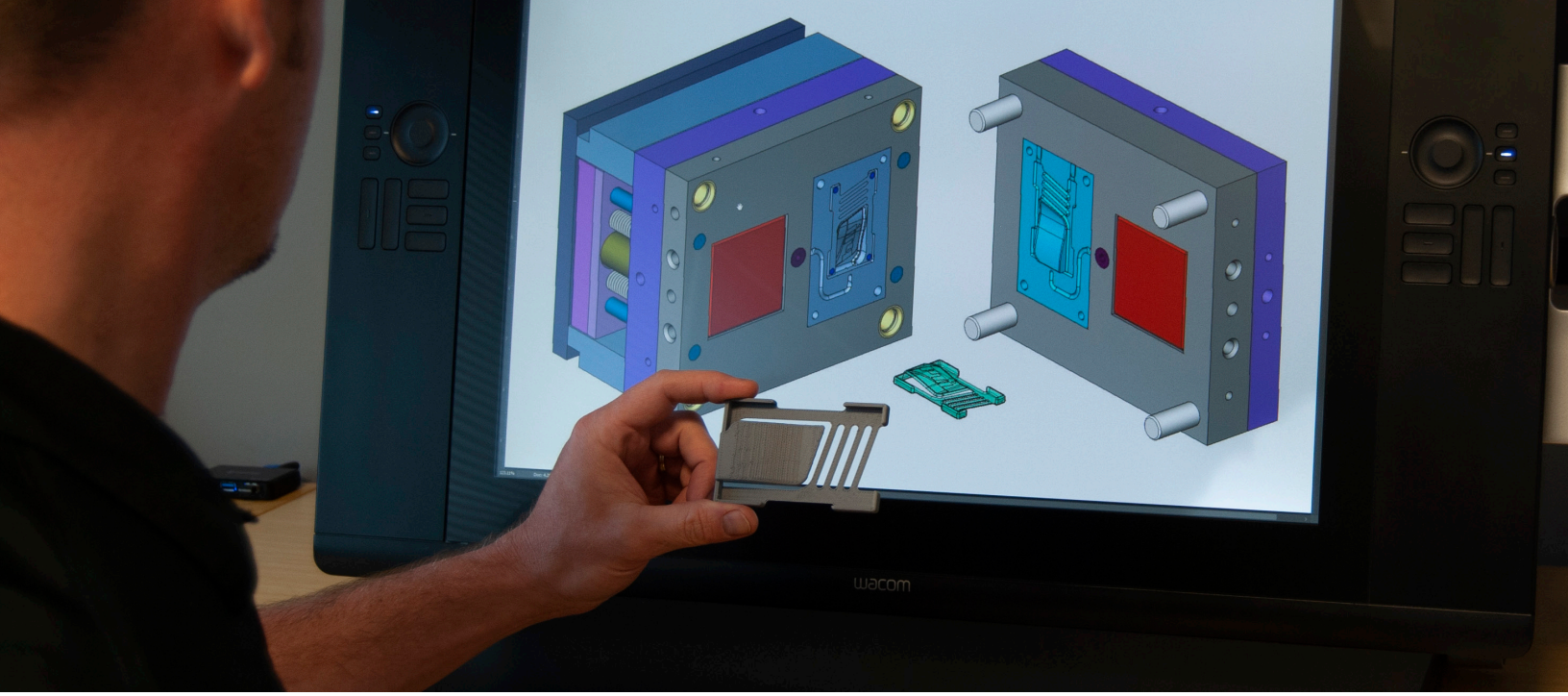

Reducing the Life Cycle Cost of Validation:

Part 2 – Mold Design, Construction, and Protocols

In Part One of this series, we covered important details you should consider during material selection and part design in order to reduce the life cycle cost of validation. Specifically, avoiding customized materials and staying true to the basic principles of good plastic part design are essential for reducing the life cycle cost of validation. In Part Two, we look at best practices for mold design, mold construction, and development of protocols, as these steps of the process also play a vital role in the long-term costs of validation.

Mold Design And Construction: Be Selective Now to Avoid Issues Later

While the part design for a medical device dictates the plan for manufacturing, the mold design is what truly shapes the end product. If you do not have a well-planned and executed mold design, it is almost guaranteed that you will face struggles down the road, especially if you end up replacing that tool for any reason. So take your time with the design and construction. Be frugal — but not cheap —with material selection and make smart decisions up front to avoid major issues later.

> ***"Be frugal – but not cheap – with material selection and make smart decisions up front to avoid major issues later."***

If you intend to use the mold to manufacture millions of parts, you must make sure you select materials that can withstand 20 years of production versus only two months. If you use a subpar material, you may have to replace it three or four times, which may not be beneficial for your overall validation costs in the future. For instance, if you have corrosive materials, such as PVC, you should use stainless-steel inserts so corrosion is limited. If you are using something abrasive, you want to have hardened S7 or H13 steel that is nickel-coated to make sure the cavity is not being eroded away by the glass that is compounded into the nylon.

If you plan to build a freestanding injection mold base, you do not want to have custom frames or components (if at all

possible). Instead, make sure you use a common mold base that is interchangeable from a catalog (as much as possible/if at all possible). This makes it easier to use and change out while maintaining good engineering fundamentals that ultimately lead to lower long-term costs. Consider prefabricated pieces that can be easily substituted at lower cost, so the component does not need to be completely revalidated.

