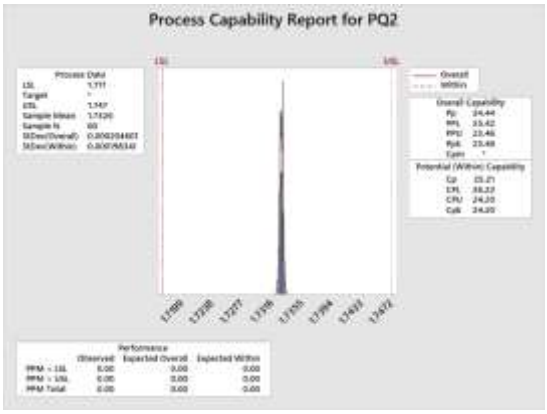

Figure 10
Process Capability PQ2

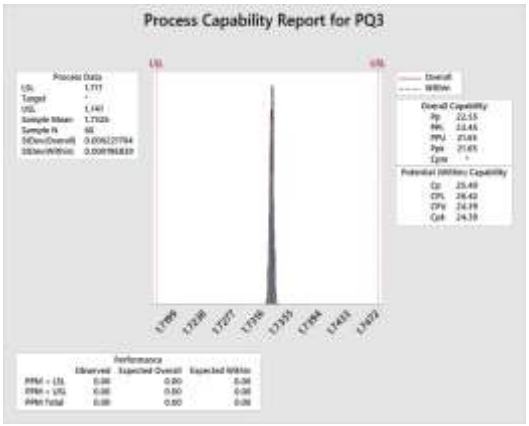

Figure 11
Process Capability PQ3

Keyence Correlation Study

A second equipment name Keyence was validated to increase the inspection capacity of the line and reduce inspection lead time. A correlation study was performed to determine if there is a statistical difference between the equipment used to measure the PQ lots, the Micro-Vu and the new Keyence measuring equipment (See Figure 12).

Figure 12
Micro-Vu and Keyence (Vision System)

To determine if the equipment are equivalent a paired t-test was performed by measuring 15 samples in both equipment and comparing their results. The test procedure consists of analyzing the differences between measurements [3]. If there is no difference between readings the mean of the difference should be zero [3]. Minitab Statistical Software was use to analyze the samples. The paired T-test resulted in no statistical difference between equipment. (See Table 1 & 2).

Table 1
Paired T-Test Descriptive Statistics

Sample	N	Mean	StDev	SE Mean
Micro Vu	15	1.73103	0.00094	0.00024
Keyence	15	1.73099	0.00103	0.00027

Estimation of Differences

Mea.	StDev	SE Mean	95% CI for μ difference
0.000047	0.000247	0.000064	(-0.000090, 0.000184)

Table 2
Paired T-Test Result

T-Value	P-Value
0.73	0.477

Process Controls

As part the PPAP the supplier must maintain the quality and establish controls to mitigate any risk. A process flow map, a PFMEA and control plan were developed to ensure the quality of the product is

maintained and completes the final requirements of the PPAP (See Figures 13, 14, 15 & 16).

Figure 13
Control Plan (CP)

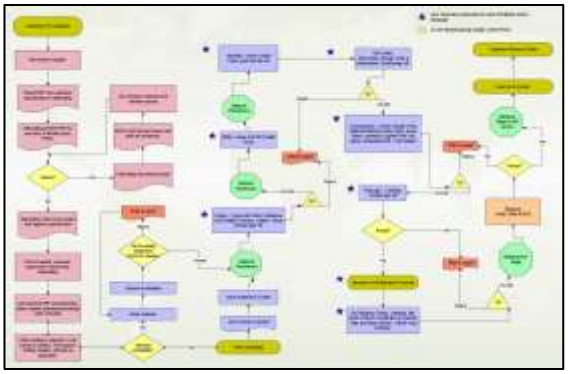

Figure 14
Process Flow Map (PFM)

Figure 15
Process Failure Mode & Analysis (PFMEA Page 1 of 2)

Figure 16
Process Failure Mode & Analysis (PFMEA Page 2 of 2)

CONCLUSION

The Production Part Approval Process (PPAP) has been completed, meeting all qualification requirements. The supplier met the process capability criteria of CpK/PpK ≥ 1.33; therefore, their process is capable of

meeting the drawing specifications to produce the raw material with a diameter of Ø 1.732" ± 0.015" (See Table 3).

Table 3
Process Capability Results

Description Ø 1.732" ±0.015"	PQ1	PQ2	PQ3
Normality RJ (P-Value ≥ 0.05)	0.055	> 0.100	> 0.100
PPK ≥ 1.33	15.10	23.46	21.65
CPK ≥ 1.33	17.12	24.20	24.39

Table 4
Keyence Correlation Results

Description	Acceptance Criteria	Result
Micro-Vu Gage R&R	% Tolerance ≤ 25%	15%
Paired T-Test	P-value ≥ 0.05	0.48

The second goal of the project was to qualify an existing inspection equipment known as the Keyence vision system to have as a backup of the original qualification. The qualification for the alternate inspection equipment consisted in comparing if there was any statistical difference between them through a paired T-test study. The first inspection equipment, Micro-Vu was successfully validated with a % tolerance of 15%, while compare to the Keyence correlation results there was no statically difference between both equipment (See Table 4).

REFERENCES

[1] *PPAP 101: What You Need to Know*. (2021, August 18). RGBSI. [Online] https://blog.rgbsi.com/what-to-know-about-ppap

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[3] Montgomery, D. C. (2006). "Applied Statistics for Engineer". Seventh Edition, pp 366-367.