Scientific Injection Molding: A Tool for Lean Manufacturing

Injection molding is a critical component fabrication technique in medical device manufacturing. Therefore, any method that can be employed to reduce costs associated with it is of much interest to device makers. This article examines how principles of lean manufacturing can be used in injection molding processes to eliminate waste and reduce costs.

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Until recently, injection molding was thought of as more of an art than a science. Times have changed and many medical device manufacturers now require that their injection molding partners have scientific injection molding (SIM) capabilities in place. The industry and device manufacturers are demanding molders to have capabilities to produce very complex parts with tighter tolerances and thin walls. Regulatory organizations are increasingly looking for more robust validation procedures. The FDA's "Guideline on General Principles of Process Validation," and The Global Harmonization Task Force's "Quality Management Systems–Process Validation Guidance" provide guidelines toward these expectations.

Scientific injection molding is a highly technical, scientific approach to developing and optimizing an injection molding process. SIM applies equally to conventional thermoplastic materials as well as liquid silicone rubber and other thermoset, high consistency rubber materials. Scientific injection molding follows a standardized, data-driven methodology to plan and collect important information about the molding process.

Past practices and "tribal knowledge" would lead a process engineer to just shoot some parts, look at the visual quality, measure a few key dimensions, and "tweak" the molding process until product specifications have been met–and there are so many process parameters to "tweak." This approach does not allow the process engineer to know if the process is as robust as it could be. Without a fundamental level of data collection, the process engineer can't even know if the process is in control, let alone robust.

The development of a robust injection molding process using SIM takes into consideration all of the following inputs:

- Part design
- Mold design/construction
- Material characteristics
- Molding machine being used
- Process parameters

Each of the above inputs also has numerous variables, or factors, that can affect the process. For example, within process parameters alone, variables such as melt temp., mold temp., shot size, injection speed, hold time, hold pressure, and cooling time are usually significant. Likewise, material characteristics, such as viscosity, vary providing another set of factors. Regardless of the numerous variables, the goal is to produce identical parts, time after time, machine after machine, set-up after set-up, and material lot after material lot.

For some molders, scientific injection molding is a way of life; it's a culture for many in the industry. But why is scientific injection molding important? Many answers to this question lie within the principles of lean manufacturing. The practice of lean manufacturing is a culture for many who realize it's critical to remaining competitive, especially in today's economy. The U.S. automotive industry has been a leader in the implementation of lean manufacturing. These practices are beginning to take hold in other industries, including the medical device industry. Lean manufacturing teaches us to reduce total cost by eliminating waste in everything we do. The seven forms of waste are:

- Defective products
- Over processing

- Over production
- Excess motion
- Waiting
- Excess inventory
- Transportation

Elimination of Defective Products

The most obvious form of waste elimination is to eliminate defective product, or scrap. Emphasis is placed on defect prevention during the molding process, rather than inspection and sorting after the parts are molded. The objective is to validate a robust molding process with an eye for zero-defect quality. Producing fewer defects during molding significantly reduces the probability of passing a defective part onto the customer. The use of scientific injection molding uncovers potential defects, or failure modes, during process development, and allows countermeasures to be taken to prevent them. Reducing or eliminating scrap reduces overall costs and allows molders to be more competitive.

Elimination of Over Processing

The past practice of shooting some parts and "tweaking" the molding process generally leads to over processing. However, the process engineer may never know it. For example, to avoid short shots or weld lines, the shot size may be set higher than necessary to fill-out some cavities, resulting in some cavities flashing, especially if the cavity balance is poor. Using scientific injection molding, cavity balance is measured, a flash-free product is molded, and over processing is eliminated. This results in lower material consumption, reducing material costs.

To draw a medical analogy, consider that the molding process is the "patient" and the process engineer is the "doctor." The doctor would like to hook up the patient to a monitor and watch the patient's "vital signs." Before that is accomplished, however, baseline tests are run. For each part/mold/material/machine/process combination, the baseline tests are:

- On-Machine Rheology Study
- Cavity Balance Study
- Pressure Drop Study
- Gate Seal Study

- Hold Pressure Study
- Process Window Definition
- Cooling Time Study

The data collected from these baseline tests characterize the molding process for a greater understanding of how the inputs and process variables affect the quality of the product. Design of Experiments and other Six Sigma tools are sometimes also used to provide an even deeper understanding of how the process variables can be optimized to reduce process variation. This results in higher process capability (Cpk).

