SiO2 Medical Products™
SCIENCE INSIDE™

Dimensional Stability of a Multicavity Injection Molded Article

Technical Report Series 2016-008

Keywords: dimensions, syringe, blood tube, vacutainer, cavity, injection, molding, diameter, variation, glass

Introduction

SiO_2 Medical Products, Inc.'s (SMP) containers for parenteral medications stand out from all other polymer and glass containers for parenteral solutions on the market today for many reasons.

1. The polymeric material's viscoelastic properties lends itself to break resistance.
2. The inner surface of the polymeric material is internally coated using plasma enhanced chemical vapor deposition (PECVD) with three layers of silicon-based material that provides pH resistance, oxygen barrier properties, and leachable resistance. In addition, due to the materials of construction, the vial is metals free.
3. Injection molding processing produces primary containers with high dimensional consistency not attainable by borosilicate glass processing.
4. The SMP container incorporates a unique unit dose identification. Traceability can be shown down to the unit level.

Purpose

This study was designed to determine relative dimensional stability of SMP injection molded articles over glass.

Background

Both glass and plastic primary containers for parenteral dosage forms are available to the pharmaceutical industry. There are many factors in making the decision to use one over the other. One of the most important factors that pharmaceutical packaging professionals need to consider when choosing container material is variation. As Dr. W. Edwards Deming proclaimed in the early 1960's "Understanding variation is the key to success in quality and business." By understanding inherent variation and its ramifications, pharmaceutical professionals can make decisions that not only save time, money, and opportunity cost but also lives. This study looks at peer processes used to manufacture articles from glass and plastic, in this case cyclic olefin polymer (COP).

Methodology

A Renishaw Equator 300 Coordinate Measuring Machine (CMM) was used to take the measurements of the components.

Results and Discussion

To illustrate the differences between glass and injection molded syringes, three key dimensions of the syringe were selected:

Figure 1. Barrel Inner Diameter

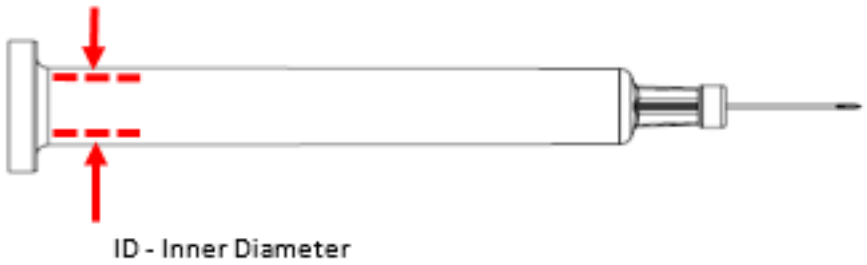


Figure 2. Flange Outer Diameter

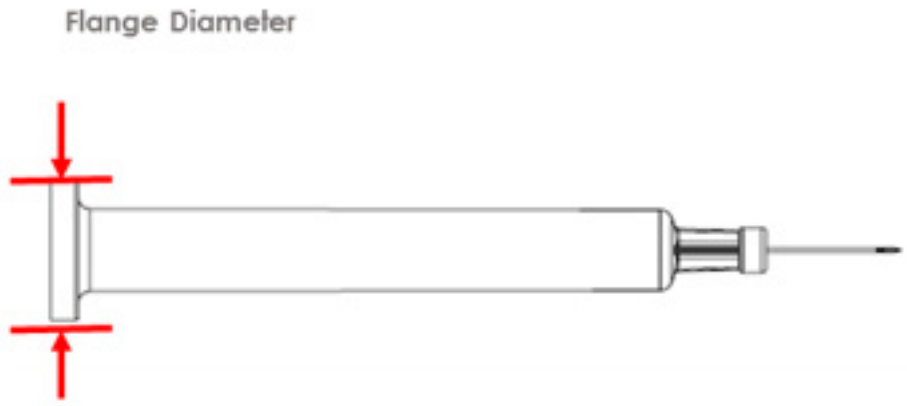
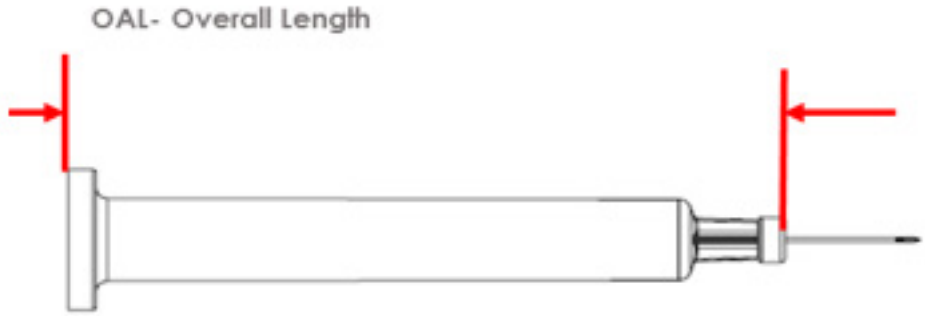


