

# INJECTION MOLDING

CHOOSE PARTNERS THAT INVEST IN  
**QUALITY ASSURANCE AND CONTROL**



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By partnering with an injection molding partner that places equal emphasis on not only engineering and design excellence but quality and service as well, OEMs can realize demonstrable payback and strategic advantages

## CHOOSE PARTNERS THAT INVEST IN QUALITY ASSURANCE AND CONTROL

Precision engineered parts and assemblies that are produced via injection molding play an essential role in applications across a diverse array of highly regulated industries – from medical, aerospace and defense to high tech electronics and industrial products. For applications where performance and durability are crucial, injection molded parts must be consistently produced with precise dimensions, and tight tolerances. Such engineered parts must be made from the most appropriate material – selected from a range of highly engineered thermoplastic resins and silicones.

### ENSURING PRECISION AND CONSISTENCY

For consistent results every time, original equipment manufacturers (OEMs) should partner with an injection molding supplier that not only has the required engineering experience and expertise, but also has a robust quality assurance (QA) and quality control (QC) framework in place. To optimize outcomes, both parties should work in close partnership and should prioritize and enforce quality at every step of the process – from upstream engineering and design to downstream manufacturing, finishing and assembly.



### PARTNERSHIP FOR QUALITY

Similarly, OEMs's should select an injection molding partner that can provide end-to-end support – from upstream design for manufacturability (DFM) services,  mold production and tooling through injection molding of the parts, finishing and assembly – provides additional opportunities for cost savings and risk reduction. Partnering with a single, vertically integrated injection molding partner minimizes costs and risk by reducing the number of handoffs, transportation costs, schedule delays and overall supply chain complexities that arise when multiple companies are otherwise engaged to produce the complex engineered parts.

### CONSISTENT QUALITY YIELDS DIRECT AND INDIRECT PAYBACK

When it comes to precision parts that are produced via injection molding, any deviation from the required engineering specifications or regulatory requirements can compromise the integrity of the molded part, rendering the part unfit for its intended purpose. Partnering with a supplier that puts a premium on QA/QC processes and protocols reduces the likelihood of defects and rework during the manufacturing process. Such a commitment to quality provides opportunities for both direct and indirect payback.

**Direct** Direct savings come from the ability to reduce the production of off-specification parts (and thus, avoid scrap and other high-cost waste streams), minimize downtime and excess labor, reduce interruptions to the manufacturing schedule and ensure faster, time to market. Similarly, the ability to reduce the production of defective parts – by enforcing consistent quality standards throughout the entire injection molding process – also reduces the risk of product recalls and warranty claims.

**Indirect** Meanwhile, indirect payback comes in other ways. For instance, consistent adherence to a robust quality framework can help to safeguard brand reputation and reduce customer dissatisfaction for both the OEM and their chosen injection molding partner.

### Case study 1: Focus on Chemical Sensor Manufacturing

Seaway partnered with a chemical sensor manufacturer to design and produce 10 injection-molded parts for a specialized new sensor to be used in oilfield filtration systems. The project faced complex engineering and design challenges, due to the tight dimensional tolerances and material science requirements for the precision parts.

The two companies developed a robust QA/QC testing strategy in accordance with ISO 9001 and ISO 13485 standards. Through this partnership, they:

- Created a design for manufacturability (DFM) strategy
- Provided in-house mold and tooling design and prototyping for the parts
- Met all material science specifications to ensure that all parts were able to withstand damage from exposure to moisture, particles and numerous chemicals while in service
- Saved the sensor manufacturer \$20,000 in shipping fees that would have been required if the company had chosen to outsource these critical operations

### DEMAND QUALITY AT EVERY STEP IN THE PROCESS

When assessing the QA/QC capabilities of potential injection molding partners, OEMs should seek partners that hold all of the requisite certifications – such as ISO 9001 and ISO 13485, which govern quality, safety and performance during manufacturing operations. Both of these standards provide essential elements of a robust QA/QC framework.

