Outsource Component for Quality Improvements

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INTRODUCTION

In a medical device facility located in Puerto Rico, the process used for the manufacturing of plastic tubes was to have an in-house extrusion machine to produce tubing of several dimensions. During the production of plastic tubing using extrusion process there are some characteristics that can deviate the final product specifications, such as wear, environmental variations or operator fatigue. Assessment of the complete process was performed in order to determine the poor quality of the product received at the assembly line. Investigation results shown deterioration of the incumbent machine causing quality defects and delays in the manufacturing line. These deterioration resulted in a qualification of a new supplier and a new supply chain for the new process established.

PROBLEM STATEMENT

The medical device facility has a Davis Standard DS-20 to extrude plastic tube components for assembly purposes.

Figure 1 is a representation of an extrusion manufacturing line. The numbers in the picture indicate the different equipment/components used in an extrusion machine as follows: (1) extruder, (2) extrusion die, (3) calibration / cooling system, (4) haul off, and (5) cutting station.

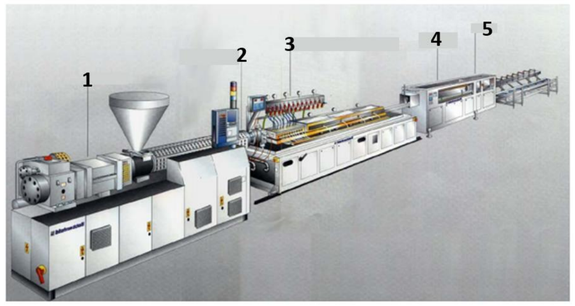

Figure 1
Extrusion line layout (J. M. Nóbrega1, Using Open FOAM® to Aid the Design of Extrusion Dies for Thermoplastics Profiles", 9th Open FOAM Workshop, 23-26 June 2014, Zagreb, CROATIA)

It was found that during production quality testing samples have been failing specifications.

The common defects in extrusion process are as follows:

1. Improper System Engineering/Installation
2. Improper Operation
3. Resin Defects
4. Improper Materials Addition
5. Surging
6. Poor mixing
7. Melt toughness or fracture
8. Overheating

PROBLEM STATEMENT (Cont.)

Due to the increase in quality issues and investment needed to restore the equipment, the senior management team took the decision to outsource the process to an outside supplier. This project is related to qualifying a new vendor to provide plastic tubing medical device facility.

QUALIFICATION

A project plan was established to track and document the activities of the project. The methodology used for this execution was PMI which consist of the following stages (*Unknown author, unknown year, Project Methodology. Available: https://www.pmi.org/)*:

1. Project Conception and initiation
2. Definition and Planning
3. Execution
4. Control and Monitor
5. Project Close

Requirements for supplier qualification were submitted to the new supplier, which were provided with acceptable results:

1. Process Control Plan
2. Failure Mode Effects Analysis FMEA
3. Process Validation (IQ, OQ, PQ)
4. Measurement System Analysis (MSA)
5. Preventive maintenance records
6. Calibrations and Certification records
7. Process Capabilities

Requirements for the qualification of the new component in the manufacturing line included the following:

1. PPAP disposition
2. Incoming Inspection
3. Engineering verification lot
4. Lot Quality testing
5. Risk Management review
6. Regulatory Assessment
7. Project documentation closure

RESULTS

Capability analysis was used to demonstrate that the component maintains it specification during it manufacturing. Ranges of Cpk's will vary from the data obtained, CPK <1.00 (Poor, incapable) 1.00 < CPK <1.67 (Fair) CPK > 1.67 (Excellent, Capable).

Figure 2 represents the data obtained for outside diameter (OD), after analysis performed in Minitab 18, Cpk obtained was 1.78, which demonstrated that the output is excellent, and supplier can produce within specification.

RESULTS (Cont.)

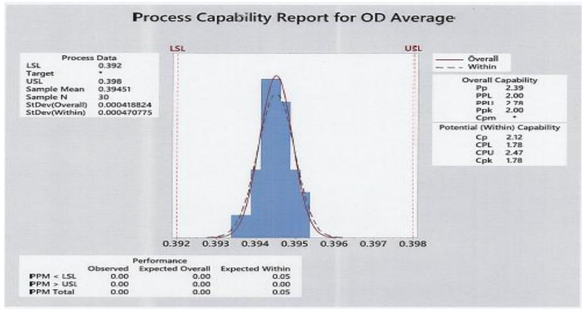

Figure 2
Capability analysis for "*Outer Diameter*"

Figure 3 denotes data obtained for the Length (L) of the components. Distribution of the data is inside specification of the drawing, and Cpk obtained is 1.97, which demonstrated that supplier can produce output within components specification limits.

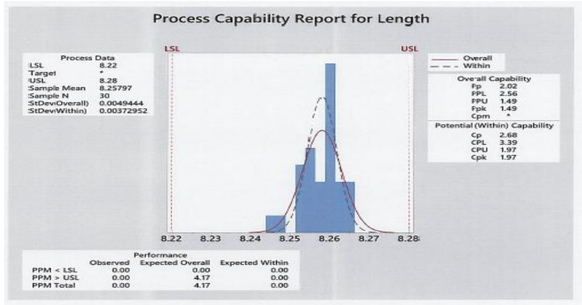

Figure 3
Capability analysis for tube "*Length*"

Figure 4 was analyzed using the data of wall thickness of the components. A total sample of thirty (3 0) plastic tubes were measure and analyzed in Minitab 18. Results obtained were acceptable with a Cpk of 2.69.

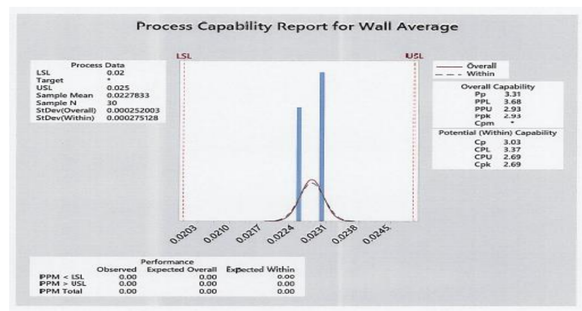

Figure 4
Capability analysis for tube "*Wall Thickness*"

RESULTS (Cont.)

Table 1 shows summary of capabilities from the supplier; this summary demonstrate that the components are within specification and can maintain it during manufacturing process at supplier.

Table 1
Summary of Capabilities and Results

	Low Temp/ Low Speed	Low Temp/ High Speed	High Temp/ Low Speed	High Temp/ High Speed
OD Average	Mean 0.3948" Cpk 2.90	Mean 0.3948" Cpk 2.76	Mean 0.3948" Cpk 2.27	Mean 0.3947" Cpk 1.85
Wall Average	Mean 0.0229" Cpk 2.92	Mean 0.0232" Cpk 3.43	Mean 0.0232" Cpk 3.09	Mean 0.0230" Cpk 2.49
Length	Mean 8.248" Cpk 2.07	Mean 8.243" Cpk 2.48	Mean 8.244" Cpk 2.62	Mean 8.241" Cpk 2.37
Visual	All Pass	All Pass	All Pass	All Pass

Lot built provided evidence that the new component performs as the current one. All tests performed to the engineering verification lot had acceptable results.

CONCLUSION

From the results of all data collected and analyzed, it can be concluded that the new component can be used in the assembly line for final product and packaging. The methodology used for the qualification has been successfully executed. The process has been followed, which demonstrates the continuity of the product.

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