Prepare for Validating the Injection Molding Process

Molding for medical devices involves critical processes that must offer repeatability, assurance of accuracy, and a high degree of quality. The following article will describe the basic fundamentals of the injection molding process that one needs to understand before developing an effective protocol for validating the injection molding process.

By Rick Puglielli

Rick Puglielli is the president of Promold Plastics. He has been working in injection molding for the medical device industry for more than 25 years. Puglielli can be reached at (860) 342-5550 or via the web at http://www.promoldplastics.com/form.php#Form

Somehow, everything seems to revolve around the molding process. With the advanced technology and scientific understanding of the injection molding process available today, process validation should be relatively easy. However, as with many regulatory requirements today, the interpretation of how to validate a process can be quite overwhelming. In fact, there are entire books written about the subject. Keeping it simple seems almost impossible.

A simple and basic definition for process validation is: Establishing, through documented evidence, a high degree of assurance that a specific process will consistently produce a product that meets its predetermined specifications.

The definition, at first, glance seems relatively simple, but the phrase “high degree of assurance” is relative, which leaves the definition subject to interpretation. The phrase does not imply a guarantee, so how can one determine when they have reached a high enough degree of assurance? Is it possible that a customer, an auditor, a quality representative, a process technician and a design engineer would all agree that the process has demonstrated a high enough degree of assurance? Probably not. Many times, a company or an industry will set a statistical standard for the amount of variation allowed in a process. Simply put, when this requirement is met, a high enough level of assurance is reached. Unfortunately designers do not always take these requirements into account when setting tolerances. Accordingly, if a designer is making a knob for a glove compartment door, it is possible that the same level of assurance could be required as if he were making a seal for the space shuttle. If there are no expectations set up front, the best approach would be to optimize the molding process. Then, a statistical study would be

performed to determine what level of assurance that the “specific process will consistently produce a product that meets its predetermined specifications” can be achieved. From there, it can then be determined if it is feasible or cost effective to increase the level of assurance. It takes a great deal of experience and diligence in the development stage to accurately predict what level of assurance a process will yield.

Ideally most manufacturers would prefer to see a robust molding process that allows inspection controls to be reduced or eliminated. However, for a product with many critical dimensions and very tight tolerances, having a degree of assurance in the injection molding process high enough to eliminate any inspection controls is not very likely. Likewise, using a material with a high shrink factor or an aggressive material that can contribute to premature mold wear will only compound the problem. Using a mold with moving parts and multiple shut offs in critical areas can play a major role in determining one’s expected degree of assurance.

One factor a process validation will not compensate for is the lack of an effective design or tooling validation. If weaknesses are not addressed early in the development stage, a process validation may not be an end all, save all solution. Adequate inspection controls will still be required where necessary.

Elements of the Injection Molding Process

The most important elements that make up the injection molding process include:

Machine—The equipment should be in good running condition and be correctly sized for the mold and part. If the manufacturer changes machines, unless it is identical, the settings would have to change to compensate for the different clamp tonnage and screw and barrel size.

Mold—The mold must be pre-qualified and demonstrate that it is capable of producing a part that meets the required specifications. Major repairs, changes, or improvements to the mold may require changes in the set up, which means re-qualifying the process.

Material—The material is a property of the product design. If a certain grade is not specified, controlling the process can become a challenge. Without using a consistent grade, variation in the material can introduce variation in the process, such as viscosity, which may impact the material flow and pressures.

Assuming the mold and the material remain constant from run to run, the one element left of concern is the machine. While a modern molding press has many different controls and settings, there are really only four variables that will impact the molded part properties. These variables are not controlled by any one

setting on a machine; however, many settings on the machine can affect them. The four variables of critical importance are as follows.

Plastic Variables

Pressure—The pressure used to pack out and form the part

Temperature—The temperature of the melted plastic as it enters into the mold cavity

Flow Rate—How long it takes to fill the mold cavities

Cooling Rate—Should not be confused with the time setting on the machine that allows for the part to cool before the mold is open. This variable determines how quickly the part will cool to room temperature. Mold temperature plays a vital role in determining this, as well as how long the part sets in the mold. Post cooling the part, such as dropping it into a bucket of cold water after it is ejected, can also affect the cooling rate. As a result, this can have an adverse effect on the final dimensions and other properties of the finished product to make it unacceptable.

The preceding four variables should be monitored regularly to ensure that the process is consistent. From time to time, machine settings may have to be adjusted to compensate for changes in the environment or to address molding issues, such as pulling, distortion, or aesthetic defects. Although the process is said to be in control to meet the stated requirements, there are still some common problems inherent to the molding process that should be monitored whether stated or not.

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