Improving Cost & Performance in Medical Molding Programs

EMPIRE PRECISION

WHERE YOUR IDEAS TAKE SHAPE

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1. Introduction

There are many cost drivers to consider when planning or managing a medical device program. The biggest opportunities to reduce total program cost are in supplier selection, material and design changes, better supplier quoting, and lifecycle planning for prototype to volume production. Taking a strategic approach to the supplier-buyer relationship can help achieve the best value when working toward program goals.

Strategic partnerships

The best value for a program is achieved when your supplier works closely with you as a strategic partner.

2. Smart Supplier Selection

Price vs. Cost

Price and true cost are not one and the same. Wise buyers look at many variables, including price, to evaluate the total cost of a program. How much time or effort will be spent on this project? How much design or development support is required or is the supplier able to provide? A combination of these factors determines a program's value—its true worth to your business.

Driving out Cost without Sacrificing Quality

Many buyers seek a compromise between the tangible and intangible costs of a program, evaluating the price paid against the larger sourcing strategy.

Tangibles

These are the measurable, physical aspects of parts such as form, fit, material content, and quality. By reviewing tangible items, a buyer can judge the supplier's level of competency.

Intangibles

These are the more abstract facets of the supplier's expertise. Intangibles might include the capacity to review a program for moldability, manufacturability, tool ability and affordability. A supplier that can provide the best value typically has:

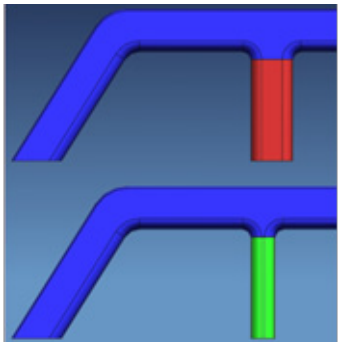
- An advance project team that will work with your technical program development group and take the time to understand your design needs
- A capable support team with powerful development tools such as process predictive software
- Robust documentation systems and data-driven methods to develop optimal work processes and clear, measurable quality objectives
- Processes for supporting other efficiency objectives such as inventory, just-in-time delivery, secondary operations, and troubleshooting

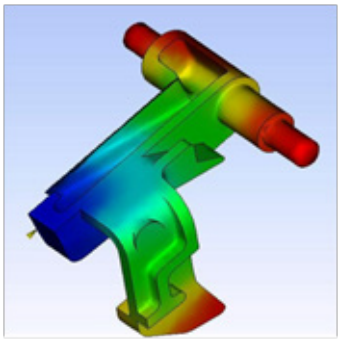
> "We have found that the supplier that provides the best balance of what our company needs at the lowest total cost is the best supplier for us."
>
> — Medical equipment purchasing agent

3. Strategic Approach to Reducing Cost

Proactive Partnerships

Given the opportunity to act as a strategic partner, your supplier will work closely with your development team to provide the best possible value for your program. This strategic approach creates an environment of continuous improvement where innovation and creativity are rewarded and encouraged. Your partner can respond quickly to ideas and generate opportunities for added value and process improvement.





Design optimization

Provide a CAD drawing to your supplier early in the design process. They may be able to suggest changes that will improve cost and performance.

Strategic partnerships between suppliers and medical device OEMs can result in:

- improved design and acquisition process for better quality and delivery
- lower-cost products and services
- innovation to support both your sourcing and procurement targets and sustainable development objectives

Suppliers can proactively suggest alternative ways of making the products that can reduce operation costs. For example, single point diamond turning of polymer lenses can be used to save time and cost in evaluating an optical system's performance and design feasibility before transitioning to a prototype tool.

Ask your injection molding partner to analyze:

- Materials: Are there alternatives that can maintain part integrity while driving out cost?
- Tooling strategy: Is this the most effective capital expenditure approach?
- Design: Would design modifications eliminate part problems, assembly complexity and delays?
- Automation: Can we reduce labor costs?

Cost Control through Full Evaluation

In a traditional supplier evaluation process, costs can creep up after locking into a program due to inaccurate quoting in the beginning; buyers are often surprised to find that the price they were given originally is not the price. A strategic supplier relationship takes into account all attributes of a program that might affect cost:

Design

It is best to provide a part drawing and CAD file. These can be used to determine factors such as part weight and cycle times and to identify any quality or design concerns.