Figure 3. Syringe Length



The following charts show the reduced variability of the SMP injection molded syringe as compared to a glass syringe with the SMP Limits delineated.

Single cavity syringe pilot mold, n = 30 samples

Commercial glass 1 mL syringes, n = 30 samples

Glass syringe data is normalized to SMP syringe nominal dimensions for comparison purposes.

Figure 4.

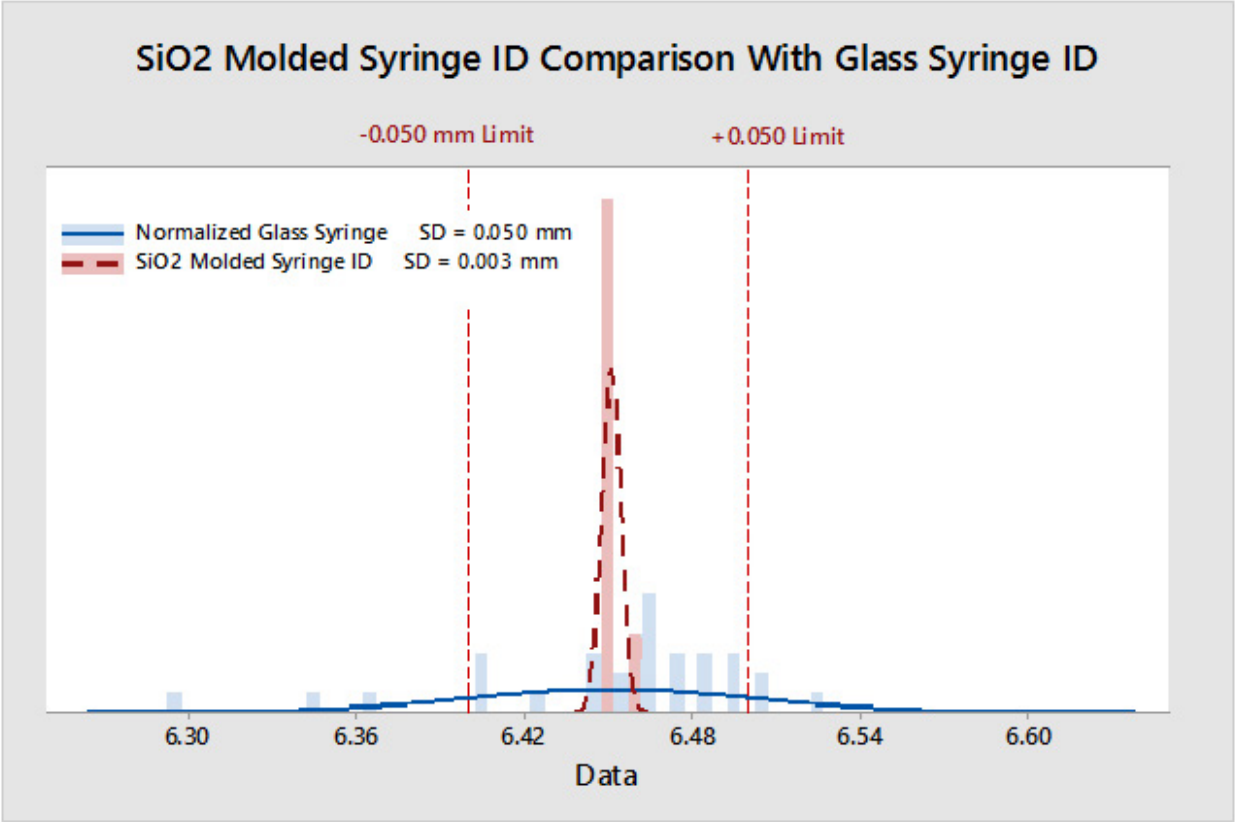


Figure 5.

