Outsource Component for Quality Improvements

Roberto C. Ortiz Ledée
Engineering Management Program
Dr. Héctor J. Cruzado
Graduate School
Polytechnic University of Puerto Rico

Abstract *— 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. These tubes then follow the normal process and are supplied to the manufacturing line for final assembly and packaging. 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. The senior management team took the decision to outsource the process to an outside supplier. The aim of this paper is to review and summarize all the activities performed to qualify and create a supply chain for the new process established.*

Key Terms *— Extrusion machine, quality defects, plastic tube, outsource.*

INTRODUCTION

A medical device manufacturer in Puerto Rico had quality issues in their plastic extrusion manufacturing line. The issues were related to wear, environmental variations and operator fatigue. In order to resolve the issue, senior management team took the decision to outsource the process to an outside supplier. To accept the new components from other supplier the established process is to qualify and confirm that the new components comply with specification. This paper includes a summary of the current process of extrusion and all activities involved to qualify new supplier.

A plastic extrusion process can be described as a "method of forming substances by forcing them through a perforated plate or die to produce tubes, rods, or other desired shapes" [1]. Machines can use different raw materials to produce the finish goods in our paper case study such as polyethylene, polystyrene, nylon, etc. An example of an extrusion line and its main components is shown in Figure 1. 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.

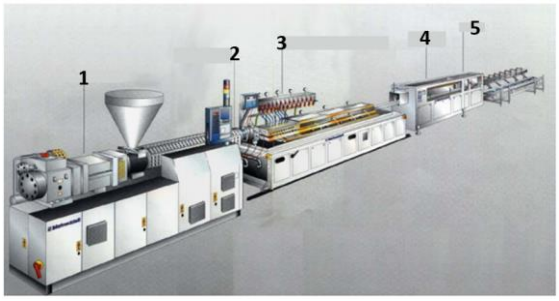

Figure 1
Extrusion line layout [2]

The medical device facility has a Davis Standard DS-20 to extrude plastic tube components for assembly purposes. It was found that during production quality testing samples have been failing specifications. These failures can be defined as "any form of deviation of the product's characteristic from the specification set up by the manufacturing process" [3]. Most of the defects root causes are identified as die design, material or processing in which the output can express in tube's "rough surface, thickness variation, uneven wall thickness, diameter variation, centering problem or extruder surging" [3].

The common defects in extrusion process are as follows [3]:

- Improper System Engineering/Installation
- Improper Operation
- Resin Defects
- Improper Materials Addition
- Surging
- Poor mixing
- Melt toughness or fracture
- Overheating
- Moisture release
- Trapped air
- Contamination

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 paper presents the steps to select and qualify a new vendor to provide plastic tubing medical device facility.

NEW SUPPLIER QUALIFICATION

Supplier Selection

Procedures for supplier selection are in place for cases like the plastic tubing with quality issues. Process stated that suppliers are selected based on their capabilities to provide direct goods, indirect goods, or sub-contract services that will support the company's goals. When the need exists for a new goods component or sub-contract service first search is to use the existing approved supplier.

To outsource the plastic tubing, a search was made of current tubing supplier to see if there was a supplier who provide the same or similar goods, products, or services. During the investigation a similar tube was being supplied from one company in Connecticut which had the necessary documentation to bid the component. Medical Device representative "Sourcing Manager" reviewed the proposal with the Category Manager and determined that the supplier was a perfect fit to the needs required. Once the supplier was selected the project plan was created between both companies to align strategy and expectation.

Qualification

Qualification of a product or process must be performed for new or modified processes based on risk assessment to ensure no impact on form, fit or function of the product, or when deemed necessary by the analysis of plant metrics such as customer complaints, amount of scrap and/or rework. Therefore, the new plastic tubing from the selected supplier needs to be qualify.

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 [4]:

- Project Conception and initiation
- Definition and Planning
- Execution
- Control and Monitor
- Project Close

Requirements for supplier qualification were submitted to the new supplier. Following are the requirements needed from the supplier to approve Production Part Approval Process (PPAP):

- Process Control Plan
- Failure Mode Effects Analysis FMEA
- Process Validation (IQ, OQ, PQ)
- Measurement System Analysis (MSA)
- Preventive maintenance records
- Calibrations and Certification records
- Process Capabilities

All documentation was reviewed and approved by supplier quality engineer (SQE) at the medical device facility in order to proceed with other requirements as part of the assembly line specification. Requirements for the qualification of the new component in the manufacturing line included the following:

- PPAP disposition
- Incoming Inspection
- Engineering verification lot
- Lot Quality testing
- Risk Management review
- Regulatory Assessment
- Project documentation closure

RESULTS

One of the most important aspect of the requirements is the capability analysis and results from the data obtained from the supplier. Capability analysis is a set of calculations used to assess whether a system is statistically able to meet a set of specifications or requirements.[5]. The importance of the capability is 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.

