

Great Prototype! Is it manufacturable?

A 2013 article in *Fast Company* magazine, titled “[This is why your Kickstarter Project is Late](#)”, covers the challenges involved in moving from a successful product prototype to a product that can be manufactured in sufficient volume to be marketable. The challenges, it turns out, are many — both technical and financial. In many cases, the end result is that production costs and delays spiral out of control such that the prototyped product never makes it to market.

If this can happen with consumer technology products, the challenges and risks are even greater with medical devices. Chief among the challenges with medical devices is the difference between creating a 3D prototype printed to CAD specifications, and migrating to a production process that involves sophisticated equipment or skilled assembly labor that perform with the effectiveness and consistency required by regulators, healthcare providers, and patients. Medical devices must meet some of the most stringent quality requirements of any industry. With medical devices, all company department/functions contribute to the medical device development — which includes supply chain, manufacturing processes, packaging, labeling and sterilization — while meeting all regulatory requirements. What follows is a summary of some of the considerations involved in developing a manufacturable medical device, and some suggestions for engaging a qualified contract manufacturing organization (CMO) to minimize the risks and improve your chances of success.

Supply Chain

Availability and cost of materials and components used in devices is one of the critical areas of device development that needs to receive a lot of attention. In most cases, every supplier involved in producing a medical device should be ISO 13485-certified, meet all applicable FDA quality requirements, verify and/or validate their manufacturing process, and routinely evaluate their process for improvement opportunities. Some of the most challenging situations occur when your device requires material or component tolerances that cannot be met by the selected production method[s] or available supplier base.

Experts also recommend qualifying multiple suppliers for each material and component to avoid being overly beholden to a single source or being limited by the capacity of one supplier. Many times the expected volume compared to the expense of qualification and testing requirements of a medical device do not justify this duplication, making OEMs even more dependent upon a single supplier. So it is critically important to choose suppliers wisely!

Raw material selection, availability, and supply longevity are also important. The requirements for your device will include a broad array of compliance testing such as: biocompatibility, cytotoxicity, RoHS, pathogens, bioburden and more. Once a manufacturing process is validated, minor changes can have major unexpected impacts.

Medical device contract manufacturers and component suppliers should be required to obtain approval for any changes to the form, fit, or function of the component or device before a change is made, and OEMs should discuss and plan proposed changes with affected suppliers before revised specifications are released for implementation. Of critical importance to your manufacturing partner is the ability for the supply chain to be able to provide consistent quality and documentation for every shipment, material, and part.

Phase 2 Medical utilizes supplier audits and close control of our approved vendor list (AVL) in conjunction with established procedures for component qualifications, process qualifications (PQ), packaging validation, and management of sterilization validation to ensure even the most complex medical devices are properly controlled and produced.

Manufacturing Processes

Perhaps the greatest challenge of moving from a prototype to a production device lies in developing a feasible and repeatable manufacturing process. Prototypes are often made with relatively low-cost systems and facilities because failing fast (and inexpensively) is a proven and successful way of managing a medical device startup. The introduction of computer-aided design (CAD) and the proliferation of additive manufacturing technologies (3D printing) over the past 20 years has allowed medical device engineers to put very sophisticated parts into the hands of potential users. Creating a prototype is one thing, but moving that part to manufacturing may involve essentially starting the design process over again - designing for manufacturability.

One of the biggest challenges for contract manufacturers such as Phase 2 Medical Manufacturing, Inc. is that different processing equipment frequently produces different results. Building a reliable, repeatable production process requires significant effort when converting a process that has made a handful of parts to one that can sustainably manufacture thousands of devices every week. Users are willing to accept the limitations of prototype products, but regulators and users will not accept performance problems when a device is released to market and used in clinical practice. Phase 2 utilizes its team of medical device product development engineers and production experts to complete design for manufacturability (DFM) and transfer to manufacturing utilizing a four-stage development process. One of the critical steps in this process is to perform rigorous design reviews at every stage to confirm that specifications are properly understood, conveyed, tested, and met.

