Understanding and Reducing the 709 Equipment Variability to Validate K3/K4 with an Alternate Resin

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Abstract

This project is focused on the quality assurance hurdles in the injection molding processes of part No. FYA1470, encountered while validating the K3/K4 product using a substitute resin required by the customer. Utilizing the Define – Measure – Analyze – Improve – Control (DMAIC) methodology, the project successfully pinpointed and improved multiple root causes affecting the process. Critical interventions included fixing the resin injection barrel temperature controller's malfunction and errors in the measurement program, which led to a reduction in process variability and an enhancement in capability indices.

Among the six Critical to Quality Dimensions (CTQs), two did not align with customer specifications, previously defined with the former resin. As result of applying the DMAIC Methodology, it was determined that CTQ2's performance remained consistent between Operational Qualification (OQ) and Performance Qualification (PQ) phases with the new resin, whereas CTQ3 exhibited marked improvement. To ensure ongoing process stability, control measures were implemented, notably the integration of temperature monitoring into the Preventive Maintenance (PM) and Calibration schedules.

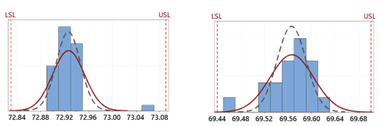
Introduction

Due to limited space in the production area, we were required to relocate five injection molding machines, including machine 709. This change has led to a loss of process control, and as a result, certain products are now failing to meet validation standards due to non-compliance with customer specifications. Moreover, we have observed an increase in defects that were not common before the relocation. It is critical to conduct a thorough root cause analysis to determine the factors contributing to this non-compliance and to implement corrective measures to realign with our client's requirements and restore product quality.

Background

When the validation process of K3/K4 with the alternate resin began, machine 709 had already been relocated due to business strategies. However, when the Operational Qualification was being executed, two of the six CTQs did not meet the requirement that the capacity indices (Cp and Cpk) be greater than or equal to 2.00. CTQ2 and CTQ3 are two diameters of the part that impact the sealing of this and, if not sealed correctly, could cause a certain type of leakage, which is critical for this type of product. For this reason, it was essential to identify the root cause of why we were not in compliance to address it and ensure the quality of the product. All of this will be made during the execution of the Performance Qualification, where we must work on improving our processes so that the customer approves its run.

CTQ2 and CTQ3 Capability Histograms During OQ Runs



Problem

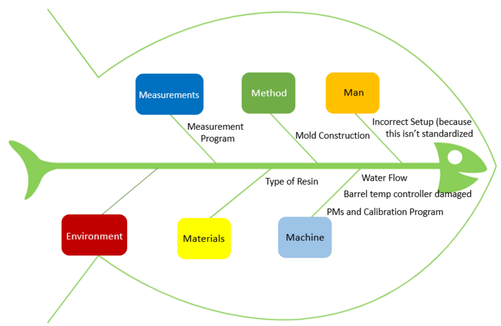
The product K3/K4 with an alternative resin wasn't complying with the customer requirements. The CTQ2 and CTQ3 during the OQ runs didn't comply with the Cp and Cp equal or greater than 2.00. After identifying the root cause, and work on this, the this part was successfully validated and the Performance Qualification lots were sold to the customer. In addition, the new non tolerable defect identified during the validation was completely removed after adding the temperature controller to the Preventive Maintenance and Calibration Programs.

Methodology

DEFINE
During this phase, the problem and aim were defined. The project aims to validate the product K3/K4 with an alternative resin as requested by the customer, because the CTQ2 and CTQ3 Cp and Cpk weren't equal or greater than 2.00 as required. In addition, new non-tolerable defects that hadn't been identified before this validation were found during its execution.

MEASURE
The Operation Qualification (OQ) for this part number was executed before starting this project, so this data was analyzed to understand why two of the six CTQs didn't comply with the Cp and Cpk requirements. In addition, each run executed during the OQ was analyzed individually, where it was noticeable that the low run had less variability and better capacity indices than the nominal and high runs.

ANALYZE
A Fishbone Diagram was created, and several tests were conducted, where it was concluded that the barrel temperature controller that injects the plastic into the mold was damaged. Injecting plastic at temperatures much higher than expected caused the pieces to inflate and show voids/bubbles, which are not allowed for the customer's specifications. Finally, the customer understood that the tolerance for this CTQ was challenging to measure, and the tolerance was too tight, so after some functional testing, it was negotiated with the customer, and the tolerance will be updating, determining this didn't affect the product quality.