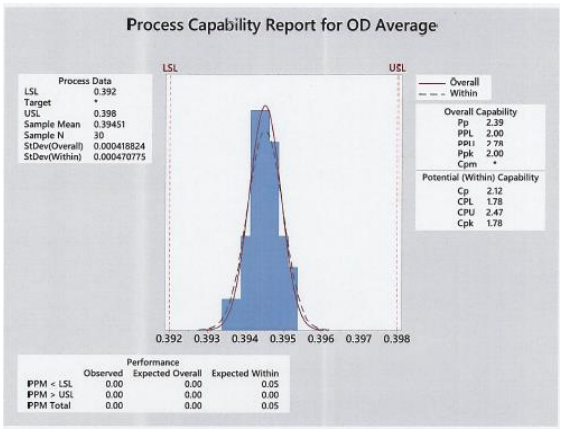

Figure 2
Capability analysis for tube "*Outer Diameter*"

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.

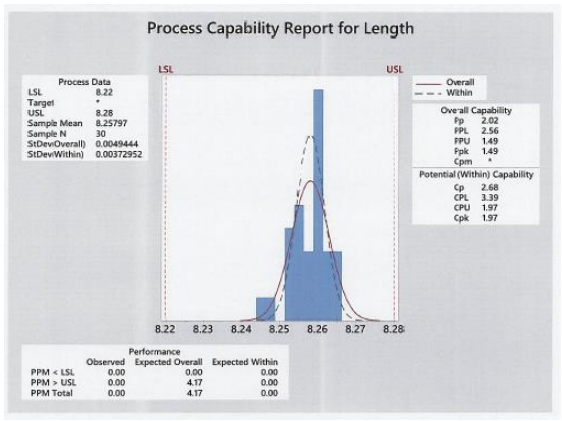

Figure 3
Capability analysis for tube "*Length*"

Figure 4 was analyzed using the data of wall thickness of the components. A total sample of thirty (30) plastic tubes were measure and analyzed in Minitab 18. Results obtained were acceptable with a Cpk of 2.69.

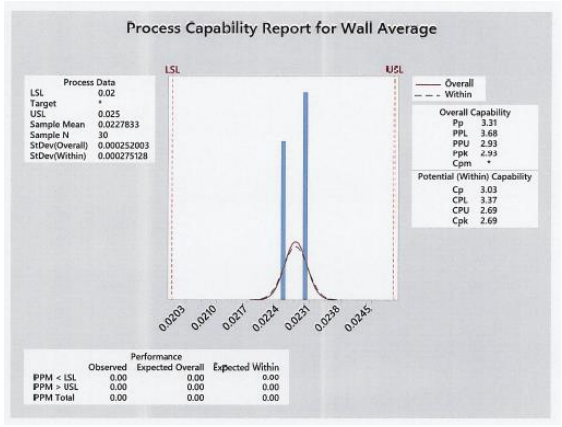

Figure 4
Capability analysis for tube "*Wall Thickness*"

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

All other documentation from the supplier passed the requirements and testing. No discrepancies were found during the qualification.

To demonstrate that the new component does not affect the functionality of the device an engineering verification lot was built with the component with satisfactory results. Sampling size was as per ANSI/ASO Zl.4 Single Tightened Level lI, AQL 0.40. Description and sampling size for each test are summarized in Table 2, each test results were acceptable as per inspection plan provided to quality technician.

Table 2
Summary of Engineering Lot results

Test	Test Description	Sampling Size	Results
VIS11.0	Visual Evaluation - 1.0 AQL	200	Passed
VIS10.4	Visual Evaluation - 0.40 AQL	200	Passed
FEBAG	Functional –Specimen Retrieval	200	Passed
REMFO	Removal Force Evaluation	200	Passed
LEAKT	Leak Test Evaluation	200	Passed

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.

REFERENCES

[1] M. Christensen. Introduction, Experience, And Application of The Extrusion Process. FDST 896, Independent Study, 2005.

[2] J. M. Nóbrega1, A. Rajkumar1, C. Fernandes1, L.L. Ferrás1, F. Habla2, O. Hinrichsen2, J. Guerrero3 and O.S. Carneiro1, "Using Open FOAM® to Aid the Design of Extrusion Dies for Thermoplastics Profiles", 9th Open FOAM Workshop, 23-26 June 2014, Zagreb, CROATIA

[3] J. G. Khan, R. S. Dalu and S. S. Gadekar. Defects in Extrusion Process and Their Impact on Product Quality. IJMERR. Vol. 3, No. 3, July 2014.

[4] Unknown author, unknown year, Project Methodology. Available: https://www.pmi.org/

[5] Unknown author, unknown year, Capability Analysis. Available: https://www.pqsystems.com/qualityadvisor/DataAnalysisTools/capability_analysis.php