- ISO 9001 – An international standard that provides specifications for a quality management system that can be applied at any organization regardless of industry, product or service, or company size
- ISO 13485 – A comprehensive management system that is specifically for the manufacture of medical devices. It places a more significant focus on regulatory compliance and offers less flexibility in the organizational process



### HALLMARKS OF A WORLD-CLASS QA/QC PROGRAM

Manufacturers should select an injection molding partner that can provide a full range of end-to-end services with complete project management capabilities to provide full turn-key solutions for its customers. These include:

- DFM engineering services and partnerships
- Engineering and prototyping services (to identify and rectify potential problems ahead of scaleup)
- In-house mold and tool design
- Injection molding of parts using the most appropriate highly engineered thermoplastic resins and silicones
- ISO Class 7 & 8 certified cleanroom molding and assembly services
- Assembly and finishing services
- Value add services such as inserts, pad printing, machining, welding, painting, shielding, heat staking, annealing and more
- Kitting, packaging, and distribution
- Sterilization management
- Tool storage for customer-owned tools in climate-controlled warehouses

## **ENSURING QUALITY THROUGH COMPREHENSIVE REAL-TIME INSPECTIONS**

The ability to carry out real time inspections using state-of-the-art equipment throughout the process is an integral part of the overall QA/QC process. When evaluating potential injection molding partner, OEMs should choose a supplier that provides:

- First Article Inspection (FAI)
- In-process inspections
- Final inspections
- Production Part Approval Processes (PPAP)
- Statistical process control (SPC)

The data driven findings that result from such efforts help to ensure consistent control of all steps in the injection molding process, which improves reliability and repeatability. The broad use of advanced inspection systems also informs troubleshooting efforts and provides an opportunity for quality-related issues to be recognized early and then quickly rectified – again helping to reduce or eliminate quality-related scrap, downtime, schedule delays and cost overruns.



The goal is to reduce variability throughout the injection molding process. A thorough inspection protocol provides critical information that is needed for injection molders to carry out the following process validations:

# **IQ**

## **Installation Qualification**

To ensure that all equipment components have been installed according to specification

# **OQ**

## **Operational Qualification**

To ensure that the molds are operating correctly in terms of assembly clearances and other key performance parameters

# **PQ**

## **Performance Qualification**

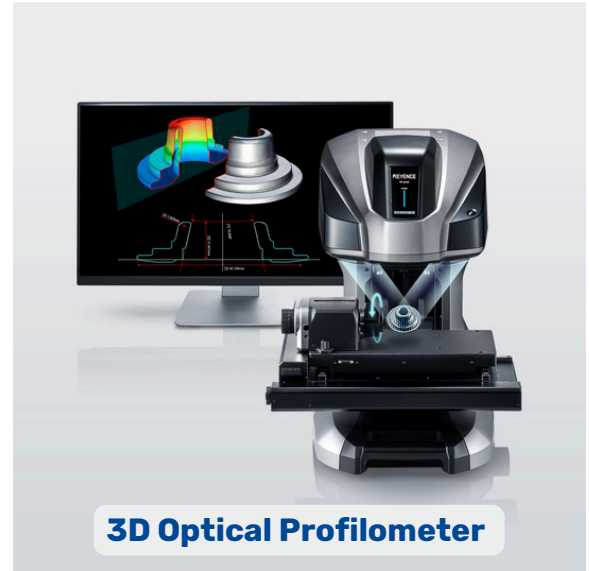
To verify minimum and maximum settings that can be used to ensure that the finished parts will meet all of required qualifications with every production run

### ADVANCED INSPECTION SYSTEMS FOR INJECTION MOLDING

It is important to note that not every injection-molding program requires the same level of rigor when it comes to quality-related inspections. As such, it's important to partner with a supplier that is able to customize the approach. The objective is to deliver the most appropriate inspection and quality-control services to meet the technical challenges and regulatory requirements associated with any given project.

Today's state-of-the-art injection molding inspection systems:

- Vision systems and coordinate measurement machines (CMM) for multi-sensor measurement of products during inspections
- Optical comparators
- Calibrated surface plates
- 3D Optical Profilometers
- Spectrometers for color shade measurement
- Melt flow testers
- Cubic feet per minute (CFM) airflow indicator for cleanroom applications
- Gram scales, microscopes, gauge blocks, gauge pins, and digital calipers
- Complete first article inspection (FAI) reports
- Advanced quality planning



### Case study 2: Focus on Medical Device Manufacturing.

Wright Engineered Plastics partnered with an OEM to establish production procedures and facilitate the transition of their medical device into manufacturing. When financial constraints led to a Spinal Implant Company acquiring the project, Wright continued its collaboration, focusing on optimizing production and scaling operations.

Wright and the Spinal Implant Company were able to successfully bring the product to market. Through this partnership, they:

- Developed procedures and constructed a new cleanroom
- Streamlined production processes and optimized efficiency
- Collaborated with engineers and developed fixtures to enhance production
- Facilitated scaling from low to mid-volume production
- Ensured quality control throughout the production process
- Reduced line fallout from 20% to 2%, demonstrating improved efficiency and quality control
- Expedited time-to-market by transitioning to plastic injection molding, contributing to overall cost savings