The Tips, Tricks, and Traps of Injection Molding Resin Selection for the Medical Industry

Each injection molding project has its own unique set of challenges, such as choosing a resin that balances high performance with the unique demands of the medical industry: compliance to FDA approval, rigorous inspection, lot traceability and more. Although there is no single "right" approach to selecting a resin for your next injection molding project, here are some tips and tricks that can simplify the process, as well as some traps to avoid.

Tip: Start the medical resin selection process with an open conversation to uncover opportunities for improvement. Both parts buyer and injection molding contract manufacturer should enter this conversation without biases about which specific resin types are most appropriate because the resin that worked well on a previous project may not be appropriate for a part of a different size or shape or that will be run on different equipment. This is particularly true in the medical industry, where resins are subject to extremely complex processes and rigorous standards. However, there is an important exception to this: most medical equipment OEMs will already have research and findings on the best available resins for their applications and products, so they will often approach a contract manufacturer with a resin already chosen and approved by their legal team. Given the cost of conducting environmental studies, when a specific resin has proven successful in use for a similar product, OEMs will typically specify the resin with which they're already familiar.

continued on page 2

continued from page 1

In most circumstances, the parts buyer needs to work with the contract manufacturer to identify the most critical characteristics of the finished part as soon as possible. Understanding the role the part will play in the end-product is crucial. The contract manufacturer needs to ask if the part will come in contact with food or beverages, biological samples or pharmaceuticals, harsh chemicals or petroleum products. Consider any chemicals to which the part will be exposed during use and cleaning. Take into account the thermal stresses on the part under both typical and extreme conditions.

Consider whether it needs to have inherent flame resistance or must be resistant to UV and gamma radiation. Is it available in opaque and transparent colors, particularly white and clear, common in the industry?

Part buyers must resist any temptation to withhold details about how the finished part will be used or the qualifying tests it must pass. If necessary, a parts buyer can ask the contract manufacturer to sign a non-disclosure agreement (NDA) to keep information on the project confidential, but it's essential to have an open conversation about all the part's requirements.

Only after this conversation takes place can the contract manufacturer start considering resin options with respect to various part performance criteria, cost, manufacturability, time to market, etc. For more guidance on what this initial conversation should cover, download a free copy of *Designing Injection Molded Parts: A Handbook for Designers & Engineers*. (http://www.ferriot.com/white-papers-guides)

Tip: Encourage parts buyers to qualify an alternative or backup resin at the same time as the primary resin is chosen. Recent disruptions in the resin supply chain have made it obvious that it's best to have a backup plan in place in order to manage materials risk appropriately. Any number of situations can create resin shortages, such as a producer's difficulty in obtaining raw materials, labor disruptions, sudden price increases, natural disasters, computer or equipment malfunctions, a facility change, a forced shutdown or other governmental action, and many others.

Molding contractors should strive to optimize the primary resin chosen for whatever balance of properties is most important to the parts buyer. The alternative or backup resin might involve some level of compromise, such as a higher price, a longer lead time, or some negotiation on one or more of the desired performance characteristics.

Identifying an alternate resin eliminates the scramble to identify and source a new one if there's a shortage of the primary choice, but most important, it presents the risk of making a less- than-optimal choice under the pressure of time.

Tip: Start the resin selection process as early as possible in the product development cycle. The longer one waits to find the right resin, the higher the likelihood of disappointment with some element of the final part, such as part performance, resin price, price point of the part, manufacturability, etc.

Tip: Take the time to educate yourself about the characteristics of the different types and grades of thermoplastic resins available. Thermoplastic resins come in two basic classes: engineering grade resins and commodity resins. Each category includes a variety of resins, which provides flexibility to match a resin to a part based upon application, part design and moldability.

Engineering Grade Resins

- Nylon: Tough, superior thermal and chemical resistance, plus a wide variety of grades available with broad scope of physical properties.Polycarbonate: Strong, high flex modulus, good temperature range, transparent for lenses and multiple colors. Sometimes blends with polyester (PCPBT) to resist harsh cleaning agents.
- ABS: Good impact strength, superior surface quality, good colorability, good rigidity, with electroplatable grades available.
- PC/ABS: Good processability, toughness at low temperature, superior dimensional stability.
- TPE: "Soft" touch, rubber replacement materials, good tear strength and good flexibility.
- Acrylic: Transparent, good for some outdoor applications.
- Acetal: Excellent wear resistance, great for gears and high wear applications.
- Structural Foam: Excellent material to be used in where metal replacement is considered. Good weight-to-stiffness ratio.

Commodities Grades

- Polypropylene: Versatile material, variety of grades in homopolymer and copolymer classes, good fatigue resistance, excellent chemical resistance, lower cost.
- Polyethylene: Very versatile, low-cost material, variety of grades in linear low-density polyethylene (LLDPE), low-density polyethylene (LDPE) and high-density polyethylene (HDPE), tough, weatherable, and easily processed.
- Polystyrene (PS): Available in general purpose and high impact (HIP) polystyrene, lower cost, range of impact from low to high, good clarity in general purpose (GPPS) grades, good rigidity.
- Polyvinyl chloride (PVC): Low cost, chemical resistant, can be colored, weatherable, and naturally flame retardant.
- Polyether etherketone (PEEK) Mechanical, chemical resistance, and biocompatibility. X-ray compatible, non-metal for CT/MRI scans.
- Ultem: Chemical, heat, flame resistance. UV/ Gamma radiation resistance. FDA compliant.

(Source: http://www.designworldonline.com/injection-molding-machining-resins-medical-devices-components/)

Trap: Don't neglect the opportunity to share desired finished product attributes with the contract manufacturer early in the selection process. It's vital that parts buyers tell the contract manufacturer about all the desired attributes of the finished part as soon as possible. That includes attributes such as FDA Approval, flexible strength, load bearing capability, fatigue resistance, impact strength, color retention, temperature operating range, chemical/environmental resistance, flammability, electrical properties, etc.), even if it doesn't seem relevant to the resin selection process. For example, if the finished part must pass a specific test procedure performed by the parts buyer or by their customer, that information can be vital to the resin selection process. For a run-down of key attributes, download a free copy of Ferriot's *Resin Selection Workbook*. (http://www.ferriot.com/white-papers-guides)

Trap: Don't let "get-to-market-first" or "we can't let our production line sit idle" timing considerations take precedence over other considerations in the selection process. Making resin selection decisions under time pressure can compromise the decision-making process and end up costing parts buyers more money in the end. The results of making a too-hasty selection can include less-than-optimal part quality, parts that fail in production, high reject rates, or end-product recalls.

Trap: Watch for contract manufacturer warning signs. Choosing the right injection molding contract manufacturer is just as important as choosing the right resin for your medical use. Here are some warning signs to keep in mind when evaluating a potential contract manufacturer for a new project:

- Be wary of contract manufacturers who are too quick to say, "Oh yeah, we can do that" without first developing a clear understanding of what's involved in a project, especially when it comes to liability around regulations and processes.
- Be worried if a contract manufacturer you're considering does not show much interest in understanding the key features of the part.
- It's a warning if the contract manufacturer doesn't ask questions that will help provide the parts buyer with some significant advantage. The parts buyer should want to know as much as possible about how the part is to be used, its role in the final product, cost considerations, and the timing/delivery issues involved.

In conclusion, starting the medical resin selection process early and with an open mind is the best way to ensure an optimal and cost-effective choice that meets the parts buyer's most important design objectives.