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Insight on Molding Innovations and Trends for the Medical Industry

Molding Technologies

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A metrologist conducts first article inspections, which consist of the measurement of all dimensional callouts on the molded product part print.

Medical Molding: How to Validate the Process

Validating the injection molding process is no longer limited to medical device components. It is increasingly becoming a requirement throughout global industries.

ED STOCKDALE

A successfully validated process is stable, dimensionally centered within the required tolerance, and minimizes rejects with significantly fewer adjustments from run to run. The adoption of process validation principles and disciplines has proven beneficial for both new and existing programs. It is essential, however, to first establish an agreed-upon procedure for the validation, known as the installation, operation, and process qualifications or IQ/OQ/PQ. This should be done in conjunction with the customer.

Early interaction identifies and resolves areas of concern between the two parties. It also details the equipment needed to manufacture, test, and measure product, and it defines dimensional tolerances, molding technique, engineering studies, the substance of the qualifications themselves, and the qualification approval and acceptance criteria. Typically, the desired acceptance criterion for critical dimensions is a Cpk of ≥1.33 (see the sidebar "Definitions" on p. 13).

The IQ/OQ/PQ procedures are outlined below. It's important to note that the use of all or any of these disciplines has proven beneficial for process and dimensional control.

Installation Qualification

The purpose of IQ is to demonstrate that the equipment and facility used to manufacture, measure, or test the product is maintained and calibrated as required. Additionally, it affords the opportunity to benchmark specific installation and process conditions that can prove valuable over the life of a molding program. For example, if a process isn't yielding the same dimensional stability after months of run time, the problem could be attributed to a number of circumstances, including restricted water circuit flow, a different style of nozzle body or tip, the use of similar but different equipment, etc.

All of these and other deviations can contribute to process and dimensional variation, as well as instability. By documenting the initial installation settings, fewer personnel will be needed to investigate and determine the root cause of the rejects. More importantly, satisfying customer delivery and quality requirements will be much more consistent.

When selecting the molding machine of choice, keep in mind the following criteria:

- Real-time closed loop technology (electric molding machines have recently demonstrated more consistent repeatability and reduced cycle times).
- The shot size of the screw should utilize 25–75% of barrel capacity (ideally, 33–66%) to avoid minimal or excessive residence time, either of which can influence process variation.
- Machine tonnage should provide enough clamping pressure to keep the mold fully closed and prevent flash; typically 5–10 tn/in.^{3} of the projected area of the molded part is adequate.

Cooling circuits in the mold should be adequately sized to satisfy the Reynolds equation for turbulent flow for good thermal coefficient (typically 1.0 gpm of flow for each 0.5 in. of cooling line is adequate. See the sidebar, "Definitions."). Additionally, the cooling lines should be sized equally to achieve balanced cooling.

The inspection area of the molded product should be benchmarked for location and lighting influence, as well as cleanliness attributes, e.g., lumens, particulate in ppm, etc. The equipment and techniques used to inspect and accept product must be calibrated and documented. Additionally, all equipment used in the direct manufacture of the product needs to be calibrated in accordance with ISO and GMP guidelines.

Operation Qualification

OQ is at the heart of evaluating and defining the injection molding process. Through the use of analytical processes, engineering studies, and statistical and dimensional evaluations, one can identify areas of concern that need to be addressed early in the program. Examples might include a small runner system that would limit pressure, a part that won't fill evenly, or less-than-desirable aesthetics that might result from shear, dimensional concerns, and so forth. In these cases, the mold can be modified to address the concerns before building a pro-

duction tool, thereby minimizing lead times to production.

For a new molding program, it is beneficial to perform process development and a design of experiments (DOE) with a prototype mold prior to building a production tool. The purpose of performing process development is to minimize areas of the process that cause variation, e.g., pressure limitations, shear rates or viscosity variations, inadequate changeover definition, proper pack and holding pressures, and time. The DOE defines which process attributes affect specific dimensional responses, the influence on the response, and the interactions between them. From the two studies, one can confidently define an ideal process with a predicted dimensional outcome.

Process development consists of a short-shot study, in-mold rheology, a stability or cavity-to-cavity balance run, gate-seal analysis, and a pack-pressure study, as well as a DOE and first article inspection (FAI). As a starting point for these studies, use the resin manufacturer's recommended process settings.

The short-shot study demonstrates that the cavity or cavities fill evenly or balanced, the injection pressure required to fill the part approximately 95–99% (used for velocity-to-pressure-changeover definition) is not limited due to the runner system in the mold, and there are no mechanical issues that prevent the mold from successfully cycling.

