MGS
Healthcare Manufacturing

Simulation Excellence in Healthcare Product Development

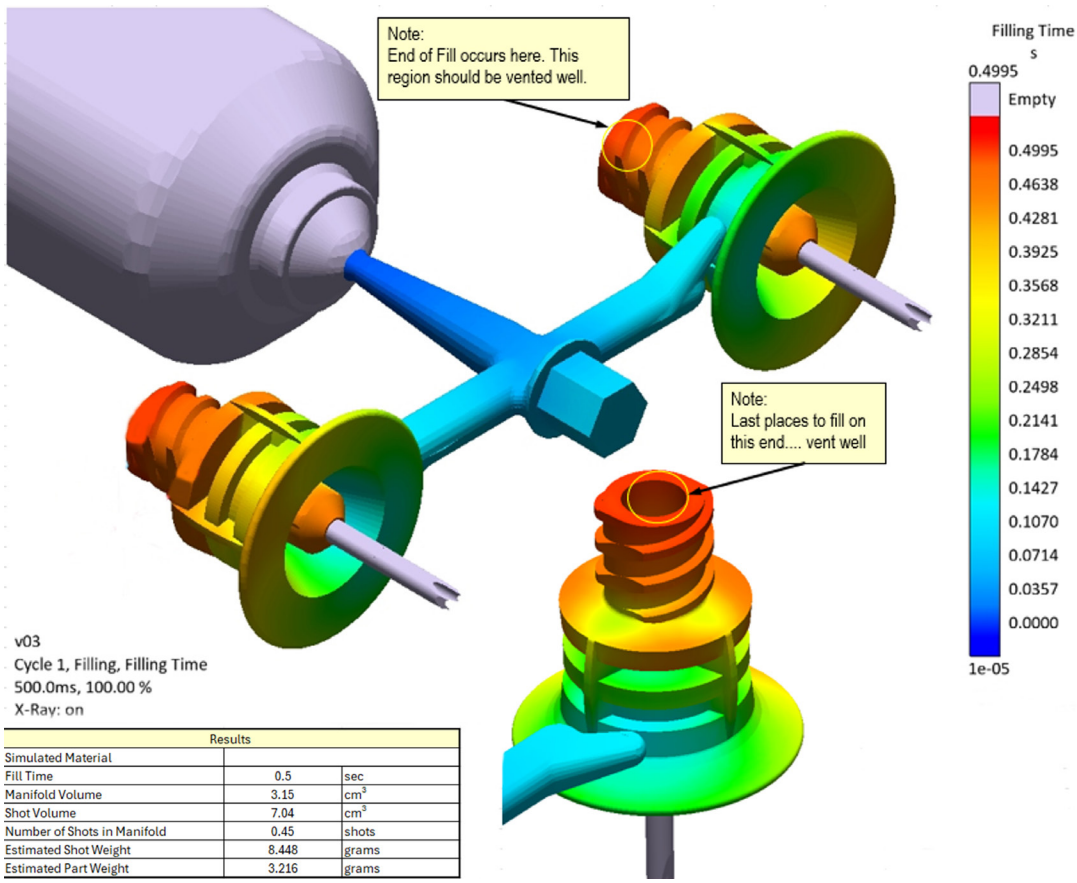
Driving Risk Mitigation and Accelerated Time to Market

From Imagination to Realization

INTRODUCTION

In the highly regulated and competitive healthcare industry, the ability to reduce project risk while accelerating time to market is a decisive success factor. From early concepts to validated production, product development must balance innovation with strict regulatory compliance, cost control and manufacturing scalability.

MGS, headquartered in Germantown, Wisconsin, has developed a holistic approach where simulation excellence is a central enabler. By combining Early Supplier Involvement (ESI), design for manufacturability (DFM) and design for assembly/automation (DFA) with decades of hands-on experience in Tooling, Manufacturing, Automation and Validation, MGS consistently delivers robust, compliant and manufacturable healthcare solutions. This whitepaper outlines how numerical simulation, when paired with expert interpretation and a closed-loop system, transforms the development of Pharma, Diagnostics, and MedTech products.



