



# 6 Six Questions You Need to Ask When Designing Polymer Components for Healthcare Devices



## INTRODUCTION

Over the years, material scientists have discovered and invented thousands of thermoplastic polymer grades. The number of options continues to grow, as developers seek new economic advantages and performance improvements.

This abundance of choices, however, can seem daunting at times. Choosing polymers from an expanding number of alternatives becomes even more complex when public health and safety are at stake. Material issues that appear in healthcare devices can prove to be both damaging and dangerous—with the risk of costly product recalls or even harm to patients.

Plastic components for this high-stakes industry are challenged to withstand attack from sterilization methods, cleaning agents, bodily fluids, and drug solutions. And of course, regulatory requirements play a big role in bringing any device to market.

Each material you consider can have widely varied tool design, molding and secondary processing requirements that can affect time to market and total production costs.

The purpose of this whitepaper is to present and explore six critical questions you should ask as you consider polymer options for healthcare applications and pharmaceutical packaging. Addressing these questions early in the product development process can help you maximize the benefits and minimize risks such as material degradation or component failure.

### 1. WILL THE POLYMER I PLAN TO USE WORK IN MY DESIGN?

Think of material selection and product design as a parallel process. Your parts may utilize undercuts, threads, living hinges, thick or thin

wall sections, snap features or draft allowances. Clearly, you will want to seek out a material that is compatible with those features. But strategically and deliberately designing parts with material characteristics in mind from the onset will optimize performance, durability and functionality.

It's important to understand how a material will behave during manufacturing, as well. For example, mold shrinkage is a key factor to consider during the design phase.

Some polymers shrink at one rate with the flow path and at another rate across the flow path within the tool. This means the dimensions of a part can vary when different materials are used. Even the slightest of changes in final dimensions can negatively affect form, fit or function—especially with parts that have critical dimensions and components that go into a multipart assembly.

It is far more expensive and time-consuming to modify tooling in order to hit target dimensions than it is to properly account for mold shrinkage in the first place. Again, you'll benefit from thinking early about part design and material selection in conjunction with one another as you move through the design process.





In a general sense, designers can follow typical plastic design guidelines when developing new applications and when investigating material alternatives for an existing component. However, there are a few additional considerations for parts currently in production. For example, converting existing parts from glass or metal to plastic will likely necessitate a complete redesign, and you may need to make a capital investment in new tooling to accommodate a material change. Include these factors in your budget and timeline.

## 2. WHAT ARE THE LIMITATIONS OF MY CHOSEN PROCESSING METHOD?

Have you ever tried to fill a complex injection-molded part with a highly viscous material? Or have you used a material without adequate melt strength in an extrusion process? The results were probably disappointing.

Different grades of thermoplastic resin families each have different processing and moldability traits. While some materials can be used in several different processes, others can cause problems. Engineers might be able to adjust a process to make an incompatible material work, but cycle times, throughput and product consistency generally suffer.

Properly matching processing technique and material will generate both economical and robust components. Knowledgeable suppliers can identify processing methods and material combinations that will not only optimize performance and minimize production costs, but also reduce cycle time and decrease scrap due to out-of-tolerance parts.

## 3. WHAT IS THE OPERATING ENVIRONMENT FOR THIS DEVICE?

When evaluating material options, it is important to consider the unique environmental exposures that are commonly present in healthcare applications.

Some products will come in direct contact with aggressive drug chemistries or bodily fluids. Many others will require repeated sterilization via steam, ultraviolet light, chemicals, heat, or radiation. Only the most resilient materials can withstand these conditions without decay or failure.

From sub-zero cryogenics to the high-pressure heat of an autoclave, healthcare products might also be subjected to a wide range of temperature extremes. Materials must be able to maintain physical and performance properties such as strength, flexibility and seal integrity, in these conditions.

Plus, facilities are increasingly applying strong disinfectants to reduce the spread of facility-borne infection. This prompts a need for materials with robust chemical resistance.

Technical data sheets should offer a basic indication of a material's ability to withstand chemicals, temperature and pressure. However, materials are measured using a specimen of a particular size and shape determined by ASTM and/or ISO standards. Your part will almost certainly be different than the standardized test sample and will, therefore, behave differently.

Ultimately, product testing under anticipated environmental conditions should be your deciding factor. Polymer performance may change over time with exposure, so you may



also want to employ predictive testing, such as accelerated aging studies. Take lifecycle planning into account when examining the results of any aging studies. Defects or failures that take a long time to manifest may not impact your product during its useful life.

#### **4. WHAT FORCES (IMPACT, LOAD, WEAR, ETC.) WILL MY DEVICE BE SUBJECT TO?**

Your application may require a certain degree of impact strength, flexural strength, tensile strength, elasticity, wearability or hardness. Determine these properties early so you have targets in mind as you evaluate potential materials.

Physical and mechanical property information on technical data sheets is a starting point to find a material that meets your needs. But the thickness, weld lines, corners and unique geometry of your component can make it respond markedly different than the test specimen.

