



KAYSUN

INJECTION MOLDING & ENGINEERING SOLUTIONS



From NPD to Production:
TIPS FOR SUCCESSFUL
MEDICAL INJECTION
MOLDING



Medical injection molding requires a rigorous, highly regulated new product development (NPD) process to ensure each part safely meets user, technical, and industry requirements.

The NPD process ends with defect-free medical devices going to market, but it begins with assessing — then leveraging — your primary custom injection molder partnership. This guide provides key information about how to prepare a medical project for injection molding, and what to look for in a medical injection molder that will best fit your needs.



Preparing Your Medical NPD Project For Injection Molding



New product development is both strategic and tactical.

Strategically, there are a number of items that factor into how your team proceeds with defining initial design and engineering requirements. As you advance your medical device from concept to bona fide project, there is another layer of decision-making regarding specific tactics. **In both areas, tapping into an [experienced medical injection molder](#) during the design phase pays dividends.**

A molder looks at your project from a different perspective, providing specific insights about end use, attributes, and potential production challenges. Their input early on aligns your plan with the medical injection molding process, prompting refinement or inclusion of key considerations surrounding:

- **Design and engineering expertise** that sheds light on your project from an injection molding perspective and prompts conversations around next steps
- **Process simulation** and how it contributes to product development and defect-free production
- **Part design guidelines** for achieving component and part consistency
- **Materials selection** that corresponds with project needs, molding compatibility, and medical industry regulations
- **Gate location** and other fundamental [tooling decisions](#)
- **Overmolding** choices and benefits for medical devices and equipment, as necessary



Taking the time to holistically understand your project and work through the specs, steps, and requirements with the help of an experienced custom injection molder eliminates missteps and prevents costly rework. It also bolsters confidence that results will match expectations.

The importance of the role of an injection molding partner, then, cannot be understated. However, the nuances of medical injection molding need to be handled by a molder with the requisite expertise and experience — and not all molders fall into this category.

How do you identify the appropriate medical injection molding partner for your project?



What To Look For in a Custom Injection Molder



When assessing injection molders, a threshold for initial consideration is the molder's proven capabilities in medical injection molding processes. **Verifying that a molder is skilled in handling complex projects is essential, but it shouldn't be the only measure of partnership potential.**

A full-service custom injection molder will think — and act — beyond manufacturing processes and encourage your team to do the same. Thorough, collaborative support during all stages of the project is pivotal in producing high quality, defect-free medical devices. A molder capable of providing this level of support using in-house resources is crucial for seamless project execution.

These five in-house value-adds signal a molder is knowledgeable, prepared, and capable of successfully supporting and producing your new medical device project:

1

Design and engineering expertise that complements your team, and also introduces specialized advanced processes such as Design for Manufacturability (DfM) and [scientific molding](#) to analyze and optimize project design, materials, and tooling to ensure repeatable, defect-free production.

Does your molder...

Have specialized DfM and scientific molding engineers?

Proactively collaborate with your NPD and engineering teams?

Challenge “on paper” design assumptions and offer alternatives?

Have in-depth knowledge of resins and how to align materials with applications?

2

Quality-control measures that encompass the entire medical injection molding project. It includes dedicated quality engineers who monitor processes, perform comprehensive laboratory-based product inspections during manufacturing, and gather/apply data-driven metrics to [verify consistency and quality](#) across departments, teams, and production runs.

Does your molder...

Have an in-house quality control lab, run by experienced engineers?

Understand the importance of monitoring quality throughout the production process, not just as it relates to finished products?

Perform in-process testing to confirm quality and consistency?

Gather and apply real-time data to optimize quality controls?

3

Medical device process validation that meets the stringent [quality requirements](#) of the medical industry, and confirm that the medical injection molder can prove proficiency in process repeatability and reproducibility in accordance with ISO 13485:2016.

As such, a molder must carry ISO 13485:2016 certification. In addition, [MedAccred accreditation](#) is highly desirable to reduce risk to patient safety, but few injection molders nationwide hold the designation. (For more on medical device process validation, see IQ, OQ, and PQ: Qualification Within Medical Device Process Validation.)

Does your molder...

Have a documented history of success in medical injection molding?

Carry certification in and comply with ISO 13485:2016?

Carry MedAccred accreditation?

Have experience in all phases of medical device process validation, including IQ, OQ, and PQ?

4

Sourcing support that includes a network of vendors and services that can be called upon to [keep supply chains flowing](#), production lines running smoothly, and timelines and budgets in check should unforeseen circumstances arise.

Does your molder...

Actively manage supply chain vendors?

Monitor vendor networks to identify potential problems and proactively develop alternative solutions?

Regularly communicate status updates to your team?

5

Secondary operations that keep injection-molded parts and medical devices from being handled by several vendors en route to completion. [In-house secondary operations](#) minimize the risk of error and foster better communication, higher product quality, lower cost, faster time to market, and rapid response time for re-design needs or market shifts.

Does your molder...

Offer in-house, value-added secondary operations?

Help you manage costs through in-house secondary operations?

Provide suggestions for leveraging secondary operations during design, and easily make adjustments, if necessary?



IQ, OQ, and PQ: Qualification Within Medical Device Process Validation



Medical device process validation is a major part of NPD. A multifunctional team comprised of OEM and molder members is responsible for planning and carrying out robust protocols that align with [ISO 13485:2016](#) and FDA regulations, with the injection molder being central to performing:

Installation Qualification (IQ) focused on equipment design features, installation conditions and maintenance schedules, operational safety, hardware and software documentation (including prints, drawings, and manuals), spare parts inventory, and environmental conditions

Operational Qualification (OQ) that defines initial process parameters, further refines those parameters using Design of Experiments (DoE), and challenges the identified parameter settings by applying controlled worst-case scenario tests to understand and verify outcomes

Performance Qualification (PQ) that tests long-term process stability, consistency, and repeatability under normal operating conditions



Medical device process validation reflects the injection molder's competencies in process repeatability and reproducibility during medical injection molding.

While process validation is completed during NPD, it is not necessarily static. NPD teams and quality and design engineers will conduct new validation in the event of a major shift in product or process parameters, such as:

- Tool damage or replacement
- Machine replacement
- Significant design changes

PARTNER WITH KAYSUN

Kaysun has earned the reputation as the preferred custom injection molder for the medical industry. Beyond our history of success in medical injection molding, medical OEMs seek out Kaysun because of our:

- Design, engineering, and [materials expertise](#)
- Commitment to quality
- ISO 13485:2016 certification and MedAccred Plastics accreditation
- Flexibility in finding practical solutions
- Value-added in-house services, such as secondary operations
- Collaborative partnership approach in all aspects of a project

Find out how Kaysun can help you navigate your new product development process and deliver trusted results.

[Schedule a free consultation with Kaysun medical injection molding experts today.](#)