

BMP medical

Case study

Maintaining Cleanroom Injection Molding Continuity Through a Material Transition and Packaging Upgrade

A disposable tissue grinder that had been manufactured reliably for 25 years suddenly faced an unexpected disruption: the material behind it was being phased out by the only supplier that had ever made it. Replacing the raw material was only part of the challenge for BMP Medical, which also needed to keep the multi-million-unit supply chain running without interruption and, simultaneously, address a packaging process already under strain.

- **Industry:** Research tools
- **Product:** Disposable tissue grinder used in research laboratories
- **Capabilities:** Cleanroom injection molding, materials engineering, automated custom packaging
- **Volume:** 3-4 million units annually, across BMP-branded and private-label customers
- **Standards:** Customer-supplied specifications, FDA-approved, sterile



The Challenge

BMP Medical has served as the original equipment manufacturer for a disposable tissue grinder used across research laboratories for more than two decades. The product reaches the market through two channels: sold directly under BMP's own brand and supplied under private label to several customers, all of whom depend on a consistent, validated product for their regulated operations.

After decades of reliable sourcing, the raw material supplier BMP depended on began phasing out the polymer used in the product. As the material had been engineered specifically for the grinding tip application, no equivalent substitute was readily available. BMP needed to identify a replacement as soon as possible to maintain supply. The new material would also need to run cleanly through BMP's existing cleanroom injection molding process without requiring new tooling or equipment.

Moreover, due to the tissue grinder being used within a regulated setting, introducing a new material required formal validation on both sides of the relationship: BMP would need to validate the replacement internally, and each customer, whether purchasing under BMP's brand or through a private-label agreement, would need to complete their own validation before accepting the reformulated product. With multiple customers relying on the same underlying material, getting the replacement right on the first attempt was crucial.

Another challenge concerned the product's packaging process itself. For a number of years, the tissue grinder had shipped in a labor-intensive, pre-printed Tyvek pouch that was costly to produce and difficult to customize for individual customers. This constraint became more apparent during the COVID-19 pandemic, when disruptions across the packaging supply chain extended lead times to 3-6 months, leading to prolonged backorders for BMP and its customers.

The Solution

BMP approached the two challenges as a single, connected effort: a materials transition paired with a proactive packaging upgrade, both of which had to hold up under the same cleanroom injection molding process the product had been built on.

To replace the phased-out polymer, BMP's team worked directly with the material manufacturer rather than waiting on a generic substitute, sending sample materials out for molecular and performance testing. The manufacturer engineered a new formulation designed to match the original material's structure and behavior. Once a candidate was identified, BMP qualified it within its current injection molding process, running it through the same tooling and cleanroom conditions used for the original formulation to confirm it molded consistently and met the same dimensional and sterility requirements before releasing it into full production.

The success of this transition was largely attributed to the upfront work of testing and characterizing the original material and then having it reformulated to achieve equivalent performance. The reformulated material was processed within the original validated molding process, and the resulting parts underwent First Article Inspection (FAI) along with the same dimensional checks and verification activities that were performed during the original validation. This approach provided objective confirmation that the reformulated material and molded parts continued to meet the established requirements and could be incorporated into production with confidence.

At the same time, BMP addressed packaging inefficiency by investing in a form-fill packaging machine that semi-automates production in-house, replacing the legacy pouch. The new system prints custom nomenclature on demand, so a packaging or labeling change that once took weeks or months to turn around now takes about ten minutes.

Both efforts drew on a manufacturing foundation BMP has built over 40+ years, including cleanroom injection molding, GMP-compliant systems, automation expertise, and an in-house quality department that writes and owns validation protocols. Every part that comes off the line moves through metrology, First Article Inspections, and Gauge R&R studies before it is cleared to ship.

The Result

Promptly switching the raw material kept the product's supply uninterrupted. Once BMP requalified the replacement polymer within its existing injection molding process, the tissue grinder continued shipping at its usual volume, roughly 3-4 million units annually, split between BMP's own brand and several private-label customers.

The packaging upgrade, on the other hand, changed how quickly BMP could respond to demand. Because the new form-fill system runs on generic raw stock and prints customer-specific nomenclature on demand, a packaging or labeling change that once required pre-printing steps can now happen within the same production run. While industry lead times commonly run 6-14 weeks, BMP now ships most orders within a week, often accommodating expedited orders within 48 hours.

Moreover, the updated packaging format reduced material waste compared to the original design, giving the product a more sustainable footprint alongside cost and time efficiencies.

Results at a Glance

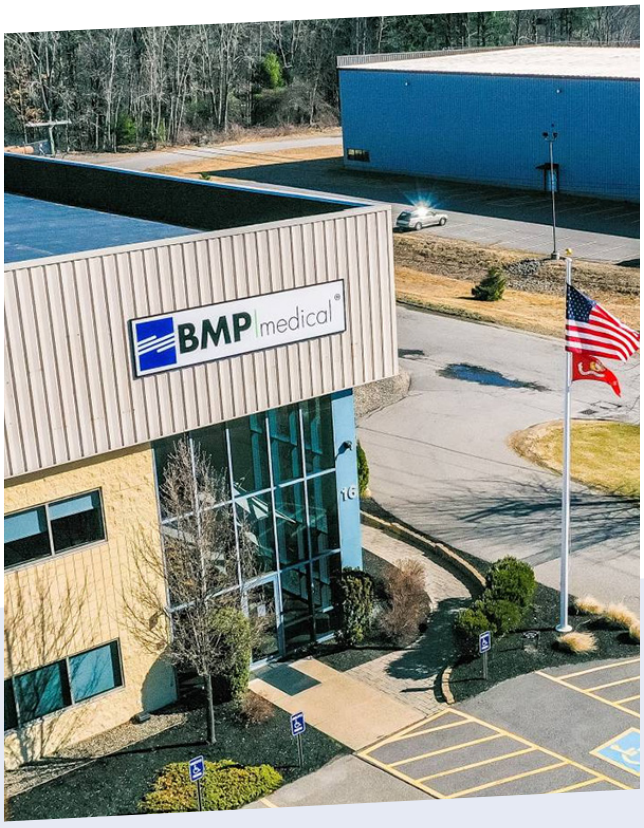
- Supply uninterrupted at **3-4 million** units shipped per year
- **~10 minutes** to execute a validated packaging or labeling change; down from weeks or months
- Most orders ship within a week; expedited orders fulfilled within **48 hours**
- **Reduced packaging waste** compared to the legacy pouch format

What This Means for Your Manufacturing Program

Legacy products and processes carry a specific type of risk: what runs smoothly for years can become a liability the moment a supplier exits, a validated process is asked to scale beyond its proven limits, or a disruption hits the supply chain.

BMP Medical supports OEMs across cleanroom injection molding, process validation, and packaging, to qualify new materials and processes, or bring legacy processes up to date.

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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