Going a step further, conducting finite elemental analysis (FEA) testing can identify weak spots or potential failure points under a particular load. Design engineers will use stress/strain ratings from technical data sheets to conduct these tests—although some FEA software already has a database of stress/strain information for many thermoplastic grades. If you don't have in-house FEA capabilities, your material supplier may be able to assist.

Also note that mechanical loads, environmental exposures and temperature may accelerate potential material issues. For instance, you may be developing an “engaged” spring-loaded component or pre-filled device. If that component is stored prior to use, the long-

term duress of a constant load or pressure may adversely affect the material before it's put into service. Engage an expert for recommendations or base your decisions on prior experience with similar applications.

#### **MORE OFTEN THAN NOT, HEALTHCARE COMPONENTS WILL ALSO INCLUDE ADDITIONAL SPECIAL REQUIREMENTS SUCH AS:**

- multi-part assembly
- living hinges
- clarity/transparency
- color
- finish
- lubricity
- flame resistance
- weldability
- paintability
- other secondary operations

Recognizing these special requirements early in the development process will help avoid potential roadblocks or missteps. For example, does your design feature overmolding? Some elastomeric polymers will chemically bond to the substrate while others need a mechanical bond that you must incorporate upfront in the part design.

#### **5. CAN I USE PRE-QUALIFIED MATERIALS TO SPEED THE REQUIRED REGULATORY APPROVALS?**

Depending on your product's classification, you may need to acquire certain regulatory certifications plus comply with particular manufacturing environment requirements,



quality control systems and traceability methods before you can go to market.

One common regulation for healthcare applications calls for using materials that have U.S. Food and Drug Administration (FDA) approval. Other regulatory groups have established additional standards to ensure safety of the patient or end user. These agencies include:

- United States Pharmacopeia (USP)
- International Standards Organization (ISO)
- Underwriters Laboratories (UL)
- National Sanitation Foundation (NSF)

Look for these ratings (FDA, USP IV, etc.) on technical data sheets. However, it is solely up to the material manufacturer to include or omit this information. So it is good practice to ask your supplier outright for compliance ratings.

Some approvals are necessary, while others are optional but can be helpful in your product development process. For example, manufacturers are not required to submit documentation for a material to the FDA Drug Master File (DMF). But choosing a material that already appears on the DMF may help you obtain other necessary regulatory approvals for a new medical device.

On the other hand, you may need express consent from the material manufacturer in order to use their polymers in medical products. The supplier may ask for detailed documentation about the device, in order to understand their potential risk as part of the device's ingredient stream, before granting approval. Be transparent to avoid being denied use later in the development path.

## 6. WHAT ARE THE MOST LIKELY WAYS MY PART MIGHT FAIL AND HOW CAN I MITIGATE THE RISK?

Consider the risk and return of a sharps container and a heart valve. A sharps container is a high-volume, low-risk product. If the product fails due to material, design or manufacturing defects, there would only be minor implications. Conversely, material issues that occur in a heart valve could harm a patient and cause serious problems for your business.

In high-risk scenarios, choosing a highly engineered, but more costly, material may be justified. But choosing materials that are “over engineered” for your needs can add unnecessary cost or complexity to your product.

Appropriately assess the risk of your application and do your due diligence in selecting a material. Using the considerations listed in this whitepaper will help you identify the ideal material for your application and establish confidence in the performance of your product.

## CONCLUSION

Clearly there are many variables to consider in order to successfully select the most suitable materials. The selection process is far from linear. By using the six questions posed in this whitepaper to guide your selection, you'll streamline your process, minimize expenses and avoid unnecessary material failures.



## QUICK REFERENCE CHECKLIST

### SIX QUESTIONS YOU NEED TO ASK WHEN DESIGNING POLYMER COMPONENTS FOR HEALTHCARE DEVICES

- 1. Will the polymer I plan to use work in my design?**

Strategically and deliberately designing parts with material characteristics in mind from the onset will optimize performance, durability and functionality.
- 2. What are the limitations of my chosen processing method?**

Properly matching processing technique and material will generate both economical and robust components.
- 3. What is the operating environment for this device?**

Consider the effects of environmental exposures (heat, chemicals, pressure, bodily fluids, etc.) when evaluating material options.
- 4. What forces (impact, load, wear, etc.) will my device be subject to?**

Determine desired properties (impact strength, flexural strength, elasticity, hardness, etc.) early so you have targets in mind as you evaluate potential materials.
- 5. Can I use pre-qualified materials to speed the required regulatory approvals?**

Some regulatory approvals are necessary, while others are optional but can be helpful in your process. Ask your supplier outright for certification ratings for materials you are considering.
- 6. What are the most likely ways my part might fail and how can I mitigate the risk?**

Choosing a highly engineered, but more costly, material may be justified. But materials that are “over engineered” for your needs can add unnecessary cost or complexity to your product.

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