PPAP Process and Correlation Study for Vision Systems

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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.

Introduction

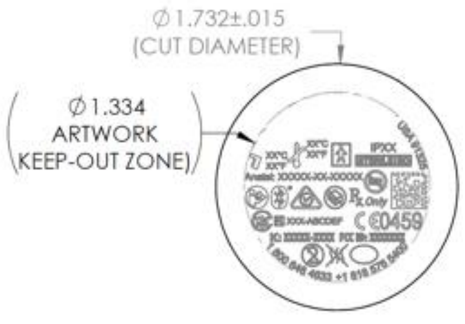
The need to standardize and streamline the new product implementation (NPI) has let the Medical Device companies to adopt what is known as PPAP from Automobiles and Aerospace companies. This research project will be focused in a new product implementation to qualify a membrane component and it's PPAP.

Background

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. 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.

Problem

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".



Membrane Component Drawing

Methodology

The PPAP documentation requirements for the membrane are:

- 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

Installation qualification (IQ):
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.

Performance Qualification (OQ)
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. A process capability analysis is required as acceptance criteria for this step.

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.

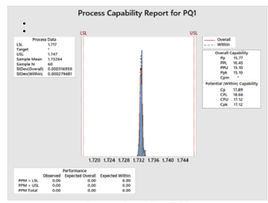
- **Gage R&R:** Refers to the variation that exist between the interactions of instrument, operator and parts.
- **Correlation:** Determines how much variation exist between multiple equipment.

Results and Discussion

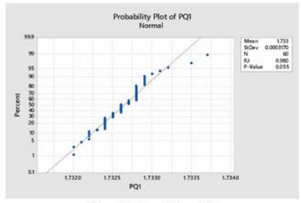
IQ exercises were completed and a checklist verifying all items in the methodology were met.

OQ is not applicable for this process since the equipment doesn't have an operating window.

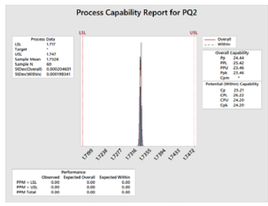
PQ process capability statistical analysis is summarized below



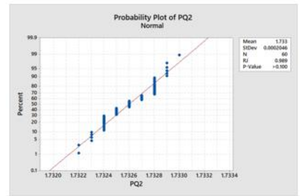
Process Capability PQ1



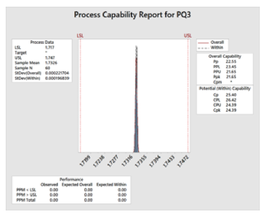
Normality Ryan-Joiner PQ1



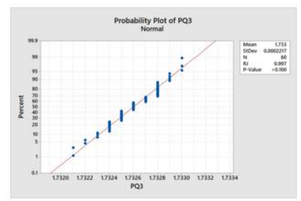
Process Capability PQ2



Normality Ryan-Joiner PQ2

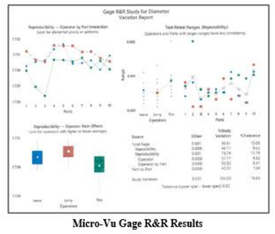


Process Capability PQ3



Normality Ryan-Joiner PQ3

A micro-vu vision system was used to inspect the 3 PQ lots, the validation consisted in a Gage R&R analysis. A different vision system will be compared through a T-Test to verify if it can be used as an alternate or equivalent inspection method.



Micro-Vu Gage R&R Results

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)

Paired T-Test Result

T-Value	P-Value
0.73	0.477

Micro-Vu and Keyence (Vision System)

Conclusions

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".

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

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

Keyence Correlation Results

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

References

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

[2] *Production Part Approval Process* (PPAP). (2021). Quality-One International. [Online] https://quality-one.com/ppap

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