MANUFACTURING

Scaling medtech innovation: A manufacturing blueprint

Medical device developers should approach manufacturing not as a final hurdle, but as a foundational element integrated from day one.

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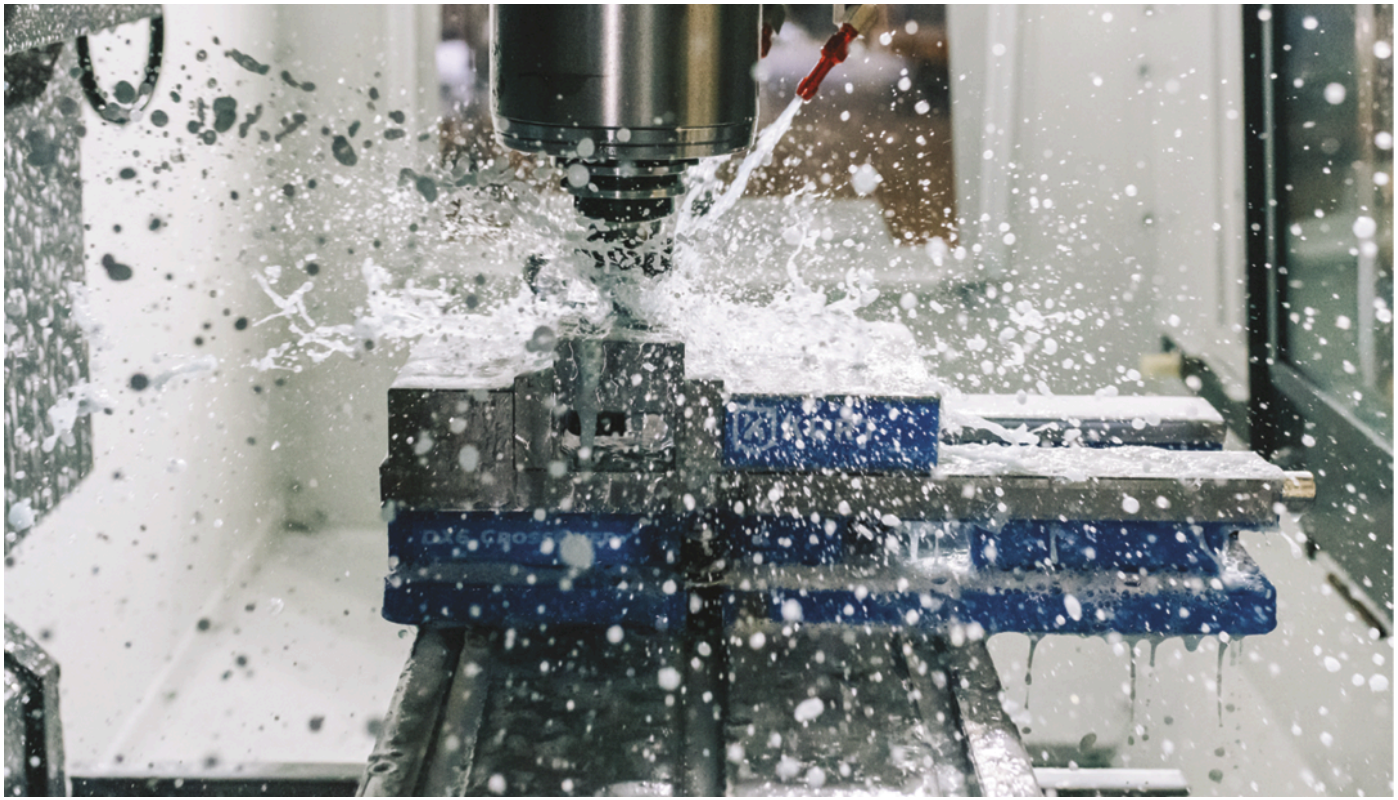

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In medical technology manufacturing, the journey from concept to a market-ready device is filled with complexities. While functional innovation often takes center stage, the path to high-volume production is just as critical. A common pitfall is treating manufacturing as a final step rather than an integral part of the design process. This oversight can lead to costly delays, redesigns, and missed market opportunities.

To navigate this journey successfully, medtech original equipment manufacturers (OEMs) must adopt a holistic approach integrating manufacturing expertise from the beginning. By collaborating with contract design manufacturing (CDM) partners early for tooling and engineering insights, OEMs can build a foundation for a scalable, cost-effective, and

Designing for scale, not just function

A successful product launch hinges on early collaboration. When tooling and manufacturing engineers are involved from the ground up, they can help shape a product's design with the end goal in mind, whether rapid prototyping or high-volume automated production. This partnership allows for a comprehensive plan that considers every aspect of the scaling process, including automation readiness and machine capacity.

Minor adjustments to a part's design at the concept stage can have a profound impact on its manufacturability. These small changes – often invisible to the end user – can significantly improve the overall quality and cost-effectiveness of the final product. An experienced CDM partner such as Trelleborg Medical Solutions can provide crucial feedback on part geometry, material selection, and tolerance requirements to ensure the design is optimized for efficient production. This collaboration is one of the most powerful tools for ensuring a smooth transition from prototype to mass production.

The digital foundation: Advanced software and simulation

Before any physical part is made, the digital groundwork must be considered. Modern manufacturing relies on a suite of sophisticated software tools that bridge the gap between design and production, compressing lead times and preventing costly errors.