In-mold rheology defines the best shear rate (injection rate) to minimize variation during fill. This rate varies from one resin to another and is influenced by the geometry of the mold and cavities. A level shear rate slope is more desirable and will exhibit less variation than one on a sharp incline or decline (see Figure 1).

A stability or cavity-to-cavity balance run demonstrates that the process to the point of velocity-to-pressure changeover is stable and balanced. It also validates process capability through the use of Cp and Cpk relative to the molding process itself (see the sidebar, "Definitions").

A gate seal or freeze study (holding and pack time) confirms when the influence of injection within the cavity and runner system is complete. An improper gate-seal or freeze-time setting can cause process variation or add unnecessary additional cycle time.

The pack-pressure study identifies the influence that the pack and holding pressure have on dimensional characteristics. It defines a proper pack-pressure process window and evaluates how the mold operates under these conditions. Dimensional studies are then necessary to evaluate these progressive influences on the molded product.

Once the process window for each process attribute has been defined, these settings can be used to define the DOE. The DOE defines the optimum process window and its respective influence on each dimensional response. A series of experiments are run, and the influences are evaluated statistically. A DOE prediction is made, and an additional run confirms that the DOE prediction is accurate and defines the optimal dimensional process window. These process limits will then be challenged and evaluated. The challenges consist of three different runs: low, high, and nominal process challenge runs. Each run is equal in run time and evaluated for dimensional, functional, and cosmetic considerations in relation to the product specifications and tolerance. The results may demonstrate conditions that do not meet the desired acceptance criteria, in which case the process, tolerance, mold, or specification needs to be modified and, if necessary, the processes rerun to verify conformance.

Beyond process development and DOE, an in-mold cavity pressure transducer equipped with a temperature sensor can also be beneficial. This equipment illustrates and defines proper velocity-to-cavity pressure settings and cooling time (see Figures 2 and 3, p. 14). The sensor and transducer combination minimizes the difference in cavity pressure between the beginning and end of fill, thereby reducing in-mold stresses while enhancing dimensional and product stability. Recent studies comparing process variation both with and without the use of a sensor and transducer demonstrated a process and dimensional stability improvement

A measuring machine is adjacent to its medical molding cell to minimize the time required for first article inspections on new medical molding programs.

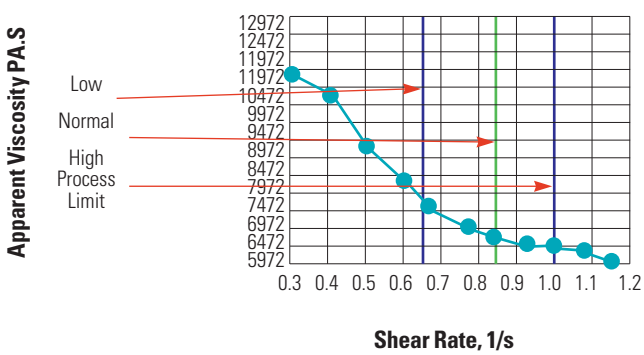

Figure 1. Defining proper In-mold rheology process window.

Definitions

The following terms are commonly used in validating molding processes.

4.1 Cp: Estimates what the process would be capable of producing if it could be centered in tolerance. Assumes that the process output is normally distributed. Cp demonstrates that the process is in control without respect to the present dimensional tolerance, so tolerance can be adjusted with confidence.

4.2 Cpk: A globally recognized measurement of the process capability index or statistical prediction of potential product at risk that could be out of dimensional tolerance. Based on (4) sigma (standard deviation), a Cpk of ≥1.33 is the commonly recognized acceptance specification for medical devices. This means that 63 of every million parts produced (ppm) are at risk of potentially being out of dimensional tolerance (99.99%). A Cpk of ≥1.67 based on (5) sigma potentially yields a process that is at risk of producing one part out of tolerance specification for every ppm or 99.9999%. The benefit of these disciplines is realized through the reduction of potential risk of out-of-tolerance product, fewer assembly issues with mating components, and less scrap and down time due to rejects.

4.3 Reynolds number equation: The measure and calculation of turbulent flow, which translates into thermal heat transfer or cooling.

