

Case study

Doubling Output on a High-Precision Blow-Molded Device Through Process Validation

A medical device OEM faced a familiar but challenging problem: scaling up production of a high-precision, blow-molded part while preserving the tight tolerances it depended on. BMP Medical addressed this through a combination of rigorous process validation and custom, in-house automation, resulting in a faster, more consistent production line that kept pace with growing demand.

- **Industry:** Medical device
- **Capabilities:** Process validation (IQ/OQ/PQ), injection blow molding, custom automation, and inline quality inspection
- **Material:** High-density polyethylene (HDPE)
- **Mold configuration:** 8-cavity blow mold



The Challenge

A long-standing BMP Medical customer needed to significantly increase production capacity for a precision blow-molded device. The part is manufactured to tight tolerances across geometry, wall thickness, and fill balance, with specifications that must be met consistently in every production cycle. As demand grew, they needed a manufacturing partner who could scale output without compromising the device's dimensional tolerances.

Process validation for blow-molded components involves a distinct set of considerations compared to standard injection molding. The process is inherently more dependent on tooling behavior and fill dynamics, and an eight-cavity blow mold introduces a substantial number of interacting dimensional parameters that must be evaluated in combination rather than in isolation.

Due to this interdependence, adjusting a single process parameter can influence others in ways that are not always immediately apparent, creating the potential for a dimensional deviation to surface only after production has scaled to the desired volume.

The Solution

BMP Medical took on two challenges at the same time: validating the process with the rigor a higher-volume run would demand, and building the automation needed to support it in-house.

For the validation work, BMP's engineers used Design of Experiments (DOE) methodology, running structured window studies that tested high, medium, and low settings across several process parameters. The studies then mapped how those parameters interacted – the very interdependencies that made this validation more demanding than a standard injection molding run. Every critical dimension was measured and analyzed in Minitab, with the team targeting process capability (Cpk) values of 1.33 to 1.66, and the validation was carried out all the way through IQ, OQ, and PQ.

On the automation side, BMP Medical chose to design and build the robotic cell in-house rather than bring in an outside vendor. The system carries each part from the molding machine through a series of cameras and lasers for inline measurement, then places it directly into cleanroom-compliant totes. In doing so, it removes the manual handling and box-based packaging that a cleanroom setting doesn't permit.

The Result

The combination of a validated process and an automated inspection line reshaped the economics of this product line. Output doubled, and labor requirements fell sharply, with the line requiring 25% fewer operators to run. The gain came from replacing manual, sample-based quality checks with full inline inspection, where every part gets measured as it comes off the line.

Additionally, the scrap rate fell from roughly 5% to about 1%, and catching defects earlier meant a higher-quality end product. Because BMP built the automation cell in-house, the cost came in at an estimated 25% of what an outside vendor would have charged, with the savings felt across the broader program rather than a single line item. The customer's challenge shifted from securing enough supply to keeping pace with the demand this improvement created.

Validation work or automation efforts alone couldn't have delivered the same result; together, they made this one of the more effective process-improvement projects BMP has completed for a customer. As is often the case with BMP Medical's engagements, validation was not the endpoint. It typically marks the first step toward a broader manufacturing partnership, with the proven process becoming the foundation for full production.

What This Means for Your Manufacturing Program

The considerations in this project – sustaining tight tolerances while significantly increasing volume – apply broadly across medical device manufacturing. For OEMs facing a similar scale-up need, structured validation supported by statistical process control provides a way to characterize a process before volume increases.

Once a process is validated, scaling it into full production depends on manufacturing capacity and assembly support that can keep pace with the added volume. BMP's Manufacturing and Assembly teams work across manual and automated workflows in cleanroom and white room settings, so a validated process can move into higher-volume production while maintaining the same quality controls established earlier.

Results at a Glance

- Production capacity **doubled**
- Scrap rate **reduced by ~80%**, from roughly 5% down to about 1%
- Per-line staffing needs **fell by 25%**
- Inline inspection **replaced** manual, sample-based quality checks
- In-house automation cell built for an estimated **25% of the cost** of an outsourced solution





If your team is considering a similar increase in production volume, [BMP's Process Validation](#) team can apply comparable methods, including DOE-based studies, statistical process control, and IQ, OQ, and PQ protocols, to establish whether the existing process will support the desired scale before production begins. Validation projects of this nature typically take 4 to 6 weeks, with timelines dependent on the specific part and requirements.

Get in touch with one of our experts today.



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