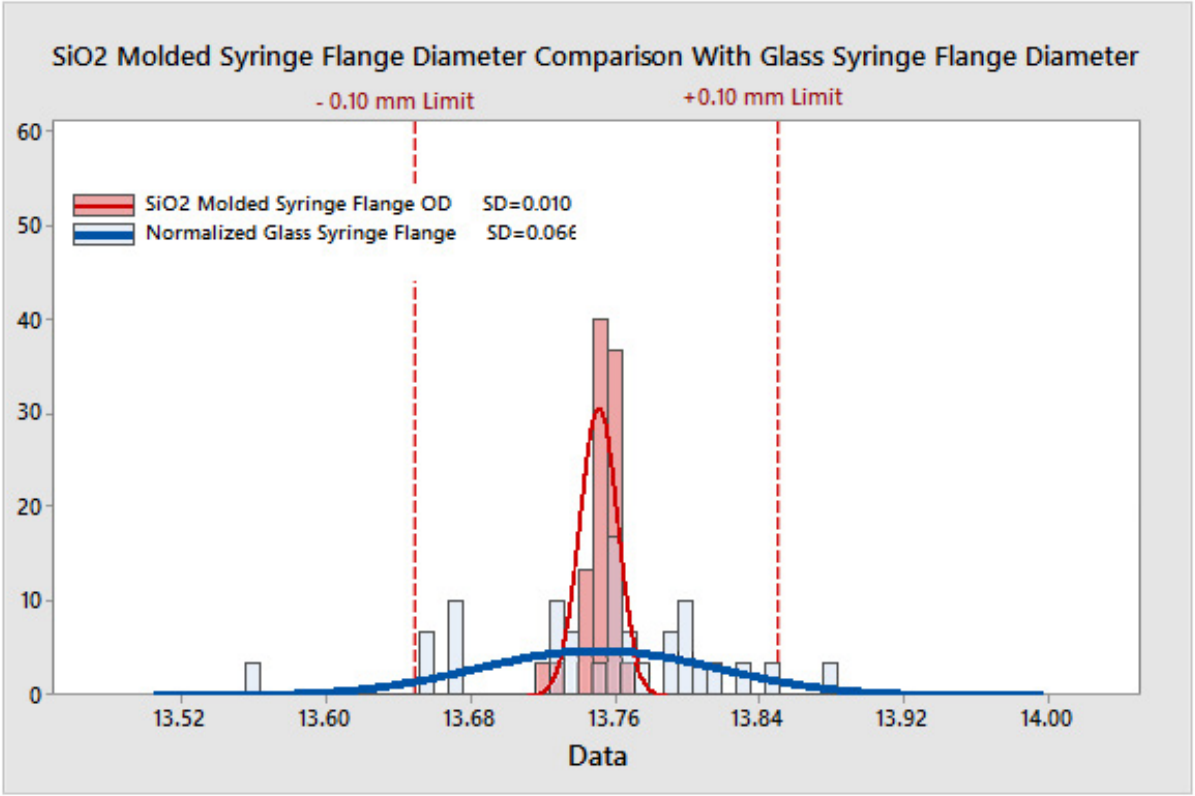
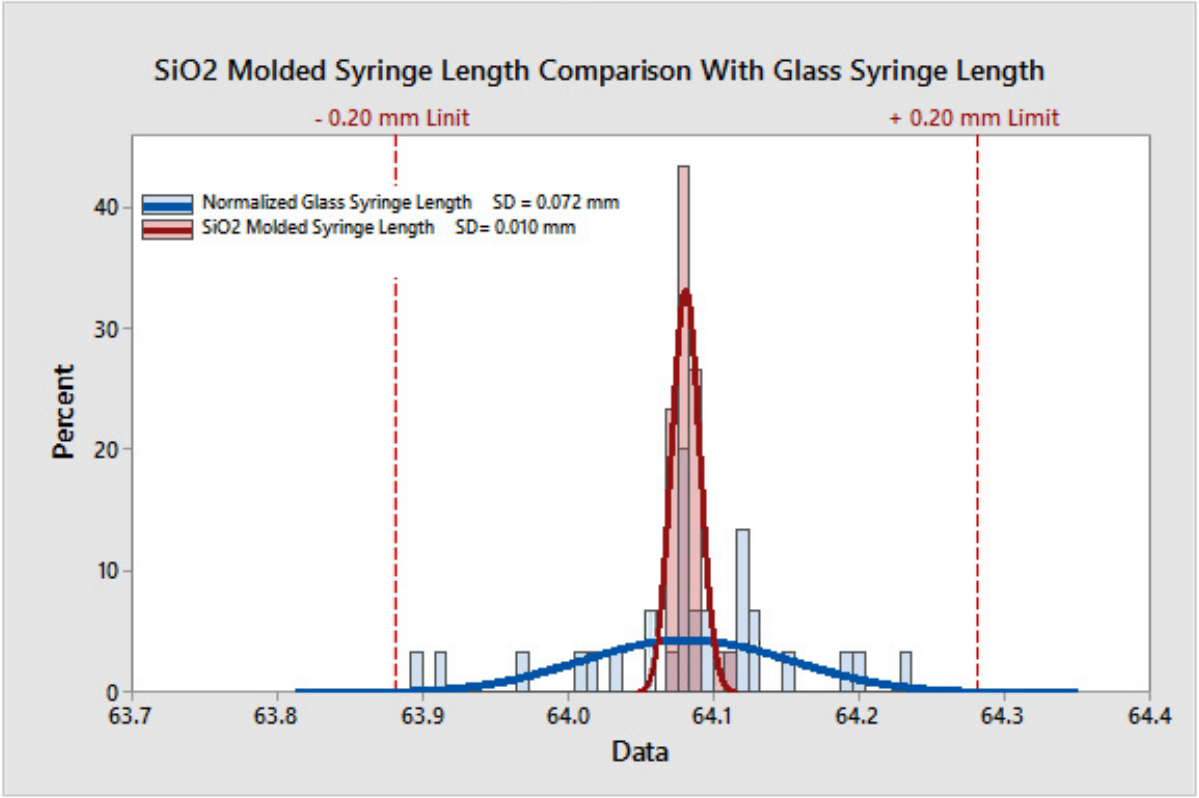


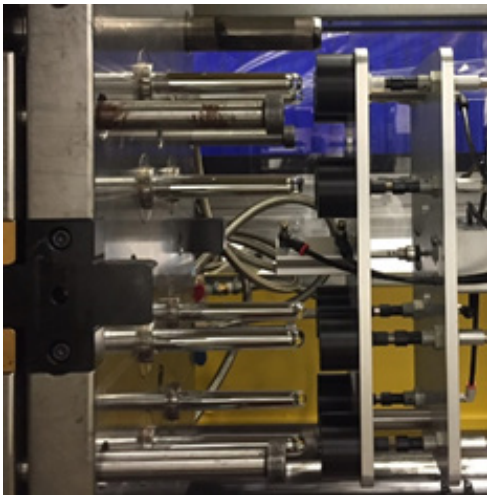
Figure 6.