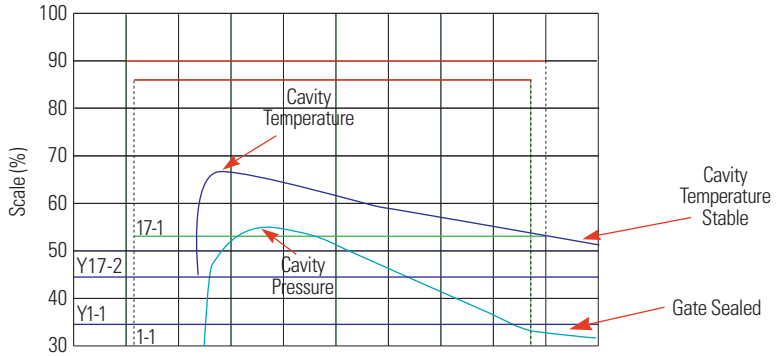

Figure 2. In-mold pressure transducer and temperature sensor application.

of greater than 50% over time when the sensor and transducer combination was used (see Figure 3).

First Article Inspection

An FAI consists of the measurement of all dimensional callouts on the molded product part print. Typically two samples are taken from the nominal process run or from the DOE conformation run and submitted to metrology for measurement. The dimensional results are evaluated by the customer and for conformity.

It is common to find out-of-specification conditions, which need to be evaluated for significance, followed by corrective action. Usually this requires a dimensional change on the part print or a tooling modification. Once the FAI is approved by the customer, process qualification begins.

Process Failure Effects and Mode Analysis (pFEMA)

Depending on the end-use of the product, a pFEMA may be conducted to identify potential areas of concern. There may be specific critical dimensions, for example, that need to be monitored closely, because if even one is out of specification periodically, it may cause significant failure or risk with the product.

Potential risks and safeguards are therefore assigned to these areas, e.g., special measurement devices or equipment, 100% inspection, etc., to ensure that product of this nature is appropriately rejected.

Process Qualification

PQ demonstrates that the process is stable and dimensionally capable and that it produces a molded part that meets the customer's expectations. Typically, PQ is accomplished by running the defined or nominal process through three separate runs. These runs are a simulation of three separate production runs and should be a minimum of four hours in length for each run with a shutdown period between each run. Additionally, three different lots of resins should be used during the PQ, which represents actual molding conditions and variation over time. Samples should be taken at even intervals throughout each run, labeled sequentially, and then submitted to metrology for measurement and conformity. Once the PQ and FAI have been approved, these samples should be kept for the life of the program for reference. This retaining policy helps with answering questions as programs develop and transition.

If the PQ is unsuccessful and the molded part does not meet customer expectations, the root cause needs to be evaluated and the two parties must work together to define and accept a resolution.

The qualification of spare mold or tooling components directly related to the molded part, e.g., spare core pins, lifters, etc., should be evaluated and validated so that they are readily available if needed. Typically, the spare part or component validation process consists of one similar PQ run that demonstrates acceptable capability.

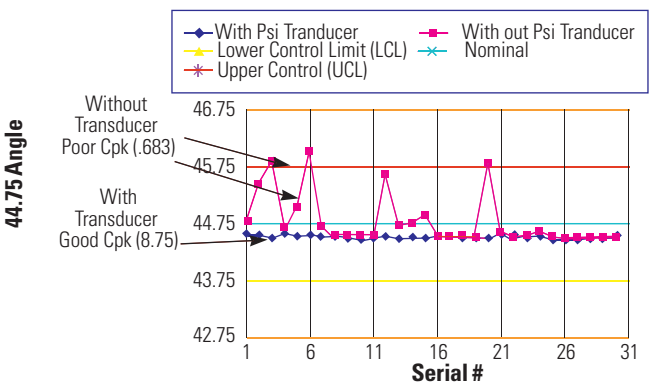

Figure 3. Typical cavity pressure transducer (with and without a sensor).

Other Considerations

Document Control and Process Documentation. The ongoing documentation of the process needs to be maintained in a controlled environment in accordance with ISO 13485 standards. This is essential in maintaining and ensuring that the same process is run from one run to another.

Variation versus Profitability. The use of these analytical and engineering concepts will stabilize process and dimensions, as well as profitability. It's worth noting, however, that sufficient resources and specific equipment are necessary to successfully incorporate these concepts into a business strategy. Resource requirements include management staff; process, quality, and tooling engineers; process technicians; metrologists; and tooling personnel experienced in Cp/Cpk disciplines and tight-tolerance molding. Specific equipment needs include well-maintained peripherals and molding machines, check ring and barrel assemblies capable of holding a molding process to a tight tolerance, coordinate measurement machine and vision system equipment for measuring tight geometric dimension and tolerance profiles, and tool room equipment.

A technician defines the optimal dimensional process window for a DOE.

The business approach that integrates process validation touches many areas of the company, so the company's commitment to the process is essential to its success. And while significant investment is required, it is recouped through stable molding programs where profitability is maintained over time.

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