Utilizing the latest mold-flow and design software is essential. These tools enable engineers to simulate critical factors such as cavity balance, air trap and vent locations, and material-based calculations for waste and press tonnage. By running these digital simulations, experts can identify and resolve potential issues virtually, bypassing multiple rounds of physical build-and-modify stages. This creates confidence in the process and allows for a smoother transition to the prototype phase.

gaps or other imperfections. Personnel need to be able to identify and correct these issues so the errors aren't directly transferred to the tooling and the finished part. Machine simulation software adds another layer of security, allowing programmers to identify potential collisions and make corrections before a program ever reaches a machine. Investing in this digital infrastructure is crucial for avoiding delays and ensuring the highest level of precision.

Accelerating the learning cycle with rapid prototyping

Getting physical parts into the hands of designers and engineers quickly is vital for validating concepts and making informed decisions. 3D printing has become an indispensable tool for this, offering a way to test form, fit, and function in a fraction of the time required by traditional machining.

Different 3D printing technologies serve different purposes. Stereolithography (SLA) printing can produce parts with extremely high layer accuracy (as fine as 25µm) from a wide variety of materials. This makes it ideal for creating highly detailed components or a series of product iterations overnight for next-day testing.

Fused deposition modeling (FDM) printing is another valuable tool. While it can be used for creating parts, its strength often lies in making complex fixtures for machining and inspection or custom end-of-arm tooling for robotics. By leveraging these rapid prototyping methods, teams can document lessons learned and apply them to subsequent project phases, creating a seamless path from concept to production.

Building in-house control for predictability and quality

To deliver high-quality tooling fast, controlling the entire manufacturing process is key. Outsourcing even a single step can add days or weeks to a project timeline. A vertically

OEMs should seek a CDM partner with the following advanced in-house machining capabilities:

- **High-speed milling:** Modern 3-, 4- and 5-axis high-speed mills produce exceptional surface finishes and accuracy, often negating the need for secondary polishing. Features such as thermal compensation allow these machines to maintain precision over long, unattended runs.
- **Electrical discharge machining (EDM):** EDM technology, both sinker and wire, remains essential for creating complex features such as deep ribs, sharp corners, and undercuts in hardened steel. Advanced applications can even replicate a polished surface finish directly in the machine.
- **Multitasking lathes:** Equipment such as lathes with sub-spindle handoffs and live tooling can create complex hardened cavity cores in a single setup. This minimizes part handling, reduces the chance of error, and frees up capacity on other machines.
- **Swiss-type machining:** For high-volume, tight-tolerance substrates used in overmolding, Swiss-type machines paired with bar feeders can run unattended for days or even weeks, ensuring a consistent supply of quality components.

This in-house arsenal, combined with robotic tending cells to combat labor shortages and increase capacity, creates a predictable, efficient, and high-quality manufacturing ecosystem.

Quality assurance as an integrated process

Quality cannot be an afterthought; it must be woven into every step of the design and manufacturing journey. Validating the process early and often builds confidence and prevents small issues from becoming major setbacks.

lights-out operation. Having dedicated coordinate measuring machines (CMM) and vision inspection equipment in the tool room eliminates the bottleneck of sending parts to a separate quality lab, only to find they need further modification.

When modifications are needed, precision fixturing systems are invaluable. They allow a part to be removed from a machine for inspection and then precisely relocated without a costly new setup. This capability is essential for automation and efficiency. Quality control also extends to the digital realm. Robust file management software controls revisions and ensures every component is marked with a unique ID providing full traceability back to its original CAD file.

By embracing a philosophy where quality and efficiency are achieved together, medtech companies can de-risk product launches and position themselves for long-term success. The result is not just premium tooling delivered fast; it's the confidence coming from a predictable, transparent, and highly capable manufacturing partnership with a CDM.

Conclusion

Navigating the path from an innovative medical device concept to high-volume production requires viewing manufacturing not as a final hurdle, but as a foundational element integrated from day one. By combining early engineering collaboration, advanced digital simulation, rapid prototyping, and tightly controlled in-house processes, medtech leaders can create a predictable and efficient development cycle. This holistic approach, where quality is validated at every stage and automation addresses modern workforce challenges, is a new benchmark for success. For OEMs, executing these ideas through strategic partnerships is the most reliable way to accelerate market delivery, reduce risk, and ensure the final product's quality matches the brilliance of its initial design.

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A closer look at automated quality assurance

Advanced CDMs such as Trelleborg Medical Solutions integrate automated quality technologies directly into the tooling and machining process, compressing timelines and reducing risk. Here are four key systems that make it possible:

Spindle probes: These high-precision sensors are mounted in the machine, allowing for in-process inspection. This means critical dimensions can be verified immediately after they are machined, without removing the part from its setup. This instant feedback loop catches deviations early, preventing entire batches of non-compliant parts and accelerating the validation process.

Automated tool setting & monitoring:
This technology uses lasers or touch probes to automatically measure tool length and diameter, and to detect if a tool has broken during operation. For OEMs, this ensures consistent precision from the first part to the last and enables reliable, unattended lights-out manufacturing. It reduces costly rework and scrap caused by tool wear or failure.

Coordinate measuring machines (CMMs):
A CMM is a device that measures the geometry of physical objects. By having dedicated CMMs in the tool room, technicians can quickly perform comprehensive quality checks without waiting in a queue for the main quality lab. This dramatically speeds up the feedback loop for first-article inspections and any necessary modifications.