Quantity

Don't just give volumes; share information about release quantities and release frequencies, as well as expected daily and weekly usage rates.

Lead Time

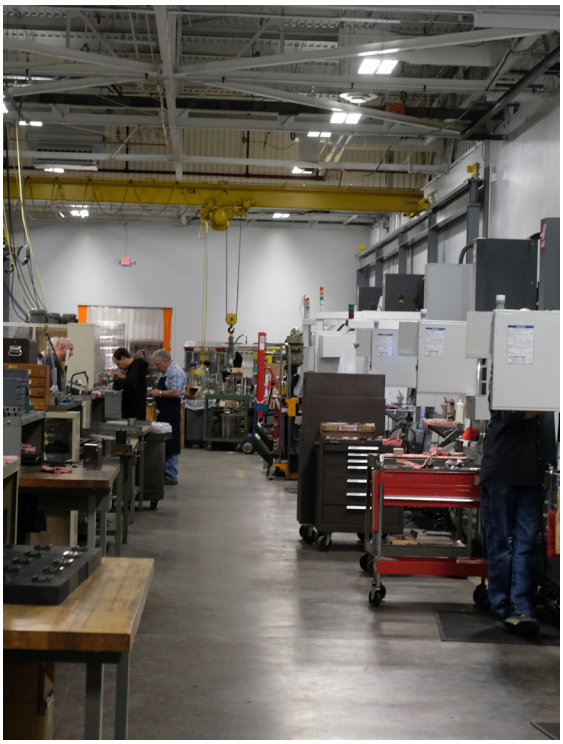
Be specific about your program-critical milestones:

- When will the orders be placed?
- When will you need the first samples or pilot builds?
- When will you need the first parts from tool?
- When will you need mature and approved parts?

Material

Depending on whether flexibility is possible in your resin selection, your supplier might be able to suggest alternates to improve part price or reduce lead time. It also helps to know any special circumstances associated with purchase, such as:

- Special price negotiation
- Minimum buys
- Secondary suppliers, such as a specific source for packaging or mating parts in an assembly



Troubleshoot your tooling

Empire has effectively transferred more than 1,500 tools, and we can help with yours.

Sign up for a **free evaluation of your quality issue** at: injectionmolding.empireprecision.com/troubleshoot-tooling

Blemish Limitations

Your supply partner will take into account any aesthetic or functional constraints; these could prevent or influence the location of tooling features such as gate location, ejection, parting lines or inserts, thus impacting tool design.

Program Longevity

The more the supplier knows about your company's total projected requirements, the better they can match them to various tooling techniques.

Approval Process

It is best for a supplier to know your company's requirements for approval up front, as they can impact many aspects of a proposal. These can include:

- Number of parts required
- First article inspection
- Statistical capability studies
- Production part approval process (PPAP)
- Operational or performance qualifications (OQ/PQ)

Target Pricing

When used appropriately, this can help save you time and money. It can facilitate a discussion about what can be done to achieve cost objectives by eliminating non-value-added items.

Additional Details

Suppose you need 100,000 parts. Do you need these parts for the life of the program? Or do you need 100,000 parts per year, per month, or per day? Different requirements have drastically different injection mold solutions, so when in doubt, share more.

Other information that can help improve a proposal includes:

- Is a quote or proposal needed for cost engineering purposes or for an actual injection molding job? Cost engineering may not require the same level of specificity.
- How do quality, cost, delivery, etc. apply to your program? How critical are design support, fast delivery, lower tool cost, or exceptional precision? Knowing your priorities can help the supplier tailor a proposal to your individual requirements.

Note: While knowing the details is important, placing the main focus on technical specifications can often limit innovation as most of the design details are fixed; a supplier acting as a strategic partner will instead work to understand the functional goals of your program to develop original ideas.

Materials Selection: Switching to Plastic

Converting your metal or glass part to plastic can have significant cost advantages. Especially in optical components, the technology and precision are newly available, and are a tremendous opportunity to drive out cost. Many disposable medical components are now possible because of materials conversion to plastic; this means increased patient safety and increased revenue for medical device companies.