Continuing with the medical analogy, what are the patient's "vital signs" that the doctor would like to monitor? Traditional process variables controlled and/or monitored by the molding machines include injection speed and pressure, shot size, material temperatures, mold temperatures, cooling times, hold pressure, and many others. Decoupled Molding, where the molding process is designed to separate the fill, pack, and hold phases of the process, is important to maintain a controlled process. Real-time process monitoring and closed-loop process control can be achieved with state-of-the-art injection molding machines. The sensors for these "vital signs," however, are physically far-removed from the cavity where the part is actually being formed.

Scientific molding now takes it to the next level by adding the ability to monitor important "vital signs" by adding in-mold cavity temperature or cavity pressure sensing, including closed-loop feedback from these signals. For example, the transfer of control from velocity to pressure can be controlled from the cavity pressure signal. Controlling the molding process using cavity pressure sensing allows identical parts to be produced consistently from machine to machine, part to part, and set-up to set-up.

Elimination of Over Production

The waste called over production comes in many forms. A molded part may be over produced during a production run because of historically high scrap rates (poor yield) or because the process is unpredictable and "as long as the job is set up, we might as well run more than enough parts." Scientific injection molding provides an optimized, robust molding process so it runs in a controlled, predictable way, eliminating the need for over production.

Lean manufacturing principles teach the concept of one-piece flow (or continuous flow manufacturing). In the purest sense, when it comes to molding, it implies all molds should run in a one-cavity configuration. From a scientific injection molding point of view, a mold with lower cavitation could more easily achieve cavity-to-cavity balance, providing a larger processing window compared to a mold with a larger number of cavities. Technology that uses in-mold temperature or pressure sensing with closed-loop feedback and control can provide significant benefits. Other advantages of lower cavitation, which are beyond the scope of this article, include increased manufacturing flexibility, reduced change-over times, and others.

Elimination of Excess Motion

Excess motion in lean manufacturing typically refers to the movement of personnel from workstation to workstation or of product from operation to operation. The use of scientific injection molding allows for the development of an optimum molding process, eliminating wasted machine movements.

Elimination of Waiting (Wasted Time)

In lean manufacturing, wait time is considered non-value added, and is a form of waste to be eliminated. In an injection molding process, valuable seconds, or even fractions of a second, of cycle time can be saved through the optimization of machine movements and timing. Using scientific injection molding, the process is optimized for the combination of product, material, tool, machine, and process being used. Once the process is characterized and the optimum process variables are known, the cycle time can be minimized by adjusting machine movements and speeds to eliminate wasted time.

Elimination of Excess Inventory

Eliminating waste in the form of excess inventory is an important lean manufacturing objective. Total manufacturing costs are reduced if excess inventory is eliminated, and instead, adopting a "Just-in-Time" delivery philosophy. But what are the reasons excess inventory is kept in the first place? It goes back to the wastes, including defective product and over production. If high scrap levels and over processing is the norm, to ensure on-time delivery to the customer, excess inventory will be the norm. Using scientific injection molding, a robust process is validated providing a controlled, predictable, highly capable molding process. With predictability, the mold can be set up with confidence, the yields will be high, and high quality parts will be available when needed.

Elimination of Transportation

In a molding process that is poorly controlled and unpredictable with low quality and poor yields, product must be inspected and sorted. This requires the product to be moved to an off-line sorting area, and later, moved again to a finished goods area. Also, unplanned transportation in the form of expedited freight may be required to deliver product to the customer. The use of scientific injection molding reduces scrap, increases yield rates, and thereby, eliminates the need for wasted product movement.

Conclusion

Scientific injection molding is a data-driven, scientific approach. Cycle times are minimized, machine efficiencies are improved, and productivity is increased. Scientific injection molding is a strong tool supporting the objectives and practices of a lean manufacturing culture. SIM reduces or eliminates many of the forms of waste by providing a robust, predictable molding process.

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