Using Simulation for Mold Design

Just as with part design, simulation can be a valuable tool for mold design. As the designer designs the mold, they can use simulation to eliminate problem areas before they happen. For instance, if the part design has a thick area, the designer can see variable temperature distribution on the part and then design better cooling for that area. The designer can also use simulation to find air traps in a blind pocket. They can then put in vent pins or use a porous steel to help eliminate the gas. The insight found during simulation allows better decisions to be made up front to avoid issues on the back end. Calculations or studies should also be done during mold design to determine the strength of the materials in order to avoid common pitfalls, such as deflection or possible fatigue failure. Another consideration should be thermal conductivity.

> ***"Most importantly, for all of the protocols, do not take any shortcuts. Give each stakeholder enough time to build and document a process that properly tests the mold/process and any equipment that could impact your outcome."***

During the design phase, it is necessary to make sure the waterlines are close to the cavity surface, so BTU energy can be pulled out of the plastic as rapidly and reliably possible. This drives down cycle time and provides a more robust plastic process. In addition to keeping the waterlines close to the cavity surface, make sure the correct material is chosen for the cavity and core. The correct material will balance the wear/lifetime needs of the mold as well as the thermal conductivity, ultimately allowing for faster cycles and a lower overall project cost over the lifetime of the mold.

Once the designer and simulation analysts have completed any studies and/or analyses, time should be scheduled with the processing engineer as well as quality engineers to review the design. The quality engineers are sometimes left out of this process; however, this complete team has the best insight into determining any critical errors and how to build in protection against those errors. The mold designer and mold builder should also be present to ensure functionality. To reduce the time it takes to build your mold, find out the shop hours of your potential mold manufacturer. For example, shop hours could be limited to eight-hour work days, five days a week versus a shop that operates 24 hours a day, five days a week. A shop with limited hours could stretch the time frame for a project from weeks to months. All of these points must be considered during mold design and construction to ensure a quality, cost-effective mold that has the ability to withstand the test of time.

Proper Protocol Documentation

Now that you have an approved mold design, you and your team must document the design specifications that outline the specific details about the mold and how it should perform. These details are then fed into the installation qualification (IQ) for the mold to ensure it is qualified and performs properly. Once the mold is complete, operational qualification (OQ) and performance qualification (PQ) protocols are generated from a process characterization report that outlines the entire process.

For generation of the IQ protocol, the mold builder, tool designer, processing engineer, manufacturing engineer, and your robotics specialist should all have input in the document for how to assess the capability of your equipment. If you are using automation, details such as what the proper interlocks are and how they perform, what parts are being used from what supplier, and the location where each part goes should be outlined. Even something as specific as steel dimensions could be included in the IQ protocol. That way, should the mold become damaged or components have to be rebuilt, the IQ protocol can be used as a reference for the steel geometry needed. Not only does this help save time, but it also helps avoid a revalidation should you have to use a spare component or rebuild the tool.

Additionally, it is wise at this point to develop and validate spare mold components. If a component breaks down, you

can sub in a spare mold component that has already been validated without any extended interruptions in production. The number of spares you have depends on the expected life of the equipment (short use versus long-term use). For OQ and PQ, make sure to include the quality, process, and manufacturing engineers to ensure that all critical features are captured. These experts often have the experience and expertise necessary to identify potential issues that can sometimes be missed by those who have not had as much exposure to the manufacturing life cycle. Also, make sure you are testing on the machine you plan to use for product runs. During IQ, review all of the pieces of the tool that are critical to its functionality. Consider questions like:

- Does the hot runner work?
- Does it pick up the proper voltage?
- Do the heater bands heat to the correct temperature?

For the OQ protocol, document the upper and lower limits that will be used in production while taking calibration into consideration. This includes details outside of the machine settings, such as plastic parameters, i.e., the mold temperature, the plastic pressure, temperature of the plastic melt, and cooling time. Once in production, the OQ limits become the validated outer limits for the process and the PQ settings become the nominal process. This ensures the same end product is produced every single time, which is why it is so important to do it correctly up front.

Most importantly, for all of the protocols, do not take any shortcuts. Give each stakeholder enough time to build and document a process that properly tests the mold/process and any equipment that could impact your outcome. Extra time spent up front will result in more uptime, less wasted materials, and a happier customer. It also provides more opportunities for additional experiments and studies to help achieve a better understanding of the process inputs and outputs that control your product quality. For example, at some point, you must test different viscosities at different temperatures and injection rates. This is because there are a variety of plastic resins that present varying viscosities, and you will need to know the impact of the viscosity shift to your process and to part quality.

Also, reduce the time it takes for protocol generation by creating a general template for future protocols, which allows for pre-documentation, so you do not have to go back and reinvent the wheel each time. When documenting future mold designs, you then have to fill in only the information that differentiates the new mold design from previously documented mold designs. To save even more time, the IQ, OQ, and PQ generation should be done in parallel so that only a few key areas have to be filled out once the final process is found.

Conclusion

In the end, proper mold design, construction, and documentation of protocols play a major role in not only reducing the life cycle cost of validation, but also reducing production downtime and ensuring the overall long-term success of your project.

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