The injection molded syringes exhibit less variability with tighter tolerances than glass syringes.

Multiple Cavity Production Variability

A typical production injection mold will have several cavities that make the same part to maximize productivity. To account for this additional source of variability, data was generated from an existing 8 cavity production mold of a 4 mL blood tube. A blood tube or vacutainer is a sterile glass or plastic tube with a closure that is evacuated to create a vacuum inside the tube facilitating the draw of a predetermined volume of liquid. Most commonly used to collect blood samples in venipuncture. SMP manufactures millions of these products using the same material and injection molding technology as used on syringes having the same inherent dimensional consistency. The blood tube is illustrative of a multiple cavity tool so the cavity to cavity and process variation can be observed and compared to glass.



The following charts offer a dimensional comparison of the relative variability of three container systems;

- SMP Single Cavity Pilot 1 mL Long Syringe Mold (same data as shown on initial figures)
- Glass 1 mL Long Glass Syringe (same normalized data as shown on initial figures)
- SMP 8 cavity production mold of 4 mL COP Blood Tube (331 Samples distributed across all 8 cavities normalized to SMP syringe dimensions for comparison)

Figure 7.

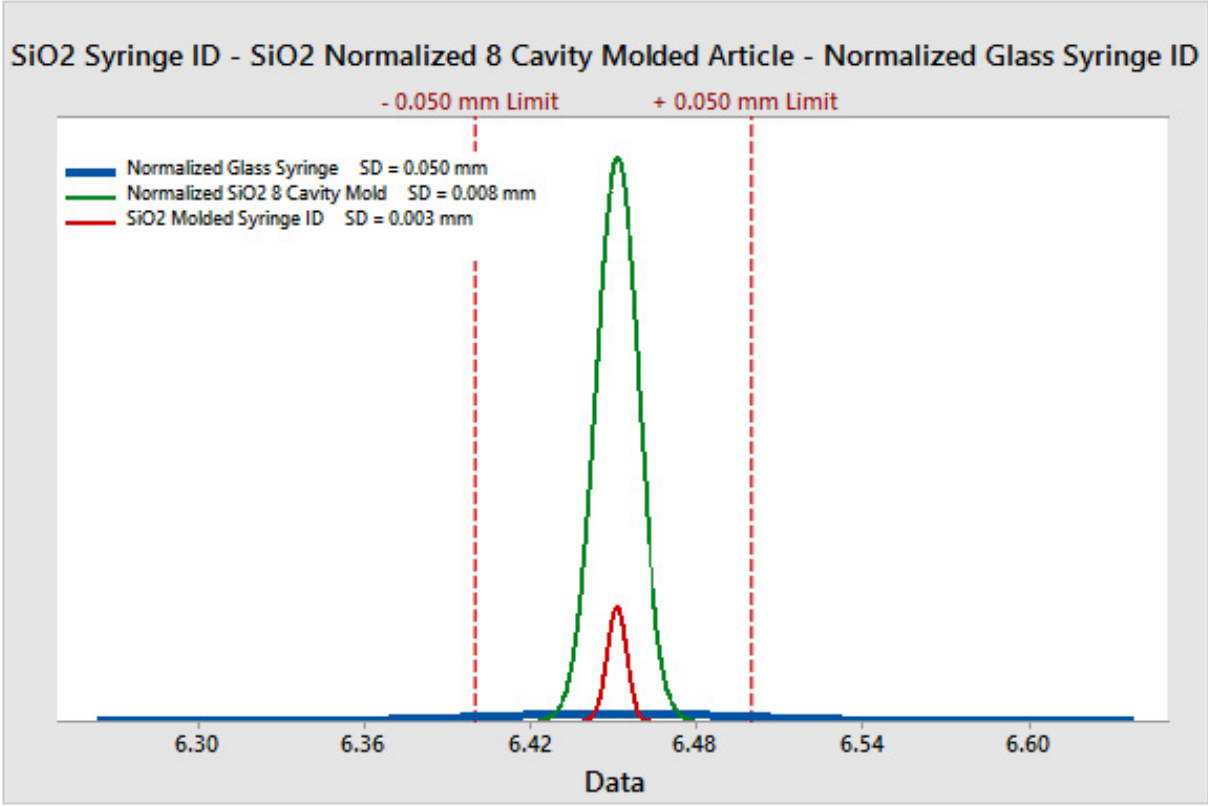


Figure 8.