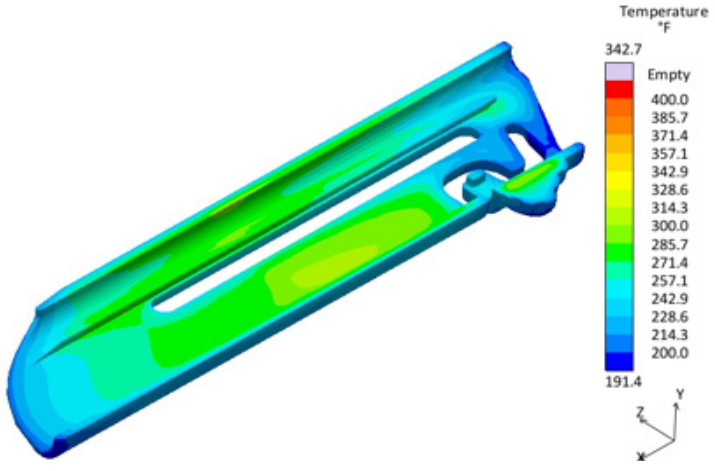
Results		
Simulated Material		
Fill Time	0.5	sec
Manifold Volume	3.15	cm^3
Shot Volume	7.04	cm^3
Number of Shots in Manifold	0.45	shots
Estimated Shot Weight	8.448	grams
Estimated Part Weight	3.216	grams

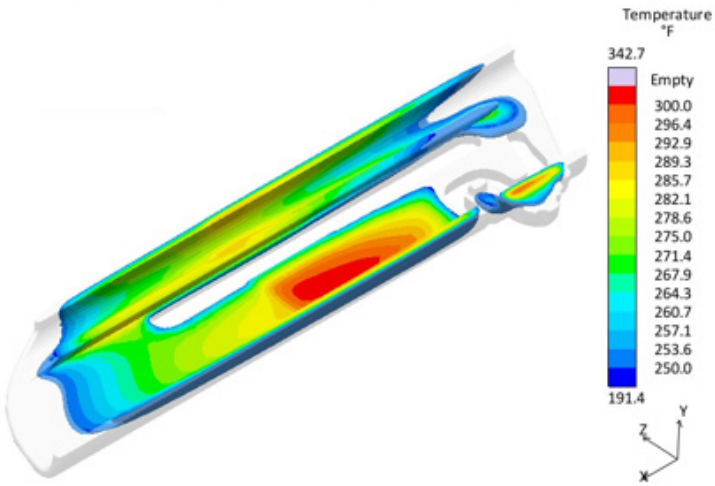
THE ROLE OF SIMULATION

Simulation at MGS is embedded at the earliest phases of a project. Instead of using numerical tools solely as verification late in the cycle, simulation is treated as a predictive and decision-driving factor throughout. From napkin sketch to scaled production, simulations guide design choices, tooling specifications and process parameters.

This approach reduces dependence on trial-and-error prototyping and simulation can identify risks with part geometry and risks during the molding process. These can be identified and mitigated early on in the mold design phase of the project. It also allows faster ramp-up of initial tooling and production scenarios, ensuring healthcare products move through regulatory validation and into market readiness more efficiently.

KEY COMPONENTS OF SIMULATION EXCELLENCE





1. Advanced Finite Element and CFD Tools

MGS employs state-of-the-art tools for mechanical, flow, filling, solidification and thermal processes. These capabilities allow precise prediction of:

- Part positioning within tools.
- Injection gate design and location.
- Cooling layouts, venting and ejection strategies.
- Shrinkage and warpage effects on tolerance-critical features.

Particularly in healthcare devices, where reference dimensions often involve multiple tight tolerances, these predictive insights are essential. Correct modeling of cavity materials, heat conduction coefficients and molding machine dynamics ensures that simulations mirror real-world outcomes.

2. Best-in-Class Software and Expert Interpretation

MGS maintains three leading simulation platforms in-house and supplements them with a trusted network of external experts for peak demand. This provides unmatched flexibility and turnaround speed for even the most complex simulation tasks.

However, software alone does not guarantee reliable results. A critical differentiator is interpretation: simulation outputs are analyzed by a multidisciplinary engineering team with more than 500 years of combined ESI/DFM/DFA experience. This expertise ensures that numerical results are translated into actionable design, tooling and process decisions. Without expert interpretation, simulations risk being misleading or incomplete.

3. Closed-Loop Feedback

In-house molding, metrology, cleanroom validation and automation systems feed live data back into simulation models. This closed-loop feedback allows continuous refinement of assumptions and parameters. The result is faster learning curves, especially in demanding applications where biocompatibility, sterility and compliance add additional layers of complexity.

This feedback-driven process also helps eliminate bottlenecks often encountered at other contract manufacturers, where validation capacity is limited or fragmented across sites.

4. Proven Methodology

MGS applies a structured simulation workflow that guarantees efficiency and repeatability:

Mechanical, functional and structural simulations during product design and development.

ESI Analysis – part design for manufacturability and moldability. Gate selection, positioning and fill simulation.

Tool Definition – including mold and cavity materials, cooling layouts, ejection and machine-specific factors.