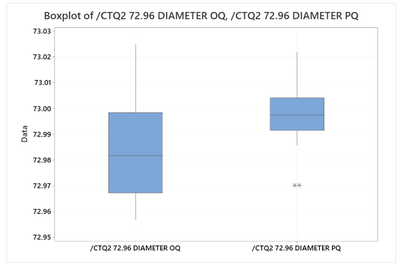
IMPROVE
The resin injection barrel temperature controller of the equipment was identified damaged during the Performance Qualification running. Also, was identified that the process setup wasn't standardized. The program to measure the parts was adding additional variance to the measures. Finally, the CTQ2 and CTQ3 tolerances were found to be too stringent for the new resin and could be expanded without affecting product performance. The measurement system of the CTQ3 was found to be a high contributor to the overall variability. Therefore, a more accurate measurement methodology was developed and implemented.

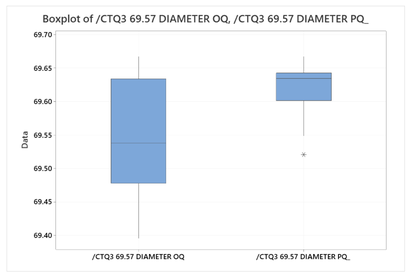
CONTROL
To control the process, the resin injection barrel temperature controller of the equipment was added to the machine's PM and Calibration Programs. Also, a new setup sheet was created to standardize the process setup including the process cycle time. The program to measure the parts was updated to reduce the measurements error. Finally, the part drawing will be updated to increases the CTQ2 and CTQ3 tolerances because, after functional testing, the customer decided these CTQs tolerances were too tight.

Results and Discussion

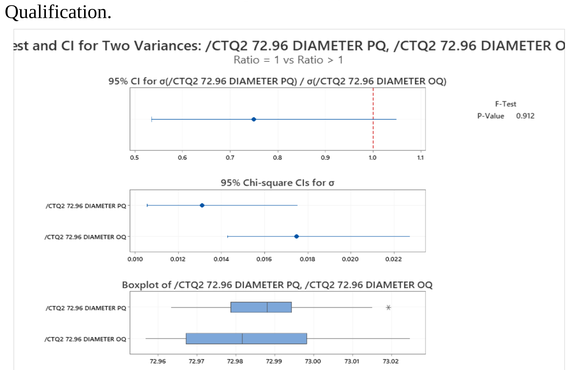
Several statistical analyses were completed to understand and represent graphically the variance reduction of the process to validate the product K3/K4. Box Plots were created to easily compare the differences in variability between the Operation Qualification and Performance Qualification runs. Also, hypothesis tests were conducted to understand if exists difference between the mean and variance of the Operational Qualification vs. Performance Qualification.

During the OQ run the observed variance of the CTQ2 and CTQ3 were high, which affected the capability analyses results. After identify and work on the identified root causes the variance was reduced, this time in compliance. Below the results:





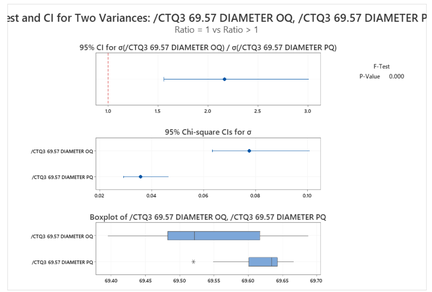
In addition, hypothesis tests were conducted to compare the variance of the CTQ2 and CTQ3 of the Operational Qualification vs. Performance Qualification.



CTQ2 Hypothesis Test:
The CTQ2 Hypothesis Test shown that there is not enough statistical difference between the variances, so the null hypothesis H0 cannot be rejected, as p-value is greater than alpha (0.05) which means that the difference between the variances is not big enough as shown in the graph below:

Results and Discussion

CTQ3 Hypothesis Test:
The CTQ3 Hypothesis Test shows that there is enough statistical difference between the variances, so the null hypothesis H0 must be rejected. It means that is the difference is statistically significant, in this case the PQ data showing a big reduction in the variance as shown in the graph below:



Conclusions

The enhancements made to the injection molding process have significantly reduced variability, guaranteeing the successful validation of part K3/K4. A detailed examination revealed that Critical to Quality Dimension 2 (CTQ2) maintained consistent results across both Operational Qualification (OQ) and Performance Qualification (PQ) stages. In contrast, Critical to Quality Dimension 3 (CTQ3) displayed a considerable enhancement in performance. The implementation of control strategies, like the inclusion of the injection barrel temperature controller in the Preventive Maintenance (PM) protocols, has been instrumental in achieving process stability. To maintain compliance and ensure adherence with the advancements achieved, it is critical to continuously monitor the critical quality metrics.

Future Work

The product part drawing will be updated with the new tolerances for CTQ2 and CTQ3 in the following steps.

Resume operations with the implemented improvements.

Another DOE needs to be completed to extend the window of operational parameters, as PQ lots were executed with low parameters. Therefore, it is important to define a new window of values for the future.

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References

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