Similar to changes to materials and components, medical device contract manufacturers must also consider development of processes that allow for some variation in components, equipment, or human beings. Using proven engineering principles – such as designs of experiments (DOE) and process failure modes and effects analyses (pFMEA) – allows manufacturing companies to evaluate effects of variations and build confidence in the manufacturing process.

Verification and Validation (V&V)

Verification and Validation are as important to the development process as the original design inputs. The needs must begin to be considered at the start of the project, both to prove your concept with your prototype and to determine how development activities will need to progress. Medical device manufacturers that do not consider V&V at the outset of their project increase the risk of failure late in the development process, when most of the anticipated development cost has been expended. Changes or fixes late in development cost more and take significantly more time, which can cause delayed market launch, redirected resources, lost profits, and inability to meet patients' and caregivers' needs.

V&V is where most cost overruns and launch delays will crop up if not thoroughly considered during the planning stages of product development process. Design reviews at each stage ensure that regulatory requirements are being fulfilled, activities to date are providing the intended results, and that subsequent activities are properly planned to continue to evaluate, address and confirm the suitability of the process outputs.

Packaging, Labeling and Sterilization

Some of the longest lead time items related to medical devices' product development include validation of packaging, shipping, and sterilization. With so much focus on the clinical use and testing of the device, these processes can get marginalized in the development process, but a failure can halt the entire operation.

To demonstrate how all of these items are intertwined, your method of sterilization is primarily driven by your material choices. No matter the sterilization method, medical device manufacturers must prove that barrier integrity and product functionality are sustained throughout the product's shelf life. And, since you will likely need to move your product around the world, you must prove that you can maintain your sterile barrier and not damage your product when they are subjected to the rigors of routine transportation.

Labeling is also of paramount importance to regulators, and must address device indications, device classification, and marketing requirements. It's not just artwork and marketing aspects of your product; this is possibly the most regulated area in launching a medical device, and manufacturers need to meet the requirements of each country to which the devices will be distributed.

One of the most unique services offered by Phase 2 is on-demand printing of IFUs (instructions for use). This paperwork is extremely important for your device and for regulatory agencies. Phase 2 has determined that many of these documents change frequently, and provides this service to reduce cost of change while maintaining consistent manufacturing output.

Is it a prototype or a product?

A prototype is not a product. A working model does not confirm that a device can be manufactured in volume, or that it will perform as expected throughout the life of the product. In an article for design software firm Autodesk, “[Manufacturing Costs: 9 Considerations to Make Before Taking Your Idea from Prototype to Production](#),” would-be entrepreneurs are warned, “whatever can go wrong, will go wrong, take longer, and cost more.”

Moving from prototype to production for medical devices can be complex and challenging, but it doesn’t have to be. Many medical device companies want the majority of their revenue to come from new products and are looking to develop therapies for unmet medical needs. Putting prototypes in the hands of clinicians is a great way to do it.

When device makers prove feasibility and complete concept development, the leaders in the industry move to the next stage of development with manufacturing in mind. The technology, skill and materials that will be required to make finished products should be considered at the earliest stages of the design process. One of the biggest challenges is recognizing what you don’t know and bringing in experts in those areas.

Experienced CMOs are often aware of critical opportunities to improve device quality, reduce development cycles, and manufacture devices at lower cost because of their focus in the industry. These companies also know the pitfalls that have hampered other companies or their projects. CMOs maintain verified supplier and subcontractors in order to meet the development timelines and device quality requirements for medical device OEMs around the world.



Phase 2 Medical Manufacturing, Inc. is a contract manufacturer specializing in complex, powered, single-use medical devices offering turnkey manufacturing and migrating prototypes to full production. Services include product development, cleanroom injection molding, cleanroom manufacturing, assembly, testing, medical packaging, shipping, and sterilization oversight. The company has ISO Class 8 cleanrooms in Rochester, NH and Tijuana, MX, and has had extensive success helping large and small manufacturers bring new medical devices to market.