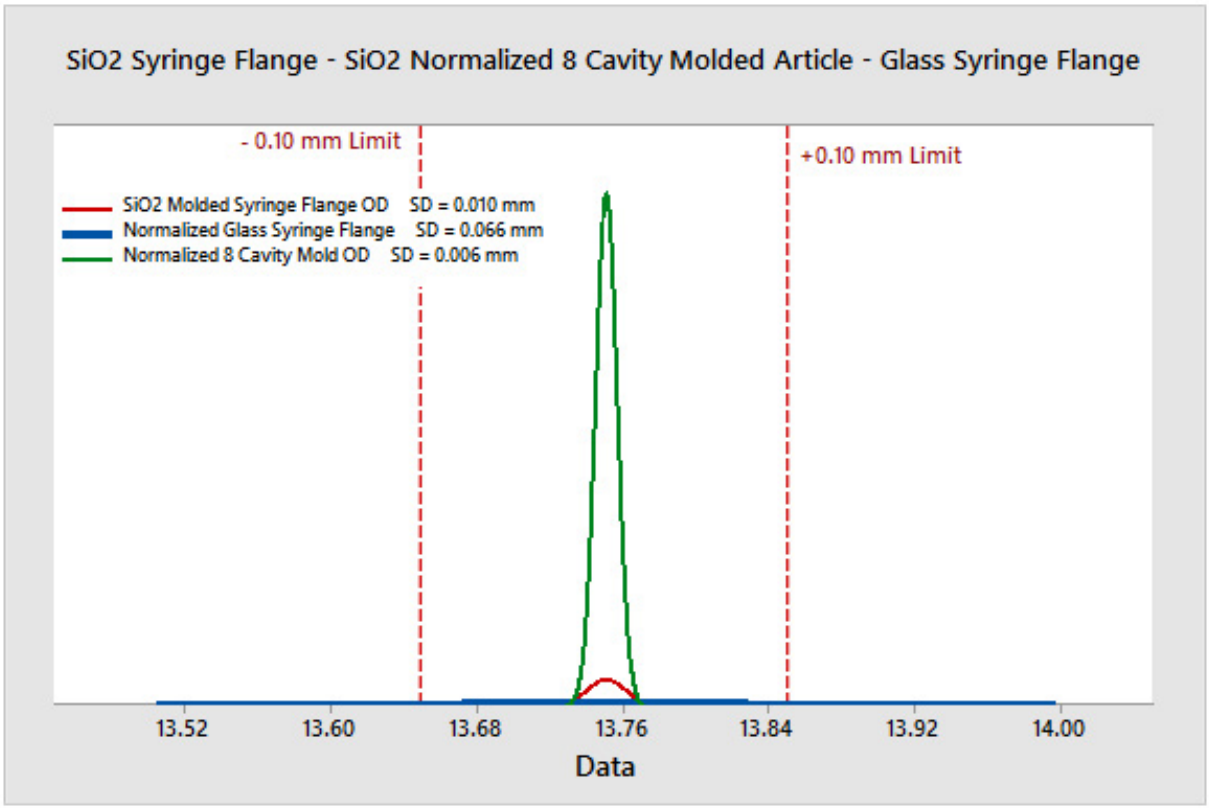
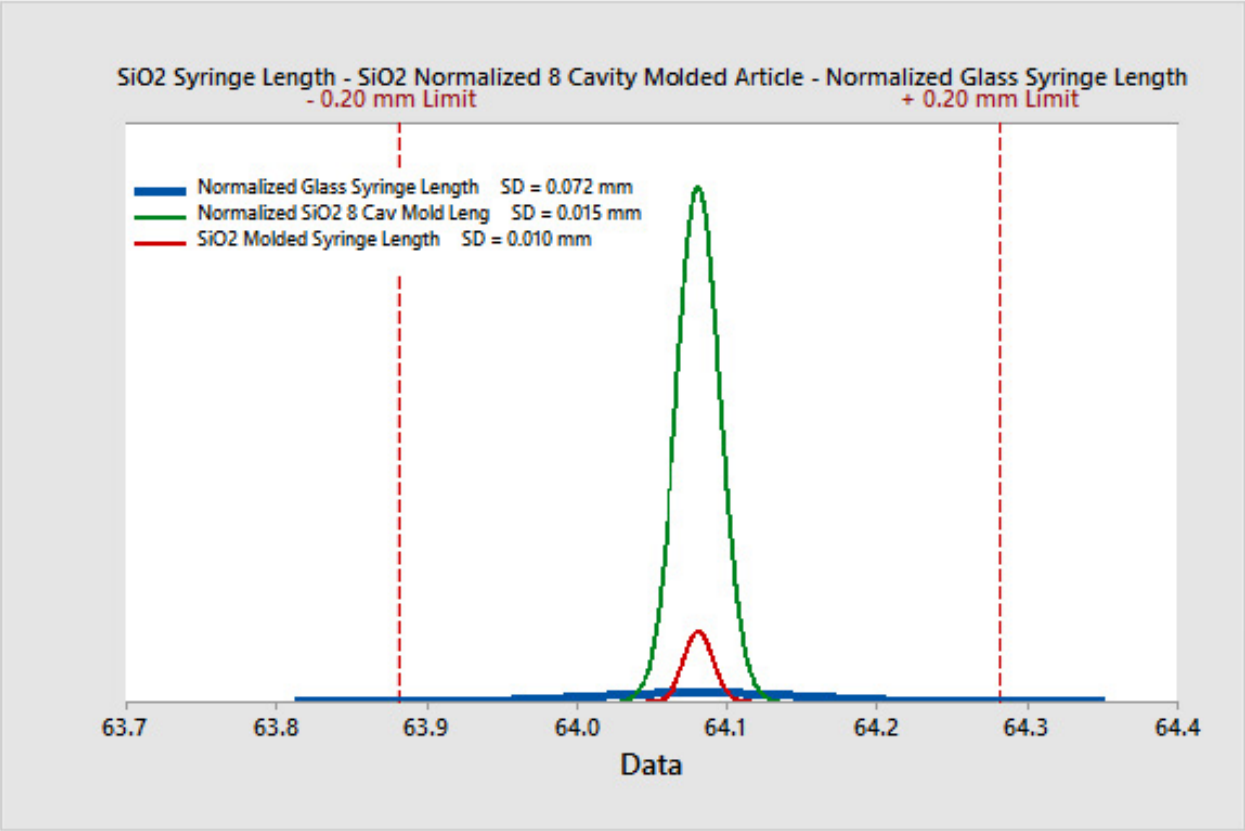


Figure 9.



Conclusions

- Both process variation and cavity to cavity variation of all COP containers are smaller (as much as an order of magnitude) compared to glass.
  - Glass has 11 times the variation as compared to multiple cavity injection tool for Flange Outer Diameter.
  - Glass has 6 times the variation as compared to multiple cavity injection tool for Internal Diameter.
  - Glass has 5 times the variation as compared to multiple cavity injection tool for Overall Length.
- By reducing variation components perform better together reducing field failures.