# Reducing the Life Cycle Cost of Validation:

## Part 1 – Appropriate Material Selection and Part Design

Reliable medical devices and equipment are essential for researchers and doctors to accurately diagnose and treat a wide range of diseases. That is why there is such stringent oversight from the FDA to ensure these products meet the necessary requirements and specifications, such as 21 CFR 820. To ensure compliance with regulators, manufacturers follow installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ) guidelines. IQ/OQ/PQ certifies the necessary equipment is present and the manufacturing process to create devices that consistently perform to the desired specifications. By completing each phase of this process, you not only greatly increase the chance of a successful validation, but you can also ensure quality for the life of the product. Several key areas with specific criteria are critical to the process, yet they are often overlooked or underestimated. In this segment of the series, we will review some of the important details you should consider during material selection and part design.

***"It is important to choose a material that is widely available in the market in which you are located."***

### *Material Selection: Availability to Ensure Dependability*

First and foremost, availability is a key factor when it comes to material selection for a medical device. It is important to choose a material that is widely available in the market in which you are located. If the material is not widely available, you could face a situation later where you must change suppliers (material maker) or the material (base resin or formulation). If there is a change in either, you will be required to prove the new material is equivalent to your previous one. If you are not able to prove equivalency, you will have to re-do validation for the entire part and possibly complete tool/mold work to make it compliant again. This adds both time and money to your validation.

It is also important to stay away from custom materials. Custom materials lock you into a supplier, which can put you at risk of the above scenario. For example, if the supplier goes out of business, where will that material come from when needed, and will it be equivalent? Custom materials also put

you at risk for higher than normal amounts of viscosity variation, which is the hardest part about maintaining a validated state in injection molding. The changes in viscosity can be attributed to molecular weight distribution changes. As the molecular weight distribution widens, the viscosity variation widens. Another reason viscosity changes occur is the feed stock variation witnessed when compounding all the individual components together. If you use a common/commodity material for your part, the viscosity variations will have a narrower range than they would in a custom material. A lower amount of viscosity change will make your run-to-run performance more repeatable with less effort and less scrap material, which means a lower cost at the end of the day. In the case of a machine setting validation, where the parameters are being validated instead of the outputs, any variation in viscosity can lead to nonconforming product. This is because the equipment cannot be changed outside of validated parameters in order to bring the plastics process back into a validated state.

Finally, do not make pricing a major factor in material selection. While material cost is a large component of the final cost of the injection-molded component, a 5- or 10-cent difference per pound is not substantial when compared to the $70,000 to $100,000 (or more) cost of completing a re-validation. Taking the time to evaluate the materials in the beginning can help ensure on-time deliveries, increased production uptime, and an overall reduced cost when considering the entire life cycle of validation. In addition to material selection, there are also some fundamentals of part design that must be considered but are often forgotten.

### *Part Design: Going Back to the Basics*

One of the basic principles of good plastic part design is to maintain uniform wall thickness. If you are not able to maintain a constant wall thickness, a thick-to-thin wall thickness is preferred for moldability. In addition, the engineer responsible for the design should try to limit undercuts and any other features that require action in the mold. Some designs need these complexities; however, make sure it is necessary before designing it in. This is because the simpler the design is, the higher degree of reliability it will have (if engineered correctly). Keeping actions to a minimum lowers the risk for mold maintenance issues and mold damage and also keeps custom components out of the mold. Other key fundamentals include proper rib-to-wall thickness ratios, proper draft for part release, and proper gating locations. Most importantly, use a geometric dimensioning and tolerancing (GD&T) scheme that is realistic and does not require unnecessary and overly controlling criteria. For example, if only 10 critical dimensions are needed to fully define how a part is going to function, do not document more than that.

Also, if it is realistic to hold the dimension to only plus or minus .003 inches and not plus or minus .001 inches, then go with plus or minus .003 inches. This is easier to validate, gives a higher capability, and reduces the overall cost because it allows more flexibility within the desired specifications and has a bigger processing window during manufacturing. If critical dimensions are overly controlled, the process window for molding is smaller. The bigger the processing window, the more variation can be absorbed in the process. This leads to lower scrap levels, more uptime, and an overall lower cost for the product.

An effective and reliable tool to use during your project, especially in the part design phase, is plastic flow simulation software. The results of a simulation show if a design is moldable as well as any issues that could occur during the molding process. These issues include warping, sink, shrinkage, molecular orientation, and glass orientation. If your simulation software has the capability to complete design of experiments (DOEs), a simulation can be done to determine how the part will react to different processing conditions. This allows you to see if your part will meet dimensional specifications across the variations of your proposed DOE.

For a simulation to be most effective, it must be done in an iterative fashion to provide more information. Simulations can be updated and rerun to give the most up-to-date predictions, so issues can be addressed as the project is advanced to the launch phase. To achieve the highest level of accuracy, you must model everything inside the mold's cubic footprint, including the part, gate, runner, sprue, and surrounding mold. If possible, at a minimum run a multicycle analysis to see if hot spots will form in the mold. Overall, various pieces of information can be obtained from a simulation to help eliminate rework and missed milestones, thus improving timing and reducing costs.

### *Conclusion*

Proper material selection and part design for new medical devices is imperative, as both can have a major impact on manufacturability, time to market, and the overall commercial success of the device. The above criteria are just a small portion of everything you must consider. It is crucial you understand your overall responsibilities in the process validation of a medical device, in order to streamline manufacturing and reduce the chance of costly errors down the road.

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