CFD Flow Simulation – with complete tool and process details. Identify areas in the plastic injection mold that could benefit from advanced additive manufacture mold components (conformal cooling).

Live Testing and Validation – in-house, with results fed back into the simulation loop.

This methodology combines the precision of advanced tools with empirical data from real-world molding and automation systems.

INTEGRATION WITH MANUFACTURING AND QUALITY

Simulation excellence at MGS is fully integrated with automation, end-of-arm tooling (EOAT), parts handling, assembly and quality inspection. This holistic scope ensures that products are not only manufacturable, but also efficiently automatable and compliant with stringent healthcare quality standards.

Dedicated cleanroom environments support validation under regulatory conditions, while separate customer work areas safeguard intellectual property. This infrastructure enables transparent collaboration without compromising security.

BENEFITS FOR HEALTHCARE PRODUCT DEVELOPMENT

Risk Mitigation: Design & Development expertise as well as early identification of tooling and process risks, prevents costly correction loops and regulatory delays.

Accelerated Time to Market: Advanced software, fast turnaround and closed-loop testing allow customers to move from design to production more quickly.

Regulatory Readiness: Integrated cleanroom validation and quality control ensure compliance with healthcare regulations from the start.

Cost Reduction: By avoiding unnecessary design iterations and ensuring right-first-time tooling, significant cost savings are realized.

Tool Transfer Success: MGS has a proven track record of taking over existing tooling programs. Through simulation-based analysis of defects, scrap rates and productivity gaps, MGS consistently increases efficiency and output stability during tool transfers.

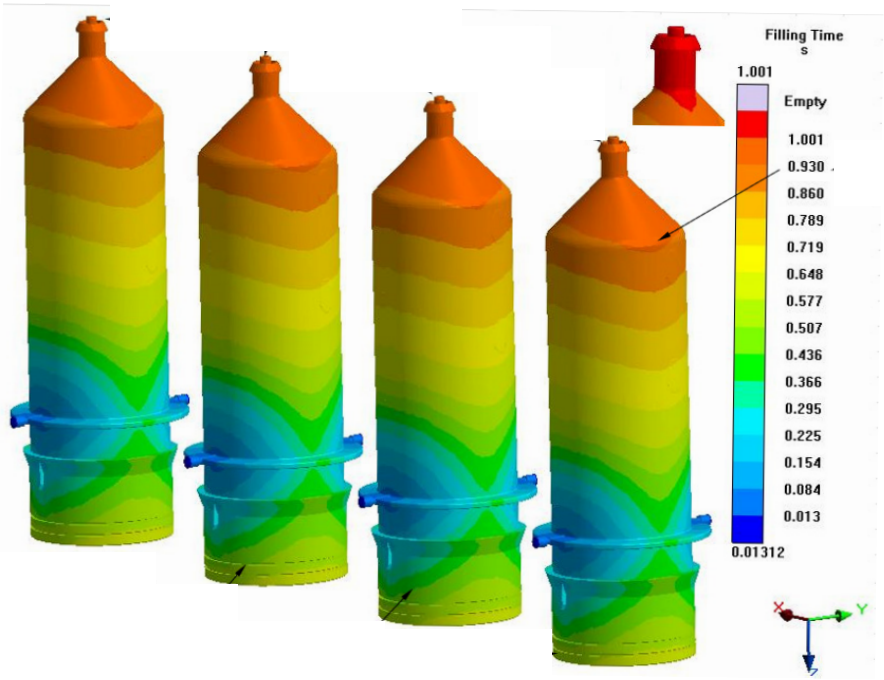
All-in-House Advantage: Design & Development, Tooling, Automation, Manufacturing, Validation and Quality Inspection are consolidated under one roof. This minimizes interfaces, enhances communication and provides customers with a single point of responsibility.

CONCLUSION

Simulation excellence at MGS is more than a technological capability — it is a proven, integrated methodology that unites advanced software, expert interpretation and closed-loop validation across the entire product lifecycle.

By embedding simulations from concept to production, MGS enables risk mitigation, rapid scaling and efficient manufacturing of highly regulated healthcare products. This approach not only accelerates time to market but also ensures robust, regulatory-compliant outcomes with minimal rework.

For Pharma, Diagnostics and MedTech innovators, MGS offers a unique combination of engineering rigor, manufacturing expertise and all-in-house execution — a strategic partner that consistently delivers both speed and reliability in product development.



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Wherever you are in your product journey, MGS is ready to help. As an end-to-end healthcare CDMO, we provide seamless support from Design and Development through Tooling, Manufacturing, Automation, and Assembly. Reach out to us today!

contact@mgsmfg.com

Together, let's bridge the gap
between imagination and realization.

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