Metal-to-Plastic Conversion

The healthcare industry has historically relied on metal components for many design applications. Yet over the past several years, numerous metal

Plastic conversion

Switching from metal or glass to a plastic material presents a tremendous opportunity to drive out cost for your medical product.

parts have been converted to plastic, and many more have the potential for conversion. The use of thermoplastics can provide cost-saving benefits such as:

- Elimination of time-consuming and costly secondary operations
- Consolidation of parts into fewer components
- Improved efficiency
- Lower manufacturing and assembly cost

In addition, switching from metal to plastic can have quality benefits such as better aesthetics, increased structural strength, reduced weight, and environmental resistance.

Glass-to-Plastic Conversion

Medical devices that contain glass lenses are an especially good fit for glass-to-plastic conversion. While a lens conversion alone is beneficial, the biggest savings result from a redesign that eliminates or minimizes optical mounts, hardware, optical alignment and assembly.

Empire was able to achieve a dramatic cost reduction for a customer's assembly by converting their seven aspheric lenses from glass to plastic. When meeting with the customer, one of our senior engineers proposed adding as many assembly features as possible to maximize the benefit of a plastic design. Empire's redesign reduced the part count from 50 to 6, and eliminated most of the assembly cost. Parts that can most benefit from glass-to-plastic conversion include:

- Aspheric lenses (may be able to simplify a more complex, multi-element design)
- When limited space or lighter weight is required
- Disposable applications such as clinical diagnostics and surgery

A misconception about polymer optics is that high-volume production is required to justify the capital tool investment; in fact, many customers experience considerable cost reductions at significantly lower production levels than are realized in typical injection molding applications.

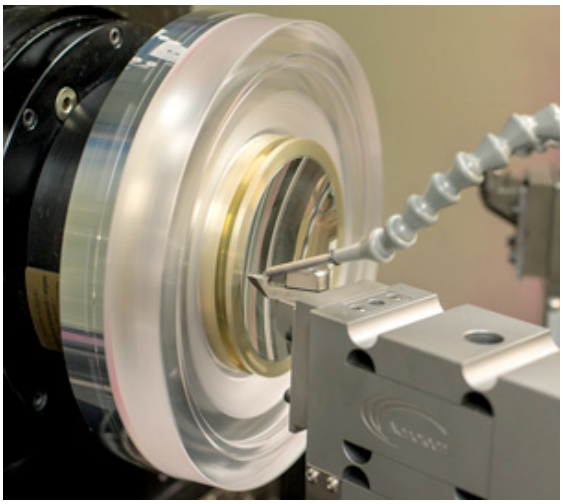
4. Lifecycle Planning: Prototype to High-Volume Production

Scalable Programs

As a program matures and product demands grow, the need often arises to switch operations to another supplier. This need is typically cost-driven, and it can cause supply chain interruption and even quality issues. Empire, however, provides complete prototyping and high volume manufacturing services for optics and other medical device components. During the product development stage, Empire focuses on large-scale production feasibility to make sure the transition from prototype to production is smooth.

Plastic Optics

Advances in plastics technology have led to innovation in medical device products that include optical components. The cost savings, biocompatibility and smaller size now possible by higher precision in plastics manufacturing are causing more and more medical device companies to turn to plastic injection molders for optics solutions.



Single point diamond turning

Our customers' medical assembly needs often include optical components. Single point diamond turning is a fast, cost-effective option for both prototype and small-volume production of optics.

Because Empire manufactures polymer optics in-house, your program can stay with the same company from start to finish. Empire has worked with medical device manufacturers to produce parts and assemblies for:

- Diagnostic equipment
- Consumables
- Surgical staplers
- Endoscope/laryngoscope

Single Point Diamond Turning (SPDT)

Single Point Diamond Turning, or SPDT, can significantly reduce the cost of prototype optics for medical devices. Plastic optical designs can be created without the added first step of building an expensive injection mold, saving time and development costs. Diamond turning is also well suited for the manufacture of precision plastic optics in limited quantities. SPDT small-volume runs help our customers meet early demands before moving into full-scale production.

Contact Empire Precision at 1.800.541.7135 or info@empireprecision.com to speak with an expert who can who can guide you through multiple considerations for improved program cost and performance.

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